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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

SENATE

NATIONAL HEALTH AMENDMENT BILL (No. 1) 1999

EXPLANATORY MEMORANDUM

(Circulated by authority of the Parliamentary Secretary to the Minister for Health and Aged Care, Senator the Hon. Grant Tambling)

NATIONAL HEALTH AMENDMENT BILL (No. 1) 1999

OUTLINE

The National Health Amendment Bill (No. 1) 1999 proposes amendments to the *National Health Act 1953* in relation to the Pharmaceutical Benefits Scheme (PBS).

Since 1 January 1997 only Australian residents and other persons eligible to receive Medicare benefits have been able to access the PBS. A person needs to be in Australia to obtain medicines under the PBS.

The proposed amendments are designed to prevent drugs supplied under the PBS from being inappropriately carried out of or exported from Australia, whilst allowing a person (the exporter) to take a reasonable quantity of PBS drugs overseas for the personal treatment of the exporter or another person, such as a child or elderly relative, accompanying the exporter.

Subsection 103(4) of the *National Health Act 1953* provides that it is an offence for a person for whom a prescription for a PBS drug is written or to whom a PBS drug is supplied to use, dispose of or otherwise deal with the drug in a way other than that for which the prescription was written or the drug supplied. However, this provision does not cover the inappropriate use or disposal of, or dealing with, PBS drugs by a person other than the person for whose treatment the prescription was written or the drugs supplied.

The Bill therefore establishes an independent control regime in relation to the export of drugs obtained under the PBS by inserting a new Division 4D in Part VII of the *National Health Act 1953*.

The Bill provides that a person shall not carry PBS drugs out of Australia or otherwise export them unless they are for the personal use of the exporter or another person accompanying the exporter. A Customs officer will be able to detain drugs attempted to be carried out or exported from Australia if the officer is not satisfied that they were not obtained under the PBS or that they are for the use of the person, and retain copies of any associated documentation.

Drugs detained by Customs will be transferred to the Health Insurance Commission (HIC), together with a copy of any document relating to the drugs. The HIC will examine the detained drugs, and if it is established that they are neither prescription drugs nor prohibited exports, return them to the exporter or re consign them for export. If the HIC establishes that the drugs are prohibited exports it must pass them to the appropriate agency. If the HIC establishes that they are prescription drugs but not prohibited exports, it will invite the exporter to apply in writing within 60 days for their return, on the basis that either they were not obtained under the PBS or that they are for the personal use of the exporter.

If an application is made for the return of the drugs and the HIC is satisfied that either they were not obtained under the PBS or that they are for the personal use of the exporter, it must return them to the exporter or re consign them for export. If it is not so satisfied, or if no application is made for the return of the drugs, it will seize the drugs as forfeited to the Commonwealth, and commence proceedings in a magistrates court for the condemnation of the drugs as forfeited

goods. Drugs condemned as forfeited to the Commonwealth will be destroyed.

The Bill provides for written guidelines to be issued by both the Chief Executive Officer of Customs and by the HIC for the performance of functions and duties, and the exercise of powers by their respective officers in relation to matters arising under this regime of export restriction. The guidelines will not commence until the time in which they could be disallowed has expired.

The Bill also amends section 103 of the *National Health Act 1953* to provide that it will be an offence for a person to have in his or her possession or to consign for export more than a designated quantity of a PBS drug, unless the person can prove that the drug was supplied under the PBS for the medical or dental treatment of the person or that there is some other reasonable excuse.

The Bill commences on Royal Assent; however, the substantive amendments to be made by the Bill will commence on a day or days to be fixed by Proclamation, up to six months after the date of Royal Assent.

FINANCIAL IMPACT STATEMENT

It is estimated that this measure will generate savings of approximately \$20 million per year.

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NOTES ON CLAUSES

Clause 1 – Short title

This clause provides that the amending Act may be cited as the *National Health Amendment Act (No. 1) 1999*.

Clause 2 – Commencement

Subclause (1) provides that the amending Act will commence on the day on which it receives Royal Assent, except for the amendments made by Schedule 1, which under subclause (2) will commence on a day or days to be fixed by Proclamation, or, under sub-clause (3) if that does not occur within six months of the Bill receiving Royal Assent, the day after the six months expires.

Clause 3 – Schedule(s)

This clause provides that the *National Health Act 1953* is amended as set out in Schedule 1.

SCHEDULE 1 - AMENDMENT OF THE NATIONAL HEALTH ACT 1953

Item 1

Item 1 inserts a new Division 4D, **Export Restriction**, after Division 4C of Part VII.

Section 99ZH - Definitions

Subsection (1) inserts several definitions relevant to the new Division 4D, including:

Commonwealth benefit: the amount payable by the Commonwealth to an approved supplier for the supply of a pharmaceutical benefit;

consign for export: the act of giving an article to another person within the intention that the person will arrange the export of the article from Australia;

Customs declaration: an export entry within the meaning of the *Customs Act 1901* or a declaration under section 99ZK;

Customs documentation purposes: the purposes of enabling the Australian Customs Service to deal with complaints or proceedings against Customs officers;

Drug like substance: a substance presented in any of the dosage forms, such as tablets, capsules, inhalations, injections, creams, ointments and the like, normally associated with the administration of pharmaceutical preparations;

Exporter: a person who leaves or attempts to leave Australia carrying a drug like substance, or who consigns for export an article containing a drug like substance;

PBS monitoring purposes: the monitoring by the HIC of the operation of the PBS;

PBS regulatory purposes: the purposes of enabling the HIC to perform its functions

under this regime, as well as its monitoring of the operation of the PBS;

Prescription drug: a substance for which the prescription of a doctor or dentist is required under the law of the State or Territory in which the substance is supplied, or under the law of any of the States or Territories if the State or Territory of supply is not known;

Prohibited export: something that is prohibited from being exported from Australia under the *Customs Act 1901* or any other Commonwealth law.

Section 99ZI – Restrictions on carriage or consignment of drug like substances

Subsection (1) provides that a person must not leave Australia carrying drug like substances unless they are for the personal use of the exporter or someone accompanying the exporter, or were not obtained under the PBS.

Subsection (2) provides that a person must not consign for export an article containing drug like substances unless they were not obtained under the PBS or are for the personal use of the exporter or a person accompanying the exporter.

Subsection (3) provides a person is taken to be carrying drugs if those drugs are contained in their baggage, even if it is not under their immediate control.

Subsection (4) provides that these provisions are in addition to any other prohibition on exports imposed by any other law of the Commonwealth or of a State or Territory.

Subsection (5) provides that “travel documents” include documents that a person can use to reclaim baggage.

Section 99ZJ – Detention of certain drug like substances being carried out of Australia and retention of related documents

Section 99ZJ covers the detention of drug like substances found in the baggage of persons attempting to leave Australia.

Subsection (1) provides that a Customs officer may detain drug like substances found in a person’s baggage for transfer to the HIC if the exporter cannot satisfy the officer that the substances are for the personal use of the exporter or a person accompanying them, or that no Commonwealth benefit was paid or payable for the substances.

Subsection (2) describes the means by which an exporter may satisfy a Customs officer that drug like substances are not prescription drugs.

Subsection (3) describes the means by which an exporter may satisfy a Customs officer that no Commonwealth benefit has been paid or is payable in respect of drug like substances.

Subsection (4) describes the means by which an exporter may satisfy a Customs officer that the drugs are for their personal use, or that of a person accompanying them.

Subsection (5) provides that the documentation suggested in the preceding sub-clauses may not

automatically be sufficient to satisfy a Customs officer.

Subsection (6) provides that if a Customs officer is provided with documents under the preceding sub-clauses, the officer must make two copies. If the document is a signed declaration, the Customs officer will keep the original for transfer to the HIC, keep one copy for Customs documentation purposes and give the other copy to the exporter. If it is any other document, the Customs officer will keep one copy for transfer to the HIC, keep one copy for Customs documentation purposes and give the original back to the exporter. The purpose is to ensure that the exporter retains a copy of the information given to the Customs officer at the time at which it is provided.

Subsection (7) provides that if a Customs officer does not detain the drug like substances, they will immediately return any evidentiary material to the exporter, subject to subsection (8).

Subsection (8) provides that if a Customs officer decides not to detain the drug like substances but in the circumstances considers it appropriate to retain information concerning the substances for transfer to the HIC for PBS monitoring purposes, the officer will make copies of the document and retain and give back the original and copies in the same way as set out in subsection (6).

Section 99ZK - Detention of certain drug like substances being consigned for export and retention of related documents

Section 99ZK covers the detention of drug like substances found in articles consigned for export.

Subsection (1) provides that if a Customs officer finds drug like substances in an article consigned for export, and the article is not covered by a satisfactory Customs declaration, then the Customs officer may detain the substances for transfer to the HIC.

Subsection (2) sets out what must appear in a signed declaration accompanying an article consigned for export that contains drug like substances.

Subsection (3) sets out ways in which an exporter may satisfy a Customs officer that drug like substances were not supplied under the PBS, or are for personal use.

Subsection (4) provides that compliance with subsection (3) will not necessarily be sufficient to satisfy a Customs officer.

Subsection (5) provides that if a Customs officer detains drug like substances, the officer must copy the Customs declaration relating to the article and keep the copy for transfer to the HIC. If the article contains supporting documentation, the Customs officer will make two copies, keep one for transfer to the HIC, one for Customs documentation purposes and replace the original.

Subsection (6) provides that if a Customs officer decides not to detain the drug like substances, but considers it appropriate to retain information for transfer to the HIC, they will copy the Customs declaration and other documents and replace the original.

Section 99ZL – Examination and inspection powers

Subsection (1) enables a Customs officer, with reasonable force if necessary, to examine and inspect baggage, or articles consigned for export, for drug like substances, or to see whether drug like substances are as disclosed by the exporter.

Subsection (2) requires a Customs officer, in exercising these powers of examination and inspection, to act in accordance with the guidelines issued under section 99ZS.

Subsection (3) sets out in what places examinations may be conducted.

Section 99ZM – Customs may detain some drug like substances and not others

Section 99ZM provides that the power contained in section 99ZJ or 99ZK for a Customs officer to detain drug like substances include a power to detain only some of them.

Section 99ZN – Customs treatment of detained substances and retained documents

Subsection (1) provides that drug like substances detained by a Customs officer must be taken to a place of security, specified by the CEO of Customs, until they are transferred to the HIC.

Subsection (2) sets out the procedure for Customs officers dealing with detained substances.

Subsection (3) sets out the procedure to be followed where a Customs officer does not detain drug like substances but does retain information relating to the substances.

Subsection (4) explains the means by which notice of detention of drug like substances may be provided to the exporter.

Subsection (5) sets out the requirements for a notice of detention of drug like substances.

Subsection (6) sets out the requirements for keeping and dealing with retained documents.

Section 99ZO – Treatment by the Commission of detained substances and retained documents

Section 99ZO deals with the treatment by the HIC of detained substances and any related documentation transferred to it by Customs officers.

Subsection (1) provides that detained substances transferred to the HIC must be taken to a place of security, pending their return, reconsignment or disposal.

Under subsection (2), if the HIC decides that the detained substances are neither prescription drugs nor prohibited exports, it must return them to the exporter with any related documentation, or reassign them for export.

Under subsection (3), if the HIC decides that the detained substances are prohibited exports, it must pass them, with any related documentation, to the agency nominated in the guidelines to deal with prohibited exports of that kind.

Under subsection (4), if the HIC decides that the substances are prescription drugs but not prohibited exports, it must notify the exporter and invite them to apply to the HIC for the return of the substances on the basis that they were not supplied under the PBS or are for personal use.

Subsection (5) provides that if the exporter does not apply for the return of the substances within the 60 day period, the substances are taken to have been seized by the HIC and condemned as forfeited to the Commonwealth.

Subsection (6) provides that substances are not taken to have been so condemned if proceedings for an offence involving those substances have been commenced before that period expires.

Subsection (7) provides that where the exporter applies for the return of the substances, the HIC must return the substances or reassign them for export if it is satisfied the substances are for personal use or were not supplied under the PBS; if not satisfied it must seize them as forfeited to the Commonwealth.

Subsection (8) provides that substances seized under subsection (7) must be returned or reassigned for export unless proceedings are commenced for condemnation of the substances as forfeited goods and the court orders accordingly.

However, under subsection (9), a court must not make an order for the condemnation of substances if proceedings for an offence involving those substances have been commenced.

Subsection (10) provides that in such proceedings a certificate from the HIC that the substances are prescription drugs is prima facie evidence of that matter.

Section 99ZP – Right of compensation in certain circumstances for substances destroyed

Subsection (1) provides that if drug like substances were destroyed because the exporter did not apply for their return, they may apply to the court for compensation.

Subsection (2) sets out the circumstances in which a person is entitled to compensation.

Subsection (3) provides that compensation will be an amount equal to the market value of the substances at the time of their destruction.

Section 99ZQ – Disposal of forfeited substances

Subsection (1) provides that title to drug like substances that are seized and condemned as forfeited vests in the Commonwealth.

Subsection (2) provides that these substances must be destroyed in accordance with the guidelines issued under section 99ZS.

Section 99ZR – Liability for acts done in good faith

Subsection (1) provides that neither the Commonwealth nor its officers are liable for acts done in good faith under these provisions.

Subsection (2) provides that if drug like substances have been lost or have ceased to be useable where the HIC should normally have returned or reconsigned them, the HIC must pay the exporter compensation if they seek it.

Section 99ZS – Guidelines for detention of, dealing with, and disposal of, substances

Subsection (1) enables the CEO of Customs to issue written guidelines in relation to the functions, duties and powers of Customs officer under this Division, including in particular, the examination of baggage and articles consigned for export, the detention of drug like substances, the transfer of detained substances to the HIC and the manner of dealing with related documents.

Subsection (2) enables the HIC to issue written guidelines in relation to the functions, powers and duties of HIC staff under this Division, including, in particular, the manner of dealing with drug like substances transferred to the HIC and claims for their return, the disposal of such substances, the manner of dealing with prohibited exports and the agencies to which prohibited exports will be passed.

Subsection (3) permits those guidelines to be varied or revoked.

Subsection (4) provides that guidelines are disallowable instruments; however, under subsection (5) (contrary to the *Acts Interpretation Act* provisions re the commencement of disallowable instruments), they will not take effect until the day after which they are no longer liable to be disallowed, or such later day as is specified in the guidelines.

Section 99ZT – Forfeiture of substances detained under section 99ZJ or 99ZK

Section 99ZT provides that drug like substances that are transferred to the HIC under section 99ZJ or 99ZK are forfeited to the Commonwealth, unless they were not supplied under the PBS or are for the personal use of the exporter of a person accompanying them.

Item 2

Item 2 inserts new subsections (4AA), (4AB), (4AC), (4AD) and (4AE) after subsection 103(4).

Subsection (4AA) provides that a person must not possess, or consign for export, more than the designated quantity of a pharmaceutical benefit, unless it has been supplied for their medical or dental treatment or they have some other reasonable excuse.

Subsection (4AB) provides that the burden of proving that excuse lies on the defendant exporter.

Subsection (4AC) defines the “designated quantity” of a pharmaceutical benefit as twice the total quantity that can properly be supplied on one PBS prescription by way of original and repeat supplies.

Subsection (4AD) provides that a certificate by the HIC that a substance is a particular pharmaceutical benefit, or that a substance exceeds the designated quantity, is *prima facie* evidence of those matters.

Subsection (4AE) provides that a person is not liable to be convicted of an offence against both subsection (4) and (4AA) in respect of the same action.