



Health Acts Amendment Act 1981

No. 118 of 1981

TABLE OF PROVISIONS

Section	
1.	Short title
2.	Commencement
PART II—AMENDMENTS OF THE HEALTH INSURANCE ACT 1973 AND RELATED PROVISIONS	
3.	Principal Act
4.	Interpretation
5.	Hospital insured persons and medically insured persons
6.	After section 4 insertion of new sections—
5.	Disadvantaged persons, being immigrants or refugees
5A.	Revocation of declaration under section 5
5B.	Disadvantaged persons, being persons on low incomes
5C.	Revocation of declaration under section 5B
5D.	Disadvantaged persons, being persons in receipt of unemployment benefit
5E.	Disadvantaged persons, being persons in receipt of special benefit
5F.	Appeal from decisions under sections 5 to 5E (inclusive)
5G.	Declarations of person to be disadvantaged person not to overlap
5H.	Regulations may vary periods referred to in sections 5 to 5E (inclusive)
5J.	Declaration not to be made in respect of dependant
7.	Persons in Australia may apply for application of Act to them
8.	Repeal of section 10 and insertion of new section—
10.	Entitlement to Commonwealth medical benefit
9.	Pathology services
10.	Forms of undertaking for approved pathology practitioners

Section	
11.	Commonwealth benefit not payable in respect of certain medical expenses
12.	Repeal of section 20A and insertion of new section—
	20A. Assignment of Commonwealth medical benefit
13.	Claims for Commonwealth medical benefit
14.	Agreements with registered organizations for registration of certain persons
15.	Medical services outside Australia
16.	Undertakings with respect to pensioners
17.	Common form of undertaking
18.	Agreements with States and Northern Territory for provision of hospital services
19.	Payments in respect of recognized hospitals in the Australian Capital Territory
20.	Daily bed payments to private hospitals
21.	Supplementary daily bed payments to private hospitals
22.	Interpretation
23.	Grants in respect of certain payments made by approved organizations
24.	Interpretation
25.	Appointment to vacant office
26.	Repeal of section 96 and insertion of new sections—
	96. Summons to practitioner to attend hearing, & c.
	96A. Attendance of practitioner at hearing
	96B. Rights of practitioner at hearing
27.	Conduct of hearing
28.	Summons to give evidence, & c.
29.	Repeal of sections 100 and 101 and insertion of new sections—
	100. Allowances for witnesses at hearing
	101. Failure to attend
30.	Refusal to be sworn or to answer questions
31.	Recommendation by Committee
32.	Determination by Minister
33.	Establishment of Optometrical Services Committees of Inquiry
34.	Recommendation by Committee
35.	Payments by the Commonwealth
36.	Health Insurance Fund
37.	False statements, & c.
38.	Insertion of new section—
	129AAA. Prohibited practices in relation to the rendering of pathology services
39.	Search of premises, & c.
40.	Prosecutions
41.	Insertion of new sections—
	130A. Statement to be furnished concerning disadvantaged person when required
	130B. Receipt of income, & c.
	130C. False representation that person is disadvantaged person
	130D. Recovery of payments due to false statement that person is, or was, disadvantaged person
	130E. Return of notice of declaration of person as disadvantaged person
	130F. Powers as to taking of evidence, and production of documents, with respect to disadvantaged persons
	130G. Evidence
	130H. Information with respect to disadvantaged persons
	130J. Delegation by Director-General of Social Services
42.	Regulations
43.	Schedule 2
44.	New forms of undertaking for approved pathology practitioners
45.	Undertakings to continue in force
46.	Continuation of undertaking not to prevent giving of further undertaking
47.	Undertakings continued in force to cease to be in force

Section

PART III—AMENDMENTS OF THE NATIONAL HEALTH ACT 1953 AND RELATED PROVISIONS

- 48. Principal Act
- 49. Interpretation
- 50. Waiting period
- 51. Interpretation
- 52. Approved patient
- 53. Approved attendants and approved escorts
- 54. Circumstances in which payment not to be made
- 55. Approval of nursing home
- 56. Determination that patient be treated as uninsured nursing home patient
- 57. Furnishing of audited accounts of proprietors of certain approved nursing homes
- 58. Effect of suspension on approval of nursing home
- 59. Interpretation
- 60. Basic benefit payable in respect of nursing home care
- 61. Extensive care benefit payable in respect of nursing home care
- 62. Payment of Commonwealth benefit and nursing home fund benefit in respect of same patient for same period
- 63. Commonwealth benefit not payable where compensation, & c., is payable to patient
- 64. Repeal of section 60A and insertion of new section—
60A. Direction that Commonwealth benefit not to be subject to reduction
- 65. Interpretation
- 66. Application by organizations for registration as hospital benefits organizations
- 67. Reinsurance Account in hospital benefits fund
- 68. Conditions of registration relating to nursing home care
- 69. Guidelines for optional tables
- 70. Exemptions of professional services and associated hospital treatment from basic table
- 71. Determination of certain hospital benefits by Permanent Head
- 72. Public officer of registered organization
- 73. Changes of rules, & c., by registered organizations
- 74. Provisions applicable to persons ceasing to be pensioners or disadvantaged persons
- 75. Schedule

PART IV—AMENDMENTS OF THE NURSING HOMES ASSISTANCE ACT 1974

- 76. Principal Act
- 77. Interpretation
- 78. Approval of nursing home
- 79. Fees
- 80. Insured nursing home patients requiring extensive care

PART V—AMENDMENTS OF THE THERAPEUTIC GOODS ACT 1966

- 81. Principal Act
- 82. Interpretation
- 83. Repeal of section 6 and insertion of new section—
6. Editions of British Pharmacopoeia having effect for the purposes of this Act
- 84. Furnishing of information with respect to composition of goods
- 85. Labelling and packaging requirements in British Pharmacopoeia
- 86. Determination of standards for specific goods
- 87. Modifications of monographs by Minister
- 88. Insertion of new section—
16A. Mode of specifying standards, & c.
- 89. Insertion of new Parts—

Section

PART IIIA—BIOLOGICAL PRODUCTS

- 23A. Interpretation
- 23B. Additional operation of Part
- 23C. Object of Part
- 23D. General information to be provided on manufacturing and testing procedures
- 23E. Information to be provided in relation to particular batches
- 23F. Prescribed methods of manufacturing and testing
- 23G. Manufacturers to keep records

PART IIIB—NATIONAL REGISTER OF THERAPEUTIC GOODS

- 23H. Interpretation
- 23J. Additional operation of Part
- 23K. Object of Part
- 23L. National Register of Therapeutic Goods
- 23M. Director-General may obtain information
- 90. Offences—General
- 91. Insertion of new sections—
 - 25A. Prosecution of offences
 - 25B. Continuing offences
- 92. Judicial notice
- 93. Insertion of new section—
 - 26A. Service of notices
- 94. Repeal of section 27 and insertion of new section—
 - 27. Delegation
- 95. Insertion of new section—
 - 29A. Applications for review
- 96. Regulations
- 97. Additional amendments

SCHEDULE



Health Acts Amendment Act 1981

No. 118 of 1981

An Act relating to sickness and hospital benefits, and for other purposes

[Assented to 25 June 1981]

BE IT ENACTED by the Queen, and the Senate and the House of Representatives of the Commonwealth of Australia, as follows:

PART I—PRELIMINARY

Short title

1. This Act may be cited as the *Health Acts Amendment Act 1981*.

Commencement

2. (1) Sections 1, 2, 3, 20, 24 to 31 (inclusive), 33 and 34 shall come into operation on the day on which this Act receives the Royal Assent.

(2) Sections 48, 51, 52, 53 and 54 shall be deemed to have come into operation on 1 January 1981.

(3) Sub-section 4 (1) and sections 6, 37 and 41 shall come into operation on 3 August 1981.

(4) The remaining provisions of this Act (other than Part V) shall come into operation on 1 September 1981.

(5) Part V shall come into operation on a date to be fixed by Proclamation.

PART II—AMENDMENTS OF THE HEALTH INSURANCE ACT 1973 AND RELATED PROVISIONS

Principal Act

3. The *Health Insurance Act 1973*¹ is in this Part referred to as the Principal Act.

Interpretation

4. (1) Section 3 of the Principal Act is amended—

(a) by omitting from sub-section (1) the definition of “dependant” and substituting the following definition:

“ ‘dependant’ means—

(a) in relation to an eligible pensioner—

(i) the wife of the pensioner;

(ii) a child under the age of 16 years who is in the custody, care and control of the pensioner or of the wife or husband of the pensioner; or

(iii) a person who—

(A) has attained the age of 16 years but is under the age of 25 years;

(B) is receiving full-time education at a school, college or university;

(C) is not in receipt of an invalid pension under Part III of the *Social Services Act 1947*; and

(D) is wholly or substantially dependent on the pensioner or on the wife or husband of the pensioner;

(b) in relation to a disadvantaged person in respect of whom there is in force a declaration under section 5 or 5B—a person who is a dependant, within the meaning of section 5B, of the disadvantaged person or would be such a dependant if section 5B applied in relation to the disadvantaged person; or

(c) in relation to a disadvantaged person in respect of whom there is in force a declaration under section 5D or 5E—a person who is a dependant of the disadvantaged person for the purposes of Part VII of the *Social Services Act 1947*;” and

- (b) by adding at the end thereof the following sub-section:

“(13) Where a person is declared to be a disadvantaged person within the meaning of section 5, 5B, 5D or 5E in respect of a period, the person shall be deemed to be, or to have been a disadvantaged person for the purposes of this Act on every day included in that period.”.

- (2) Section 3 of the Principal Act is amended—

- (a) by omitting from sub-section (1) the definition of “patient contribution” and substituting the following definition:

“ ‘patient contribution’ means—

- (a) in relation to a nursing-home type patient of a recognized hospital in a State that is a party to an agreement that provides for an eligible person who is a nursing-home type patient of a recognized hospital to be required to make a patient contribution, calculated in accordance with the agreement, in respect of his care and treatment for each day as an in-patient in the hospital, an amount equal to the amount of that patient contribution;
- (b) in relation to a nursing-home type patient of a recognized hospital in a State (other than a State referred to in paragraph (a)) such amount as is determined by the Minister from time to time for the purposes of this paragraph with respect to that State;
- (c) in relation to a nursing-home type patient of a recognized hospital in an internal Territory, such amount as is determined by the Minister from time to time for the purposes of this paragraph in relation to that Territory; or
- (d) in relation to a nursing-home type patient of a private hospital, an amount equal to the amount in force, from time to time, for the purposes of sub-paragraph 47 (2) (b) (iii) of the *National Health Act 1953*, for each day on which the nursing-home type patient is an in-patient in the private hospital;”;

- (b) by omitting from sub-section (1) the definition of “recognized hospital” and substituting the following definition:

“ ‘recognized hospital’ means—

- (a) in relation to a State that is a party to an agreement—a hospital in that State that is a recognized hospital for the purposes of that agreement;
- (b) in relation to a State that is not a party to an agreement—a hospital in that State that is declared, by writing signed by him, by the Minister to be a recognized hospital for the purposes of this Act; or

- (c) in relation to an internal Territory—a hospital in that Territory that is declared by the Minister, by writing signed by him, to be a recognized hospital for the purposes of this Act;”;
- (c) by omitting from sub-section (1) the definition of “standard hospital fees” and substituting the following definition:
 - “ ‘standard hospital fees’, in relation to a State or an internal Territory, means such fees as the Minister, by instrument in writing, declares to be the standard hospital fees in relation to that State or Territory;”;
- (d) by inserting after sub-section (5) the following sub-section:
 - “(5A) For the purposes of this Act, a pathology service shall be deemed to include any necessary interpretation, analysis or reporting.”; and
- (e) by adding at the end thereof the following sub-section:
 - “(13) A declaration for the purposes of the definition of ‘standard hospital fees’ in sub-section (1) may specify fees in relation to a class of patients or classes of patients and, in that case, the fees so specified in relation to a class of patients shall be deemed to be the standard hospital fees in relation to each patient in the relevant State or Territory who is included in that class.”.

Hospital insured persons and medically insured persons

5. Section 3A of the Principal Act is amended—

- (a) by omitting from sub-section (1) “or an optional table”;
- (b) by omitting from sub-section (2) “eligible person” (wherever occurring) and substituting “person”;
- (c) by omitting from sub-section (2) “an optional table or any other table providing benefits in respect of professional services,”; and
- (d) by omitting from sub-section (3) “(other than rules providing for a waiting period or making any other prescribed provision)”.

6. After section 4 of the Principal Act the following sections are inserted:

Disadvantaged persons, being immigrants or refugees

“5. (1) An application for a declaration under this section in relation to an eligible person—

- (a) shall be made in writing in accordance with a form approved by the Director-General of Social Services; and
- (b) shall be lodged with the Department of Social Security.

“(2) Where the Director-General of Social Services is satisfied, with respect to an applicant under sub-section (1), that—

- (a) the applicant is, or was, an immigrant and entered Australia after 1 March 1981; or

- (b) the applicant has, or had, refugee status granted by the Australian Government and entered Australia after 1 March 1981,

the Director-General shall, subject to sub-section (3), declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period of 6 months that commenced on the day on which the applicant entered Australia (excluding any part of that period earlier than 1 September 1981).

“(3) Where the Director-General of Social Services is satisfied, with respect to an applicant under sub-section (1), that—

- (a) the applicant had ceased to be an immigrant; or
- (b) the applicant had had his refugee status revoked by the Australian Government,

before the expiration of the period of 6 months referred to in sub-section (2), the period specified in the declaration shall not include any period after—

- (c) the date on which, in the opinion of the Director-General, the applicant so ceased to be an immigrant; or
- (d) the date from which the applicant had his refugee status revoked,

as the case may be.

“(4) Where the Director-General of Social Services is not satisfied that an applicant under sub-section (1) meets the requirements of sub-section (2), he shall refuse to grant the application.

“(5) A declaration under sub-section (2) shall be in writing and notice of it shall be given to the applicant.

“(6) A refusal under sub-section (4) to grant an application shall be made in writing and notice of it shall be given to the applicant.

“(7) In this section, ‘applicant’, in relation to an application under sub-section (1), means the eligible person to whom the application relates.

Revocation of declaration under section 5

“5A. (1) Where the Director-General of Social Services is satisfied, with respect to a person in respect of whom there is in force a declaration under section 5, that—

- (a) the person has never been, or has ceased to be, an immigrant; or
- (b) the person has never had refugee status granted by the Australian Government or has had his refugee status revoked by the Australian Government,

the Director-General shall revoke the declaration of the person under section 5 as from a date specified in the revocation, not being a date earlier than the date on which the revocation is made.

“(2) A revocation of a declaration under sub-section (1) does not affect the operation of the declaration in respect of any period before the date on which the revocation takes effect.

“(3) A revocation under sub-section (1) shall be in writing and notice of it shall be given to the person concerned.

Disadvantaged persons, being persons on low incomes

“5B. (1) An application for a declaration under this section in relation to an eligible person—

- (a) shall be made in writing in accordance with a form approved by the Director-General of Social Services; and
- (b) shall be lodged with the Department of Social Security.

“(2) Where the Director-General of Social Services is satisfied, with respect to an applicant under sub-section (1), that the income of the applicant during the prescribed period was less than the amount of the allowable income in relation to the applicant, the Director-General shall, subject to sub-section (5), declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period of 6 months that commenced on the last day of the prescribed period (excluding any part of that period of 6 months that is earlier than 1 September 1981).

“(3) Where, in the period of 13 weeks (or such longer period as the Director-General of Social Services having regard to all the circumstances of the case approves) ending on the day on which an application under sub-section (1) is lodged, a professional service is rendered to, or hospital treatment is provided for, the applicant or a dependant of the applicant, sub-section (2) applies in relation to the applicant as if the reference in that sub-section to the prescribed period included a reference to—

- (a) the period of 4 weeks ending on the day on which that professional service was rendered or that hospital treatment was provided; or
- (b) if there were 2 or more days on which a professional service was so rendered or hospital treatment was so provided—each period of 4 weeks that is a period that ended on any one of those days.

“(4) For the purposes of sub-section (3)—

- (a) any period earlier than 1 September 1981 that is included in the period of 13 weeks referred to in that sub-section shall be disregarded;
- (b) the Director-General of Social Services shall not approve a period that includes a period earlier than 1 September 1981.

“(5) Where an applicant under sub-section (1) is a person referred to in sub-section (3), the Director-General of Social Services shall not make a declaration under sub-section (2) with respect to the applicant by reason that the applicant satisfied the requirements of that sub-section during any prescribed period if—

- (a) there is in force a declaration under sub-section (2) with respect to the applicant that was made by reason that the applicant satisfied the requirements of that sub-section during an earlier prescribed period; or

- (b) such a declaration would have been made and in force if the Director-General had considered the circumstances of the applicant during an earlier prescribed period.

“(6) Where—

- (a) a declaration is to be made under sub-section (2) with respect to an applicant by reason that the applicant satisfied the requirements of that sub-section during a prescribed period referred to in a paragraph of sub-section (3); and
- (b) having regard to the circumstances of the applicant during any period of 4 weeks that ended at any time after the expiration of the prescribed period referred to in paragraph (a) and before the date on which the application under sub-section (1) was lodged, the Director-General of Social Services would have been required, if, at the expiration of that period of 4 weeks—
- (i) the declaration had been in force; and
- (ii) the Director-General of Social Services had considered the circumstances of the applicant during that period of 4 weeks,

to take action under section 5C to revoke the declaration,

the declaration shall be expressed to be in respect of a period that ended at the expiration of that period of 4 weeks.

“(7) Where the Director-General of Social Services is not satisfied that an applicant under sub-section (1) meets the requirements of sub-section (2), he shall refuse to grant the application.

“(8) A declaration under sub-section (2) shall be in writing and notice of it shall be given to the applicant.

“(9) A refusal under sub-section (7) to grant an application shall be made in writing and notice of it shall be given to the applicant.

“(10) Where a declaration in force under this section with respect to a person ceases to have effect at the expiration of the period specified in the declaration, being a period that expired after the lodging of the application as a result of which the declaration was made, then, on the last day of the expired period, the person shall be deemed, for the purposes of this section, to have made an application under sub-section (1) for a declaration under this section with respect to the person.

“(11) The regulations may make provision for methods of ascertaining the income of a person during a period for the purposes of this section, including methods that have regard to income earned, derived or received, or to be earned, derived or received, at any time, whether during that period or otherwise.

“(12) In this section—

‘allowable income’, in relation to any period of 4 weeks, means—

- (a) in relation to a person who had a dependant or dependants on the last day of that period—4 times, or such other number of times as is prescribed, the aggregate of—
- (i) the amount of the weekly rate of income that, if—
 - (A) the person were, during that period, in receipt of income at that rate or, in the case of a married person, the person and the spouse of the person were, during that period, jointly in receipt of income at that rate;
 - (B) the person (not being a person eligible for unemployment benefit) were otherwise eligible for unemployment benefit;
 - (C) in the case of a married person—any children of the person were disregarded; and
 - (D) in the case of an unmarried person—the person were a married person with no children, the person's receipt, during that period, of income at that rate would be sufficient, but no more than sufficient, to prevent him from being entitled to any unemployment benefit;
 - (ii) \$20 or such other amount as is prescribed; and
 - (iii) an amount equal to the product of—
 - (A) the number of the children of the person on the last day of that period; and
 - (B) an amount equal to twice, or such other number of times as is prescribed, the amount of the weekly rate of increase of benefit in respect of a child set out in sub-section 112 (5) of the *Social Services Act 1947*; or
- (b) in relation to a person who had no dependants on the last day of that period—an amount equal to four times, or such other number of times as is prescribed, an amount calculated for the purposes of this paragraph, being an amount equal to 60%, or such other percentage as is prescribed, of the aggregate of the amount calculated in accordance with sub-paragraph (a) (i) and the amount referred to in sub-paragraph (a) (ii);

'applicant', in relation to an application under sub-section (1), means the eligible person to whom the application relates;

'child', in relation to a person, means a child (whether or not under the age of 16 years) in respect of whom child endowment under Part VI of the *Social Services Act 1947* is payable to the person or to the spouse of the person;

'dependant', in relation to a person, means—

- (a) the spouse of the person, being a spouse who—
 - (i) where the person is in receipt of unemployment benefit—is a dependant of the person for the purposes of Part VII of the *Social Services Act 1947*; or
 - (ii) in any other case—would be a dependant of the person for the purposes of Part VII of the *Social Services Act 1947* if the person were in receipt of unemployment benefit; or
- (b) a child of the person;

'income' means income within the meaning of Part VII of the *Social Services Act 1947*, and includes—

- (a) a payment under the *Social Services Act 1947* (other than a payment of child endowment, double orphans' pension, handicapped child's allowance or funeral benefit);
- (b) a pension payable under the *Repatriation Act 1920*, the *Repatriation (Far East Strategic Reserve) Act 1956* or the *Repatriation (Special Overseas Service) Act 1962*;
- (c) a pension that is payable under the law of a country other than Australia and, in the opinion of the Director-General of Social Services, is similar in character to a pension specified in paragraph (b); and
- (d) a pension payable under the *Seamen's War Pensions and Allowances Act 1940*;

'married person', 'unmarried person' and 'spouse' have the same respective meanings as they have in Part VII of the *Social Services Act 1947*;

'prescribed period', in relation to an applicant, means the period of 4 weeks ending on the day on which the application is lodged;

'unemployment benefit' means an unemployment benefit under Part VII of the *Social Services Act 1947*.

“(13) Where the weekly rate of income referred to in sub-paragraph (a) (i) of the definition of 'allowable income' in sub-section (12) includes an amount of cents, the amount of that weekly rate shall, for the purposes of that definition, (other than paragraph (b)) be increased by an amount equal to the amount by which that amount of cents is less than \$1.

“(14) For the purposes of the application of sub-paragraph (a) (iii) of the definition of 'allowable income' in sub-section (12) in relation to an unmarried person—

- (a) if that person had one child only on the last day of the relevant period of 4 weeks—that fact shall be disregarded; or
- (b) if that person had 2 or more children on the last day of the relevant period of 4 weeks—the number of those children shall be reduced by one.

“(15) Where an amount calculated for the purposes of paragraph (b) of the definition of ‘allowable income’ in sub-section (12) includes an amount of cents, the amount so calculated shall, for the purposes of that paragraph, be increased by an amount equal to the amount by which that amount of cents is less than \$1.

Revocation of declaration under section 5B

“5C. (1) Where, at any time, the Director-General of Social Services is satisfied, with respect to a person in respect of whom there is in force a declaration under section 5B, that the income of the person, during any period of 4 weeks that ended within one month of that time, was not less than an amount equal to 125%, or such other percentage as is prescribed, of the amount of the allowable income of the person, the Director-General shall revoke the declaration in respect of the person under section 5B as from a date specified in the revocation, not being a date earlier than the date on which the revocation is made.

“(2) For the purposes of sub-section (1), where a dependant of a person in respect of whom there is in force a declaration under section 5B ceases to be such a dependant, then—

- (a) the fact that the dependant has so ceased shall be disregarded unless the loss of the dependant continues for a period of 4 weeks; and
- (b) if that loss does so continue, the dependant shall be deemed to have ceased to be a dependant only at the expiration of that period of 4 weeks.

“(3) A revocation of a declaration under sub-section (1) does not affect the operation of the declaration in respect of any period before the date on which the revocation takes effect.

“(4) A revocation under sub-section (1) shall be in writing and notice of it shall be given to the person concerned.

“(5) In this section, a word or expression defined for the purposes of section 5B has the same meaning as in that section.

Disadvantaged persons, being persons in receipt of unemployment benefit

“5D. (1) Where—

- (a) at any time on or after 1 September 1981, a determination is made, following an investigation of the income of an eligible person during a period, to pay unemployment benefit to the person; and
- (b) the Director-General of Social Services is satisfied that, in respect of that period, the person is not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*,

the Director-General shall declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period of 2 weeks commencing 1 week after the expiration of the first-mentioned period (excluding any part of that period of 2 weeks earlier than 1 September 1981).

“(2) For the purposes of the application, for the purposes of sub-section (1) of this section, of section 83CA of the *Social Services Act 1947* in relation to a person in receipt of an unemployment benefit

- (a) a reference in that section to income shall be read as a reference to income within the meaning of Part VII of the *Social Services Act 1947*; and
- (b) the unemployment benefit shall be treated as not being income.

“(3) Where, under sub-section (3) of section 107 of the *Social Services Act 1947*, the Director-General of Social Services treats a person as having been unemployed throughout a particular period notwithstanding that the person undertook paid work during the whole or a part of that period, the Director-General may, for the purposes of the application, for the purposes of sub-section (1) of this section, of section 83CA of the *Social Services Act 1947* in relation to the person, disregard any income of the person that resulted from that paid work.

“(4) Where a declaration to be made under this section is in respect of a person in respect of whom no earlier declaration under this section is in force, the period that would otherwise be specified in the declaration shall be extended by fixing as its date of commencement—

- (a) the date of commencement of the period in respect of which the unemployment benefit of which he is in receipt is paid; or
- (b) 1 September 1981,

whichever is the later date.

“(5) Where, on the making of a determination referred to in sub-section (1) with respect to an eligible person, the Director-General of Social Services is not satisfied that, in respect of the relevant period in relation to that determination, the person was not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*, the Director-General shall record a decision accordingly.

“(6) A notice of a decision recorded under sub-section (5) shall be given to the person concerned upon request made by him.

“(7) A declaration under sub-section (1) shall be in writing and notice of it shall be given to the person concerned.

“(8) In this section, ‘unemployment benefit’ means unemployment benefit under Part VII of the *Social Services Act 1947*.

Disadvantaged persons, being persons in receipt of special benefit

“5E. (1) Where—

- (a) at any time on or after 1 September 1981, an eligible person is granted a special benefit; and
- (b) the Director-General of Social Services is satisfied that, in respect of a period of 2 weeks commencing on the date of the grant, the person will

not be a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*,

the Director-General shall declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period of 3 weeks commencing on the date of the grant.

“(2) Where a grant of a special benefit referred to in sub-section (1) is to operate with effect from a date before the date on which the grant is made, the period that would otherwise be specified in any declaration under sub-section (1) resulting from the making of that grant shall be extended by fixing as the date of commencement of that period—

- (a) the date with effect from which the special benefit is to be paid; or
- (b) 1 September 1981,

whichever is the later date.

“(3) Where—

- (a) on 1 September 1981, an eligible person is in receipt of a special benefit; and
- (b) the Director-General of Social Services is satisfied that, in respect of the period of 2 weeks that ended on 31 August 1981, the person was not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*,

the Director-General shall declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period commencing on 1 September 1981 and ending 3 weeks after the date of the declaration.

“(4) Where the Director-General of Social Services is satisfied, with respect to a person in receipt of a special benefit in respect of whom there is in force a declaration under this section, that, in respect of the period of 2 weeks that ended one week before the expiration of the period specified in the declaration, the person was not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*, the Director-General shall declare the person to be a disadvantaged person within the meaning of this section in respect of a period specified in the declaration, being a period of 2 weeks commencing on the expiration of the period specified in the first-mentioned declaration.

“(5) Where, at any time after 1 September 1981—

- (a) a person is paid a special benefit in respect of a period of 2 weeks; and
- (b) at the time of that payment, a declaration under this section in respect of the person is not in force,

the Director-General of Social Services shall consider the circumstances of that person and, if he is satisfied that, in respect of a period of 2 weeks that ended a week before the date of the payment, the person was not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*, the Director-General shall declare the person to be a disadvantaged person within

the meaning of this section in respect of a period specified in the declaration, being a period of 3 weeks commencing on the date of the payment.

“(6) For the purposes of the application, for the purposes of sub-section (1), (3), (4) or (5) of this section, of section 83CA of the *Social Services Act 1947* in relation to a person in receipt of a special benefit—

- (a) a reference in that section to income shall be read as a reference to income within the meaning of Part VII of the *Social Services Act 1947*; and
- (b) the special benefit shall be treated as not being income.

“(7) Where, under sub-section (3) of section 107 of the *Social Services Act 1947*, the Director-General of Social Services treats a person as having been unemployed throughout a particular period notwithstanding that the person undertook paid work during the whole or a part of that period, the Director-General may, for the purposes of the application, for the purposes of sub-section (1), (3), (4) or (5) of this section, of section 83CA of the *Social Services Act 1947* in relation to the person, disregard any income of the person that resulted from that paid work.

“(8) Notwithstanding any preceding provision of this section, a period specified in a declaration under this section in relation to a person shall not extend beyond the period in respect of which the special benefit payable to the person is granted.

“(9) Where—

- (a) on the making of a grant of a special benefit referred to in sub-section (1) to an eligible person;
- (b) on a consideration of the application of sub-section (3) to an eligible person who is in receipt of a special benefit on 31 August 1981; or
- (c) on a consideration, at any time, of the application of sub-section (4) or (5) to an eligible person who is in receipt of a special benefit,

the Director-General of Social Services is not satisfied that, in respect of the relevant period for the purposes of sub-section (1), (3), (4) or (5), as the case may be, the person was not a prescribed person within the meaning of section 83CA of the *Social Services Act 1947*, the Director-General shall record a decision accordingly.

“(10) A notice of a decision recorded under sub-section (9) shall be given to the person concerned upon request made by him.

“(11) A declaration under sub-section (1), (3), (4) or (5) shall be in writing and a notice of it shall be given to the person concerned.

“(12) In this section, ‘special benefit’ means a special benefit under Part VII of the *Social Services Act 1947*.

Appeals from decisions under sections 5 to 5E (inclusive)

“5F. (1) Section 14 of the *Social Services Act 1947* applies in relation to decisions under sections 5 to 5E (inclusive) of this Act (whether decisions of the

Director-General of Social Services or of his delegates) as if those decisions were decisions of officers under the *Social Services Act 1947*, and the Director-General of Social Services may, in pursuance of that first-mentioned section, affirm, vary or annul those decisions accordingly.

“(2) Section 15 of the *Social Services Act 1947* applies in relation to decisions under section 5 to 5E (inclusive) of this Act (except decisions of the Director-General of Social Services) as if those decisions were decisions of officers under the *Social Services Act 1947*, and the Director-General of Social Services may, in pursuance of that first-mentioned section, affirm, vary or annul those decisions accordingly.

Declarations of person to be disadvantaged person not to overlap

“5G. Nothing in section 5, 5B, 5D or 5E requires the making of a declaration with respect to a person under any of those sections in respect of any day on which the person is a disadvantaged person for the purposes of this Act by virtue of a declaration under one of those sections.

Regulations may vary periods referred to in sections 5 to 5E (inclusive)

“5H. The regulations may provide that section 5, 5A, 5B, 5C, 5D or 5E shall have effect as if a period of a specified length referred to in that section were a period of a different length prescribed by the regulations.

Declaration not to be made in respect of dependant

“5J. Nothing in section 5 or 5B permits the making of a declaration with respect to a person under either of those sections in respect of any day on which the person—

- (a) is, or was, a dependant, within the meaning of section 5B, of any person; or
- (b) is, or was, wholly or substantially dependent on a resident of a country other than Australia.”.

Persons in Australia may apply for application of Act to them

7. Section 6 of the Principal Act is repealed.

8. Section 10 of the Principal Act is repealed and the following section substituted:

Entitlement to Commonwealth medical benefit

“10. (1) Where, on or after 1 September 1981—

- (a) medical expenses are incurred by a person who is a medically insured person in respect of a professional service rendered in Australia to that medically insured person or to another person who is a medically insured person by reason of being a dependant of that first-mentioned person;
- (b) medical expenses are incurred by an eligible person who is an eligible pensioner in respect of a professional service rendered in Australia to that eligible pensioner or to a dependant of that eligible pensioner; or

(c) medical expenses are incurred by a person who is a disadvantaged person in respect of a professional service rendered in Australia to that disadvantaged person or to a dependant of that disadvantaged person, Commonwealth medical benefit calculated in accordance with sub-section (2) is payable, subject to and in accordance with this Act, in respect of that professional service.

“(2) A Commonwealth medical benefit under sub-section (1) in respect of a professional service is an amount equal to—

- (a) where a person who has incurred the medical expenses is an eligible pensioner or a disadvantaged person and the service is rendered to him or to his dependant—
 - (i) 85% of the fee specified in respect of the service in the table in relation to the State in which the service is rendered; or
 - (ii) if the amount calculated under sub-paragraph (i) is less by more than \$5 than the fee from which it is calculated—an amount that is less by \$5 than that fee; or
- (b) in any other case—30% of the fee specified in respect of the service in the table in relation to the State in which the service is rendered.

“(3) Where an amount calculated in accordance with sub-section (2) is not a multiple of 5 cents, the amount of cents shall be increased to the nearest higher amount that is a multiple of 5 cents.”.

Pathology services

9. Section 16A of the Principal Act is amended—

(a) by inserting after sub-section (2) the following sub-section:

“(2A) The reference in paragraph (1) (a) to a request made in writing or to a confirmation in writing of a request shall be read as including a reference to a request or a confirmation, as the case may be, in such other form as the Minister approves, in writing, from time to time.”; and

(b) by inserting after sub-section (4) the following sub-sections:

“(4A) For the purposes of this section, where—

- (a) a written request or a written confirmation of a request has been recorded on film or on any other medium approved, in writing, by the Minister from time to time; or
- (b) in accordance with an approval, in writing, of the Minister, a request or confirmation (other than a written request or a written confirmation) has been recorded on a tape, disc, film or other medium,

for the purposes of storage and subsequent retrieval when required—

- (c) the retention of the record so made shall be deemed to be a retention of the request or the confirmation, as the case may be; and

- (d) the production, or the reproduction, of the record so made shall be deemed to be a production of the request or the confirmation, as the case may be.

“(4B) Where the Minister gives an approval for the purposes of paragraph (4A) (b), he may set out in the instrument of approval any condition to which the approval is subject, and any recording that is not in accordance with such a condition shall be deemed to be not in accordance with the approval.”

Forms of undertaking for approved pathology practitioners

10. Section 16B of the Principal Act is amended—

- (a) by inserting after sub-section (3) the following sub-section:

“(3A) The Minister shall forward to the Australian Medical Association—

- (a) a copy of any reference made by him under sub-section (3) to the Medical Benefits Advisory Committee; and
- (b) a copy of any recommendation made to him under sub-section (3) by the Medical Benefits Advisory Committee.”; and

- (b) by inserting after sub-section (4) the following sub-section:

“(4A) Where a recommendation to the Minister under sub-section (3) by the Medical Benefits Advisory Committee is that a proposal be adopted with amendments specified in the recommendation, the Minister shall consult with the Australian Medical Association concerning the implementation of the recommendation.”

Commonwealth benefit not payable in respect of certain medical expenses

11. Section 17 of the Principal Act is amended by omitting sub-section (2).

12. Section 20A of the Principal Act is repealed and the following section substituted:

Assignment of Commonwealth medical benefit

“20A. (1) Where a Commonwealth medical benefit is payable to an eligible pensioner in respect of a professional service rendered to the pensioner or to a dependant of the eligible pensioner, the eligible pensioner may, in accordance with the approved form, assign his right to the payment of that benefit to the person by whom, or on whose behalf, the professional service is rendered.

“(2) Where a practitioner determines that a pathology service is necessary to be rendered to an eligible pensioner, the eligible pensioner may, in accordance with the approved form, offer to assign to the approved pathology practitioner by whom, or on whose behalf, the pathology service is to be rendered the right of the eligible pensioner to the payment of any Commonwealth medical benefit that may become payable to the eligible pensioner when the service is so rendered.

“(3) An assignment the subject of an offer under sub-section (2) takes effect if, and only if—

- (a) the offer is accepted by the approved pathology practitioner to whom it is made; and
- (b) the pathology service to which the offer relates is rendered.

“(4) Where a Commonwealth medical benefit is payable to a disadvantaged person in respect of a professional service rendered to the disadvantaged person or a dependant of the disadvantaged person, the disadvantaged person and the person by whom, or on whose behalf, the professional service is rendered (in this sub-section referred to as ‘the practitioner’) may enter into an agreement, in accordance with the approved form, under which—

- (a) the disadvantaged person assigns his right to the payment of the Commonwealth medical benefit to the practitioner; and
- (b) the practitioner accepts the assignment in full payment of the medical expenses incurred in respect of the professional service by the disadvantaged person.

“(5) Where an assignment of the right to the payment of Commonwealth medical benefit in respect of a professional service is made in accordance with an agreement under sub-section (4), the right so assigned is a right to the payment of an amount equal to the amount that the Commonwealth medical benefit would be if it were calculated in accordance with the following formula:

An amount equal to 85% of the fee specified in respect of the professional service in the table in relation to the State in which the service is rendered.

“(6) Where a practitioner determines that a pathology service is necessary to be rendered to a disadvantaged person, the disadvantaged person may, in accordance with the approved form, make an offer to the approved pathology practitioner by whom, or on whose behalf, the pathology service is to be rendered to enter into an agreement with him under sub-section (4), when the pathology service is so rendered, with respect to the Commonwealth medical benefit payable in respect of the pathology service so rendered.

“(7) Where an assignment under this section takes effect, or an agreement under this section is entered into, with respect to a Commonwealth medical benefit, the Commonwealth medical benefit is, subject to section 20B, payable in accordance with the assignment or the agreement, as the case may be.

“(8) A reference in this section to a person by whom a professional service is rendered shall be read as not including a reference to a person (in this sub-section referred to as ‘the agent’) who renders a professional service on behalf of another person or of an organization, but the agent may, if so authorized by that other person or that organization, on behalf of that other person or that organization, accept an offer made under sub-section (2) or enter into an agreement under sub-section (4).

“(9) An assignment of a Commonwealth medical benefit shall not be made except in accordance with this section.”.

Claims for Commonwealth medical benefit

13. Section 20B of the Principal Act is amended by omitting sub-section (3) and substituting the following sub-section:

“(3) A claim referred to in sub-section (2) shall not be paid unless the claimant satisfies the Permanent Head that—

- (a) in the case of an assignment under sub-section 20A (1)—the assignor retained in his possession after making the assignment a copy of the assignment;
- (b) in the case of an assignment that was the subject of an offer to assign made under sub-section 20A (2)—the offeror retained in his possession after making the offer a copy of the offer;
- (c) in the case of an agreement under sub-section 20A (4) that was signed by each party in the presence of the other—the assignor retained in his possession after the agreement was so signed a copy of the agreement; or
- (d) in the case of an agreement under sub-section 20A (4) that was signed by the assignor in circumstances other than those referred to in paragraph (c)—the assignor retained in his possession after so signing a copy of the document so signed.”.

Agreements with registered organizations for registration of certain persons

14. (1) Section 20C of the Principal Act is amended—

- (a) by omitting from paragraph (1) (a) “eligible persons” and substituting “persons to whom this section applies”;
- (b) by omitting from sub-section (2) “all persons” and substituting “all persons to whom this section applies”;
- (c) by inserting in sub-section (5) “, or such other period as is prescribed”, after “6 months”; and
- (d) by adding at the end thereof the following sub-section:

“(8) In this section, ‘persons to whom this section applies’ means persons who are eligible pensioners or disadvantaged persons.”.

(2) Notwithstanding the amendments made by sub-section (1), any agreement in force under section 20C of the Principal Act immediately before the commencement of this section continues in force on and after the commencement of this section as if it had been entered into under section 20C of the Principal Act as amended by this section.

Medical services outside Australia

15. Section 21 of the Principal Act is amended—

- (a) by omitting sub-section (1) and substituting the following sub-section:

“(1) Subject to this section, where—

- (a) medical expenses are incurred by a medically insured person in respect of a medical service specified in an item that is rendered outside Australia to the medically insured person, or to another

person who is a medically insured person by reason of being a dependant of that first-mentioned person, by, or on behalf of, a prescribed person; or

(b) medical expenses are incurred by an eligible pensioner in respect of a medical service specified in an item that is rendered outside Australia to that eligible pensioner, or to a dependant of that eligible pensioner, by, or on behalf of, a prescribed person, a Commonwealth medical benefit is payable in respect of that medical service as if—

(c) that medical service had been rendered in New South Wales by, or on behalf of, a medical practitioner; and

(d) where the person who incurred the medical expenses was, at the time when he incurred the medical expenses, a disadvantaged person—the person was not, at that time, a disadvantaged person.”;

(b) by omitting from paragraph (4) (b) “or”; and

(c) by adding at the end of sub-section (4) the following paragraphs:

“(d) a medical service rendered to a person who is not an eligible person; or

(e) a medical service in respect of which the medical expenses are incurred by a person who is not an eligible person.”.

Undertakings with respect to pensioners

16. Section 23 of the Principal Act is amended—

(a) by inserting after sub-section (1) the following sub-section:

“(1A) The Minister shall request every medical practitioner whom he considers is engaged in Australia in rendering professional services to persons to undertake that, where, on or after the date fixed for the purposes of this sub-section, the practitioner determines that a pathology service is necessary to be rendered to a person who identifies himself to the practitioner as an eligible pensioner or a dependant of an eligible pensioner, the practitioner will ensure that—

(a) the person who identifies himself as an eligible pensioner is asked whether he wishes to make an offer under sub-section 20A (2) to assign to the approved pathology practitioner by whom, or on whose behalf, the pathology service is to be rendered the right of the person to the payment of any Commonwealth medical benefit that may become payable to the person when the pathology service is so rendered; and

(b) if the person indicates that he so wishes, arrangements are made for the making of the offer under sub-section 20A (2) and the transmission of that offer to the approved pathology practitioner to whom it is made.”; and

(b) by inserting in sub-sections (2) and (4) “or (1A)” after “sub-section (1)”.

Common form of undertaking

17. (1) Section 23A of the Principal Act is amended by omitting paragraph (2) (d) and substituting the following paragraph:

“(d) an assurance by the optometrist (in this paragraph referred to as ‘the practitioner’) that, where—

(i) a professional service, not being—

(A) a service covered by item 186 that is included in a course of attention to which section 13 applies; or

(B) a service rendered at premises owned by, or in the possession of, the optometrist that are not covered by the undertaking,

is rendered by the practitioner on his own behalf or by another optometrist acting on his behalf;

(ii) Commonwealth medical benefit in respect of that service is payable to a person (in this paragraph referred to as “the beneficiary”) who identifies himself to the optometrist rendering the service as an eligible pensioner or a disadvantaged person; and

(iii) the person to whom the service is rendered is the beneficiary or his dependant,

the practitioner will ensure that the beneficiary is asked whether he wishes to assign his right to the payment of the Commonwealth medical benefit, being an assignment in accordance with section 20A, in full payment of the medical expenses in respect of the professional service and, if the person indicates that he so wishes, arrangements are made for making the appropriate assignment;”.

(2) On the commencement of this section—

(a) the common form of undertaking in force for the purposes of the Principal Act immediately before the commencement of this section shall, by force of this paragraph, be deemed to have been varied to conform with the requirements of sub-section 23A (2) of the Principal Act, as amended by this section; and

(b) undertakings in relation to participating optometrists in force for the purposes of the Principal Act immediately before the commencement of this section shall, by force of this paragraph, be deemed to have been varied to accord with the common form of undertaking as deemed to have been varied by force of paragraph (a).

Agreements with States and Northern Territory for provision of hospital services

18. Section 30 of the Principal Act is amended—

(a) by omitting sub-section (2);

(b) by omitting from sub-section (3) “, but so that the agreement as varied shall comply with sub-section (2)”;

(c) by adding at the end thereof the following sub-sections:

“(4) Subject to sub-sections (5) and (6), this section does not apply in relation to any of the States and any agreement in force under this section immediately before the commencement of this sub-section between the Commonwealth and a State ceases to have effect on the commencement of this sub-section.

“(5) This section continues to have effect in relation to South Australia and Tasmania up to and including such date as is fixed by Proclamation for the purposes of this sub-section, not being a date later than 30 June 1985.

“(6) An agreement under this section between the Commonwealth and South Australia or Tasmania ceases to have effect when this section ceases to apply in relation to South Australia or Tasmania, as the case may be.”.

Payments in respect of recognized hospitals in the Australian Capital Territory

19. Sections 32 and 32A of the Principal Act are repealed.

Daily bed payments to private hospitals

20. Section 33 of the Principal Act is amended—

(a) by omitting sub-section (1) and substituting the following sub-section:

“(1) There is payable by the Commonwealth to a private hospital in a State or in the Australian Capital Territory a daily bed payment, for each approved bed in the hospital for each day upon which the bed is occupied by an eligible person who is an in-patient at the hospital, of an amount of—

(a) in the case of a surgical bed—\$28; or

(b) in any other case—\$16.”;

(b) by omitting from sub-sections (2) and (3) “(other than a bed that is an approved bed for the purposes of section 34)”;

(c) by adding at the end thereof the following sub-sections:

“(5) Subject to sub-section (6), where, at any time during the stay in hospital as an in-patient at the hospital of an eligible person, the eligible person has rendered to him a surgical procedure, any approved bed in the hospital occupied by the eligible person during that stay (whether the occupation was before or after the rendering of the surgical procedure) shall be deemed to be, for the purposes of this section, a surgical bed on each day of that occupation.

“(6) The Permanent Head may, having regard to the circumstances of the stay in hospital of an eligible person referred to in sub-section (5), declare that that sub-section does not apply in relation to the whole or a specified part of the stay in the hospital of the eligible person.

“(7) The proprietor of a hospital may make an application to the Permanent Head for a declaration that, having regard to the reasons for admission of an eligible person as an in-patient at the hospital, any

approved bed in the hospital occupied by the eligible person during the whole, or a part, of his stay in hospital as an in-patient at the hospital should be declared to be, for the purposes of this section, a surgical bed on each day of that occupation.

“(8) On receipt of an application under sub-section (7), the Permanent Head shall—

- (a) if he is satisfied that, having regard to the reasons for admission of the eligible person as an in-patient at the hospital, any approved bed in the hospital occupied by the eligible person during the whole, or a part, of his stay in hospital as an in-patient at the hospital should be declared to be, for the purposes of this section, a surgical bed on each day of that occupation—make a declaration, in writing, accordingly; or
- (b) if he is not so satisfied—refuse to grant the application.

“(9) A person affected by a decision of the Permanent Head under sub-section (6) or (8) may request the Minister to review the decision.

“(10) Upon receipt of a request under sub-section (9), the Minister shall, after such investigation of the matter as he considers necessary, either confirm, vary or revoke the decision.

“(11) An application under sub-section (7)—

- (a) shall be made in accordance with the approved form;
- (b) shall be lodged with the Department; and
- (c) shall be accompanied by such information relating to the application as is shown in the approved form to be required or as is prescribed.

“(12) In this section, ‘surgical procedure’ means a service to which a prescribed item relates.”.

Supplementary daily bed payments to private hospitals

21. Section 34 of the Principal Act is repealed.

Interpretation

22. Section 39 of the Principal Act is amended by omitting “or an optional table” from the definition of “eligible person”.

Grants in respect of certain payments made by approved organizations

23. Section 42B of the Principal Act is amended—

- (a) by omitting from sub-sections (1) and (2) “amount of the Commonwealth medical benefit that would, but for paragraph 17 (1) (d), be payable under Part II in respect of” and substituting “prescribed amount in relation to”; and
- (b) by adding at the end thereof the following sub-section:
 - “(3) In this section, ‘prescribed amount’ means—
 - (a) in relation to a professional service rendered to a person who is a medically insured person—the amount of the Commonwealth

medical benefit that would, but for paragraph 17 (1) (d), be payable under Part II in respect of that service; or

- (b) in relation to a professional service rendered to a person who is not a medically insured person—the amount of the Commonwealth medical benefit that would, but for paragraph 17 (1) (d), be payable under Part II in respect of that service if the person were a medically insured person.”.

Interpretation

24. Section 79 of the Principal Act is amended by inserting in sub-section (1) after the definition of “Deputy Chairman” the following definition:

“ ‘document’ includes—

- (a) a book, plan, paper, parchment, film or other material on which there is writing or printing, or on which there are marks, symbols or perforations having a meaning for persons qualified to interpret them;
- (b) a disc, tape, paper, film or other device from which sounds or images are capable of being reproduced; and
- (c) any other record of information;”.

Appointment to vacant office

25. Section 88 of the Principal Act is amended by omitting from sub-section (2) “the Minister shall appoint a medical practitioner to that office and, before making that appointment, shall consult the Australian Medical Association” and substituting “the Minister shall not appoint a person to that office for a period of more than 3 months except after consultation with the Australian Medical Association”.

26. Section 96 of the Principal Act is repealed and the following sections are substituted:

Summons to practitioner to attend hearing, &c.

“96. (1) For the purposes of this Act, a member may, by writing under his hand, summon the practitioner, or any of the practitioners, concerned to attend a hearing and to produce such documents (if any) as are referred to in the summons and to appear at the hearing to give evidence for the purpose only of identifying any such documents.

“(2) Where a summons is served on a practitioner under sub-section (1) at least 10 days before a hearing specifying the time and place of the hearing and giving particulars of the matter to which the hearing relates, the Committee is not required to cause a notice to be given to the practitioner under section 95.

“(3) A summons under this section may be served on the practitioner personally or by post.

Attendance of practitioner at hearing

“96A. (1) Where a practitioner is summoned under section 96 to attend a hearing, he shall attend in person, and may be represented by another person, at the hearing.

“(2) Where a notice has been served on a practitioner under section 95 in relation to a hearing and the practitioner has not been summoned under section 96 to attend the hearing, he may appear in person, or may be represented by another person, at the hearing.

Rights of practitioner at hearing

“96B. Where a practitioner attends, appears or is represented at a hearing in accordance with sub-section 96A (1) or (2), he or his representative, as the case requires, shall be given the opportunity to give evidence, and to call witnesses, on behalf of the practitioner, to examine other witnesses appearing at the hearing and to address the Committee.”.

Conduct of hearing

27. Section 97 of the Principal Act is amended by omitting from sub-section (4) “, book or writing” (wherever occurring).

Summons to give evidence, &c.

28. Section 99 of the Principal Act is amended by omitting from sub-section (1) “document, book or writing as is” and substituting “documents (if any) as are”.

29. (1) Sections 100 and 101 of the Principal Act are repealed and the following sections are substituted:

Allowances for witnesses at hearing

“100. A person summoned (otherwise than under section 96) to appear as a witness at a hearing before the Committee is entitled to be paid allowances, fixed by or in accordance with the regulations, for expenses in respect of his attendance.

Failure to attend

“101. (1) A person served with a summons to appear at a hearing shall not, without reasonable excuse—

- (a) fail to attend as required by the summons; or
- (b) fail to appear and report himself from day to day unless excused, or released from further attendance, by a member.

“(2) A practitioner served with a summons to attend a hearing shall not, without reasonable excuse—

- (a) fail to attend as required by the summons; or
- (b) fail to attend and report himself from day to day unless excused, or released from further attendance, by a member.

Penalty: \$1,000.”.

(2) Regulations in force at the commencement of this section for the purposes of section 100 of the Principal Act continue in force as if made for the purposes of section 100 of the Principal Act as amended by this Act.

Refusal to be sworn or to answer questions

30. Section 102 of the Principal Act is amended—

- (a) by omitting from paragraph (1) (c) “, book or writing”;
- (b) by omitting the penalty set out at the foot of sub-section (1) and substituting the following penalty:
“Penalty: \$1,000.”;
- (c) by inserting after sub-section (1) the following sub-section:
“(1A) A practitioner attending before the Committee shall not, without reasonable excuse, refuse or fail to produce a document that he is required to produce by a summons under section 96.
Penalty: \$1,000.”;
- (d) by inserting after sub-section (2) the following sub-section:
“(2A) A document produced at a hearing by a practitioner is not admissible in evidence against him in criminal proceedings except in a prosecution under or arising out of this Act or the regulations or the *National Health Act* 1953 or regulations made under that Act.”; and
- (e) by omitting from sub-section (3) “, book or writing” (wherever occurring).

Recommendation by Committee

31. Section 105 of the Principal Act is amended—

- (a) by inserting after paragraph (2) (c) the following paragraph:
“(ca) that the practitioner be counselled;”;
- (b) by inserting after paragraph (3) (a) the following paragraph:
“(aa) that the practitioner be counselled;”.

Determination by Minister

32. Section 106 of the Principal Act is amended by adding at the end thereof the following sub-section:

“(4) Where a determination under sub-section (1) provides for the payment of an amount to a registered organization, the Minister shall, as soon as practicable after the determination takes effect, forward to the organization a copy of the determination.”.

Establishment of Optometrical Services Committees of Inquiry

33. Section 106B of the Principal Act is amended by omitting from sub-section (5) “and, before making that appointment, shall consult the Australian Optometrical Association” and substituting “but he shall not so appoint an optometrist to that office for a period of more than 3 months except after consultation with the Australian Optometrical Association”.

Recommendation by Committee

34. Section 106F of the Principal Act is amended by inserting after sub-paragraph (2) (b) (i) the following sub-paragraph:

“(ia) that the participating optometrist be counselled;”.

Payments by the Commonwealth

35. Section 125 of the Principal Act is amended by omitting sub-section (2) and substituting the following sub-section:

“(2) All amounts (including advances) payable by the Commonwealth under Part III (including an agreement under that Part) or Part IV and amounts of hospital benefits payable under the regulations shall be paid out of amounts appropriated by the Parliament from time to time for that purpose.”.

Health Insurance Fund

36. Section 126 of the Principal Act is repealed.

False statements, &c.

37. Section 129 of the Principal Act is amended by inserting after sub-section (2) the following sub-section:

“(2A) A person shall not make a statement, either orally or in writing, or issue or present a document, that is false or misleading in a material particular and is capable of being used in, in connection with or in support of—

- (a) an application under section 5 or 5B;
- (b) a statement or report under section 130A; or
- (c) a notification under section 130B.

Penalty: \$500 or imprisonment for 6 months.”.

(2) The amendment made by this section does not affect any proceedings pending under section 129 of the Principal Act immediately before the commencement of this section.

38. After section 129AA of the Principal Act the following section is inserted:

Prohibited practices in relation to the rendering of pathology services

“129AAA. (1) An approved pathology practitioner who accedes to a request from a practitioner (in this sub-section referred to as ‘the requesting practitioner’) to provide pathology services to a patient shall not make a payment, directly or indirectly, to the requesting practitioner for the services provided by the requesting practitioner to that patient in connection with the making of that request and, in particular, shall not make a payment, directly or indirectly, to the requesting practitioner in respect of any use of the staff of the requesting practitioner for the purpose of taking pathology specimens from that patient.

“(2) Where an approved pathology practitioner has entered into an arrangement with a practitioner under which there are shared between the 2

practitioners the cost to them of employing staff or of buying, renting or maintaining items of equipment, whether or not the arrangement involves the payment of money or the provision of other consideration, the approved pathology practitioner shall not, during the period when that arrangement is in force, accede to a request from that other practitioner to provide pathology services to a patient.

“(3) An approved pathology practitioner shall not provide at the premises of a practitioner nursing or other staff to take pathology specimens from patients for use in rendering pathology services, whether the staff is stationed on those premises full-time or part-time or visits those premises from time to time.

“(4) Where—

- (a) there is in force between an approved pathology practitioner and a practitioner an arrangement under which—
 - (i) the 2 practitioners share a particular space in a building; or
 - (ii) one practitioner provides space in a building for the use or occupation of the other practitioner or permits the other practitioner to use or occupy space in a building; and
- (b) the charges payable under the arrangement are not charges fixed at normal commercial rates,

the approved pathology practitioner shall not, during the period when that arrangement is in force, accede to a request from the practitioner to provide pathology services to a patient.

“(5) A person who contravenes sub-section (1), (2), (3) or (4) is guilty of an offence against this section.

“(6) Where an offence against this section is committed by a corporation, an officer of the corporation who is in default is guilty of an offence against this section.

“(7) A reference in sub-section (6) to an officer who is in default, in relation to an offence committed by a corporation, includes a reference to an officer who wilfully authorizes or permits the commission of the offence.

“(8) A person who is convicted of an offence against this section is punishable by a fine not exceeding \$10,000 or imprisonment for a period not exceeding 5 years.

“(9) In this section—

‘approved pathology practitioner’ does not include—

- (a) the Commonwealth or the Northern Territory;
- (b) an authority established by a law of the Commonwealth; or
- (c) a person referred to in paragraph (c) of the definition of ‘eligible applicant’ in sub-section 16C (1);

‘officer’ and ‘pathology service’ have the same respective meanings as in section 129AA.”.

Search of premises, &c.

39. Section 129AB of the Principal Act is amended—

- (a) by inserting in sub-section (4) “or 129AAA” after “section 129AA”; and
- (b) by adding at the end of sub-section (7) “or 129AAA”.

Prosecutions

40. Section 129AC of the Principal Act is amended—

- (a) by omitting from sub-sections (1) and (2) “or 129AA” (wherever occurring) and substituting “, 129AA or 129AAA”; and
- (b) by omitting from sub-section (3) “or of section 129AA” and substituting “, 129AA or 130C”.

41. After section 130 of the Principal Act the following sections are inserted:

Statement to be furnished concerning disadvantaged person when required

“130A. (1) A person in respect of whom there is in force a declaration under section 5 or 5B shall, whenever so required by the Director-General of Social Services, furnish to such officer, and within such time, as the Director-General specifies, a statement in accordance with a form approved by the Director-General, relating to any matter that might affect the continuation in force of that declaration.

“(2) The Director-General of Social Services or an officer authorized by him may, in writing served by post on a person whom he believes to be in a position to do so, require that person to furnish to him a confidential report relating to any matter that might affect the continuation in force of a declaration under section 5 or 5B with respect to another person.

Penalty: \$100.

Receipt of income, &c.

“130B. (1) Where the Director-General of Social Services gives a person a notice under sub-section 5B (8), he may also give the person a notice requiring the person to notify the Department of Social Security if his income during any prescribed period exceeds an amount specified in the notice.

“(2) A person to whom a notice under sub-section (1) has been given shall not refuse or fail to comply with the notice.

Penalty: \$100.

“(3) Whenever a dependant of a person in respect of whom there is in force a declaration under section 5B ceases to be such a dependant, the person shall, immediately after the dependant so ceases to be a dependant, notify the Department of Social Services accordingly.

Penalty: \$100.

“(4) In this section, ‘prescribed period’, in relation to a notice under sub-section (1), means any period of 4 weeks, or such other number of weeks as

is specified in the notice, that ends on a day within the period specified in the declaration under section 5B in relation to the person to whom the notice is given.

False representation that person is disadvantaged person

“130C. (1) A person shall not, with intent to obtain any benefit or advantage, impose or endeavour to impose upon—

- (a) a practitioner;
- (b) a registered organization; or
- (c) the proprietor of a hospital,

by any untrue representation, made in any manner whatsoever, that the person is, or was, a disadvantaged person for the purposes of this Act.

Penalty: \$500 or imprisonment for 6 months.

“(2) In this section, ‘practitioner’ means—

- (a) a medical practitioner;
- (b) a dental practitioner;
- (c) an approved pathology practitioner; or
- (d) a participating optometrist.

Recovery of payments due to false statement that person is, or was, disadvantaged person

“130D. Where, in consequence of an untrue representation, made in any manner whatsoever, by a person that the person is, or was, a disadvantaged person for the purposes of this Act, an amount had been paid to the person by way of Commonwealth medical benefit that would not have been paid but for the untrue representation, the amount so paid is recoverable in a court of competent jurisdiction from that person, or from the estate of that person, as a debt due to the Commonwealth.

Return of notice of declaration of person as disadvantaged person

“130E. A person who has been served, either personally or by post, with a notice under sub-section 5A (3) or 5C (4) of the revocation of a declaration in force under section 5 or 5B shall not, without reasonable excuse (proof whereof shall lie upon him), fail or refuse to return to the Department of Social Security, within 7 days after the service of that notice on him, the notice of the making of that declaration that was given to him under sub-section 5 (5) or 5B (8), as the case may be.

Penalty: \$100.

Powers as to taking of evidence, and production of documents, with respect to disadvantaged persons

“130F. (1) The Director-General of Social Services or an authorized officer may, for the purposes of the provisions of this Act that relate to disadvantaged persons—

- (a) summon witnesses;

- (b) receive evidence on oath or affirmation; and
- (c) require the production of documents.

“(2) A person who has been summoned to appear before the Director-General of Social Services or an authorized officer shall not, without lawful excuse, after tender of reasonable expenses, fail to appear in obedience to the summons.

Penalty: \$100.

“(3) A person, whether summoned or not, who appears before the Director-General of Social Services or an authorized officer shall not—

- (a) refuse to be sworn as a witness or to make an affirmation;
- (b) fail to answer any question that he is lawfully required to answer; or
- (c) fail to produce any document that he is lawfully required to produce.

Penalty: \$100.

“(4) In this section, ‘authorized officer’ means an officer authorized by the Director-General of Social Services for the purposes of this section.

Evidence

“130G. (1) All courts shall take judicial notice of the signature of any person who holds or who has held the office of Director-General, Deputy Director-General, Assistant Director-General, Director or Registrar, and of the fact that that person holds or has held that office, if the signature purports to be attached or appended to any official document and any such document purporting to be so signed shall be received in all courts as *prima facie* evidence of the facts and statements contained therein.

“(2) A document referred to in sub-section (1) may relate to any matter in connection with the operation of this Act in relation to disadvantaged persons.

“(3) In this section, a word or phrase defined for the purposes of the *Social Services Act* 1947 has the meaning that it would have if used in that Act.

Information with respect to disadvantaged persons

“130H. Notwithstanding section 17 of the *Social Services Act* 1947, the Director-General of Social Services or an officer authorized by him for the purpose may communicate to the Permanent Head of the Department of Health or an officer authorized by him any information with respect to the operation of sections 5 to 5E (inclusive).

Delegation by Director-General of Social Services

“130J. (1) The Director-General of Social Services may, either generally or as otherwise provided by the instrument of delegation, by writing signed by him, delegate to a person all or any of his powers under this Act, other than this power of delegation.

“(2) A power so delegated, when exercised by the delegate, shall, for the purposes of this Act, be deemed to have been exercised by the Director-General of Social Services.

“(3) A delegation under sub-section (1) does not prevent the exercise of a power by the Director-General of Social Services.”.

Regulations

42. Section 133 of the Principal Act is amended by omitting sub-section (3).

Schedule 2

43. Schedule 2 to the Principal Act is repealed.

New forms of undertaking for approved pathology practitioners

44. (1) The regulations under the *Health Insurance Act 1973* may prescribe forms of undertaking in substitution for the forms of undertaking drawn up by the Minister and in force under section 16B of the Principal Act immediately before the commencement of this section.

(2) The forms of undertaking prescribed under sub-section (1) shall be deemed to have come into force on the date of commencement of this section and the forms of undertaking for which those forms are substituted shall be deemed to have ceased to be in force on that date.

(3) The forms of undertaking prescribed under sub-section (1) shall, for all purposes, be deemed to be forms of undertaking drawn up by the Minister under sub-section 16B (1) of the *Health Insurance Act 1973*.

Undertakings to continue in force

45. Notwithstanding the operation of section 44 of this Act, an undertaking in force immediately before the commencement of this Act under section 16C of the Principal Act continues in force after the commencement of this Act subject to section 47 of this Act.

Continuation of undertaking not to prevent giving of further undertaking

46. A person in respect of whom an undertaking is continued in force by section 45 of this Act is not, by reason only that that undertaking is in force, prevented from giving a further undertaking under section 16C of the *Health Insurance Act 1973*.

Undertakings continued in force to cease to be in force

47. (1) In this section—

“continuing undertaking” means an undertaking that is continued in force by section 45 of this Act;

“further undertaking” means an undertaking given under section 16C of the *Health Insurance Act 1973* by a person in respect of whom there is in force a continuing undertaking.

(2) A continuing undertaking shall cease to be in force on a date fixed by the Minister, by notice published in the *Gazette*, for the purposes of this sub-section.

(3) A further undertaking, if accepted, shall not come into force before the date fixed for the purposes of sub-section (2).

(4) A further undertaking given, but not accepted, before the date fixed for the purposes of sub-section (2) shall, on and after that date and until accepted or until the determination of the Minister refusing to accept it takes effect, be deemed to be in force as if it had been accepted.

(5) Sub-section 106 (3) of the *Health Insurance Act 1973* applies, by force of this sub-section, to a determination of the Minister refusing to accept a further undertaking, and such a determination takes effect in accordance with that sub-section as so applied.

(6) Notwithstanding any other provision of this section, a continuing undertaking, or a further undertaking that is deemed to be in force by virtue of sub-section (4), may cease to be in force by virtue of the operation of sub-section 16C (9) of the *Health Insurance Act 1973*.

PART III—AMENDMENTS OF THE NATIONAL HEALTH ACT 1953 AND RELATED PROVISIONS

Principal Act

48. The *National Health Act 1953*² is in this Part referred to as the Principal Act.

Interpretation

49. Section 4 of the Principal Act is amended—

(a) by omitting paragraphs (a) and (b) of the definition of “basic hospital benefits table” or “basic table” in sub-section (1) and substituting the following paragraphs:

“(a) in respect of hospital treatment provided to persons as in-patients in a hospital in the State or Territory to which the table relates, being patients who are not nursing-home type patients—benefits equal to the amount of the standard hospital fees in relation to that State or Territory;

“(b) in respect of hospital treatment provided to persons as in-patients in a recognised hospital in the State or Territory to which the table relates, being the nursing-home type patients—benefits equal to the amount of the standard hospital fees in relation to that State or Territory less the amount of the patient contribution in relation to that patient for each day on which that patient is an in-patient in the hospital;”;

(b) by omitting from paragraph (ba) of the definition of “basic hospital benefits table” or “basic table” in sub-section (1) “(other than nursing-home type patients referred to in paragraph (a)) but not being patients in respect of whose occupation of an approved bed in the

hospital a supplementary daily bed payment is payable under section 34 of the *Health Insurance Act 1973*”;

- (c) by omitting paragraph (e) of the definition of “basic hospital benefits table” or “basic table” in sub-section (1);
- (d) by omitting from sub-section (1) the definition of “basic medical benefits table” or “basic table” and substituting the following definition:

“‘basic medical benefits table’ or ‘basic table’, in relation to a registered medical benefits organization, means a table that incorporates a range of benefits of the following kinds and no other benefits:

- (a) a range of benefits in respect of the provision of every professional service, such that, if, in respect of any particular professional service a Commonwealth medical benefit is payable to a person, then, and only then—

- (i) a benefit is payable in accordance with the table in respect of that professional service; and

- (ii) the amount of that benefit is an amount equal to the amount by which the amount of the guaranteed medical benefit in respect of that professional service exceeds the amount of the Commonwealth medical benefit so payable;

- (b) such other benefits (if any) as are prescribed for the purposes of this definition;”;

- (e) by omitting from sub-section (1) the definition of “guaranteed medical benefit” and substituting the following definition:

“‘guaranteed medical benefit’, in relation to a particular professional service in respect of which a Commonwealth medical benefit is payable to a person, means an amount equal to the amount that that Commonwealth medical benefit would be if it were calculated, in accordance with the *Health Insurance Act 1973*, on the assumption that sub-section (2) of section 10 of that Act provided that the amount of a Commonwealth medical benefit should be calculated in accordance with the following formula:

An amount equal to 85% of the fee specified in respect of the service in the table in relation to the State or Territory in which the service is rendered or, if that amount is less by more than \$10 than that fee, an amount that is less by \$10 than that fee;”;

- (f) by adding at the end of the definition of “nursing home care” in sub-section (1) “, and includes any prescribed service of a kind provided in a nursing home”;
- (g) by omitting from sub-section (1) the definition of “nursing home fund benefit”;

- (h) by omitting from sub-section (1) the definitions of “optional hospital benefits table” or “optional table” and “optional medical benefits table” or “optional table”;
- (j) by omitting from sub-section (1) the definition of “prescribed professional service”;
- (k) by omitting from paragraph (a) of the definition of “supplementary hospital table” in sub-section (1) “or an optional table”; and
- (l) by omitting from sub-section (1) the definition of “uninsured nursing home patient”; and
- (m) by omitting sub-section (1B).

Waiting period

50. Section 4A of the Principal Act is amended—

- (a) by omitting from sub-section (1) “or an optional table”; and
- (b) by omitting sub-section (2).

Interpretation

51. Section 12 of the Principal Act is amended by omitting from sub-section (1) the definition of “referring medical practitioner” and substituting the following definition:

“ ‘referring medical or dental practitioner’, in relation to a patient, means—

- (a) in the case of a patient to whom an application under sub-section (1) of section 13 relates—the medical practitioner who made the reference referred to in that application; or
- (b) in the case of a patient to whom an application under sub-section (1A) or (1C) of section 13 relates—the medical practitioner or dental practitioner who made the reference referred to in that application;”.

Approved patient

52. Section 13 of the Principal Act is amended—

- (a) by inserting after sub-section (1) the following sub-sections:

“(1A) Where a person who resides in an isolated area has been referred by a medical practitioner or a dental practitioner to an approved dental practitioner for the rendering to the person of a service that, by virtue of paragraph (b) of the definition of “professional service” in sub-section (1) of section 3 of the *Health Insurance Act 1973*, is a professional service for the purposes of that Act, an application, in accordance with a form approved by the Minister, may be made to the Permanent Head by, or on behalf of, the person for the approval by the Permanent Head of the person as an approved patient in relation to the rendering of that professional service.

“(1B) The reference in sub-section (1A) to an approved dental practitioner shall be read as a reference to a dental practitioner who—

- (a) is approved by the Minister for the purposes of the definition of “professional service” in sub-section (1) of section 3 of the *Health Insurance Act 1973*; and
- (b) is approved by the Permanent Head for the purposes of this sub-section.

“(1C) Where a referred dental patient resides in an isolated area, an application, in accordance with a form approved by the Minister, may be made to the Permanent Head by, or on behalf of, the referred dental patient for the approval by the Permanent Head of the referred dental patient as an approved patient in relation to the rendering to him by the accredited dental practitioner to whom he has been referred of a service that, by virtue of paragraph (ba) of the definition of “professional service” in sub-section (1) of section 3 of the *Health Insurance Act 1973*, is a professional service for the purposes of that Act.”;

- (b) by inserting in sub-section (2) “, (1A) or (1C)” after “sub-section (1)”;
- (c) by omitting from paragraph (2) (c) “or consultant physician” and substituting “, consultant physician or dental practitioner”;
- (d) by inserting in sub-section (3) “, (1A) or (1C)” after “sub-section (1)”;
- (e) by omitting paragraph (b) of sub-section (3) and substituting the following paragraph:

“(b) the specialist, consultant physician or dental practitioner concerned is, or was at the relevant time, the nearest suitable specialist, consultant physician or dental practitioner, as the case may be, with respect to the patient; and”.

Approved attendants and approved escorts

53. Section 14 of the Principal Act is amended by omitting from sub-sections (1), (2) and (3) “referring medical practitioner” and substituting “referring medical or dental practitioner”.

Circumstances in which payment not to be made

54. Section 20 of the Principal Act is amended—

- (a) by omitting from sub-section (1) “this section” and substituting “sub-sections (2) and (3)”;
- (b) by adding at the end thereof the following sub-section:
 - “(4) A payment under this Part shall not be made if—
 - (a) the application for the approval of the approved patient was made under sub-section (1A) or (1C) of section 13; and
 - (b) the rendering of the relevant professional service to the approved patient occurred, or commenced, before 1 January 1981.”.

Approval of nursing home

55. (1) Section 40AA of the Principal Act is amended—

- (a) by omitting from sub-section (3) “(not being a Government nursing home)”; and
- (b) by omitting sub-sections (5A) and (5B) and substituting the following sub-sections:

“(5A) The approval of premises as an approved nursing home is subject to the condition that, where a Commonwealth benefit is payable, or has been paid, to the proprietor of the nursing home in respect of a patient for a period, the proprietor shall deduct the amount of that benefit from the fees charged in respect of nursing home care for that patient during that period.

“(5B) For the purposes of the operation of the condition set out in sub-section (5A), any Commonwealth benefit that would be payable to the proprietor of the nursing home but for the suspension of the approval of the nursing home shall be deemed to be payable to that proprietor.”;

- (c) by omitting sub-paragraph (6) (c) (ii) and substituting the following sub-paragraph:

“(ii) no extra charge will be payable by or on behalf of a qualified nursing patient in the nursing-home unless—

- (A) the charge is in respect of a matter that is not related to the nursing-home care provided for the patient; and
- (B) the service for which the charge is made has been requested by the patient;”;

- (d) by inserting after paragraph (6) (c) the following paragraph:

“(ca) a condition that, where the proprietor of the nursing-home charges a qualified nursing-home patient in the nursing-home with a fee or extra charge, the proprietor shall—

- (i) furnish to the patient an account setting out the amount of that fee or extra charge and the service to which it relates; and
- (ii) file, and keep filed, with the records of the nursing-home kept in compliance with section 61 a copy of the account so furnished;”;

- (e) by inserting after sub-section (6) the following sub-section:

“(6A) A reference in the condition set out in paragraph (6) (c) to a request by a patient for a service for which a charge is made shall be read as not including a request the making of which by the patient is, or was, a condition of his admission to, or of his remaining in, the nursing home.”.

(2) Notwithstanding the amendment made by sub-section (1), a condition to which the approval of premises as an approved nursing home was subject under sub-section 40AA (5A) of the Principal Act immediately before the

commencement of this section, being a condition that was set out in paragraph (b) or (c) of that sub-section, continues to apply in relation to—

- (a) any payment of nursing home fund benefit to the proprietor of the nursing home made after the commencement of this section; or
- (b) any entitlement to the payment of nursing home fund benefit that accrues to the proprietor of the nursing home after the commencement of this section.

(3) In sub-section (2), “nursing home fund benefit” means an amount payable under the rules of a registered hospital benefits organization in respect of a person who was an insured nursing home patient for the purposes of the *National Health Act 1953* at any time before the commencement of this section.

Determination that patient be treated as uninsured nursing home patient

56. Section 40AG of the Principal Act is repealed.

Furnishing of audited accounts of proprietors of certain approved nursing homes

57. Section 43A of the Principal Act is amended—

- (a) by omitting sub-section (3) and substituting the following sub-section:
 - “(3) Before furnishing to the Permanent Head under sub-section (1) a copy of accounts prepared with respect to a nursing home, the proprietor of the nursing home shall cause a person having the prescribed qualifications to audit those accounts and to report whether, in his opinion, the accounts were properly drawn up so as to give a true and fair view of—
 - (a) the financial affairs of the nursing home as at the end of the period to which the accounts relate; and
 - (b) the income and expenditure of the nursing home for the period to which the accounts relate.”; and
- (b) by adding at the end thereof the following sub-section:
 - “(5) In this section, ‘accounts’ includes a balance sheet and such other statements as are prescribed.”.

Effect of suspension on approval of nursing home

58. Section 45B of the Principal Act is amended by omitting paragraph (d).

Interpretation

59. Section 46 of the Principal Act is amended by omitting from sub-section (2) “uninsured” and substituting “qualified”.

Basic benefit payable in respect of nursing home care

60. Section 47 of the Principal Act is amended by omitting from sub-sections (1) and (2) “uninsured” and substituting “qualified”.

Extensive care benefit payable in respect of nursing home care

61. Section 49 of the Principal Act is amended by omitting “uninsured” and substituting “qualified”.

Payment of Commonwealth benefit and nursing home fund benefit in respect of same patient for same period

62. Section 50 of the Principal Act is amended by adding at the end thereof the following sub-section:

“(4) In this section, ‘nursing home fund benefit’ means an amount payable under the rules of a registered hospital benefits organization in respect of a person who was an insured nursing home patient for the purposes of this Act at any time before the commencement of this sub-section.”.

Commonwealth benefit not payable where compensation, &c., is payable to patient

63. Section 59 of the Principal Act is amended by omitting from paragraph (1) (a) “uninsured” and substituting “qualified”.

64. Section 60A of the Principal Act is repealed and the following section substituted:

Direction that Commonwealth benefit not to be subject to reduction

“60A. Where the Permanent Head considers that the fees in respect of nursing home care for qualified nursing home patients in a nursing home are less than is appropriate having regard to the standard of nursing home care provided in that nursing home and to any other matter that he considers relevant, the Permanent Head may, by instrument in writing, direct that sub-section (2) of section 47 does not apply in relation to any of the qualified nursing home patients in that nursing home.”.

Interpretation

65. Section 66 of the Principal Act is amended by omitting from sub-section (1) the definitions of “insured nursing home patient” and “nursing home fund benefit”.

Application by organizations for registration as hospital benefits organizations

66. Section 68 of the Principal Act is amended—

- (a) by omitting from sub-paragraph (2) (c) (iii) “nursing home care,” (wherever occurring);
- (b) by omitting from sub-paragraph (2) (c) (iv) “nursing home care,”; and
- (c) by omitting from sub-paragraph 4 (c) (iii) “nursing home care,”.

Reinsurance Account in hospital benefits fund

67. Section 73BB of the Principal Act is amended by inserting in sub-section (11), after the definition of “hospital treatment”, the following definitions:

“ ‘nursing home fund benefit’ means any amount payable under the rules of a registered hospital benefits organization in respect of a person who was an insured nursing home patient, within the meaning of this Act, at any time before the commencement of this definition;

‘optional table’, in relation to a registered hospital benefits organization, means a table of benefits that was, at any time before the commencement of this definition, declared by the Minister in this Act to be an optional hospital benefits table;”.

Conditions of registration relating to nursing home care

68. Section 73C of the Principal Act is repealed.

Guidelines for optional tables

69. Section 73É of the Principal Act is repealed.

Exemptions of professional services and associated hospital treatment from basic table

70. (1) Section 73F of the Principal Act is amended—

(a) by omitting sub-section (1) and substituting the following sub-section:

“(1) A registered organization may make application to the Minister for—

(a) an exemption from the requirement to include in the basic medical benefits table provided, or intended to be provided, for the benefit of the contributors to a medical benefits fund conducted, or to be conducted, by it benefits in respect of professional services of a kind or kinds specified in the application; or

(b) an exemption from the requirement to include in the basic hospital benefits table provided, or intended to be provided, for the benefit of the contributors to a hospital benefits fund conducted, or to be conducted, by it—

(i) any benefits in respect of any day on which hospital treatment is provided to a person for the purpose of permitting the rendering to the person of a professional service, or professional services, of a kind or kinds specified in the application and no other professional service; and

(ii) any benefits, other than the benefits determined by the Permanent Head or the Minister under section 73G, in respect of any day on which hospital treatment is provided to a person for the purpose of permitting the rendering to the person of a professional service, or professional services, of a kind or kinds specified in the application together with a professional service that is not a professional service of a kind specified in the application.”;

- (b) by omitting from sub-section (2) “medical benefits”;
- (c) by inserting after sub-section (2) the following sub-sections:
 - “(2A) Subject to sub-section (2B), an exemption granted under this section does not take effect until the expiration of 1 month after the granting of the exemption.
 - “(2B) An exemption in force under this section does not apply in relation to a person who—
 - (a) was, immediately before the exemption took effect, a contributor, in accordance with a basic table, to a medical benefits fund, or to a hospital benefits fund, conducted by the organization concerned; and
 - (b) continues to be such a contributor, until the expiration of a period of 2 months after the exemption took effect, and, for the purpose of determining the entitlement of such a person to benefits, in accordance with a basic table, in respect of the rendering of a professional service, or the provision of hospital treatment, during that period to the person or to a dependant of the person, the exemption shall be disregarded.”;
- (d) by omitting from sub-section (3) “medical benefits” (first occurring); and
- (e) by adding at the end of sub-section (3) “or as a registered hospital benefits organization, as the case may be”.

(2) The amendments made by sub-section (1) do not affect any exemption in force under section 73F of the Principal Act immediately before the commencement of this section.

71. After section 73F of the Principal Act the following section is inserted:

Determination of certain hospital benefits by Permanent Head

“73G. (1) In this section—

‘applicant’, in relation to a claim to which this section applies, means the person who makes application under this section for a determination of the benefits that are to be payable in respect of the provision of the hospital treatment to which the claim relates;

‘claim to which this section applies’ means a claim for benefits, in accordance with a basic hospital benefits table conducted by a registered organization, in respect of the provision of hospital treatment to a person for the purpose of permitting the rendering to the person of a professional service, or professional services, of a kind or kinds specified in an exemption granted to the organization under section 73F (not being an exemption that, by virtue of sub-section (2B) of section 73F or in compliance with the condition set out in paragraph (sb) of the Schedule, is to be disregarded in relation to the person during the period, or any part of a period, to which the claim relates) together with a professional service that is not a professional service of a kind specified in that exemption;

'claimant', in relation to a claim to which this section applies, means the person who makes the claim;

'other party', in relation to a claim to which this section applies, means the claimant or the registered organization, whoever is not the applicant.

"(2) The claimant in relation to a claim to which this section applies or the registered organization concerned may make application, in writing, to the Department for a determination of the benefits that are to be payable in respect of the provision of the hospital treatment to which the claim relates.

"(3) Where an application is made under sub-section (2), the Permanent Head shall serve by post on the other party a notification of the receipt of the application and request the other party to furnish to the Permanent Head, in writing, within 14 days after receipt of the notification, any comments that he may wish to make with respect to the claim the subject of the application.

"(4) In considering a claim to which this section applies, the Permanent Head shall have regard to the relationship between the hospital treatment to which the claim relates and the professional services for the purpose of permitting the rendering of which the hospital treatment was provided.

"(5) After consideration of a claim in accordance with sub-section (4), the Permanent Head shall determine the benefits that are to be payable in respect of the provision of the hospital treatment to which the claim relates, not being benefits greater than the benefits that would be payable in relation to that hospital treatment if no exemption had been in force under section 73F at the time when the hospital treatment was provided, and shall serve by post on the applicant and the other party a notification of the determination.

"(6) A person who has been notified of a determination of the Permanent Head under sub-section (5) may, within one month of the receipt of that notification, lodge with the Minister an appeal against that determination.

"(7) The Minister shall consider any appeal under sub-section (6) and shall either confirm the determination of the Permanent Head or allow the appeal and determine the benefits that are to be payable in respect of the provision of the hospital treatment to which the appeal relates, not being benefits greater than the benefits that would be payable in relation to that hospital treatment if no exemption had been in force under section 73F at the time when the hospital treatment was provided.

"(8) Where the Minister under sub-section (6) confirms a determination of the Permanent Head, or determines the benefits that are to be payable in respect of the provision of hospital treatment, in respect of a claim to which this section applies, he shall serve by post on the applicant and on the other party a notification of the confirmation or of his determination, as the case may be.

"(9) A determination of the Permanent Head under sub-section (5) shall, unless an appeal against it is lodged in accordance with sub-section (6), come into operation at the expiration of the period in which such an appeal may be lodged.

“(10) A determination of the Permanent Head that is confirmed by the Minister under sub-section (7) shall come into operation on the day on which it is so confirmed.

“(11) A determination of the Minister under sub-section (7) shall come into operation on the day on which it is made.”.

Public officer of registered organization

72. Section 74 of the Principal Act is amended by adding at the end thereof the following sub-sections:

“(9) A registered organization shall appoint a person to act in the place of the public officer of the organization whenever that public officer is absent from duty.

Penalty: \$200.

“(10) Where a person (in this sub-section referred to as ‘the acting officer’) is acting in the place of the public officer of a registered organization by virtue of an appointment (in this sub-section referred to as ‘the acting appointment’) referred to in sub-section (9), then, for the purposes of this Act (including the purposes of sub-section (5) of this section)—

- (a) the acting officer shall be deemed to be the public officer of the organization during the whole of the period of the acting appointment; and
- (b) the person in whose place the acting officer is acting shall be deemed not to be the public officer of the organization during any part of the period of the acting appointment.”.

Changes of rules, &c., by registered organizations

73. Section 78 of the Principal Act is amended—

- (a) by omitting from sub-section (3) “The Permanent Head” and substituting “Subject to sub-section (3A), the Permanent Head”;
- (b) by inserting after sub-section (3) the following sub-section:

“(3A) The Permanent Head may refer to the Minister for his consideration under sub-section (8A) a notification under sub-section (1) of a change in relation to which sub-section (2) applies.

“(3B) If, after consideration of a change referred to him under sub-section (3A), the Minister is not satisfied that he should refuse to approve the change, the Minister shall refer the change to the Permanent Head for action under sub-section (3).”;

- (c) by omitting sub-section (4); and
- (d) by omitting sub-section (8) and substituting the following sub-sections:

“(8) The Minister shall not refuse to approve of a change to which sub-section (2) applies if the change is required, or permitted, to be made by or under this Act.

“(8A) The Minister shall refuse to approve of a change to which sub-section (2) relates if he is of the opinion that the change would, or

might, result in a breach by the organization of a condition of registration imposed on the organization by or under this Act and, in that case, he shall give to the registered organization notification in writing of his refusal.”.

Provisions applicable to persons ceasing to be pensioners or disadvantaged persons

74. Section 81A of the Principal Act is amended—

- (a) by inserting in paragraphs (1) (a) and (c) “or a disadvantaged person” after “pensioner”;
- (b) by omitting from paragraphs (1) (c) and (d) “, hospital treatment or nursing home care” and substituting “or hospital treatment”; and
- (c) by inserting at the end thereof the following sub-section:

“(4) In this section, the ‘contributor’ means the contributor in accordance with a basic table.”.

Schedule

75. (1) The Schedule to the Principal Act is amended—

- (a) by omitting from paragraph (c) “other than in accordance with a basic table or an optional table”;
- (b) by omitting from paragraph (g) “or an optional table”;
- (c) by omitting from paragraph (h) “or an optional table”;
- (d) by omitting from paragraph (j) “or an optional table”;
- (e) by omitting paragraph (n) and substituting the following paragraphs:
 - “(n) the rules of the organization will not provide for a waiting period for—
 - (i) contributors for benefits in accordance with a basic table who have transferred to a medical benefits fund or a hospital benefits fund conducted by the organization from such a fund conducted by another organization whose registration under Part VI has been cancelled or is under consideration by the Minister with a view to cancellation; or
 - (ii) eligible persons who, on or before 1 November 1981, become contributors to a medical benefits fund or a hospital benefits fund conducted by the organization, being contributors for benefits in accordance with a basic table.
 - “(na) The organization will not, in determining, in relation to any contributor to a basic table or to a contributor included in a class or kind of contributors to a basic table—
 - (i) whether or not benefits are payable in accordance with the table;
 - (ii) if benefits are payable in accordance with the table—the amount of the benefits so payable; or

- (iii) the amount of the contributions payable in respect of the table,

have regard to any of the following matters:

- (iv) the suffering by the contributor, or a dependant of the contributor, from a chronic disease, illness or other medical condition or from a disease, illness or medical condition of a particular kind;
- (v) the age of the contributor or of a dependant of the contributor;
- (vi) the frequency of the rendering of professional services to the contributor or to a dependant of the contributor;
- (vii) the amount, or extent, of the benefits to which the contributor becomes, or has become, entitled during a period; or
- (viii) any matter prescribed for the purposes of this sub-paragraph.”; and

- (f) by omitting paragraphs (r) and (s) and substituting the following paragraphs:

“(r) Where the determination of a claim for a Commonwealth medical benefit, or for a benefit in accordance with a basic medical benefits table, that is lodged with the organization (whether in pursuance of section 20B of the *Health Insurance Act 1973* or in pursuance of the rules of the organization) is subject to, or may be affected by, the exercise of a power conferred on the Permanent Head of the Department of Health or on a Minister by a provision of Part II of the *Health Insurance Act 1973* in relation to a matter, the organization will refer the claim to the Department so that the matter may be considered by the Permanent Head or the Minister, as the case may be, in accordance with that Act.

“(s) Where a claim for a benefit payable by the organization out of a medical benefits fund or a hospital benefits fund conducted by the organization is, or has been, lodged with the organization, the organization will pay that claim within 2 months, or such longer period as the Permanent Head approves in a particular case, after—

- (i) the date of commencement of this condition; or
- (ii) the date of lodgement of the claim with the organization,

whichever is the later date.

“(sa) Where an exemption has been granted under section 73F in relation to a basic medical benefits table conducted by the

organization, the organization will, within a period of 1 month after the granting of the exemption --

- (i) furnish to all contributors to any medical benefits fund conducted by the organization and to all persons registered with it as registered persons; and
- (ii) publish, in a manner satisfactory to the Minister, for the information of persons who may wish to become contributors to a basic medical benefits fund conducted by the organization and persons who may wish to register with the organization as registered persons,

the particulars of the exemption, including the date on which the exemption takes effect and a description of the professional service or professional services affected by the exemption, and a statement setting out the effect of the exemption on the rights of contributors and registered persons.

“(sb) Where an exemption has been granted under section 73F in relation to a basic hospital benefits table conducted by the organization, the organization will, within a period of one month after the granting of the exemption —

- (i) furnish to all contributors to any hospital benefits fund conducted by the organization; and
- (ii) publish, in a manner satisfactory to the Minister, for the information of persons who may wish to become contributors to a hospital benefits fund conducted by the organization,

the particulars of the exemption, including the date on which the exemption takes effect and a description of the hospital treatment affected by the exemption, and a statement setting out the effect of the exemption on the rights of contributors.

“(sc) Where—

- (i) an exemption is in force under section 73F in relation to the organization;
- (ii) at any time during the period of 3 months from the granting of that exemption, a contributor, in accordance with a basic table, to a medical benefits fund, or to a hospital benefits fund, conducted by the organization (being a person who has been such a contributor since before the granting of the exemption) transfers to another registered organization and becomes a contributor, in accordance with a basic table, to a medical benefits fund, or to a hospital benefits fund, conducted by that other organization; and
- (iii) that person, as such contributor in relation to the other organization, is subject to a waiting period commencing from the date of that transfer,

the first-mentioned organization will continue to treat that person, during that waiting period, as a contributor, in accordance with a basic table, to the relevant fund conducted by that first-mentioned organization and, for that purpose, will disregard the exemption.

“(sd) Where a payment of a benefit may be made by the organization, by virtue of section 81A, notwithstanding the rules of the organization, the organization will make that payment.”.

(2) The conditions set out in paragraphs (1) (e) and (f) apply in relation to a registered organization whether the registration of the organization was effected before, or is effected after, the commencement of this section.

PART IV—AMENDMENTS OF THE NURSING HOMES ASSISTANCE ACT 1974

Principal Act

76. The *Nursing Homes Assistance Act 1974*³ is in this Part referred to as the Principal Act.

Interpretation

77. (1) Section 3 of the Principal Act is amended—

- (a) by adding at the end of the definition of “eligible organization” in sub-section (1), after paragraph (e) of that definition, “but does not include an organization that conducts, or has at any time conducted, a public hospital”;
- (b) by adding at the end of the definition of “nursing home care” in sub-section (1) “, and includes any prescribed service of a kind provided in a nursing home”;
- (c) by omitting from sub-section (1) the definition of “premises” and substituting the following definition:
 - “ ‘premises’ includes a part of premises, but does not include—
 - (a) any premises on Crown land, whether in a State or an internal Territory;
 - (b) any premises on land held under a lease or licence from the Crown, whether in a State or in an internal Territory;
 - (c) any premises on land that has been the subject of a deed of gift by a State or by the Commonwealth;
- (d) by adding at the end of sub-section (1) the following definition:
 - “ ‘State’ includes the Northern Territory.”; and
- (e) by omitting sub-sections (1A) and (2) and substituting the following sub-sections:
 - “(2) Where the Minister, having regard to the particular circumstances of the case, considers that an organization (whether an

eligible organization or not) should be treated, for the purposes of this Act, as an eligible organization with respect to particular premises (whether premises within the meaning of this Act or not), the Minister shall, by instrument in writing, make a declaration accordingly.

“(2A) A declaration under sub-section (2) may be expressed to take effect as from a date before the making of the declaration, not being a date before the commencement of this sub-section.

“(2B) A reference in this Act to a nursing home to which this Act applies shall be read as a reference to—

- (a) a nursing home, other than a Government nursing home, conducted by an eligible organization; or
- (b) a nursing home conducted on premises to which a declaration under sub-section (2) applies by the organization to which the declaration applies.

“(2C) Where a nursing home is a nursing home to which this Act applies by virtue of a declaration under sub-section (2), the premises on which the nursing home is conducted shall, if they are not otherwise premises within the meaning of this Act, be deemed to be, by force of this sub-section, premises within the meaning of this Act.”.

(2) Subject to sub-section (3), the amendments made by sub-section (1) do not affect an approval under section 4 of the Principal Act in force immediately before the commencement of this section.

(3) Where the Minister is satisfied that an approval referred to in sub-section (2) would not have been given if the amendments made by sub-section (1) had been in force at the time that the application for the approval was considered, the Minister may, having regard to all the circumstances of the case, revoke the approval as from a date specified in the revocation, not being a date earlier than the date on which the revocation is made.

(4) A revocation under sub-section (3) shall not be made after the expiration of 3 months after the commencement of this section.

Approval of nursing home

78. Section 4 of the Principal Act is amended by omitting paragraphs (6) (ba), (bb) and (bc).

Fees

79. Section 13 of the Principal Act is amended by omitting sub-section (1A).

Insured nursing home patients requiring extensive care

80. Section 13A of the Principal Act is repealed.

**PART V—AMENDMENTS OF THE THERAPEUTIC GOODS ACT
1966****Principal Act**

81. The *Therapeutic Goods Act 1966*⁴ is in this Part referred to as the Principal Act.

Interpretation

82. Section 5 of the Principal Act is amended—

(a) by inserting in sub-section (1) before the definition of “general standard” the following definitions:

“ ‘batch’ includes a number of batches and a part of a batch;

“ ‘British Pharmaceutical Codex’ means the book called the British Pharmaceutical Codex published by direction of the Council of the Pharmaceutical Society of Great Britain;

“ ‘British Pharmacopoeia’ means—

(a) the latest edition (being an edition that has taken effect for the purposes of this Act in accordance with section 6) for the time being of the book called the British Pharmacopoeia published under the direction of the Medicines Commission of the United Kingdom; or

(b) if that edition has been added to or amended by additions or amendments that have taken effect for the purposes of this Act in accordance with section 6—that edition as affected by those additions or amendments;

“ ‘British Pharmacopoeia (Veterinary)’ means the book called the British Pharmacopoeia (Veterinary) published on the recommendation of the Medicines Commission of the United Kingdom;

“ ‘British Veterinary Codex’ means the book called the British Veterinary Codex published by direction of the Council of the Pharmaceutical Society of Great Britain;

“ ‘Director-General’ means the Director-General of Health;

“ ‘European Pharmacopoeia’ means the book called the European Pharmacopoeia published in accordance with the terms of the convention known as the Convention on the Elaboration of a European Pharmacopoeia;

“ ‘former British Pharmacopoeia’ means the book called the British Pharmacopoeia published under the direction of the General Medical Council of the United Kingdom;”;

(b) by omitting from sub-section (1) the definition of “specific standard” and substituting the following definitions:

“ ‘orthotics’ means the complementing, supplementing or replacing of a physiological function of the body and includes the

provision of contact lenses, hearing aids, heart pace-makers and similar aids;

“ ‘Pharmaceutical Codex’ means the book called the Pharmaceutical Codex published by direction of the Council of the Pharmaceutical Society of Great Britain;

“ ‘prescribed corporation’ means a foreign corporation, or a trading corporation formed within the limits of the Commonwealth, within the meaning of paragraph 51 (xx) of the Constitution;

“ ‘prescribed publication’ means—

- (a) the British Pharmaceutical Codex;
- (b) the British Pharmacopoeia (Veterinary);
- (c) the British Veterinary Codex;
- (d) the former British Pharmacopoeia; or
- (e) the Pharmaceutical Codex;

“ ‘prosthetics’ means the making up of a deficiency in the body and includes the provision of dentures, artificial organs or limbs or similar aids;

“ ‘relevant date’ means the date of commencement of Part V of the *Health Acts Amendment Act 1981*;

“ ‘specific standard’, in relation to goods for therapeutic use, means a standard for a substance or article of which the goods consist, or are represented to consist, that—

- (a) if the goods are for human use—
 - (i) is specified in an order under section 11 that has effect in relation to goods for human use; or
 - (ii) where a standard for the substance or article is not specified in such an order but the substance or article is the subject of a monograph in the British Pharmacopoeia—is constituted by the statements in that monograph; or
- (b) if the goods are for veterinary use—is specified in an order under section 11 that has effect in relation to goods for veterinary use;”;

(c) by omitting from sub-section (1) the definitions of “the British Pharmaceutical Codex”, “the British Pharmacopoeia”, “the British Veterinary Codex” and “therapeutic use” and substituting the following definitions:

“ ‘supply’ includes—

- (a) supply by way of sale, exchange, gift, lease, hire or hire-purchase;
- (b) supply (whether free of charge or otherwise) by way of sample or advertisement; and

- (c) supply (whether free of charge or otherwise) in the course of research undertaken to test the safety or efficacy of goods for therapeutic use;

“ ‘therapeutic use’ means use in, or in connection with—

- (a) the preventing, diagnosing, curing or alleviating of a disease, ailment, defect or injury in persons or animals;
- (b) the influencing, inhibiting or modifying of a physiological process in persons or animals; or
- (c) the testing of the susceptibility of persons or animals to a disease or ailment,

and, without limiting the generality of the foregoing, includes use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics.”; and

- (d) by adding at the end thereof the following sub-sections:

“(5) Where a statement in a monograph in a publication refers to a statement in a monograph in another publication, the statement in the monograph in the other publication shall be deemed to be a statement in the first-mentioned monograph.

“(6) A monograph in the British Pharmacopoeia that purports to reproduce statements in a monograph in the European Pharmacopoeia shall not be construed for the purposes of this Act by reference to the monograph in the European Pharmacopoeia notwithstanding anything to the contrary in the British Pharmacopoeia.

“(7) A reference in this Act to a book, other than the British Pharmacopoeia, shall be read as a reference to any edition of that book, whether published before or after the relevant date, or any such edition as added to or amended by any addition to or amendment of that edition.

“(8) A reference in this Act to goods for therapeutic use does not include a reference to goods for use in, or in connection with, testing for pregnancy, contraception, prosthetics or orthotics unless the goods are declared, or are included in a class of goods that are declared, by the regulations to be goods for therapeutic use to which this Act applies.”.

83. Section 6 of the Principal Act is repealed and the following section substituted:

Editions of British Pharmacopoeia having effect for the purposes of this Act

“6. The edition of the British Pharmacopoeia that was published in 1973 shall be deemed to have taken effect for the purposes of this Act on the relevant date, and any additions to, or amendments of, that edition (whether made before or after the relevant date), any subsequent edition of the British Pharmacopoeia and any additions to, or amendments of, any subsequent edition shall take effect for the purposes of this Act upon such dates as are respectively fixed by the Minister by notices published in the *Gazette*.”.

Furnishing of information with respect to composition of goods

84. Section 9 of the Principal Act is amended—

(a) by omitting sub-section (2) and substituting the following sub-sections:

“(2) A person shall not fail to comply with a notice served on him under this section.

Penalty: \$200.

“(2A) A person shall not, in purported compliance with a notice served on him under this section, knowingly furnish information that is false or misleading in a material particular.

Penalty: \$2,000.”;

(b) by omitting from sub-section (3) “this Act” and substituting “sub-section (2A)”;

(c) by omitting sub-section (4).

Labelling and packaging requirements in British Pharmacopoeia

85. Section 10 of the Principal Act is amended—

(a) by omitting from paragraph (1) (a) “, the British Pharmaceutical Codex or the British Veterinary Codex”;

(b) by omitting from paragraph (1) (b) “, the British Pharmaceutical Codex or the British Veterinary Codex, as the case may be”;

(c) by omitting from paragraph (2) (b) “, the British Pharmaceutical Codex or the British Veterinary Codex”.

Determination of standards for specific goods

86. Section 11 of the Principal Act is amended by omitting from sub-section (1) “, the British Pharmaceutical Codex or the British Veterinary Codex”.

Modifications of monographs by Minister

87. Section 12 of the Principal Act is amended—

(a) by omitting from sub-section (1) “, the British Pharmaceutical Codex or the British Veterinary Codex”;

(b) by omitting from sub-section (2) “, a monograph in the British Pharmaceutical Codex or a monograph in the British Veterinary Codex”.

88. The Principal Act is amended by inserting after section 16 the following section:

Mode of specifying standards, &c.

“16A. (1) The Minister may specify a standard in relation to goods for therapeutic use in pursuance of section 11, 13, 14 or 15—

(a) by setting out in the order specifying the standard the statements that are to constitute the standard;

- (b) by reference to a monograph in—
 - (i) a prescribed publication;
 - (ii) the European Pharmacopoeia;
 - (iii) a publication of the organization known as the Standards Association of Australia; or
 - (iv) any other publication that the Minister is satisfied is a proper source for the standard; or
- (c) by reference to a monograph in the British Pharmacopoeia or in a publication referred to in paragraph (b), being that monograph as modified in such manner as is specified in the order specifying the standard.

“(2) Where a standard is specified in the manner referred to in paragraph (1) (b), the standard shall be constituted by the statements in the monograph.

“(3) Where a standard is specified in the manner referred to in paragraph (1) (c), the standard shall be constituted by the statements in the monograph as modified in the manner specified in the order specifying the standard.

“(4) The Minister shall not be satisfied for the purposes of sub-paragraph (1) (b) (iv) that a publication is a proper source for a standard unless he has been advised that the publication is such a source by a committee in respect of which a declaration under sub-section (5) was in force at the time when the advice was given.

“(5) Where the Minister is satisfied that a committee established by the regulations is so constituted that it would be appropriate for it to give advice to him with respect to standards in relation to goods for therapeutic use, he may, by writing signed by him, declare that committee to be a therapeutic goods standards committee for the purposes of this section.

“(6) In this section, unless the contrary intention appears, ‘standard’ includes a test and a labelling and packaging requirement.”.

89. After Part III of the Principal Act the following Parts are inserted:

“PART IIIA—BIOLOGICAL PRODUCTS

Interpretation

“23A. (1) In this Part, unless the contrary intention appears—

‘biological product’ means goods for therapeutic use that are, are produced from, or the production of which involves the use of, organisms or the tissue or body fluids of organisms, and includes vaccines and toxoids, but does not include antibiotics or products derived from plants, other than antibiotics or such products that are used as antigens or haptens;

‘manufacturing corporation’ means a prescribed corporation that produces, or proposes to produce, biological products;

‘procedures’, in relation to the production of a biological product, includes testing procedures in relation to the production of the product,

whether carried out during, or after the completion of, the production of the product.

“(2) Nothing in this Part shall be taken as limiting the operation of the other Parts of this Act in relation to biological products.

Additional operation of Part

“23B. Without prejudice to its effect apart from this section, this Part also has, by force of this section, the effect it would have if—

- (a) any references in sections 23D, 23E, 23F and 23G to the production in Australia of biological products were, by express provision, confined to—
 - (i) the production in Australia of those products for supply—
 - (A) in the course of trade or commerce among the States, between a State and a Territory or between two Territories;
 - (B) under a law of the Commonwealth relating to the provision of pharmaceutical benefits;
 - (C) to the Commonwealth or the Northern Territory or to an authority of the Commonwealth or of a Territory; or
 - (D) in an internal Territory; or
 - (ii) the production of those products in an internal Territory;
- (b) any references in those sections to the supply in Australia of biological products were, by express provision, confined to—
 - (i) the supply in Australia of biological products—
 - (A) in the course of trade or commerce among the States, between a State and a Territory or between two Territories;
 - (B) under a law of the Commonwealth relating to the provision of pharmaceutical benefits; or
 - (C) to the Commonwealth or the Northern Territory or to an authority of the Commonwealth or of an internal Territory; or
 - (ii) the supply of biological products in an internal Territory; and
- (c) any references in those sections to a manufacturing corporation included a reference to a person, not being a prescribed corporation, who produces, or proposes to produce, biological products.

Object of Part

“23C. The object of this Part is to ensure, so far as the Constitution permits, the safety, quality and efficacy of biological products that are supplied in Australia or produced in Australia.

General information to be provided on manufacturing and testing procedures

“23D. (1) The Director-General may, by notice in writing served on a manufacturing corporation, require the manufacturing corporation to furnish

to him such information in writing as is required by the notice with respect to the procedures carried out, or to be carried out, by the manufacturing corporation in the production in Australia of a biological product specified in the notice.

“(2) Where the Director-General has, by notice under sub-section (1), required a manufacturing corporation to furnish to him information in writing with respect to the production in Australia of a biological product, the manufacturing corporation shall not produce in Australia that biological product, or supply in Australia that biological product to another person, unless—

- (a) the manufacturing corporation has furnished the information required; or
- (b) the Director-General has, upon application in writing made to him by the manufacturing corporation or on his own initiative, authorized the manufacturing corporation, by notice in writing served on the manufacturing corporation, to produce that biological product or to supply that biological product to other persons and that notice is in force at the time when the manufacturing corporation produces that biological product or supplies that biological product to that other person, as the case requires.

“(3) The Director-General may, where he considers it appropriate to do so, include in a notice under sub-section (1) a direction that the manufacturing corporation shall comply with sub-section (4) in relation to a biological product to which the notice relates.

“(4) Where—

- (a) a manufacturing corporation has been served with a notice under sub-section (1) that contained a direction referred to in sub-section (3) in relation to a biological product; and
- (b) the manufacturing corporation has, in accordance with the requirement in that notice, furnished information with respect to the procedures carried out, or to be carried out, by the manufacturing corporation in the production in Australia of that biological product,

the manufacturing corporation shall not—

- (c) produce in Australia that biological product in accordance with procedures that differ from the procedures specified in the information furnished; or
- (d) supply in Australia to another person that biological product if that biological product has been produced in accordance with procedures that differ from the procedures specified in the information furnished,

unless the manufacturing corporation has, not less than 28 days before commencing to produce that biological product, furnished to the Director-General information, in writing, with respect to the procedures to be carried out by the manufacturing corporation in the production of that biological product.

“(5) The Director-General may, by notice in writing served on a manufacturing corporation that has been served with a notice under paragraph (2) (b), revoke that last-mentioned notice.

Information to be provided in relation to particular batches

“23E. (1) The Director-General may, by notice in writing served on a manufacturing corporation, require the manufacturing corporation to furnish to him such information in writing, records or samples as are required by the notice with respect to the procedures carried out, or to be carried out, by the manufacturing corporation in the production in Australia of a specified batch or other quantity of a specified biological product.

“(2) Where, in accordance with a requirement in a notice under sub-section (1), a manufacturing corporation has furnished to the Director-General information in writing, records or samples with respect to the procedures carried out in the production in Australia of a specified batch or other quantity of a biological product, the Director-General may, by notice in writing served on the manufacturing corporation, direct the manufacturing corporation not to supply in Australia to any person any part of that batch or other quantity of the biological product.

“(3) Where, in accordance with a requirement in a notice under sub-section (1), a manufacturing corporation has furnished to the Director-General information in writing, records or samples with respect to the procedures to be carried out in the production in Australia of a specified batch or other quantity of a biological product, the Director-General may—

- (a) by notice in writing served on the manufacturing corporation, direct the manufacturing corporation not to take any step or further step in the production in Australia of any part of that batch or other quantity of the biological product; or
- (b) by notice in writing served on the manufacturing corporation, direct the manufacturing corporation not to supply in Australia to any person any part of that batch or other quantity of the biological product.

“(4) Where a manufacturing corporation has, by notice under sub-section (1), been required to furnish information in writing, records or samples with respect to the procedures carried out in the production in Australia of a specified batch or other quantity of a biological product, the manufacturing corporation shall not supply in Australia to another person any part of that batch or other quantity of the biological product unless the manufacturing corporation has furnished the information, records or samples required.

“(5) Where, in accordance with a requirement in a notice under sub-section (1), a manufacturing corporation has furnished to the Director-General information in writing, records or samples with respect to the procedures carried out in the production in Australia of a specified batch or other quantity of a biological product, the manufacturing corporation shall not—

- (a) in a case where the Director-General has served notice on the manufacturing corporation under sub-section (2) in relation to that batch or other quantity of the biological product—supply in Australia to another person any part of that batch or other quantity of the biological product unless the Director-General has, upon application in writing made to him by the manufacturing corporation or on his own initiative, authorized the manufacturing corporation, by notice in writing served on the manufacturing corporation, to supply to other persons that batch or other quantity of the biological product and that notice is in force at the time when the manufacturing corporation supplies that part of that batch or other quantity of the biological product to that other person; or
- (b) in any other case—supply in Australia to another person any part of that batch or other quantity of the biological product unless a period of 28 days has elapsed since the manufacturing corporation furnished the information, records or samples.

“(6) Where a manufacturing corporation has, by notice, under sub-section (1), been required to furnish information in writing, records or samples with respect to the procedures to be carried out in the production in Australia of a specified batch or other quantity of a biological product, the manufacturing corporation shall not take any step or further step in the production in Australia of any part of that batch or other quantity of the biological product unless the manufacturing corporation has furnished the information, records or samples required.

“(7) Where, in accordance with a requirement in a notice under sub-section (1), a manufacturing corporation has furnished to the Director-General information in writing, records or samples with respect to the procedures to be carried out in the production in Australia of a specified batch or other quantity of a biological product, the manufacturing corporation shall not—

- (a) in a case where the Director-General has served notice on the manufacturing corporation under paragraph (3) (a) in relation to that batch or other quantity of the biological product—take any step or further step in the production in Australia of any part of that batch or other quantity of the biological product unless the Director-General has, upon application in writing made to him by the manufacturing corporation or on his own initiative, authorized the manufacturing corporation, by notice in writing served on the manufacturing corporation, to produce that batch or other quantity of the biological product and that notice is in force at the time when the manufacturing corporation takes that step or further step in the production of that part of that batch or other quantity of the biological product;
- (b) in a case where the Director-General has served notice on the manufacturing corporation under paragraph (3) (b) in relation to that batch or other quantity of the biological product—supply in Australia to another person any part of that batch or other quantity of the

biological product unless the Director-General has, upon application in writing made to him by the manufacturing corporation, or on his own initiative, authorized the manufacturing corporation, by notice in writing served on the manufacturing corporation, to supply to other persons that batch or other quantity of the biological product and that notice is in force at the time when the manufacturing corporation supplies that part of that batch or other quantity of the biological product to that other person; or

- (c) in any other case—take any step or further step in the production in Australia of any part of that batch or other quantity of the biological product unless a period of 28 days has elapsed since the manufacturing corporation furnished the information, records or samples.

“(8) Where a manufacturing corporation has been served with a notice under sub-section (2) or paragraph (3) (a) or (b), the Director-General may, upon application in writing made to him by the manufacturing corporation or on his own initiative, revoke that notice by notice in writing served on the manufacturing corporation.

“(9) The Director-General may, by notice in writing served on a manufacturing corporation that has been served with a notice under paragraph (5) (a), (7) (a) or (7) (b), revoke that last-mentioned notice.

Prescribed methods of manufacturing and testing

“23F. (1) The Minister may, by order in writing, determine the procedures to be carried out in the production in Australia of a biological product specified in the order.

“(2) Where, in pursuance of sub-section (1), procedures are determined in relation to the production in Australia of a biological product—

- (a) a manufacturing corporation shall not supply in Australia that biological product to another person unless that biological product has been produced in accordance with those procedures; and
- (b) a person shall not import, without the authority in writing of the Director-General, that biological product into Australia unless that biological product has been produced in accordance with those procedures.

“(3) Without limiting the generality of sub-section (1), the Minister may determine procedures under that sub-section by reference to a monograph in the British Pharmacopoeia or in a publication referred to in paragraph 16A (1) (b), with or without modification of that monograph.

“(4) Sections 16, 17 and 18 apply to an order made under sub-section (1) of this section as if it were an order made under Part II.

Manufacturers to keep records

“23G. (1) The Director-General may, by notice in writing served on a manufacturing corporation, require the manufacturing corporation to keep such records as are specified in the notice with respect to the procedures carried

out by the manufacturing corporation in relation to the production in Australia of each batch or other quantity of a biological product specified in the notice that the manufacturing corporation produces after the date on which the notice is served.

“(2) The Director-General may, by notice in writing served on a manufacturing corporation required to keep records in pursuance of a notice under sub-section (1), require that manufacturing corporation to furnish to the Director-General such of those records, or copies of such of those records, as are specified in the notice under this sub-section.

“(3) The Director-General may, by notice in writing served on a manufacturing corporation that has been served with a notice under sub-section (1), amend or revoke that notice.

“(4) A manufacturing corporation shall not fail to comply with a notice served on the manufacturing corporation under this section that is in force.

Penalty: \$5,000.

“PART IIIB—NATIONAL REGISTER OF THERAPEUTIC GOODS

Interpretation

“23H. A reference in this Part to goods for therapeutic use does not include a reference to goods that are not for human use.

Additional operation of Part

“23J. Without prejudice to its effect apart from this section, this Part also has, by force of this sub-section, the effect it would have if—

- (a) any reference in section 23M to the production in Australia of goods for therapeutic use were, by express provision, confined to—
 - (i) the production in Australia of such goods for supply—
 - (A) in the course of trade or commerce among the States, between a State and a Territory or between two Territories;
 - (B) under a law of the Commonwealth relating to the provision of pharmaceutical benefits;
 - (C) to the Commonwealth or the Northern Territory or to an authority of the Commonwealth or of a Territory; or
 - (D) in an internal Territory; or
 - (ii) the production of such goods in an internal Territory; and
- (b) any reference in that section to the supply in Australia of goods for therapeutic use were, by express provision, confined to—
 - (i) the supply in Australia of such goods—
 - (A) in the course of trade or commerce among the States, between a State and a Territory or between two Territories;

- (B) under a law of the Commonwealth relating to the provision of pharmaceutical benefits; or
- (C) to the Commonwealth or to the Northern Territory or to an authority of the Commonwealth or of an internal Territory; or
- (ii) the supply of such goods in an internal Territory;
- (c) any reference in that section to a prescribed corporation included a reference to a person not being a prescribed corporation.

Object of Part

“23K. The object of this Part is to provide for the establishment and maintenance, so far as the Constitution permits, of a record of such information relating to goods for therapeutic use that are supplied in Australia, or produced in Australia, as is necessary to be kept in the interest of the public health of the people of the Commonwealth.

National Register of Therapeutic Goods

“23L. (1) There shall be a register, to be known as the National Register of Therapeutic Goods, in which shall be entered such information in relation to goods for therapeutic use that are supplied in Australia or produced in Australia as the Director-General determines.

“(2) The National Register of Therapeutic Goods shall be maintained in accordance with directions given by the Director-General and may, if he so directs, be maintained in a computer.

Director-General may obtain information

“23M. (1) For the purpose of compiling and maintaining the National Register of Therapeutic Goods, the Director-General may, by notice in writing served on a prescribed corporation that supplies in Australia, or produces in Australia, goods for therapeutic use, require that prescribed corporation to furnish, in writing, to the Director-General, or another person specified in the notice, within such period as is specified in the notice, such information in respect of goods for therapeutic use that the prescribed corporation has supplied in Australia, or has produced in Australia, as is required by the notice.

“(2) A notice served on a prescribed corporation under sub-section (1) shall not require the prescribed corporation to furnish information in respect of goods for therapeutic use that consist of a substance unless—

- (a) the goods are declared, or are included in a class of goods that are declared, by the regulations to be goods to which this section applies; and
- (b) the information relates to prescribed matters.

“(3) A notice served on a prescribed corporation under sub-section (1) may relate to—

- (a) specified goods that have been supplied in Australia or produced in Australia by the prescribed corporation;

- (b) all goods of a specified description that the prescribed corporation has, within a period specified in the notice, supplied in Australia or produced in Australia; or
- (c) all goods for therapeutic use that the prescribed corporation has, within a period specified in the notice, supplied in Australia or produced in Australia.

“(4) The Director-General may, where he considers it appropriate to do so, include in a notice under sub-section (1) a direction that a prescribed corporation shall, not less than 14 days before supplying in Australia any goods for therapeutic use to which the notice relates and in respect of any matter relating to which the information furnished in accordance with the notice is not correct, furnish to the Director-General in writing correct information in relation to those matters.

“(5) Where a notice served on a prescribed corporation under sub-section (1) is in the form referred to in paragraph (3) (b) or (c), the Director-General may, if he considers it appropriate to do so, include in that notice a direction that, if at any time the prescribed corporation commences to supply in Australia, or to produce in Australia, goods of the description to which the notices relates, being goods that the prescribed corporation has not, within the period specified in the notice in accordance with paragraph (3) (b) or (c), as the case may be, so supplied or produced, the prescribed corporation shall not supply those goods in Australia to another person unless the prescribed corporation has, not less than 14 days before supplying those goods, furnished to the Director-General in writing the information required by the notice in respect of the goods.

“(6) Where—

- (a) a prescribed corporation has, in compliance with a notice under this section, furnished information in relation to goods; and
- (b) the corporation ceases to supply in Australia, or to produce in Australia, such goods,

the corporation shall forthwith notify the Director-General in writing that it has so ceased to supply or to produce such goods, as the case requires.

“(7) A person shall not fail to comply with a notice served on him under this section.

Penalty: \$200.

“(8) A person shall not, in purported compliance with a notice served on him under this section, knowingly furnish information that is false or misleading in a material particular.

Penalty: \$2,000.

“(9) A prescribed corporation is not excused from furnishing information in pursuance of a notice served on it under this section on the ground that the information might tend to incriminate it, but any information furnished in pursuance of the notice is not admissible in evidence against it in any criminal proceedings, other than proceedings under sub-section (8).”.

Offences—General

90. Section 25 of the Principal Act is amended—

- (a) by inserting “(unless section 41 of the *Acts Interpretation Act* 1901 in its application in relation to that provision otherwise provides that the person is guilty of an offence)” before “guilty” in sub-section (1); and
- (b) by omitting sub-sections (2) and (3) and substituting the following sub-sections:

“(2) Subject to sub-section 25A (1), an offence against this Act (other than an offence against sub-section 9 (2), 9 (2A), 23G (4), 23M (7), 23M (8) or 25B (1)) is an indictable offence.

“(3) Subject to sub-section 25A (2), the punishment for an offence against this Act (other than an offence against sub-section 9 (2), 9 (2A), 23G (4), 23M (7), 23M (8) or 25B (1)) is punishable on conviction—

- (a) if the offender is a natural person—by a fine not exceeding \$10,000 or imprisonment for a period not exceeding 2 years, or both; or
- (b) if the offender is a body corporate—by a fine not exceeding \$50,000.”.

91. After section 25 of the Principal Act the following sections are inserted:

Prosecution of offences

“25A. (1) Notwithstanding that an offence referred to in sub-section 25 (2) is an indictable offence, a court of summary jurisdiction may hear and determine proceedings in respect of such an offence if the court is satisfied that it is proper to do so and the defendant and the prosecution consent.

“(2) Where, in accordance with sub-section (1), a court of summary jurisdiction convicts a person of an indictable offence, the penalty that the court may impose is—

- (a) if the offender is a natural person—a fine not exceeding \$1,000 or imprisonment for a period not exceeding 6 months, or both; or
- (b) if the offender is a body corporate—a fine not exceeding \$5,000.

Continuing offences

“25B. (1) Where—

- (a) by or under a provision of this Act a person is required or directed to do an act or thing within a particular period;
 - (b) failure by that person to do that act or thing within that period constitutes an offence; and
 - (c) the person does not do that act or thing within that period,
- the following provisions of this sub-section have effect:
- (d) the obligation of the person to do that act or thing continues, notwithstanding that that period has expired, until that act or thing is done;

- (e) the person is guilty of a separate and further offence in respect of each day after the expiration of that period during which the failure to do that act or thing continues; and
- (f) the punishment for each such separate and further offence is a fine not exceeding \$200.

“(2) Charges against the same person for any number of offences under paragraph (1) (e) may be joined in the same information or complaint if those offences relate to a failure to do the same act or thing.

“(3) If a person is convicted of more than one offence under paragraph (1) (e), the court may impose one fine in respect of all the offences of which the person is so convicted under that paragraph but that fine shall not exceed the sum of the maximum fines that could be imposed if a fine were imposed in respect of each offence separately.”.

Judicial notice

92. Section 26 of the Principal Act is amended by omitting “, the British Pharmaceutical Codex and the British Veterinary Codex” and substituting “and of any publication referred to in paragraph 16A (1) (b)”.

93. The Principal Act is amended by inserting after section 26 the following section:

Service of notices

“26A. A notice under section 9, 23D, 23E, 23G or 23M may be served on a person—

- (a) in the case of a natural person—by serving the notice or a copy of the notice personally on the person or by sending the notice or a copy of the notice by post to the person at his last known place of residence or business; or
- (b) in the case of a body corporate—by sending the notice or a copy of the notice by post to the registered office (if any) of the body corporate or by serving the notice or a copy of the notice personally on the secretary or another executive officer of the body corporate or on a person who, at the time of service, apparently manages a place of business of the body corporate.”.

94. (1) Section 27 of the Principal Act is repealed and the following section substituted:

Delegation

“27. (1) The Minister or the Director-General may, either generally or as otherwise provided by the instrument of delegation, by writing signed by him, delegate to a person any of his powers under this Act, other than this power of delegation.

“(2) A power so delegated, when exercised by the delegate, shall, for the purposes of this Act, be deemed to have been exercised by the Minister or the Director-General, as the case may be.

“(3) A delegation under this section does not prevent the exercise of a power by the Minister or the Director-General, as the case may be.”.

(2) An instrument of delegation in force under section 27 of the Principal Act immediately before the commencement of this section shall, after the commencement of this section, have effect as if it were an instrument of delegation under section 27 of the Principal Act as amended by this Act.

95. After section 29 of the Principal Act the following section is inserted:

Applications for review

“29A. Applications may be made to the Administrative Appeals Tribunal for a review of—

- (a) a refusal by the Director-General to grant an application made under paragraph 23D (2) (b);
- (b) a revocation by the Director-General pursuant to sub-section 23D (5) of a notice under paragraph 23D (2) (b);
- (c) a refusal by the Director-General to grant an application made under paragraph 23E (5) (a), (7) (a) or (7) (b);
- (d) a refusal by the Director-General to grant an application made under sub-section 23E (8); and
- (e) a revocation by the Director-General pursuant to sub-section 23E (9) of a notice under paragraph 23E (5) (a), (7) (a) or (7) (b).”.

Regulations

96. Section 30 of the Principal Act is amended by omitting paragraph (b) and substituting the following paragraph:

- “(b) for prescribing penalties for offences against the regulations not exceeding—
- (i) in the case of offenders who are natural persons—a fine of \$1,000 or imprisonment for 6 months; or
 - (ii) in the case of offenders that are bodies corporate—a fine of \$2,000.”.

Additional amendments

97. The Principal Act is amended as set out in the Schedule.

SCHEDULE

Section 97

1. The following provisions of the *Therapeutic Goods Act 1966* are amended by omitting "of this Act" and "of this section" (wherever occurring):

Sub-section 5 (1) (definitions of "general standard", "goods for therapeutic use" and "labelling and packing requirements"), paragraph 5 (2) (b), paragraph 10 (2) (a), section 14, sub-section 15 (5), sub-section 19 (3), sub-section 29 (4), sub-section 29 (5), sub-section 29 (7) and sub-section 29(8).

2. The *Therapeutic Goods Act 1966* is further amended as set out in the following table:

Provision	Amendment
Sub-section 5 (1) (definition of "goods for therapeutic use")	(a) Omit "the last preceding sub-paragraph", substitute "sub-paragraph (ii)". (b) Omit "(ii) or (iii) of the last preceding paragraph", substitute "(a) (ii) or (iii)".
Sub-section 5 (4)	Omit "the last two preceding sub-sections", substitute "sub-sections (2) and (3)".
Sub-section 8 (2)	Omit "the last preceding sub-section", substitute "sub-section (1)".
Paragraph 9 (1) (d)	Insert after "Commonwealth" (first occurring) "or the Northern Territory".
Sub-section 10 (1)	Omit "the next succeeding sub-section", substitute "sub-section (2)".
Sub-section 10 (2)	(a) Omit "the last preceding paragraph", substitute "paragraph (b)". (b) Omit "of this sub-section".
Sub-section 12 (2)	Omit "the last preceding sub-section", substitute "sub-section (1)".
Sub-section 13 (2)	Omit "the last preceding sub-section", substitute "sub-section (1)".
Paragraph 19 (1) (c)	Omit "of this Act".
Sub-section 19 (2)	Omit "the last preceding sub-section", substitute "sub-section (1)".
Paragraph 20 (c)	Omit "of this Act".
Sub-paragraph 21 (1) (a) (iii)	Omit "of this Act".
Section 22	Insert after "Commonwealth" (first occurring) "or the Northern Territory".
Paragraph 22 (c)	Omit "of this Act".
Sub-section 23 (1)	Omit "any of the last three preceding sections", substitute "section 20, 21 or 22".
Sub-section 24 (2)	Omit "the last preceding sub-section", substitute "sub-section (1)".
Paragraph 24 (3) (e)	Insert after "Commonwealth" (first and last occurring) "or the Northern Territory".
Sub-section 29 (2)	Omit "(a) of the last preceding sub-section", substitute "(1) (a)".
Sub-section 29 (3)	Omit "the last preceding sub-section", substitute "sub-section (2)".
Sub-section 29 (4)	Omit "(a) of sub-section (1)", substitute "(1) (a)".
Sub-section 29 (5)	Omit "(b) of sub-section (1)", substitute "(1) (b)".
Sub-section 29 (6)	Omit "the last preceding sub-section", substitute "sub-section (5)".

NOTES

1. No. 42, 1974, as amended. For previous amendments, see No. 58, 1975; Nos. 59, 91, 101 and 109, 1976; No. 75, 1977; Nos. 89 and 133, 1978; Nos. 53 and 123, 1979; and No. 132, 1980.
2. No. 95, 1953, as amended. For previous amendments, see No. 68, 1955; Nos. 55 and 95, 1956; No. 92, 1957; No. 68, 1958; No. 72, 1959; No. 16, 1961; No. 82, 1962; No. 77, 1963; No. 37, 1964; Nos. 100 and 146, 1965; No. 44, 1966; Nos. 14 and 100, 1967; No. 100, 1968; No. 102, 1969; No. 41, 1970; No. 85, 1971; No. 114, 1972; Nos. 49 and 202, 1973; No. 37, 1974; Nos. 1, 13 and 93, 1975; Nos. 1, 60, 91, 99, 108, 157 and 177, 1976; Nos. 98 and 100, 1977; Nos. 36, 88, 132 and 189, 1978; Nos. 54, 91 and 122, 1979; and Nos. 117 and 131, 1980.
3. No. 147, 1974, as amended. For previous amendments, see No. 91, 1976; No. 100, 1977; and No. 118, 1980.
4. No. 29, 1966, as amended. For previous amendments, see No. 216, 1973; and No. 37, 1976.