Australian Government

Department of Health and Ageing

Mr Elton Humphery
Committee Secretary
Community Affairs Legislation Committee
Parliament House
Canberra ACT 2600

Dear Mr Humphery

National Health Amendment (Budget Measures – Pharmaceutical Benefits Safety Net) Bill 2005

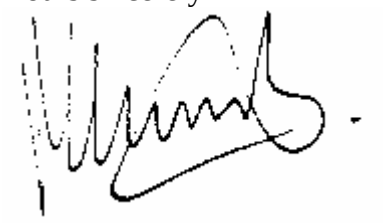
Health Legislation Amendment Bill 2005

I refer to your letter of 6 October 2005, which invited the Department of Health and Ageing to provide a written submission to the Senate Committee inquiry into the above Bills.

This letter has two attachments. Attachment A is in response to issues concerning the National Health Amendment (Budget Measures – Pharmaceutical Benefits Safety Net) Bill 2005 and Attachment B is in response to issues raised in relation to the Health Legislation Amendment Bill 2005. The Department's submission has been prepared to assist the Committee in its deliberations. It responds to the specific issues identified by the Selection of Bills Committee. Officers of the Department will be available to attend the Committee's public hearing if required.

I trust that this information is of assistance.

Yours sincerely



Mr Philip Davies
Deputy Secretary

13 October 2005

Enc.

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Attachment A

National Health Amendment (Budget Measures – Pharmaceutical Benefits Safety Net) Bill 2005

Increase in PBS Safety Net thresholds

(a) Need for increase in PBS Safety Net thresholds

The Pharmaceutical Benefits Scheme (PBS) Safety Net plays an important role in helping to limit out-of-pocket expenses for people who need a large number of medicines.

The Safety Net thresholds work in conjunction with patient co-payment amounts to limit the cost to patients for individual prescriptions and also to limit total expenditure for individuals and families for PBS medicines. These mechanisms also have a role in ensuring that people accessing PBS medicines contribute a fair and reasonable amount to the cost of those medicines, in line with their treatment needs and ability to pay.

The cost to a patient for a PBS medicine is often only a fraction of the actual total cost. Increases in the cost of the PBS have meant that the relative contribution of patient payments as a proportion of total PBS costs has fallen from around 20% in the early 1990's to 16.4% in 2004-05.

The incremental increases in the Safety Net thresholds will result in a gradual adjustment over four years which will help to rebalance the way costs for the PBS as a taxpayer-funded scheme are shared between the government and individuals. The on-going benefits of the PBS Safety Net will continue to protect individuals and families.

Increases in the PBS Safety Net have occurred in the past. Since the introduction of the PBS Safety Net in 1986, this is the fifth time that an adjustment other than indexation has needed to be made. This type of periodic adjustment reflects a commitment to responsible management of the PBS and to keeping the PBS both accessible and affordable for individuals and the community into the future.

(b) Similar method of PBS Safety Net adjustment for all patient categories

The general and concessional Safety Net thresholds will be increased by the value of two patient co-payments in addition to the usual annual indexation according to CPI, each year for four years.

For general patients, this will mean that the current Safety Net threshold of $874.90 will increase by the equivalent of two indexed co-payments (currently $28.60 each) on 1 January of each year until 2009. By 2009, the general Safety Net threshold will include eight additional co-payments. For concessional patients, the Safety Net will increase by the equivalent of two co-payments each year from 52 prescriptions currently ($239.20) to 60 co-payments by 2009.

The change to the concessional threshold will apply also for veterans under the Repatriation Pharmaceutical Benefits Scheme.

There is no change to the way co-payment charges are reduced after the Safety Net threshold is reached. For concessionals and Repatriation patients, the co-payment for medicines

supplied after realising the Safety Net will continue to be free. For general patients, the co-payment for medicines supplied after the Safety Net will reduce to the concessional co-payment amount.

New Safety Net and co-payment arrangements for supply within 20 days of some PBS medicines

(a) Effects of, and need for, the proposed changes

The proposed new arrangements to reinforce Safety Net and co-payment arrangements for some PBS medicines (the 'Safety Net 20 day rule'), support the responsible use of PBS entitlements by discouraging people from obtaining supplies of medicines earlier than they are needed. The changes are necessary because Safety Net entitlements can act as an incentive to obtain additional supplies of medicines early at the reduced Safety Net rate. The Safety Net 20 day rule is expected to assist in reducing the "stockpiling" of PBS medicines that occurs towards the end of each calendar year when many people reach the Safety Net.

The medicines covered by the new Safety Net arrangements are discussed at (d) below. If a medicine subject to the new rule is resupplied within 20 days of a previous supply of the same medicine:

- The co-payment will not count towards the Safety Net threshold tally; and
- If the threshold has been reached, the usual copayment amount, not the reduced Safety Net co-payment amount, will apply.

This measure supports access to PBS medicines. It does not prevent supply at the subsidised rate – even where additional supplies are required. The financial effects are modest. The changes will not stop people obtaining the medicines they need.

The new Safety Net rule is a logical extension of the Regulation 25 "Immediate Supply" provision which has been in place for around 10 years. Regulation 25 is intended to ensure that pharmacists resupply medicines early only when genuinely required.

Under the existing PBS rules, repeat supplies of most medicines for long-term therapy cannot be obtained within 20 days of a previous supply. However, Regulation 25 allows the pharmacist to dispense a prescription as an early PBS subsidised resupply (within 20 days) where there is a genuine need (ie. if the medicine has been destroyed, lost, stolen or is required without delay for the treatment of the person).

When the Safety Net 20 day rule comes into effect, the pharmacist will still need to ensure that Regulation 25 is satisfied before proceeding with an early supply.

The proposed amendment supports Quality Use of PBS Medicines by discouraging stockpiling, reducing wastage, and reducing risks associated with excess medicines in the community. It is a sensible way to encourage responsible use of PBS entitlements.

(b) Effects for consumers

The Safety Net 20 day rule results in there being no financial advantage in obtaining excess early supplies as there is no benefit for the Safety Net tally, and the co-payment is the same as it would otherwise be without the Safety Net. This removes the incentive to obtain extra PBS medicines for the purpose of accessing Safety Net benefits. Patients will achieve the best value for PBS co-payments by complying with entitlements.

Many people will already be familiar with the existing PBS rule that repeat supplies of some medicines cannot be obtained within 20 days, unless the circumstances meet requirements under the "immediate supply" provisions. The new rule is very similar in many respects – except that an early repeat supply made as an "immediate supply" will fall outside Safety Net entitlements if the drug is one that is subject to the new 20 Day Rule.

Pharmacists will be able to assist consumers with specific enquires regarding the medicines they are taking or if the need arises for an additional or early resupply of a medicine.

(c) Role of pharmacists and doctors

Pharmacists, doctors and consumers will be provided with clear information prior to the changes coming into effect.

The introduction of the Safety Net 20 day rule should largely be seamless for the pharmacist because there will be no change to the operation of Regulation 25.

- Pharmacy software will adjust the Safety Net accrual and the patient charge automatically.
- Pharmacists do not need to remember which drugs are subject to the Safety Net 20 day rule. The drugs subject to the new rule will be flagged within the pharmacy software and the appropriate dialogue box prompts will be displayed automatically as part of the dispensing process.

No doctor's consultation is required for patients to access additional quantities of medicines via the "immediate supply" provisions. Pharmacists can make these supplies on repeat prescriptions where they are genuinely needed.

The pharmacist's interaction with the consumer should not be significantly different from that currently, when early supply of a medicine is requested. The pharmacist will need to ensure that the consumer is aware of the implications when an early supply of their medicine falls outside Safety Net benefits.

There is no reason why people with chronic conditions will be worse off under the new Safety Net rule. People who use a large number of medicines or who are prescribed higher than usual dosages should not usually need to have additional prescriptions dispensed to meet their treatment needs. Where more than the standard PBS quantity of a medicine is required, approval to prescribe a larger quantity can be requested by the doctor so that repeat

prescriptions can be obtained at the usual interval and for the usual patient co-payment. As part of the communication strategy for the Safety Net 20 Day rule, doctors will be reminded of the need to obtain authority approval from Medicare Australia if a larger quantity of a medicine is required for a patient's dosage needs.

Under the existing Regulation 24 provision a doctor can endorse a prescription at the time of writing so that the original and all repeats can be dispensed at the one time if that is necessary for the patient due to distance from a pharmacy or chronic illness and hardship in obtaining repeats on separate occasions. For example, doctors can use Regulation 24 for prescriptions for people who live or work in remote areas.

There will be no change to the operation of Regulation 24. Supply of multiple repeats of a prescription on the same day as the original under Regulation 24 will not be affected by the new Safety Net rule.

(d) Medicines involved

The Safety Net 20 Day rule will apply only to medicines for long-term therapy. It is not intended to apply to all PBS medicines. It will not apply to medicines such as morphine; palliative care medicines; chemotherapy medicines; Section 100 items (eg. medicines for HIV); or medicines for acute conditions or short-term use (eg. antibiotics for acute infections).

The Safety Net 20 Day rule will only apply where the same PBS item (any brand) is resupplied early for the same person. This means that where the doctor writes a prescription for the same medicine but for a different dosage or formulation (eg tablets instead of a liquid), there will be no financial penalty to the patient from the supply of both prescriptions within 20 days even where the medicine is one that is subject to the new rule.

The Pharmaceutical Benefits Advisory Committee will provide expert advice to ensure the new rule applies only to medicines where it is appropriate.

(e) Repatriation Pharmaceutical Benefits Scheme (RPBS) and pharmaceuticals supplied in hospitals

The Safety Net 20 Day rule will apply to the RPBS where the medicine supplied is the same as a PBS-listed medicine. There are no RPBS-only medicines listed only for veterans that will fall under the new rule.

The new rule will not apply to prescriptions originating in a hospital or day hospital facility. PBS medicines prescribed in private hospitals, discharge prescriptions from participating PBS-Reform hospitals, and outpatient medications at public hospitals will not be affected.

Attachment B

Health Legislation Amendment Bill 2005

a) Consider the evidence that the powers are necessary

Section 4BAA amendment

The purpose of the proposed legislative change is to clarify regulation making powers of the *Health Insurance Act 1973* ('the Act') and not to present new powers. The existing provisions (sections 4, 4A, and 4AA) within the Act for the establishment of Tables (the General Medical Services Table, the Pathology Services Table, and the Diagnostic Imaging Services Table) specify that the regulations may prescribe Tables containing:

a) items of services;
b) the amount of fees applicable in respect of each item; and
c) rules for interpretation of the table.

It has been a long standing practice to specify conditions that must be met before items in the Tables apply and thereby specify the circumstances in which Medicare benefits are payable for services described in the items. These conditions take a variety of forms to ensure that items clearly reflect current and appropriate clinical practice. Conditions include limiting the number of times that an item may be claimed, requiring medical practitioners to have specific qualifications, requiring the service to be provided with specific equipment, requiring the service to be provided to patients who meet certain criteria or requiring the service to be provided for a specific purpose.

These conditions are set out in the description of the services covered by the items and the rules of interpretation that are contained in the Tables. In recent years, the Office of Legislative Drafting and Publications has suggested that it would be more appropriate for the Act to be amended to clarify that these Tables may set conditions, limitations or restrictions on the circumstances in which Medicare benefits are payable for health services and to make clear the regulation making power of the Act.

Section 19A amendment

Some medical practitioners use existing Medicare Benefits Schedule (MBS) items for new technologies or procedures which were never envisaged when the items were created and which may not yet be proven to be safe, effective or cost effective through the Medical Services Advisory Committee (MSAC) process. With rapid advances in medical technology, it is difficult to anticipate and exclude such medical technologies from being claimed, until they are proven to be safe and effective.

The proposed amendment is designed to enable the Minister to respond more immediately when concerns about possible misuse of MBS items arise.

b) Identify if the Bill has sufficient mechanisms to ensure that decisions to impose conditions, limitations and restrictions are made in line with scientific evidence

Section 4BAA amendment

The Tables prescribed under the Act are re-made in November each year and amended the following May. This coincides with the regular printing of the Medicare Benefits Schedule Book. Decisions to impose conditions, limitations or restrictions on health services are made through either an assessment of the MSAC or by agreement with the relevant medical profession/s through the Medicare Benefits Consultative Committee (MBCC). Both of these bodies provide advice and recommendations to the Minister who considers the advice before making a decision.

Section 19A amendment

It is Australian Government policy that new medical technologies or procedures must be assessed by the Medical Services Advisory Committee (MSAC) before they are publicly funded under Medicare.

The MSAC is an independent scientific committee comprising individuals with expertise in medical, economic and consumer matters. It advises the Minister for Health and Ageing on whether new medical services should be publicly funded based on an assessment of their safety, effectiveness and cost effectiveness, using the best available evidence.

This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for both patients and taxpayers.

The rationale for the proposed legislative change is to preserve the evidence based approach to the use of MBS items. The proposed amendment will provide the Minister with a power to exclude medical procedures from Medicare funding until the scientific evidence has been gathered.

c) Determine the need for appropriate structures to guarantee consumer and expert consultation in the decision making of the power

Section 4BAA amendment

The MSAC includes relevant medical expertise and consumer representation as an important aspect of its constitution.

The MBCC is an informal consultative forum established by agreement between the Minister and the Australian Medical Association (AMA) to facilitate discussion on the review and implementation of items in the Tables. In addition, a MBCC is generally formed following a positive recommendation from the MSAC to assist with the drafting of necessary item descriptors, including any clinical requirements and fees. Representation is drawn from the Department of Health and Ageing, Medicare Australia, and the AMA as well as the relevant professional craft group/s. The Department considers that the most value from consumer representation is gained through the MSAC, given its wider focus on assessments of new technologies and procedures from a variety of perspectives, rather than the MBCC which is largely technical in nature.

Section 19A amendment
It is intended that Determinations made using this power will be consistent with current arrangements, and involve consultation with the medical profession.

d) Examine the need for appeals mechanisms to prevent arbitrary application of the power

Section 4BAA amendment
The powers prescribed within the Bill are necessary to remove any doubt as to the regulation making powers of the Act. There are existing mechanisms to ensure that any decisions to impose such conditions, limitations or restrictions are made so that the Tables reflect and encourage appropriate clinical practice, in line with scientific evidence. The decision making process includes appropriate expert consultation in order to achieve this. No appeal mechanism is envisaged or has been necessary to date.

Section 19A amendment
Determinations under this power, along with any Regulations would be disallowable instruments.