

## EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health

*National Health Act 1953*

*National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019*

The *National Health Act 1953* (the Act) relates to the provision of pharmaceutical, sickness and hospital benefits and medical and dental services.

Section 140 of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by the Act are required or permitted or are necessary or convenient to be prescribed for carrying out or giving effect to the Act.

Subsection 99YBA(1) of the Act provides that the regulations may make provision in relation to services provided by the Commonwealth in relation to the exercise of a power by the Minister under section 9B or Part VII of the Act:

- Section 9B of the Act provides that the Minister may provide, or arrange for the provision of, designated vaccines and goods and services associated with or incidental to the provision or administration of designated vaccines.
- Part VII of the Act concerns pharmaceutical benefits and deals with matters including the supply of and payments concerning pharmaceutical benefits and the pharmaceutical benefits scheme.

Services provided by the Commonwealth in relation to section 9B include services provided in connection with the National Immunisation Program, including the activities of the Australian Technical Advisory Group on Immunisation.

Services provided by the Commonwealth in relation to Part VII include the administration of the Pharmaceutical Benefits Scheme (PBS). This includes the activities of the Pharmaceutical Benefits Advisory Committee (PBAC) and its sub-committees and other services carried out by the Department of Health. These services are directed at assisting the Minister to exercise the relevant powers under Part VII of the Act.

Subsection 99YBA(2) further provides that regulations may make provision in relation to matters including the prescribing of fees, the making of applications, and exemptions from the prescribed fees, in relation to services provided by the Commonwealth under section 9B and Part VII of the Act.

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019* (the Principal Regulations) amend the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the Amended Regulations) to:

- introduce fees for the provision of Australian Technical Advisory Group on Immunisations (ATAGI) services;
- introduce fees for pre-submission meetings and prior notice for submissions and pricing applications to support the implementation of PBS process improvements;
- introduce expanded pricing services and associated fees from three pricing pathways to five;
- introduce fees for sponsor-driven PBS list management services for price increase requests and ministerial discretion requests; and
- increase fees for existing submission and independent review services, to reflect the true and current costs of providing these services.
- align all fees to ensure they have consistent payment points, terms and conditions for services provided by the Commonwealth in relation to an exercise of powers by the Minister under section 9B and Part VII of the Act.

The amendments in the Amended Regulations allow the Commonwealth to support the sustainability of the PBS and manage applications effectively.

Details of the operation of the Amended Regulations are provided in [Attachment](#).

A Statement of Compatibility with Human Rights has been completed for the Amended Regulation, in accordance with the *Human Rights (Parliamentary Scrutiny) Act 2011*. The Statement's assessment is that the measures in the Amended Regulations are compatible with human rights.

### **Consultation**

The policy position reflected in the regulations have been developed following extensive consultation with relevant industry bodies during 2017-18 and continuing into 2018-19. Consultations canvassed changes to the existing fees and the introduction of new fees and associated processes.

**Details of the National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019**

**Section 1—Name of Regulations**

This section provides that the name of the Amended Regulations is the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment Regulations 2019*.

**Section 2—Commencement**

This section provides for the Amended Regulations to commence on 1 July 2019.

**Section 3—Authority**

This section provides that the Amended Regulations are made under the *National Health Act 1953*.

**Section 4—Schedules**

This section provides that each instrument specified in the Schedule is amended or repealed as set out in the Schedule and that any other item in the Schedule has effect according to its terms.

**Schedule 1—Amendments**

**Item [1]—Regulation 1.3**

This item inserts new definitions into the Principal Regulations to provide for a definition of ‘amount’, ‘ATAGI’, ‘ATAGI application’ and ‘Australian Register of Therapeutic Goods’:

- The definition of ‘amount’ confirms that an amount charged or refunded under the Regulations can be a nil amount.
- The definition of ‘ATAGI’ confirms that ATAGI is an entity that does not have separate legal personality from the Commonwealth.
- The definition of ‘ATAGI application’ means an application made under Division 1A.1 of the Regulations.
- The definition of ‘Australian Register of Therapeutic Goods’ allows the Regulations to provide for matters dealt with in the *Therapeutic Goods Act 1989*.

These new definitions provide for new concepts not dealt with in the Principal Regulations, and are necessary to give effect to the Amended Regulations.

**Item [2]—Regulation 1.3 (definition of *Committee*)**

This item amends the definition of ‘Committee’ in the Principal Regulations to provide that ‘Committee’ means ‘the Commonwealth acting through the Pharmaceutical Benefits Advisory Committee’. The item makes it clear that the Pharmaceutical Benefits Advisory Committee (the Committee) is an entity that does not have separate legal personality from the Commonwealth.

**Item [3]—Regulation 1.3**

This item provides that the term ‘designated orphan drug’ has the same meaning as in the *Therapeutic Goods Regulations 1990*. The item is necessary to ensure that the Amended Regulations effectively make provision in relation to matters dealt with in the *Therapeutic Goods Regulations 1990*.

**Item [4]—Regulation 1.3 (definition of *economic evaluation*)**

This item amends the definition of ‘economic evaluation’ in the Principal Regulations to provide that an application made for an economic evaluation is an application made under Part 2 of the Amended Regulations.

**Item [5]—Regulation 1.3 (definition of *evaluation fee*)**

This item repeals the definition of ‘evaluation fee’ currently provided for in the Principal Regulations. This definition is no longer necessary in the Amended Regulations.

**Item [6]—Regulation 1.3**

This item inserts multiple new definitions into the Principal Regulations. These new definitions are necessary to ensure that the Amended Regulations amend the Principal Regulations effectively to support the sustainability of the PBS and allow the Commonwealth to manage its processes more effectively. These processes are in relation to services the Commonwealth provides to people in relation to the exercise of a power by the Minister under section 9B or Part VII of the Act.

**Item [7]—Regulation 1.3 (definition of *pricing fee*)**

This item repeals the definition of ‘pricing fee’ from the Principal Regulations. This is a minor consequential amendment.

**Item [8]—Regulation 1.3**

This item inserts new definitions of ‘pricing services’, ‘submission due day’ and ‘submission services’ into the Principal Regulations. These new definitions provide for new concepts not dealt with in the Principal Regulations, and are minor amendments necessary to give effect to the Amended Regulations.

**Item [9]—Regulation 1.3 (definition of *therapy*)**

This item amends the definition of ‘therapy’ in the Principal Regulations to provide that an application for therapy for the purpose of the Principal Regulations is an

application made under Part 2 of the Amended Regulations. This is a minor consequential amendment.

### **Item [10]—Regulation 1.3**

This item inserts a new definition of ‘usual ATAGI fee’ into the Principal Regulations. This definition is necessary to give effect to amendments made by the Amended Regulations. This is a minor consequential amendment.

### **Item [11]—After Part 1**

This item inserts a new Part 1A—Pre-submission services into the Principal Regulations to deal with the following matters:

#### Division 1A.1—Providing ATAGI advice

The Australian Technical Advisory Group on Immunisation (ATAGI) provides advice to support the Committee’s evaluation of vaccines for the National Immunisation Program (NIP), including on clinical, technical and implementation matters. A 2018 review of ATAGI processes and procedures, in consultation with industry, suggested enhancements to improve timeframes, improve transparency, and provide clarity regarding requirements and expectations for ATAGI and companies seeking advice. These regulations set out cost recovery arrangements that are consistent with the Australian Government’s Charging Framework and which are required to support implementation of the enhanced arrangements.

#### *Regulation 1A.1: Fees for providing ATAGI advice*

Regulation 1A.1 provides that a fee is payable for receiving advice from ATAGI. ATAGI is an entity that provides expert advice to a person for that person to include in their application to the Committee, which recommends that the Minister exercise a relevant power under section 9B the Act to specify a vaccine as a designated vaccine.

#### *Regulation 1A.2: Partial exemption from usual ATAGI fee for simple ATAGI applications*

Regulation 1A.2 provides that the Secretary may decide whether to partially exempt a person from the usual fee payable (the usual ATAGI fee) under regulation 1A.1, where the person has made a written request.

It specifies that the Secretary must decide to partially exempt a person from the usual fee if certain criteria are met. These include whether the person is seeking advice from ATAGI in relation to a vaccine that is substantially similar to an existing designated vaccine or the application does not involve a degree of analysis sufficient to justify the usual fee payable under regulation 1A.1.

If the Secretary decides, or is required to exempt a person, the partial exemption fee is prescribed. The capacity to pay the partial exemption fee ensures that a fee payable

for receiving ATAGI advice has a reasonable relationship to the cost of the service provided by the Commonwealth to that person.

*Regulation 1A.3: How to make an ATAGI application*

Regulation 1A.3 provides the process by which a person must make an application for ATAGI advice under regulation 1A.3. This process is an administrative requirement.

*Regulation 1A.4: Notification (including invoicing of fees)*

Regulation 1A.4 provides a process by which the Secretary must notify a person that the Department has received their application made under proposed regulation 1A.3. Regulation 1A.4 also requires the Secretary to notify the person of the amount of fee payable by that person for receiving ATAGI advice. It also provides that the fee is payable by that person to the Department.

*Regulation 1A.5: Withdrawal of an ATAGI application*

Regulation 1A.5 allows a person to withdraw their application made under the Amended Regulation 1A.1 by providing written notice to the Department. It requires the Department to refund any fee paid by that person for the provision of a service under regulation 1A.1 if the application is withdrawn within 14 calendar days after receiving the notice (1A.4).

*Regulation 1A.6: Resending ATAGI applications*

Regulation 1A.6 allows a person to remake or resend an application for receiving advice from ATAGI. It also provides that the regulations apply to the resent application as if it is a new application. This has the consequence that, for example, a new fee is payable with respect to the resent application.

Division 1A.2—Holding pre-submission meetings

The purpose of Division 1A.2 is to increase access to and better support quality pre-submission discussions in the preparation of uncertain or complex submissions to the PBAC. Increasing the transparency, consistency, accountability and quality of pre-submission meetings is a commitment under the Government's Strategic Agreement with Medicines Australia.

*Regulation 1A.7: Fees for holding pre-submission meetings*

Regulation 1A.7 provides that a fee is payable by a person for the service of the Commonwealth holding a pre-submission meeting for that person. The pre-submission meeting is intended to assist that person prepare a submission to the Committee. The Committee may in turn recommend or advise the Minister to exercise a relevant power under the Act following this submission.

*Regulation 1A.8: How to apply for a pre-submission meeting*

Regulation 1A.8 provides the process by which a person must make an application for a pre-submission meeting.

*Regulation 1A.9: Agreeing to hold a pre-submission meeting*

Regulation 1A.9 provides that the Secretary may agree to hold a pre-submission meeting after considering an application made under regulation 1A.8. The Secretary may also decide not to agree to hold a pre-submission meeting. The sole reason for the refusal is that holding a meeting isn't an efficient use of the finite Commonwealth resources allocated to the PBS program. This decision is reviewable under regulation 6.1A.

*Regulation 1A.10: Notification (including invoicing fees)*

Regulation 1A.10 specifies a process by which the Secretary must notify a person that the Department has received their application made under regulation 1A.8 for a pre-submission meeting and whether the Secretary agrees to hold such a meeting. If the Secretary agrees to hold a meeting, it also requires the Secretary to set out matters including the category of pre-submission meeting and the prescribed fees payable.

*Regulation 1A.11: Withdrawal of a meeting application*

Regulation 1A.11 allows a person to withdraw their application by providing written notice to the Department. It requires the Department to refund any fee paid by that person for the provision of a service under regulation 1A.8 if the application is withdrawn within 14 calendar days of making the application or the last business day prior to meeting, whichever occurs earlier.

*Regulation 1A.12: Resending meeting applications*

Regulation 1A.12 allows a person to remake or resend an application for a pre-submission meeting. It also provides that the Amended Regulations will apply to the resent application as if it were a new application.

**Item [12]—Part 2 (heading)**

This item inserts a new heading into Part 2 of the Amended Regulations and inserts a new simplified outlined concerning Division 2.1A into the Amended Regulations.

**Item [13]—Division 2.1 of Part 2 (heading)**

This item inserts a new heading into Division 2.1 of Part 2 of the Principal Regulations.

**Item [14]—Subdivision 1 of Division 2.1**

This item repeals existing Subdivision 1 of Division 2.1 of the Principal Regulations and substitutes it with the following:

*Regulation 2.1: Which submissions (also known as applications for services) are relevant?*

Regulation 2.1 provides that a person may prepare a submission requesting that the Committee recommend that the Minister exercise a relevant power under the Act. This section also provides that the person may make a submission requesting the Minister exercise a relevant power under the Act.

*Regulation 2.2: Fees for submission services*

Regulation 2.2 provides that the prescribed fees are payable for an application made under regulation 2.1. This section sets out categories of applications for which fees are prescribed. These fees are payable in exchange either for the service of the Committee considering whether to make the recommendation requested by the person in accordance with regulation 2.1, or in exchange for the service of the Minister considering whether to exercise a power referred to in regulation 2.1. Fees payable in respect to applications made to the Committee also include a non-refundable deposit.

#### **Item [15]—[20] Regulation 2.3 and subparagraph 2.4(1)(a)(i)**

The items [15]—[20] makes minor technical changes to regulations 2.3, 2.4, 2.7, 2.8, 2.9 and 2.12 of the Amended Regulations. These regulations specify the kinds of applications for services from the Committee that are in the major, minor or Committee Secretariat categories.

The changes have:

- omitted reference to the Minister taking an action mentioned in certain items in the Schedules to the Amended Regulations and replace with reference to the Minister exercising a power mentioned in those items; or
- omitted reference to the Committee giving advice in relation to a matter and replace with reference to the Committee advising the Minister in relation to a power.

These amendments are technical in nature only to improve drafting and there has been no change to the categories that apply to an application.

#### **Item [21]—Paragraph 2.10(a)**

This item implements a minor consequential amendment in relation to the definition of when an application will be in the minor category currently in force under regulation 2.10 of the Principal Regulations, reflecting revised drafting of regulation 2.19 (see item [25]).

#### **Item [22]—Paragraph 2.12(1)(a) and subregulation 2.12(2)**

This item is a minor consequential amendment.

**Item [23]—Regulations 2.13 and 2.14**

This item is a minor consequential amendment.

**Item [24]—Subdivision 5 of Division 2.1**

This item repeals existing subdivision 5 of Division 2.1 of the Principal Regulations.

**Item [25]—Division 2.2**

This item repeals Division 2.2 of the Principal Regulations and substitutes it with the following:

Division 2.2—Application procedure including prior notice

This item repeals Division 2.2 of the Principal Regulations and substitute it with the following:

*Regulation 2.15: Prior notice needed for major or minor applications to the Committee*

Regulation 2.15 requires a person who proposes to make an application in the ‘major’ or ‘minor’ category for the purpose of regulation 2.2 to give prior notice to the Department in writing at least 28 calendar days before the application is made. The purpose of this requirement is to ensure that the Department can properly prepare for the provision of the relevant services to the person once the application is made.

This regulation also sets out requirements as to how the person is to give this prior notice, including giving power to the Secretary to approve the use of forms for this purpose.

Regulation 2.15(3) provides for the Secretary to accept an application to the Committee without prior notice if the application is required to address an urgent public health need. This decision is reviewable under regulation 6.1A.

*Regulation 2.16: How to apply for submission services*

Regulation 2.16 provides for how an application for services is to be made under Division 2.1 of the Amended Regulations.

*Regulation 2.17: Notification (including invoicing fees)*

Regulation 2.17 provides that the Department must notify a person that it has received their prior notice given under regulation 2.15. It provides for the Department to also notify the person that it has received their application made for the purpose of regulation 2.16. The Department must provide these notices within 14 calendar days of receiving the notice prior or application from a person (where prior notice is not required).

This regulation also requires the Secretary to notify the person, having first considered statements by the person, which of the prescribed fees is payable for the

relevant services provided by the Commonwealth. It also makes the prescribed fee payable to the Department unless an exemption or waiver is granted.

#### *Regulation 2.18: Withdrawal*

Regulation 2.18 provides that a person may withdraw their prior notice or application given under regulations 2.16 and 2.17 and the circumstances in which the withdrawal will require the Department to refund any fee paid.

#### *Regulation 2.19: Resending applications*

Regulation 2.19 provides that an applicant may remake and resend an application made under Part 2 of the Principal Regulation, which deals with submission services, if the Committee or the Minister decides not to give advice or exercise the power initially requested by the applicant. It also provides that the remake application is treated as a new application.

It also provides that the Secretary may agree that prior notice of a resent application to the Committee need not be given in accordance with regulation 2.15 if:

- the Secretary agrees that the resent application will be in the minor category; and
- the absence of prior notice will not unduly affect the provision of services by the Commonwealth.

A note for readers makes clear that the resent application will attract a new fee under regulation 2.2. Additionally, prior notice is not be required if the resent application is one of the evaluation categories in item 3 to 5 of the table in subregulation 2.2(1).

### Division 2.3—Validating evaluation categories and assessing applications

#### *Regulation 2.20: Validating an application's evaluation category*

Regulation 2.20 provides that the Secretary is able to determine that an application made under Part 2 of the regulations is within one of the categories mentioned in Division 2.1. The Secretary must have regard to specified matters before making this determination.

This regulation allows the Secretary to determine that the application is in a different category to that initially notified to the person under regulation 2.17. The purpose of this determination is to ensure the fee paid by the person under regulation 2.2 continues to have a reasonable relationship to the cost of the services provided by the Commonwealth. This determination can be made when the Secretary is in a position to assess the entirety of the service provided to the person.

The regulation also provides how the Secretary is to give notice to the person of this determination, including the amount that may be refunded to the person as well as the person's review rights that are available under Part 6 of the Regulations.

#### *Regulation 2.21: Assessing applications*

Regulation 2.21 provides that the Committee can request further information from the applicant about an application to the Committee under Part 2 of the regulations. It also allows the assessor of the application to request that the Secretary consider making a determination under regulation 2.20(1) as to which category the application should be in or otherwise review a previous determination or decision about the application.

### **Item [26]—Part 3**

Part 3 introduces an expanded range of pricing pathway options and services which better reflect the pricing arrangements available to people after a positive recommendation from the Committee. This part also introduces a prior notice step to enable better planning and allocation of resourcing and provide increased certainty regarding pricing activities to support greater transparency and accountability of these processes.

Part 3 also changes the pay point for pricing services to the commencement of the process rather than at time of listing. This change ensures the Department is able to cost recover for activities undertaken to negotiate pricing outcomes and align the processes for all fees charged.

This item repeals Part 3 of the Principal Regulations and substitutes it with the following:

#### Division 3.1—Preliminary

##### *Regulation 3.1: Simplified outline of this Part*

Regulation 3.1 inserts a new simplified outline into the Amended Regulations to explain the effect of Part 3.

#### Division 3.2—Fees and associated applications

##### *Regulation 3.2 Applications for pricing services*

Regulation 3.2 allows a person to make an application for the Commonwealth to provide pricing services to that person. Under section 85AD of the Act, the Minister and the responsible person for the pharmaceutical item may agree as to the appropriate maximum price of that pharmaceutical item. Under section 85B of the Act, the Minister may determine an appropriate maximum price for a pharmaceutical item if the Minister and the responsible person have been unable to agree. Under section 85E of the Act, the Minister may enter into deeds with the responsible person in relation to pharmaceutical items, which could include an agreement for the Commonwealth to be reimbursed in relation to the provision of pharmaceutical benefits.

Pricing services involve the Commonwealth assisting the Minister in relation to the Minister's exercise of the powers described above. For example, a person will be able to request that the Commonwealth assist the Minister to negotiate or make an appropriate determination in relation to that person's drugs or medicinal preparations. However, a person can only make such an application if the Committee

has previously made a positive recommendation or given positive advice in relation to that person's drugs or medicinal preparations.

*Regulation 3.3: Fees for providing pricing services*

Regulation 3.3 prescribes the amount of fees payable by a person for the Commonwealth to provide pricing services to the person. The fee payable will depend on the category of the pricing application. The categories of application are related to the complexity and resourcing requirements of the pricing services to be provided to the person.

*Regulation 3.4: Pricing Pathway A applications*

Regulation 3.4 prescribes the definition of when a person's application is in the 'Pathway A' application category. An application will be in this category if the drugs or medicinal preparations are expected to provide a substantial and clinically relevant improvement in efficacy, or reduction in toxicity, over any alternative therapies; address an urgent and high clinical need; and; where it is in the public interest for a pricing application relating to the drug or medicinal preparation to be in this category.

Pricing Pathway A only applies if the Committee has identified that the submission application meets the required criteria and the person making the pricing application accepts the Committee's recommendation of this pathway in their prior notice.

*Regulation 3.5: Pricing Pathway B applications*

Regulation 3.5 prescribes the definition of when a person's application is in the 'Pathway B' application category. An application will only be in this category if it seeks the Minister to enter into a deed under s85E of the Act in relation to the relevant drugs or medicinal preparations.

Additionally, there must be no deed currently in force between the Commonwealth and any person about reimbursing the Commonwealth or providing information to the Commonwealth that are substantially similar to those that are appropriate for the drugs or medicinal preparations that the person's application relates to (the new drugs).

Regulation 3.7 deals with when terms in an existing deed made under section 85E of the Act will be substantially similar to those appropriate for the new drugs.

An application for pricing services will not be in Pathway B if it is in Pathway A.

*Regulation 3.6: Pricing Pathway C applications*

Regulation 3.6 prescribes the definition of when a person's application is in the 'Pathway C' application category. As for Pathway B applications, an application will only be in this category if it seeks the Minister to enter into a deed under section 85E of the Act.

However, for Pathway C to apply there must be a deed currently in force between the Commonwealth and any person with terms that are substantially similar to those that are appropriate for the new drugs.

An application for pricing services will not be in Pathway C if it is in Pathway A or B.

*Regulation 3.7: When pricing terms are substantially similar to those appropriate for the new drugs*

Regulation 3.7 sets out certain circumstances when terms in a deed currently in force are or are not substantially similar to those that may apply to the new drugs.

The terms of an existing deed relating to reimbursing the Commonwealth or providing information to the Commonwealth will be substantially similar terms appropriate for the new drugs if:

- the new drugs can share an existing subsidisation cap with the drugs in the existing deed; or
- the Committee's recommendation or advice to the Minister suggested that terms in the existing deed would be appropriate for the new drugs.

However, the terms of an existing deed will not be substantially similar to those appropriate for the new drugs if the terms relate to further clinical testing or requirements for the provision of further clinical data or include taking the clinical response of patients into account in calculating reimbursement amounts. They also will not be substantially similar if they include a subsidy cap that cannot be shared with the new drugs or, in calculating the amount of reimbursement to the Commonwealth, take into account expenditure of therapies that involve using the new drugs in combination with drugs covered by the existing deed.

Regulation 3.7 will not limit the circumstances in which the terms of an existing deed relating to reimbursement of the Commonwealth or the provision of information to the Commonwealth are, or are not, substantially similar to terms appropriate for the new drugs.

*Regulation 3.8: Pricing Pathway D applications*

Regulation 3.8 prescribes the definition of when a person's application is in the 'Pathway D' application category. An application is in this category if it is not in the Pathway A category, the application does not seek entry into a deed under section 85E of the Act, and the remaining criteria in regulation 3.8 are satisfied. These criteria broadly relate to the complexity of the application. This ensures that any fee payable by the person for an application in this category has a reasonable relationship to the cost of the service provided to the person.

*Regulation 3.9: Pricing Secretariat applications*

Regulation 3.9 prescribes the definition of when a person's application is in the 'Pricing secretariat' application category. An application is in this category if it is not in Pathway A, B, C or D. This category is intended for the simplest of applications.

#### Division 3.3—Application procedure including prior notice

##### *Regulation 3.10: Prior notice of pricing applications needed*

Regulation 3.10 requires people to give the Department prior notice of their pricing offer before the application itself is made. The purpose of requiring people to give this notice is to ensure that the Department is able to resource and prepare to assess the application effectively once the application itself is provided.

This regulation requires that people may submit their pricing offer a minimum of 7 calendar days and a maximum of 42 calendar days after lodging the prior notice. The Department will not be required to assess the application for pricing services unless the prior notice has been given, although the Secretary will be able to decide the prior notice is not required in urgent public health situations. Regulation 3.10 also sets out the requirements for how the prior notice is to be given.

##### *Regulation 3.11: How to apply for pricing services*

Regulation 3.11 sets out how an application for pricing services may be made. It also gives the Secretary the power to approve a form for the making of pricing applications.

##### *Regulation 3.12: Notification (including invoicing of fees)*

Regulation 3.12 provides how the Secretary is to notify a person that he or she has received the person's prior notice of their application for pricing services. It also makes the prescribed fee payable to the Department unless an exemption or waiver is granted.

##### *Regulation 3.13: Withdrawal*

Regulation 3.13 provides how a person may withdraw their application for pricing services. It also provides that the Department must refund any fee paid by the person in relation to pricing services in certain circumstances.

#### Division 3.4—Validating categories of pricing applications

##### *Regulation 3.14: Validating a pricing application's category*

Regulation 3.14 provides that the Secretary is able to determine that an application made under Part 3 of the Regulations is within one of the categories listed in regulations 3.4 to 3.9. The Secretary must have regard to the matters set out in the regulation before making this determination.

This regulation allows the Secretary to determine that the application is in a different category to that initially notified to the person under regulation 3.12. The purpose of this determination is to ensure the fee paid by the person under regulation 3.3 has a

reasonable relationship to the cost of the services provided by the Commonwealth when the Secretary is in a position to assess the entirety of the service provided to the person.

The regulation also provides how the Secretary is to give notice to the person of this determination, including the amount that may be refunded to the person as well as the person's review rights that are available under Part 6 of the Amended Regulations.

#### Part 3A—List management services

Part 3A deals with list management services. Part 3A includes new fees for requests from sponsors for services from the Commonwealth to assist the Minister make certain decisions relating to the price of PBS medicines, in particular certain requests relating to price changes and requests for the Minister to exercise certain discretions in relation to the application of statutory price reductions.

##### *Regulation 3A.1: Fees for providing list management services*

Regulation 3A.1 establishes a fee for list management services provided by the Commonwealth in relation to an exercise of power by the Minister under the relevant parts of the Act. List management services are services provided by the Commonwealth at the request of a person, which are intended to assist the Minister to make a decision about the price of a pharmaceutical item.

This regulation establishes fees in relation to services provided by the Commonwealth in relation to the exercise of powers by the Minister under the relevant provisions of section 85AD(1), section 85B, section 99ACB, section 99ACBA, section 99ACD, section 99ACE, section 99ACEA and section 99ACF of the Act. These sections broadly concern the Minister's power to agree, determine or reduce the maximum price of pharmaceutical items.

##### *Regulation 3A.2: How to apply for list management services*

Regulation 3A.2 provides for how an application for list management services is to be made.

##### *Regulation 3A.3: Notification (including invoicing of fees)*

Regulation 3A.3 provides for how the Secretary must notify a person that their application for list management services has been received as well as the fees payable as prescribed under regulation 3A.1 for those services.

##### *Regulation 3A.4: Withdrawal of a list management application*

Regulation 3A.4 allows a person to withdraw an application for list management services. It also makes provision for the Department to refund any fee paid by the person for list management services in certain circumstances.

#### **Item [27]—Part 4 (heading)**

This item repeals the current heading in Part 4 of the Amended Regulations and replaces it with a new heading.

**Item [28]—Regulations 4.1 and 4.2**

This item repeals regulations 4.1 and 4.2 of the Principal Regulations and substitutes the following:

*Regulation 4.1: Payment of fees*

Regulation 4.1 outlines common rules for all fees payable to the Commonwealth under the Regulations. This includes that the fee must be paid in full to the Commonwealth and within the prescribed 28 calendar day period after the Secretary gives notice to the person that the fee is payable. It also allows the Secretary to accept payment by instalment or to grant a longer period for the payment of an amount of a fee. It also requires the Secretary to refund an amount of fee paid to the Commonwealth in certain circumstances.

*Regulation 4.2: Delay in paying a fee*

Regulation 4.2 provides that if a fee payable under the regulations has not been paid by the time it is due and payable, the Commonwealth may refuse to consider any application made under the regulations or provide any service in relation to the application until the fee has been paid.

**Item [29]—Subregulation 4.3(3)**

This item repeals existing subregulation 4.3(3) of the Principal Regulations. Existing subregulation 4.3(3) concerns the fee payable for independent review of a decision by the Committee not to recommend that the Minister exercise a power under s 85(2) or s 85(7) of the Act. This item provides the fee now payable for independent review is the same as that payable for the major submission services provided under Part 2 of the Amended Regulations.

**Item [30]—Regulations 4.4 to 4.6**

This item repeals regulations 4.4, 4.5 and 4.6 of the Principal Regulations. These regulations made provision in relation to the payment of evaluation and pricing fees and delay in paying evaluation and pricing fees. These regulations are no longer necessary as a result of the inclusion of new regulation 4.1, which establishes rules relating to the payment of all fees under the regulations.

**Item [31]—Subregulation 4.7(1)**

This item inserts a definition of ‘fee’ into regulation 4.7 of the Amended Regulations (which concerns the indexation of fees) to provide that a ‘fee’ includes any amount of the fee that is stipulated as being a deposit under the regulations. This makes it clear that any deposit component of a fee payable under the regulations is also subject to indexation in accordance with regulation 4.7.

**Item [32]—Subregulation 4.7(1) (definition of *relevant financial year*)**

This item amends the definition of ‘relevant financial year’ provided for in regulation 4.7(1) of the Amended Regulations to allow the indexation provisions in regulation 4.7(1) to apply from 2021.

**Item [33]—Before subregulation 5.1(1)**

This item inserts a new heading into subregulation 5.1(1).

**Item [34]—Subregulation 5.1(1)**

This is a minor consequential amendment to align the regulations more closely with the section 99YBA of the Act.

**Item [35]—Paragraph 5.1(1)(a)**

This item repeals existing paragraph 5.1(1)(a) of the Principal Regulations to remove the exemption from a fee in relation to a drug designated as an orphan drug under regulation 16J of the *Therapeutic Goods Regulations 1990*. This exemption is now provided for by Item 36.

**Item [36]—Subregulation 5.1(2)**

This item amends regulation 5.1 of the Principal Regulations, which deals with exemptions from fees.

Subregulation 5.1(1) of the Amended Regulations sets out a range of circumstances in which an exemption will apply. These include, for example, that the requested services are only to change the name of the responsible person for a PBS drug or to revoke the specification of a designated drug.

Subregulation 5.1(2) provides that a fee exemption is not available in relation to services to be provided by the Commonwealth under Division 1A.2 or regulation 4.3. Division 1A.2 concerns fees for pre-submission meetings and regulation 4.3 concerns fees for independent review. Pre-submission meetings are an optional part of the process and do not directly apply to the category of submissions covered by exemptions. This does not exclude a person requesting a pre-submission meeting.

Subregulation 5.1(3) provides for some fee exemption for submission services provided in relation to drugs designated as orphan drugs under the *Therapeutic Goods Regulations 1990*. Subregulation 5.1(3) provides that a fee is not payable in relation to submission services for a drug to which subregulation 5.1(4) applies. Subregulation 5.1(4) applies to a drug that is a designated orphan drug or was included on the Australia Therapeutic Goods Register within 12 months the person making an application for submission services.

The purpose of this exemption is to provide that a person whose drugs that have received an orphan designation under the *Therapeutic Goods Act 1989* is not required to pay a fee for submission services under the Regulations if that person’s

application is made within 12 months of receiving this orphan designation. This exemption is available once per therapy only.

The regulation also requires a person making an application for services to state why they believe an exemption should apply to them.

**Item [37]—Subregulations 5.2(1) and (2)**

This item repeals subregulations 5.2(1) and (2) in the Principal Regulations and provides that a person may apply for the Secretary to waive fees payable under the regulations. The provision amends the Principal Regulations to more closely reflect the terms of section 99YBA of the Act.

It also gives the Secretary a power to waive the fee payable in certain circumstances.

**Item [38]—Subregulation 5.2(3)**

This is a minor consequential amendment.

**Item [39]—At the end of Regulation 5.2**

This item inserts a new subregulations 5.2(4) to (8), dealing with requests for a waiver of fees.

Subregulation 5.2(4) provides that where a person had requested a waiver of some or all of the fees payable by them under the Regulations that directly or indirectly relate to submission services and the Secretary declines the request, the person could not later make another request in relation to those fees.

Subregulations 5.2(5) to (8) provides that a person could request the waiver of some or all list management fees, being fees specified in regulation 3A.1. Such a request must be made as part of the application for list management services. The Secretary may choose to waive some or all list management fees where the list management application involves the public interest and the payment of the fee makes the application financially unviable. For the purposes of determining whether a list management application involves the public interest, subregulation 5.2(3) applies to list management applications in the same way as to ATAGI, submission and pricing services. That subregulation sets out circumstances in which an application will be in the public interest, namely that the application:

- is for a drug or vaccine that represents a suitable therapy for a patient population that is not large enough to make the application financially viable; and
- the drug or vaccine is to be used for palliative care, as a paediatric medicine, or for medical treatment of Aboriginal and/or Torres Strait Islander peoples.

**Item [40]—Before Regulation 6.1**

This item inserts a new regulation 6.1A setting out the decisions that are reviewable decisions for the purposes of the regulations. Reviewable decisions may be reviewed

internally or, following internal review, by the Administrative Appeals Tribunal (see items 43 and 46).

Reviewable decisions include:

- decisions not to partially exempt a person from the usual ATAGI fee;
- decisions that provision of submission or pricing services are not required to address an urgent public health need (and therefore requirements relating to giving prior notice of a submission or pricing application do not apply); and
- decisions about the waiver of fees.

#### **Item [41]—Subregulations 6.1(1)**

This item replaces existing subregulation 6.1(1) with a new subregulation that makes consequential changes to reflect the requirements to give an applicant notice about certain reviewable decisions and the person's review rights are included in other provisions of the regulations and do not need to be repeated in regulation 6.1.

#### **Item [42]—Subregulation 6.1(2)**

This is a minor consequential amendment to change reference to 'applicant' to 'person'.

#### **Item [43]—Regulation 6.2**

This item inserts a new regulation 6.2 in the Amended Regulations dealing with internal review rights for reviewable decisions made under the regulations. This includes both review by the initial decision maker as well as a capacity for further internal review by people independent from the initial decision and review.

New regulation 6.2 makes no substantive change to the process or scope of internal reviews.

#### **Item [44]—Regulation 6.3**

This item inserts a new subregulation to provide that the Secretary may at any time initiate review of a reviewable decision for the purpose of the regulations. It provides that if the Secretary thinks appropriate under this subregulation 6.1(1), the Secretary may affirm, vary or revoke the decisions if the Secretary revokes the decision and make any other decision.

The Principal Regulations allowed the Secretary to initiate reviews of decisions. This amendment is consequential in the new regulation 6A.1 to define a class of reviewable decisions.

#### **Item [45]—Regulation 6.4**

This item repeals and replaces regulation 6.4 of the Amended Regulations. That regulation provided for the refund of amounts that became overpaid following an applicant initiated internal review decision made under regulation 6.2 or a Secretary initiated internal review decision under regulation 6.3.

Regulation 6.4 provides that the Secretary must notify a person where, following an applicant or Secretary initiated internal review decision; an amount becomes underpaid or overpaid. A note to the regulation provides that further payment or refund would be required under regulation 4.1.

**Item [46]—Regulation 6.5**

This is a minor consequential amendment relating to the availability of a review by the Administrative Appeals Tribunal. The amendment does not make any substantive change to an applicant's right to review by the Administrative Appeals Tribunal following a further internal review.

**Item [47]—Part 7 (heading)**

This item provides for a new heading to Part 7 of the Principal Regulations to reflect the fact it concerns transitional matters.

**Item [48]—At the end of Part 7**

This item makes provision for application and transitional arrangements. This includes making provision in relation to applications made before the commencement date of the Amended Regulations.

Part 7—Application and transitional provisions provide information about how transitional arrangements will apply in implementing changes to fees from July 2019. In general, the amendments made by the Amended Regulations apply in relation to applications made on or after 1 July 2019, even where a related application had been made before 1 July 2019. For example, the amendments by the new regulations apply to a request for pricing services made on or after 1 July 2019 even where a related request for evaluation services from the Committee had been made before 1 July 2019.

**Item [49]—Items 2.15 and 2.16 in Schedule 1**

This item amends Schedule 1 to the Principal Regulations to make technical amendments to items 2.15 and 2.16 of Schedule 1 to reflect revised drafting throughout the regulations to replace references to the taking of an action by the Minister with references to the exercise of a power by the Minister.

No substantive change to the items were made.

**Item [50]—Schedules 3 and 4**

This item repeals schedules 3 and 4 to the Principal Regulations.

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

***National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment Regulations 2019***

The Amended Regulations are 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 Regulations**

The Amended Regulations are made under section 140 of the *National Health Act 1953* (the Act). Section 140 provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which by this Act are required or permitted to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Act. Subsection 99YBA(2) of the Act further provides that regulations may make provision in relation to matters including the prescribing of fees, the making of applications, and exemptions from the prescribed fees, in relation to services provided by the Commonwealth under section 9B or Part VII of the Act.

The Amended Regulations amend the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations). The Amended Regulations establish fees for services provided by the Commonwealth in relation to an exercise of power by the Minister under section 9B or Part VII of the Act:

- The Minister's powers under section 9B of the Act broadly relate to the National Immunisation Program (NIP).
- The Minister's powers under Part VII broadly concern the listing process for applications seeking inclusion in the Pharmaceutical Benefits Scheme (PBS).

**Human rights implications**

The Amended Regulations engage Article 2 and Article 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 and NIP are benefit schemes which assist with advancement of this human right by providing for subsidised access by patients to medicines. Revised listing processes, cost recovery changes accompanying these revised processes, and the regulatory amendments necessary for these changes to be implemented, have been devised to improve the efficiency, transparency and timeliness of listing processes, to ensure access to cost-effective, innovative, clinically effective medicines under these schemes.

## **Conclusion**

This Legislative Instrument is compatible with human rights. Human rights continue to be protected by retaining on the PBS clinically important medicines and placing them in formularies that ensure the most cost effective pricing for supply of each medicine to Australians.

The Hon Greg Hunt MP

Minister for Health