EXPLANATORY STATEMENT

National Health Act 1953

National Health (Continued Dispensing) Determination 2012

Authority

Subsection 89A(3) of the *National Health Act 1953* (the Act) provides that the Minister may determine the pharmaceutical benefits that can be supplied by an approved pharmacist under Part VII of the Act without a prescription, and the conditions for such a supply ('Continued Dispensing').

Purpose

New section 89A of the Act (Continued Dispensing) will commence on 1 July 2012 when Schedule 1 of the *National Health Amendment (Fifth Community Pharmacy Agreement Initiatives) Act 2012* commences.

This instrument, made under subsection 89A(3) of the Act, determines both the conditions under which Continued Dispensing can occur and the eligible pharmaceutical benefits that can be supplied in this way.

Continued Dispensing will enable the provision of a PBS maximum quantity of an eligible medicine to a person by an approved pharmacist, under specific circumstances, on the basis of a previous prescription, where a valid prescription is unavailable.

The eligible pharmaceutical benefits that can be provided as a continued dispensing supply will be limited to Oral Hormonal Contraceptives for systemic use and Lipid Modifying Agents, specifically the HMG CoA reductase inhibitors (statins). No other Lipid Modifying Agents, including combination agents will be included. It is not intended to modify the benefits in scope for this type of supply without consultation, including with states and territories, and recommendation from an appropriate clinical body.

The Fifth Community Pharmacy Agreement (Fifth Agreement) between the Australian Government and the Pharmacy Guild of Australia commenced on 1 July 2010. The Fifth Agreement provides funding for the development of a number of professional programs to be implemented in community pharmacy including the *Continued Dispensing of PBS Medicines in Defined Circumstances* initiative.

In conducting a continued dispensing supply, the Determination requires pharmacists to consider the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists* (PSA Guidelines), prepared and issued by the Pharmaceutical Society of Australia, as the document exists on 1 July 2012. Hard copies of the guidelines will be provided to all registered pharmacists and will also be

available from the Pharmaceutical Society of Australia website at http://www.psa.org.au/.

The PSA Guidelines provide advice and guidance to assist pharmacists to meet their professional responsibilities, exercise professional judgement in individual circumstances and manage risks associated with the Continued Dispensing of eligible prescribed medicines.

This instrument does not override state and territory poisons laws. States and territories have been informed of the intended Commonwealth changes and asked to consider amendments that may be required to their law to allow access to this initiative.

Consultation

Broad consultation has been undertaken throughout the development of the initiative. A public written consultation process was undertaken in 2011. Responses were received from a broad cross section of stakeholders within key industry groups including prescribers, pharmacists and consumers. The responses provided both positive and constructive feedback that was used in finalising policy parameters for the initiative. The Department has continued to engage with stakeholder groups as individual issues are identified. In particular, throughout the development of the professional guidelines to support Continued Dispensing the Pharmaceutical Society of Australia established an expert reference group made up of key industry representatives. This group was integral to the development of the implementation models for this initiative.

In addition, the Department has also undertaken direct consultation with the Department of Human Services and has also engaged and consulted with state and territory Departments of Health to seek their input and support for the initiatives.

Details of the Determination are set out in the Attachment.

This Determination commences 1 July 2012.

This Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT

Details of the *National Health (Continued Dispensing) Determination 2012*

Part 1 Preliminary

1.03 Name of Determination

This section states that the name of the Determination is the *National Health (Continued Dispensing) Determination 2012.*

1.02 Commencement

This section states that this Determination commences on 1 July 2012.

1.03 Definitions

This section provides definitions for the *National Health Act 1953* and the *Guidelines for the Continued Dispensing of eligible prescribed medicines by pharmacists* developed by the Pharmaceutical Society of Australia. This section also indicates that approved pharmacist, PBS prescriber, pharmaceutical benefit and pharmaceutical item have the same meaning as provided for within part VIII of the Act.

1.04 Purpose

This section establishes that the purpose of the determination is to specify the pharmaceutical benefits that can be supplied and the conditions that must be met when a pharmacist chooses to supply a pharmaceutical benefit as a continued dispensing supply without a current prescription, but on the basis of a previous prescription from a PBS prescriber.

Part 2 Conditions

2.01 General

This section establishes the conditions that must be satisfied when making a continued dispensing supply of a pharmaceutical benefit in accordance with subsection 89A(1) of the Act.

This section requires the pharmacist to consider the PSA Guidelines when both undertaking a continued dispensing supply and assessing the appropriateness of this form of supply.

This section also clarifies that a person means the person requesting the supply of the pharmaceutical benefit under subsection 89A(1) of the Act and that a reference to a PBS prescriber means the PBS prescriber who provided the person with their most recent prescription for the supply of the pharmaceutical benefit.

2.02 Not practicable to obtain prescription

In determining whether to undertake a continued dispensing supply of a pharmaceutical benefit under subsection 89A(1) the pharmacist must be satisfied that the person receiving the benefit has demonstrated that it is not practicable for them to obtain a prescription from a prescriber prior to the supply needing to occur. For example, the person may be unable to obtain an appointment to arrange a new prescription before their current supply runs out.

In addition, the pharmacist must also determine that other types of emergency supply options, such as a communicated prescription, are not suitable for the circumstances.

2.03 Previous supply of pharmaceutical benefit

In undertaking a supply in accordance with subsection 89A(1) of the Act, the pharmacist must be satisfied that the person requesting the supply has previously been supplied that same pharmaceutical benefit on the basis of a prescription provided by a PBS prescriber. This benefit must also have been for a PBS listed indication. If the previous supply was via a PBS prescription, this would indicate to the pharmacist that the prescriber had determined that the PBS prescribing restrictions (if any) had been satisfied.

2.04 Stability of therapy

This condition requires the approved pharmacist to be satisfied that the person's therapy is stable. To establish stability of therapy, the pharmacist should consider evidence of adherence to, and persistence with, prescribed therapy, both in relation to the requested medicine and other medicines being taken by the person. As outlined in the PSA Guidelines, in establishing stability of therapy the pharmacist should also consider such things as the length of time that the person has been taking the medicine being sought, and the absence of a hospital admission since last having the medicine prescribed. A further prescription for the medicine following initial prescribing can also be of assistance in demonstrating stability of therapy.

2.05 Prior clinical review by PBS prescriber

When establishing a person's clinical history and their suitability for a continued dispensing supply, the pharmacist must determine that the person has been taking the requested medicine consistently for an uninterrupted period of time up to, and preceding, the request for a supply without a prescription.

The pharmacist must also be satisfied that since the person began taking the medicine that they have received at least one clinical review by a PBS Prescriber that indicated an ongoing need for that medicine. For example, this could be demonstrated in the person's dispensing history by consideration of the number of original prescriptions received.

Further detail on how a pharmacist can satisfy these requirements is outlined in the PSA Guidelines.

2.06 Prescription for last supply of pharmaceutical benefit

Under this condition, the pharmacist must be satisfied that the persons last supply of that medicine was via a prescription issued in accordance with Part VII of the Act. Without evidence that the previous supply was made via a 'valid' prescription the pharmacist should not undertake a continued dispensing supply. If the previous supply was a continued dispensing supply the pharmacist must not provide a subsequent consecutive supply via this mechanism (clause 2.07 refers). The pharmacist should instead consider other available emergency supply options.

In determining if this condition is met, the pharmacist should not rely solely on the Department of Human Services – Medicare PBS claiming information to determine if a continued dispensing supply is appropriate. The PSA Guidelines provide further guidance for pharmacists in how to establish this information.

2.07 No continued dispensing in previous 12 months

A person may only receive one continued dispensing supply per eligible medicine within a twelve month period. Where the pharmacist identifies that the person has received a supply of the eligible pharmaceutical benefit as a continued dispensing supply within the previous twelve months they must not undertake a continued dispensing supply.

2.08 Declaration by person supplied with pharmaceutical benefit

This condition requires the person receiving the continued dispensing supply, or their agent, to sign a declaration acknowledging that they have been supplied a pharmaceutical benefit without a valid PBS prescription. The acknowledgement demonstrates that the person, or their agent, understands that the supply has been undertaken without consultation from the person's prescriber. Where a continued dispense supply occurs, the agent signing on behalf of the person cannot be the pharmacist who undertook the continued dispensing supply. This acknowledgement forms part of the documentation required to be prepared and recorded by clause 2.10.

2.09 Maximum quantity of supply

This condition restricts a continued dispensing supply to a single maximum quantity or number of units of the eligible pharmaceutical benefit. Maximum quantities and number of units are provided for under paragraph 85A(2)(a) of the Act. Pharmacists will not be able to provide repeat supplies, increased maximum quantities or multiples of a maximum quantity on one occasion under a continued dispensing supply.

2.10 Preparing and recording information

This condition requires the pharmacist to record any information gathered during the interaction with the person that the pharmacist uses to substantiate their decision to undertake a continued dispensing supply. This could include for example, a record of the person's history that captures information relating to stability of therapy, when the person's last clinical review by a prescriber was undertaken, reasons why the person is unable to obtain a prescription and that their previous supply was via usual PBS supply mechanisms.

This condition also requires the pharmacist to prepare a record of the continued dispensing supply to be provided to the person's regular PBS prescriber (or practice where specific prescriber cannot be ascertained). The PSA Guidelines requires that this communication occur within a 24 hour period of the continued dispensing supply occurring and should include the person's name, address, date the medicine was supplied without a valid prescription, details of the medicine provided (including strength, form and instructions for use), reason for the continued dispensing supply and a declaration by the person that they understood the supply was undertaken without consultation from their prescriber.

Part 3 Pharmaceutical Benefits

3.01 Pharmaceutical Benefits and Schedule 1

This section establishes Schedule 1 which sets out a complete list of those pharmaceutical benefits eligible to be supplied under subsection 89A(1) of the Act without a current prescription, on the basis of a previous prescription by a PBS prescriber.

The list of eligible benefits will not be amended without consultation, including with states and territories, and recommendation from an appropriate clinical body.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Continued Dispensing) Determination 2012

This determination is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the regulation

The purpose of determination is to enable the implementation of a new initiatives referred to in the Fifth Community Pharmacy Agreement, *Continued Dispensing of PBS Medicines in Defined Circumstances* which will allow pharmacists to supply certain medicines to a person in the absence of a valid prescription, under specified circumstances.

Specifically, this determination specifies the conditions that must be met in order to undertake a continued dispensing supply and the eligible medicines that can be supplied on the basis of a previous prescription, where a valid prescription is unavailable.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access for people to medicines. This is a positive step towards attaining the highest standard of health for all Australians. Efficient operational arrangements for the PBS support effective administration of the Scheme.

Conclusion

This regulation is compatible with human rights because it advances the protection of human rights.

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