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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

COMMUNITY SERVICES AND HEALTH LEGISLATION AMENDMENT BILL 1991

EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Aged, Family and Health Services, the Honourable Peter Staples, MP)

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COMMUNITY SERVICES AND HEALTH LEGISLATION AMENDMENT BILL 1991

GENERAL OUTLINE

One purpose of this Bill is to make a number of amendments to the Health Insurance Act 1973.

The first of these amendments will clarify the scope of a 'professional service' in Section 3 of the Health Insurance Act, and will introduce the notion of "clinical relevance" to that definition. From a strictly legal standpoint, as the legislation is currently worded, a medical practitioner could itemise an account and claim Medicare benefits for a service where a physical attendance on the patient occurs, but during which no "clinically relevant service" takes place.

The new definition of 'professional service' incorporates within it a new definition being a definition of a "clinically relevant service".

The proposed amendment requires that a "professional service" be related to a medical examination, treatment, diagnosis or test that is necessary for the appropriate treatment of the patient.

The Bill also contains amendments to the Health Insurance Act in relation to Medicare benefits for pathology services.

Medicare benefits for pathology services are only payable where a number of criteria are met. One of these is that the laboratory premises where the services are rendered must meet certain standards. These standards are defined by the Minister and are adopted from standards and guidelines set by the National Pathology Accreditation Advisory Council. The Commonwealth contracts an independent organisation - the National Association of Testing Authorities - to carry out assessment of these premises.

There have been occasions recently where pathology laboratories have failed to reach an acceptable standard of operation and the approval has been revoked. The Department has become aware that the operators of some of these revoked premises have continued to perform pathology services without informing either the referring practitioners or the patients. (No charges have been raised against the patient.)

The purpose of these changes in this Bill is to require the proprietor of a laboratory that has had the approval revoked, to take all reasonable steps to inform the referring practitioner and the patient that a Medicare benefit will not be payable in respect of the pathology service and require the Minister to advertise such a decision.

The relevant provisions in this Bill are similar to those offences relating to the disqualification of practitioners in section 19D of the Health Insurance Act.

A further purpose of this Bill is to make a number of amendments to the National Health Act 1953 and the Nursing Homes and Hostels Legislation Amendment Act 1986 in relation to nursing home matters.

The Bill contains provisions which enable more information about nursing homes to be made publicly available. These changes will enable three further categories of information to be released directly to the public:

(1) plans submitted by proprietors of action to be taken to satisfy standards;

(2) basic descriptive information concerning each nursing home, such as its name, address, number of beds and fees charged;

(3) action taken, or intended to be taken, to suspend or revoke the approval of a nursing home, vary the conditions of its approval, cease benefits for new admissions, or remove or vary exempt status.

The Bill requires that information about to be released under category (3) above be provided to the proprietor for 30 days to allow submissions about the information to be made, except where the information needs to be released urgently to protect the welfare or interests of patients.

The Bill also introduces a new section into the National Health Act to provide a new penalty for nursing homes not complying with conditions of approval. The new penalty involves suspending Commonwealth benefits for new patients after a home has been declared to be not satisfying the conditions of its approval.

The Bill also makes some technical amendments to the National Health Act and the Nursing Homes and Hostels Legislation Amendment Act 1986 to enable a section of the latter Act concerned with defining government nursing homes to be proclaimed.

A further purpose of the Bill is to amend the Therapeutic Goods Act 1989 to:

(1) remove certain administrative difficulties associated with the present effect of a determination by the Secretary to aggregate therapeutic goods, which is that that they must be treated as single goods for administrative and other purposes under Part 3 of the Principal Act;

(2) provide the basis for introducing a scheme to allow for the payment of evaluation fees by instalments where goods are evaluated for registration in the Australian Register of Therapeutic Goods (ARTG);

(3) provide the basis for delegating approvals, for the use of goods not included in the Register for the treatment of another person, to appropriately qualified persons outside the Department, subject to appropriate constraints;

(4) enable regulations to be made to allow fees, similar to those levied under the Freedom of Information Act 1982, to be charged for processing the release of information relating to therapeutic goods in the ARTG; and

(5) make other minor or consequential amendments.

Financial Impact Statement

The amendment to the definition of "professional service" in the Health Insurance Act is expected to yield savings of $2.5 million in 1991-92 and $5 million in a full year.

The amendments relating to Medicare benefits for pathology services have no cost implications for the Commonwealth.

There is no financial impact from the amendments to the National Health Act and the Nursing Homes and Hostels Legislation Amendment Act in relation to nursing home matters.

The amendments to the Therapeutic Goods Act 1989 described in paragraph (2) will reduce the financial burden on applicants for registerable therapeutic goods by allowing the applicant to pay in instalments. The proposal under paragraph (4) will permit the expenses of providing information from the ARTG to be recovered. It is estimated that potential costs to the Commonwealth of administration and forgone interest will be less than $0.5 Million per year.

NOTES ON CLAUSES

PART 1 - PRELIMINARY

Clause 1 - Short title

This is a formal provision that specifies the short title of the Act as the Community Services and Health Legislation Amendment Act 1991.

Clause 2 - Commencement

This clause provides that, with the exception of the matters dealt with in subclause (2), the provisions of the Act will commence on the day on which the Act receives Royal Assent.

Subclause 2 ensures that the amendments to the National Health Act concerning the definition of government nursing home, and the amendment to the Nursing Homes and Hostels Legislation Amendment Act commence at the same time as the commencement of section 7 of the Nursing Homes and Hostels Legislation Amendment Act, which has not yet been proclaimed.

PART 2 - AMENDMENT OF THE HEALTH INSURANCE ACT 1973

Clause 3 - Principal Act

This is a formal provision identifying the Health Insurance Act 1973 as the Principal Act referred to in this Part.

Clause 4 - Interpretation

Subclause 4(a)

This amendment specifically excludes diagnostic imaging services from medical services as diagnostic imaging is specifically included in a latter clause of the definition.

Subclause 4(b)

This amendment incorporates into the definition of professional service, where appropriate, the concept of a clinically relevant service.

Subclause 4(c)

This clause inserts a technical amendment required for the structure of the proposed new section.

Subclause 4(d)

Amends the definition of "professional service" to ensure that a medical examination, treatment, diagnosis or test is necessary for the appropriate treatment of the patient. New paragraph (d) enables referred pathology services to be excluded from the requirement of being a clinically relevant service. New paragraph (e) ensures that non-referred pathology services are clinically relevant services when performed under a grandfather clause by other than a medical practitioner. New paragraph (f) enables referred diagnostic imaging services to be excluded from the requirement of being a clinically relevant service. New paragraph (g) ensures that a non-referred diagnostic imaging service is a clinically relevant service.

Subclause 4(e)

For the purposes of the definition of "professional service" this clause incorporates a new definition of a clinically relevant service.

Clause 5 - Offence where approval of premises as accredited pathology laboratory has been revoked.

This clause requires the proprietor of a pathology laboratory, the approval for which has been revoked, to take all reasonable steps to ensure that both the person intending to render the service and the person for whom the service is to be rendered, are informed that no Medicare benefit will be payable for that service.

Clause 6 - Accredited pathology laboratories.

This clause requires the Minister to advertise, by Gazettal or other means, the fact that an approval has been revoked and to cause a copy of that notice to be laid before both Houses of Parliament.

PART 3 - AMENDMENT OF THE NATIONAL HEALTH ACT 1953

Clause 7 - Principal Act

This clause defines "Principal Act" as being the National Health Act 1953, for the purposes of Part 3 of this Bill.

Clause 8 - Approval of nursing home

This is a technical amendment concerned with the sequencing of paragraphs.

Clause 9 - Statements may be published about satisfaction of standards for nursing home care

Subclause 9(a) broadens the application of s45DA of the Principal Act to include premises that have been an approved nursing home at any time during the 5 years before the statement is published.

Subclause 9(b) adds to the list of relevant information that the Minister may publish under s45DA the action plans relating to measures to be taken by a proprietor to ensure that the standards of nursing home care referred to in s45D of the Principal Act will be satisfied.

Subclause 9(c) deletes paragraphs (c) to (h) from s45DA(2) of the Principal Act with a view to transferring them in an amended form to a new s45DB.

Subclause 9(d) exempts the new item of relevant information concerning action plans, added by sub-clause 9(b), from the requirement of s45DA(5) of the Principal Act which allows the proprietor 30 days to consider the Minister's statement and make submissions on it.

Clause 10 - Insertion of new sections

This clause inserts two new sections, 45DB and 45DC, in the Principal Act.

General information about approved nursing homes may be mad available to the public

The new subsection 45DB(1) enables the Secretary of the Department to release relevant information concerning currently approved nursing homes or nursing homes that were approved homes at any time during the previous 5 years.

The new subsection 45DB(2) of the new section lists what is "relevant information" for the purposes of 45DB(1).

The new subsection 45DB(3) makes it clear that no information can be released under this section which would enable the identification of an individual patient of a nursing home.

Information about Ministerial action and other information about approved nursing homes that may be available to the public

The new section 45DC(1) also enables the Secretary to release relevant information concerning currently approved nursing homes or nursing homes that were approved home at any time during the previous 5 years.

The new subsection 45DC(2) defines what is relevant information for the purposes of 45DC(1).

The new subsection 45DC(3) clarifies that the matters listed in 45DC(2) (a) includes action taken by the Minister under section 105AAB in relation to a review of a decision, and action taken by the Administrative Appeals Tribunal in relation to a Ministerial decision on the matters listed in 45DC(2)(a), or in relation to a decision under s105AAB to revoke such a Ministerial decision.

The new subsection 45DC(4) clarifies that matters listed in 45DC(2)(b) should be taken to include action the Minister intends to take under s105AAB in relation to a review of a decision.

The new subsection 45DC(5) makes it clear that no information can be released under this section such as to enable the identification of an individual patient of a nursing home.

The new subsection 45DC(6) requires the Secretary to allow the proprietor at least 30 days to consider the information that is intended to be released under this section and to make submissions to the Secretary about it.

The new subsection 45DC(7) requires the Secretary to alter information before it is released if he considers, in the light of any submission from the proprietor, the information should be altered.

The new subsection 45DC(8) exempts the Secretary from the requirements of sub-sections 45DC(6) and (7) where the Secretary considers there is an urgent need to make the information available in order to protect the welfare or interests of current or prospective patients of the nursing home.

Clause 11 - Insertion of new section

Clause 11 will insert a new section 45EA into the principal Act.

Declaration of non-compliance with conditions

The new subsection 45EA(1) will provide that, where the conditions to which the approval of a nursing home under the Principal Act have not been complied with, the Minister will be able to issue a written notice to the proprietor of the nursing home. This notice will declare that the nursing home is in breach of its conditions of approval.

The new subsection 45EA(2) will provide that, where the Minister has made a declaration under the proposed new subsection (1), the Minister may serve a notice on the proprietor, which declares that Commonwealth benefit will not be payable to the proprietor in respect of patients admitted to the nursing home following the declaration.

The new subsection 45EA(3) will provide that, where a determination under the proposed new sub-section (2) is in force, Commonwealth benefit is not payable to the proprietor of a nursing home in respect of patients admitted following that determination. It also provides that the proprietor is obliged to deduct from the gross daily approved accommodation fee charged to patients admitted whilst a determination under the proposed new sub-section (2) is in force, the amount of Commonwealth benefit that would otherwise be payable in respect of those residents.

The new subsection 45EA(4) will provide that, where a declaration under the proposed new subsection (1) that conditions of approval have not been met is revoked, any determination that may have been made under the proposed new sub-section (2) ceases to have effect.

The new subsection 45EA(5) will provide that, where the conditions of a nursing home's approval have not been complied with, and if the Minister considers it more appropriate to do so, he or she is not restricted from suspending or revoking the nursing home's approval, whether or not any action under the proposed new section 45EA has been taken.

The new subsection 45EA(6) will provide that the operation of the proposed new section 45EA will be independent of section 45E of the Principal Act.

Clause 12 - Applications for review by Tribunal of certain decisions under Part V

This clause makes the Secretary's decisions under the new sections 45DB and 45DC, which concern the release of information, and the Minister's decisions under the new section 45EA, which concerns decisions following non-compliance with conditions of approval of a nursing home, subject to Ministerial review and appeal to the Administrative Appeals Tribunal.

Clause 13 - Statements to accompany notification of decisions

This clause amends s105AC(1A) and s105AC(1B) of the Principal Act to enable these sections, which require statements to accompany notification of decisions, to include decisions made by the Secretary as well as those made by the Minister.

Clause 14 - Certain instruments subject to disallowance

This is a technical amendment which amends s139B of the Principal Act. It makes the prescribed list of Government nursing homes a disallowable instrument. It replaces a previous similar amendment which was originally to have been made by section 22 of the Nursing Homes and Hostels Legislation Amendment Act 1986. The previous amendment was to have commenced by Proclamation, but has not been proclaimed, it is repealed by Clause 16 of this Bill.

PART 4 - AMENDMENT OF THE NURSING HOMES AND HOSTELS LEGISLATION AMENDMENT ACT 1986

Clause 15 - Principal Act

This clause defines the Principal Act for the purposes of this Part as the "Nursing Homes and Hostels Legislation Amendment Act 1986".

Clause 16 - Repeal of section 22

This clause repeals (unproclaimed) section 22 of the Principal Act. Clause 14 of this Bill substitutes an amended version of this repealed section in the National Health Act 1953.

PART 5 - AMENDMENT OF THE THERAPEUTIC GOODS ACT 1989

Clause 17 - Principal Act

This clause identifies the Therapeutic Goods Act 1989 as the Principal Act for the purposes of Part 5 of the Bill.

Clause 18 - Interpretation

This clause amends subsection 3(1) of the Principal Act by including the following definitions:

- 'data processing device' means any article or any material from which information may be produced, whether with or without the aid of another article or device;
- 'gazetted therapeutic devices group' refers to a group of therapeutic devices identified in an order gazetted by the Secretary under subsection 16(3) of the Principal Act;
- 'gazetted therapeutic goods group' refers to a group of therapeutic goods, not being therapeutic devices, identified in an order gazetted by the Secretary under subsection 16(2) of the Principal Act;
- 'grouped therapeutic goods' means goods included in a particular 'gazetted therapeutic devices group' or 'gazetted therapeutic goods group'.

Clause 19 - Power to obtain information with respect to therapeutic goods

This clause amends section 8 of the Principal Act by providing that where, in accordance with that provision, the Secretary gives a person written notice requesting that person to give information to an officer of the Department, the notice may require the information to be provided either in writing or in accordance with specified software requirements.

Clause 20 - Therapeutic goods, gazetted therapeutic goods groups and gazetted therapeutic devices groups

The effect of paragraph 20(a) is to remove words in subsection 16(1) of the Principal Act that allow for exceptions to be made to the general rule that therapeutic goods would, because of any one or more of the differences set out in subsection 16(1), be treated as separate and individual goods for the purposes of Part 3 of the Principal Act. This amendment is consistent with the changes made by this Bill to the remaining provisions in s16 of the Principal Act.

Paragraph 20(b) amends subsection 16(2) to change the effect of the Secretary's determination to group together a group of goods (not being therapeutic devices) sharing common characteristics. The present effect is to render the whole group of goods, as a group, to be single therapeutic goods. Under the amended subsection 16(2), all goods so grouped will remain separate goods, and will merely fall within a particular 'gazetted therapeutic goods group' for the purposes of Part 3 of the Principal Act.

Paragraph 20(c) amends subsection 16(3) in the same way paragraph 20(b) amends subsection 16(2), except the changes relate to the grouping of therapeutic devices where they share common characteristics and have been produced by the same manufacturer, and where the Secretary has so grouped devices, all the devices identified as belonging to a group will come within a 'gazetted therapeutic devices group' for the purposes of Part 3 of the Principal Act.

Paragraph 20(d) inserts a new subsection 16(4) to allow the Secretary, when grouping therapeutic goods, to group goods (providing they share common characteristics and, in the case of therapeutic devices, they also have been produced by the same manufacturer) by reference, with or without modification, to any description or other matter set out in a document that is in force from time to time and that is:

- published by the Department;
- available for sale to the public; and
- available for inspection by the public at offices of the Department specified by the Secretary.

Any such document may be applied, adopted or incorporated, with or without modification, in the Secretary's order.

Clause 21 - Australian Register of Therapeutic Goods

This clause amends section 17 of the Principal Act by inserting new subsection 17(4) to allow regulations to be made to prescribe how registration and listing numbers of therapeutic goods in the Australian Register of Therapeutic Goods may be altered.

Clause 22 - Applications generally

Paragraph 22(a) amends subsection 23 of the Principal Act by providing that the Secretary's approval of any application form or any other method of application under paragraph 23(a) of the Principal Act is to be in writing.

Paragraph 22(c) removes paragraphs 23(c) and 23(d) of the Principal Act.

Paragraph 22(d):

- partly reinstates the substance of paragraph 23(c) of the Principal Act in new paragraph 23(2)(b);

- reinstates the substance of paragraph 23(d) of the Principal Act as new paragraph 23(2)(c); and

- inserts new paragraph 23(2)(a) and new subsection 23(3)

New paragraph 23(2)(a) provides that, in relation to therapeutic goods that are not grouped therapeutic goods, the prescribed application fee must be paid for every application to include such goods in the Register. However, if an application is for goods that belong to any gazetted therapeutic devices group, or gazetted therapeutic goods group, then no prescribed fee need be paid by the applicant if that applicant already has included in the ARTG goods belonging to the same gazetted therapeutic devices group, or gazetted therapeutic goods group, as the goods included in the application. New paragraph 23(2)(b) now requires the Secretary's approval, relating to the form in which information is to be supplied under that provision, to be in writing. New subsection 23(3) provides that an approval of a form by the Secretary may permit or require that an application, or information, must be given in accordance with specified software requirements, either on a specified kind of data processing device, or by way of a specified kind of electronic transmission.

Clause 23 - Applications for registration

Paragraph 23(b) substitutes subsection 24(2) of the Principal Act with a new subsection that takes into account any payment of evaluation fees in instalments that may be permitted by Regulations. Substituted subsection 24(2) therefore provides that if any part of an evaluation fee payable in respect of a particular application to register goods in the ARTG remains unpaid after the period specified in that subsection, that application for registration lapses.

Clause 24 - Insertion of new sections

This clause inserts new sections 24A, 24B and 24C into the Principal Act.

When evaluation fee due for payment

New subsection 24A provides that subject to new section 24B, an evaluation fee payable by an applicant under section 24 becomes payable on the day the applicant is notified of the amount of tha fee.

Payment of evaluation fees by instalments

New section 24B provides:

- in new subsection (1) that regulations may be made to allow for the payment of evaluation fees, for the purposes of s24 of the Principal Act, by instalments. What instalments, and when these are to be due and payable, is to be prescribed in the Regulations;

- in new subsection (2) that the Regulations may prescribe how an applicant may, in relation to any application lodged by the applicant under section 24 of the Principal Act, be precluded from a right to pay an evaluation fee by instalments in the event that person fails to pay any instalment of any evaluation fee that, under the Regulations became due and payable in respect of that applicant;

- in new subsection (3) that new subsection 24B(2) is not to limit the generality of new subsection 24B(1).

Recovery of evaluation fee

New section 24C provides that unpaid evaluation fees payable unde section 24 of the Principal Act is recoverable by the Commonwealt as a debt due to it.

Clause 25 - Evaluation of therapeutic goods

This clause amends section 25 of the Principal Act to take into account any arrangements introduced by Regulations for the paymen of evaluation fees by instalments. Paragraph 25(1)(b) of the Principal Act has therefore been substituted with a paragraph tha requires:

- the full evaluation fee due and payable in respect of an application to evaluate goods under that section to be paid before an evaluation of the goods is to take place or,

- where an applicant is entitled to pay by instalments, and has not lost that right, the relevant instalment owing in relation to an application must be paid before any evaluation, or further evaluation, of that application may begin or continue under that section.

Clause 26 - Repeal of section 27 and substitution of new section 27

R gistration or listing number

This clause repeals section 27 of the Principal Act and substitutes a new section 27 to accommodate the effect of the changes made in this Bill to section 16 of the Principal Act. New section 27 therefore provides that the Secretary is to assign a unique registration or listing number to every therapeutic good entered in the ARTG, unless the goods are grouped therapeutic goods. Where the goods fall into the latter category, a single, unique registration or listing number, as appropriate, is to be assigned to all the goods included in the same group of 'grouped therapeutic goods' entered in the ARTG in relation to a person.

Clause 27 - Conditions on registration or listing

This clause inserts new subsections 28(3A) and (6) into the Principal Act.

New subsection 28(3A) provides that the Secretary's power to impose new conditions on the registration or listing of goods, or vary or remove existing conditions, may be exercised either at the request of the person whose goods are included in the ARTG or on the initiative of the Secretary.

New subsection 28(6) provides that where the Secretary imposes new conditions, varies or removes these in accordance with section 28 of the Principal Act, regulations may prescribe fees to be charged for such actions where they have been made at the request of the person concerned.

Clause 28 - Secretary may require information

This clause inserts new subsection 31(3) to provide that the Secretary's power to determine what form information or documents of the kind described in that section is to be provided, includes a power to require the information to be given in accordance with specified software requirements, either on a specified kind of data processing device, or by way of a specified kind of electronic transmission.

Clause 29 - Inspection and variation of entries in Register

This clause inserts new subsection 32(2A) to provide the Secretary with the discretion to provide copies of an entry on the ARTG, to a person applying for that information under that section, either on a data processing device or by way of electronic transmission, where the person requests that the information be provided in electronic form.

Clause 30 - Time for payment of charges

This clause amends subsection 44(1) of the Principal Act, and inserts new subsection 44(1A) in that Act.

Subsection 44(1) is amended so that its operation is confined to goods that are not grouped therapeutic goods.

New subsection 44(1A) provides that, in relation to grouped therapeutic goods, the date upon which the annual registration an annual listing charges becomes payable in respect of each group o those goods is that specified by the Secretary in a written notic given to the person liable to pay the charges.

Clause 31 - Delegation

This clause amends subsection 57(2) of the Principal Act and inserts new subsections 57(3), (4) and (5) in that Act.

Paragraph 31(a) amends subsection 57(2) by making it clear that the constraints applying to the Secretary's delegation powers set out in subsection 57(1) of the Principal Act apply only to delegations made under subsection 57(2), in respect of paragraph 19(1)(a) of the Principal Act, unlike the case for new subsection 57(3).

New subsection 57(3) will allow the Secretary, in accordance with regulations to be made for this purpose, to delegate his or her powers under paragraph 19(1)(a) of the Principal Act to a person, other than a departmental officer, who is registered (and not merely eligible for registration), in a State or internal Territory, as a medical or dental practitioner.

New subsection 57(4) provides that a delegate described in new subsection 57(3) is to be subject to the directions of the Secretary or of an officer of the Department authorised in writin for this purpose by the Secretary.

New subsection 57(5) provides that Regulations made for the purposes of allowing delegations to be made to persons described in new subsection 57(3) may provide for matters which include:

- the persons who may be delegates;
- the circumstances in which the Secretary may delegate his powers under s19(1)(a) of the Principal Act to the persons described in new subsection 57(3) and the Regulations;
- the conditions that should attach to any approvals granted by delegates;
- information required to be provided to the Secretary by the delegate.

Clause 32 - Release of information

This clause inserts new subsections 61(8A), (8B) and (8C) in the Principal Act.

New subsection 61(8A) provides that Regulations may be made for charging fees, including requiring deposits on account of any fees, for processing requests for information under subsection 61(6) of the Principal Act.

New subsection 61(8B) provides that matters that may be covered in any such Regulations may include the charging of fees that takes into account:

- time spent by the Department in searching for and retrieving information, and in making or doing anything else related to the making of a decision in response to applications for information under subsection 61(6);

- costs incurred in making officers available to supervise any inspection of documents containing information sought under subsection 61(6) of the Principal Act.

New subsection 61(8C) provides that where a person is liable under the Regulations to pay a fee for an application for information, the person must be notified in writing of the amount of the fee and the basis upon which that amount is calculated.

Clause 33 - Application of amendments - registration or listing applications

This clause provides that amendments to Part 3 of the Principal Act made by clauses 22, 23, 24 and 25 will operate in relation to applications made on or after the date this clause comes into effect.

Clause 34 - Application of amendments - time for payment of charges

This clause provides that the changes made by clause 30, to provide appropriate payment dates for annual registration or listing charges for "single" therapeutic goods and the proposed "grouped" therapeutic goods, will begin to operate as follows:

- in relation to registrations or listings made during the financial year in which this clause commences, on or after the date of commencement of this clause;

- in relation to all registrations or listings after the above financial year, upon the commencement of those registrations or listings.

Clause 35 - Transitional - grouped therapeutic goods

This clause sets out the transitional arrangements to cover any action or decision made or taken on the basis of determinations already made by the Secretary under subsections 16(2) and (3) of the Principal Act.

For the purposes of this clause, subclause (1) inserts a definition for "amended Act" to mean the Principal Act after amendment by this Bill . It also defines "deemed single therapeutic goods" as goods which, under the Principal Act, were treated as single goods because of action taken under s16 of the Principal Act before the commencement of the amended Act.

Subclause 35(2) provides that any determination made by the Secretary under subsection 16(2) of the Principal Act (which rendered each group of goods grouped to be single therapeutic goods for the purposes of Part 3 of that Act) will, after the commencement of this Bill, be treated as a determination made by the Secretary under subsection 16(2) of the amended Act (thereby rendering the goods within each grouped goods to be separate goods, but falling within a gazetted therapeutic goods group).

Subclause 35(3) provides that any determination made by the Secretary under subsection 16(3) of the Principal Act (which rendered each group of goods grouped to be single therapeutic goods for the purposes of Part 3 of that Act) will, after the commencement of this Bill, be treated as a determination made by the Secretary under subsection 16(3) of the amended Act (thereby rendering the goods within each grouped goods to be separate goods, but falling within a gazetted therapeutic devices group).
Subclause 35(4) provides that where any notice was issued by the Secretary under sections 19 or 31 of the Principal Act that related to or included deemed single therapeutic goods, that notice will be deemed to be a notice issued under sections 19 or 31 of the amended Act, so as to relate to or cover the corresponding grouped therapeutic goods.

Subclause 35(5) provides that where an application for registration or listing of deemed single therapeutic goods was made under s23 of the Principal Act, then that application will b treated as an application to register or list, as appropriate, th corresponding grouped therapeutic goods under section 23 of the amended Act.

Subclause 35(6) provides that where a registration or listing of deemed single therapeutic goods was in force immediately before the commencement of this subclause, then under the amended Act, the goods will, as of the date of registration or listing of thos deemed single therapeutic goods, be deemed to be registered or listed as the corresponding grouped therapeutic goods.

Subclause 35(7) provides that a number assigned to therapeutic goods under section 27 of the Principal Act will, providing they are not 'deemed single therapeutic goods', continue to have effec as if the assignment occurred under section 27 of the amended Act.

Subclause 35(8) provides that a number assigned to 'deemed single therapeutic goods' under section 27 of the Principal Act will continue to have effect as if it had been assigned to the corresponding grouped therapeutic goods under subsection 27(2) of the amended Act.

Subclause 35(9) provides that, during the period covering the financial year in which this clause commences, or any earlier financial year, where:

- therapeutic goods were treated as single therapeutic goods for the purposes of Part 3 of the Principal Act;

- such goods were registered or listed as such;

then they will be treated as single therapeutic goods for the purposes of the application of Part 5 of the Principal Act.

Clause 36 - transitional - prescribed application fees and approved forms - section 23 of the Principal Act

This clause ensures that application fees prescribed, and forms approved, under relevant paragraphs of section 23 of the Principal Act before their amendment or substitution by clause 22 of this Bill will continue to have effect as if the prescription and approval had been made under section 23 as amended by clause 22 of this Bill.

Subclause 36(1) provides that, for the purposes of this clause, "amended Act" means the Principal Act as amended by this Bill.

Subclause 36(2) provides that application fees prescribed under a provision of section 23 of the Principal Act will continue to have effect as if it had been prescribed under the corresponding provision of section 23 of the amended Act.

Subclause 36(3) provides that any form approved by the Secretary for the purposes of a provision of section 23 of the Principal Act will have effect as if it had been approved by the Secretary under the corresponding provision of section 23 of the amended Act.