

EXPLANATORY STATEMENT

Issued by the authority of the Minister for Health

National Health Act 1953

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020

The *National Health Act 1953* (the Act) makes provision in relation to matters including national health services and pharmaceutical benefits.

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.

The Department of Health assesses the cost-effectiveness of vaccines for inclusion on the National Immunisation Program (NIP) as well as drugs for listing on the Pharmaceutical Benefits Scheme (PBS). Much of the assessment work is out-sourced to external evaluators at a cost to Government, and the regulations implement cost-recovery arrangements whereby these evaluation costs are recouped from industry through fees provided in the regulations.

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 the following provisions:

- 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 NIP, including the activities of the Australian Technical Advisory Group on Immunisation (ATAGI).

Services provided by the Commonwealth in relation to Part VII include the administration of the 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.

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 such services.

The regulations prescribe fees and the making of applications for services provided by the Commonwealth in relation to the exercise of a power by the Minister under section 9B and Part VII of the Act.

The *National Health (Pharmaceutical and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020* (the Amendment Regulations) amend the *National Health (Pharmaceutical and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations) to:

- reduce fees for the provision of ATAGI services to \$180,960 (the usual ATAGI fee) for a complex submission and \$103,270 (partial exemption) for a simple submission.
- introduce a prior notice requirement for all committee secretariat submissions and increase the associated evaluation fee to \$11,280 which includes the prior notice processing fee.
- change references to ‘days’ throughout to ‘business days’.
- update the pricing applications description to reflect all relevant powers under the Act.

The Amendment Regulations carry on the arrangements made by the Principal Regulations which sunset on 1 April 2022.

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

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

The Amended Regulations commenced on 1 July 2020.

The Principal Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

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

Consultation

The fees provided in the regulations reflect feedback from industry stakeholder consultation regarding costs previously proposed for provision of ATAGI advice. In 2019, a competitive tender process was undertaken by the Department which identified evaluators who can provide the required ATAGI services at a lower cost.

The administrative amendments in the regulations follow consultation undertaken in early-2020 and seek to clarify the Department’s cost recovery administration processes.

Details of the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020*

Section 1 – Name of Regulations

This section provides that the name of the Amendment Regulations is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020*.

Section 2 – Commencement

This section provides for the Amendment Regulations to commence on 1 July 2020.

Section 3 – Authority

This section provides that the Amendment 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] – Subregulation 1A.1(1)

This item removes the wording ‘On or after 1 July 2020,’ from the Principal Regulations as it is now redundant.

Item [2] – Subregulation 1A.1(2)

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.

This item decreased the usual ATAGI fee payable to \$180,960, to reflect the efficient costs of providing these services.

Item [3] – Subregulation 1A.2(3)

Regulation 1A.2 provides that a person may be partially exempt from the usual ATAGI fee.

This item decreased the fee payable if a person is partially exempt to \$103,270, to reflect the efficient costs of providing these services.

Item [4] – Subregulation 1A.2(6)

Subregulation 1A.2(6) provides that the Department’s notification period for consideration of fee exemption application may be paused until requested information is provided.

This item replaced the ‘21-day period’ with ‘period of 15 business days’.

The time periods have not changed, they are being expressed in business days. This approach relies on the definition of **business day** in section 2B of the *Acts Interpretation Act 1901*, which is as follows: ‘**business day** means a day that is not a Saturday, a Sunday or a public holiday in the place concerned.’ Items 5-8, 12, 15-19 and 21-34 would also adopt this definition.

Item [5] – Subregulation 1A.4(1)

This item replaced the words ‘21 days’ with ‘15 business days’ for the Department to notify a person of the ATAGI fee payable.

Item [6] – Subregulation 1A.5(2) and 1A.10

This item replaced the words ‘14 days’ with ‘10 business days’ for withdrawal to result in a refund of ATAGI fees paid.

This item also replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of pre-submission meeting acceptance and the fee payable.

Item [7] – Paragraph 1A.11(2)(a)

Subregulation 1A.11 provides for withdrawal of a pre-submission meeting application.

This item replaced the words ‘15th day’ with ‘11th business day’. For withdrawal to result in a refund of any pre-submission fees paid, a pre-submission meeting application must be withdrawn between the earlier of the 11th business day after the Department has issued a notice or the business day before the scheduled meeting date.

Item [8] – Regulation 2.1A (paragraph beginning “If the person’s application”)

Regulation 2.1A provides an outline of submission services.

This item amended Paragraph 2 to clarify that prior notice is required for all applications to the Committee; and replaced the words ‘28 days’ with ‘20 business days’ before date required by the Committee for a person to provide prior notice to the Department.

Item [9] – Subregulation 2.2(1) (table item 4)

Regulation 2.2 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 deposit.

This item amended the fee payable for a committee secretariat submission to \$11,280 to include the prior notice fee (deposit).

Item [10] – Regulation 2.15 (heading)

This item amended the heading. This is a minor consequential amendment.

Item [11] – Subregulation 2.15(1)

This item amended the wording to include the evaluation category item 4 (committee secretariat).

Item [12] – Subregulation 2.15(1)(b)

This item replaced the words ‘28 days’ with ‘20 business days’ before the application’s submission due day for a person to provide prior notice to the Department.

Item [13] – Paragraph 2.15(5)(c)

This item replaced the existing paragraph to clarify that applications may be sent to different areas of the Department depending on the application type. This is a minor consequential amendment.

Item [14] – Regulation 2.17 (heading)

This item amended the heading. This is a minor consequential amendment.

Item [15] – Subregulation 2.17(1)

This item replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of the fee payable for submission services.

Item [16] – Subregulation 2.17(2)

This item replaced the words ‘21 days’ with ‘15 business days’ for the Department to notify a person in relation to a fee exemption or waiver.

Item [17] – Subregulation 2.18(2)

This item replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for withdrawal to result in a refund of fees paid for submission services.

Item [18] – Paragraph 2.18(3)(c)

This item replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for withdrawal to result in a refund of fees paid for submission services.

Item [19] – Regulation 3.1 (paragraph beginning “The person”)

Regulation 3.1 of the Principal Regulations provides an outline of pricing services.

This item replaced the words ‘7 days’ with ‘5 business days’ before lodgement of a pricing application for a person to provide prior notice to the Department.

Item [20] – Subregulation 3.2(1)

Regulation 3.2 (1) of the Principal Regulations provide the pricing services that involve the Commonwealth assisting the Minister to exercise one or more powers under section 85AD, 85B or 85E of the Act.

This item added the powers under section 85(2), (2A) or (3) and paragraph 85(7)(b), to reflect all relevant pricing application powers under the Act.

Item [21] – Paragraph 3.10(1)(b)

This item replaced the words ‘7 days’ with ‘5 business days’ before lodgement of a pricing application for a person to provide prior notice to the Department.

Item [22] – Subregulation 3.10(1) (note 2)

This item replaced the words ‘42 days’ with ‘30 business days’ for a person to lodge a pricing application after prior notice has been provided to the Department.

Item [23] – Subregulation 3.10(4)

This item replaced the words ‘7 days’ with ‘5 business days’ for the Department to commence pricing services where prior notice was required but not provided.

Item [24]—Paragraph 3.11(1)(d)

This item replaced the words ‘42 days’ with ‘30 business days’ for a person to lodge a pricing application after prior notice has been provided to the Department.

Item [25] – Subregulation 3.12(1)

This item replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of the fee payable for pricing services.

Item [26] – Subregulation 3.12(2)

This item replaced the words ‘21 days’ with ‘15 business days’ for the Department to notify a person in relation to a fee exemption or waiver decision.

Item [27] – Subregulation 3.13(2)

This item replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for withdrawal to result in a refund of fees paid for pricing services.

Item [28] – Paragraph 3.13(3)(c)

This item replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for withdrawal to result in a refund of fees paid for pricing services.

Item [29] – Subregulations 3A.3(1) and 3A.4(2)

This item replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of the fee payable for list management services.

This item also replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for withdrawal to result in a refund of any list management fees paid.

Item [30] – Subregulation 4.1(4)

This item replaced the words ‘28 days’ with ‘20 business days’ for the Department to refund fees paid in excess of the amount required. The Department has between the later of 20 business days from the date the payment was made or the notification was given to provide this refund.

Item [31] – Subregulation 6.1(1)

This item replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of a reviewable decision outcome.

Item [32] – Subparagraph 6.2(2)(a)(i)

This item replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued a notice, for lodgement of an application for an initial internal review.

Item [33] – Subregulations 6.2(3), (4) and (5)

This item replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of the initial review decision.

This item also replaced the words ‘14 days’ with ‘10 business days’ after the Department has issued the initial internal review decision notice, for a person to make a request for a further review.

This item further replaced the words ‘14 days’ with ‘10 business days’ for the Department to notify a person of the further review decision.

Item [34] – Regulation 6.4

This item replaced the words ‘28 days’ with ‘20 business days’ for the Department to notify a person of any fee adjustment following an initial or further review.

Item [35] – Before regulation 7.1

Part 7 outlines the application and transitional provisions. This item inserted a new heading ‘Division 1—Application of these Regulations as originally made’ before regulation 7.1. This is a minor consequential amendment.

Item [36]—Before regulation 7.2

This item inserted a new heading ‘Division 2—Application and transitional provisions relating to 2019 amendments’ before regulation 7.2. This is a minor consequential amendment.

Item [37]—Before regulation 7.2

This item inserted a new heading ‘Division 3—Application and transitional provisions relating to amendments commencing on 1 July 2020’ and new Regulation 7.3.

Regulation 7.3 provides that prior notice is required for committee secretariat submissions submitted after 28 July 2020.

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 (2020 Measures No. 1) Regulations 2020

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 1) Regulations 2020* (the Amendment 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 Amendment 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 Amendment Regulations amend the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009* (the Principal Regulations). The Amendment 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 Amendment 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 subsidised access by patients to medicines.

Conclusion

This Legislative Instrument is compatible with human rights. Human rights continue to be protected by retaining on the PBS and NIP clinically important medicines or vaccines 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