

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. 2) Regulations 2020

The *National Health Act 1953* (the Act) makes provision in relation to pharmaceutical, sickness and hospital benefits, and of 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 the following provisions:

- Section 9B of the Act, which 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, which concerns pharmaceutical benefits and deals with matters including the supply of and payments concerning pharmaceutical benefits and the PBS.

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 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) Regulations 2009* (the Principal Regulations) prescribe fees and matters relating to 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. Much of the assessment work is outsourced to external evaluators at a cost to Government, and the regulations implement cost-recovery arrangements whereby these evaluation costs and the costs the Department itself incurs in PBS approval and management are recouped from industry through fees provided in the regulations.

The purpose of the proposed *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment (2020 Measures No. 2) Regulations 2020* (the Amendment Regulations) is to ensure the sustainability of the PBS by assisting the Department to recover its costs associated with PBS and National Immunisation Program listing and make it more efficient for applicants to obtain PBS listing.

The Amendment Regulations:

- update 2020-21 fees for PBAC/PBS services to accurately reflect the costs of providing these services; including removing indexation of fees by Consumer Price Index (CPI);

- remove partial fee waivers and make amendments to the timing for lodgement, notification and withdrawal for fee waiver or exemption requests;
- amend pre-submission meeting acceptance requirements and notification timing;
- revise Part 2 – Submission Services, to support implementation of changes to PBAC submission evaluation categories (Stage 2 PBS process improvements);
- add new provisions in Part 3 – Pricing Services, to allow the Department to cease pricing services after 26 weeks when there is no active negotiation occurring; and to support implementation of cost recovery for deed management services;
- add new provisions in Part 3A – List Management Services to support implementation of cost recovery for deed renewal and deed variation requests; and
- make minor administrative amendments; including wording amendments, updating the existing internal review provision and removing Schedule 2.

These amendments reflect the Government’s approval through the 2020-21 Budget measure *Improving Access to Medicines — Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme — new and amended listings*, to implement the second stage of PBS process changes and revised cost recovery arrangements. These changes allow the Commonwealth to continue to support the sustainability of the PBS and manage applications effectively.

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

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

The Amended Regulations commenced on 1 January 2021.

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

PBS process improvements were developed in collaboration with industry through the Access to Medicines Working Group – Streamlined Pathways Subgroup, to meet the objectives of clause 10.3 of the Government’s five-year Strategic Agreement with Medicines Australia. In August 2018, Minister Hunt approved broad consultation on proposed framework and endorsed a staged implementation approach. The first stage of PBS process improvements were implemented on 1 July 2019.

Public consultation on the second stage of process changes commenced in November 2019, followed by public consultation on fee changes in February 2020. A further public webinar on process and fee changes was undertaken in September 2020, with 230 registered online participants. Public consultation on supporting documentation was undertaken in September and October 2020. A total of seven submissions were received in response to this consultation. Stakeholder feedback included seeking timely advice on a fee waivers, further clarification on deed management fees, particularly where they are terminated early. The Department also consulted with peak bodies (Medicines Australia and the Generic and Biosimilar Medicines Association) on an Exposure Draft of the Amendment Regulations.

Details of the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 2) 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. 2) Regulations 2020*.

Section 2 – Commencement

This section provides for the Amendment Regulations to commence on 1 January 2021.

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] – Regulation 1.3 (after the heading)

This item inserted a note within the Principal Regulations to advise certain expressions are defined in the *National Health Act 1953* (the Act).

Item [2] – Regulation 1.3

This item inserted new definitions for ‘cost-effectiveness test’, ‘evaluation category’, ‘high-added therapeutic value’ and ‘MSAC’ into the Principal Regulations.

Item [3] – Regulation 1.3 (paragraphs (b), (c), (d), (e) and (f) of the definition of notification)

This item replaced paragraphs (b), (c) and (d), amending in the definition of ‘notification’ within the Principal Regulations to align with the changes made by items 20, 41 and 58.

Item [4] – Regulation 1.3 (definition of Secretary)

This item removed the definition of ‘Secretary’ from the Principal Regulations. ‘Secretary’ is defined in the Act.

Item [5] – Regulation 1.3 (definition of submission services)

This item amended the reference in the definition of ‘submission services’ within the Principal Regulations.

Item [6] – Regulation 1.3

This item inserted a new definition of ‘Therapeutic Goods Administration’ into the Principal Regulations.

Item [7] – Regulation 1.3 (definition of therapy)

This item removed the definition of ‘therapy’ from the Principal Regulations as this definition is no longer required.

Item [8] – Subregulation 1A.1(2)

This item removed the words ‘if the notification for the person’s ATAGI application is given during the financial year starting on 1 July 2020’ from the Principal Regulations as they are no longer required.

Item [9] – Subregulation 1A.1(2) (note)

This item removed the note related to indexation of fees by CPI from the Principal Regulations to reflect the change made by item 75.

Item [10] – Subregulation 1A.2(3)

This item removed the words ‘(if the notification for the person’s ATAGI application is given during the financial year starting on 1 July 2020)’ from the Principal Regulations as they are no longer required.

Item [11] – Subregulation 1A.2(3) (note)

This item removed the note related to indexation of fees by CPI from the Principal Regulations to reflect the change made by item 75.

Item [12] – Paragraph 1A.4(1)(b)

This item amended the wording of paragraph (b) within the Principal Regulations to clarify that fee exemption applications must include the reasons why Regulation 5.1 applies.

Item [13] – Subregulation 1A.4(2)

This item removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [14] – Paragraph 1A.7(b)

This item replaced the words ‘in Schedule 1’ with ‘of Schedule 1’ within the Principal Regulations.

Item [15] – Regulation 1A.7 (table)

This item replaced the fee table within the Principal Regulations to reflect the revised 2020-21 fees approved by Government in the 2020-21 Budget. These revised fees reflect the costs incurred by the Department in providing pre-submission services.

To support implementation of the second stage of PBS process improvements, the department further reviewed and updated the 2018-19 activity based cost model. Additional activities were identified as part of revising submission categories and the new resubmission pathways. In addition, there have been changes to all fees as a result of parameter changes which include changes to IT costs, depreciation, salary and wage costs to meet whole-of-Government requirements. In line with the Australian Government Cost Recovery Guidelines (CRGs), the cost model only recovers the costs of those services directly requested by sponsors.

Item [16] – Regulation 1A.7 (note)

This item removed this note from the Principal Regulations to reflect the change made by item 75. Indexation of fees by CPI is no longer provided for in the Principal Regulations.

Item [17] – Regulation 1A.9

This removed the words ‘and briefing papers’ from the Principal Regulations, to allow the Department to agree or not agree to hold a pre-submission meeting after only considering the meeting application. This amendment allows for increased efficiencies in the Secretary determining whether to hold a pre-submission meeting.

Item [18] – Subregulation 1A.10(1)

This item amended the wording of this subregulation within the Principal Regulations to align with the changes made by item 17. This amendment requires the Department to issue a notification within 10 business days after receiving a meeting application.

Item [19] – Paragraph 1A.10(1)(a)

This item removed the words ‘and briefing papers’ from paragraph (a) within the Principal Regulations to align with the changes made by item 17.

Item [20] – Subregulations 1A.10(2) and (3)

This item replaced these subregulations within the Principal Regulations to provide the matters which the Secretary must notify the applicant of when agreeing to hold a pre-submission meeting. The timeframe for providing these matters to the applicant varies depending on the time between the Secretary providing notice to the applicant under subregulation (1) and when the Secretary agrees to the Department holding the pre-submission meeting.

These amendments streamline the invoicing process and reduce the administrative burden on the Department in cancelling and reissuing invoices by allowing additional time for the Department to issue a notification (and invoice) where a pre-submission meeting is accepted at least 30 business days prior to the meeting date.

This item also removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [21] – Subregulation 1A.11(2)

This item amended the wording of this subregulation within the Principal Regulations to allow for a refund of any fee paid where a pre-submission meeting application is withdrawn before the last business day before the meeting is to be held. This amendment simplifies the refund withdrawal window.

Item [22] – Regulation 2.1A (paragraph beginning ‘Submission services are provided’)

This item replaced the paragraph beginning ‘Submission services are provided’ within the Principal Regulations to provide a simplified outline of the changes to Part 2 made by the Amendment Regulations.

Item [23] – Regulation 2.1A

This item inserted the word ‘generally’ to the paragraph beginning ‘If the person’s application is to the Committee, the person will’ within the Principal regulations to align with the changes made to Part 2.

Item [24] – Subdivision 1 of Division 2.1 (heading)

This item removed this heading from the Principal Regulations as it is no longer required.

Item [25] – Paragraph 2.1(1)(a)

This item replaced the words ‘in Schedule 1’ with ‘of Schedule 1’ within the Principal Regulations.

Item [26] – At the end of subregulation 2.1(1)

This item inserted a note into the Principal Regulations to refer to Regulation 2.16 for detail on how to apply (for submission services).

Item [27] – Subregulation 2.1(2) (note)

This item inserted a note into the Principal Regulations to clarify the evaluation category that applies where an application includes two or more requests.

Item [28] – Subregulation 2.2(1)

This item replaced the words ‘(1) For’ with the word ‘For’ within the Principal Regulations.

Item [29] – Subregulation 2.2(1)

This item replaced the fee table within the Principal Regulations to reflect the revised 2020-21 fees approved by Government in the 2020-21 Budget. These revised fees reflect the expected costs incurred by the Department following implementation of changes to submission services.

This item also inserted three notes into the Principal Regulations to clarify:

- that an evaluation category generally depends on the request made in the application, unless the application is resent;
- how an evaluation category should be determined (unless the application is resent); and
- that the deposit referred to in column 3 of the table may not be refunded.

To support implementation of the second stage of PBS process improvements, the Department further reviewed and updated the 2018-19 activity based cost model. Additional activities were identified as part of revising submission categories and the new resubmission pathways. In addition, there have been changes to all fees as a result of parameter changes which include changes to IT costs, depreciation, salary and wage costs to meet whole-of-Government requirements. In line with the CRGs, the cost model only recovers the costs of those services directly requested by sponsors.

Item [30] – Subregulation 2.2(2)

This item removed this subregulation from the Principal Regulations as it is no longer necessary to specify deposit amounts for the 2019-20 and 2020-21 financial years. Revised deposit amounts for the 2020-21 financial year are specified in the fee table.

This item also removed the note related to indexation of fees by CPI from the Principal Regulations to reflect the change made by item 75.

Item [31] – Subdivisions 2, 3 and 4 of Division 2.1

Summary

This item amended Part 2 of the Principal Regulations to reflect Government approval through the 2020-21 Budget measure: *Improving Access to Medicines — Pharmaceutical Benefits Scheme and Repatriation Pharmaceutical Benefits Scheme — new and amended listings* to implement the second stage of PBS process improvements and revised cost recovery arrangements. Stage 2 changes include:

- revised PBAC submission categories for applications to the PBAC (Categories 1, 2, 3, and 4); and introduction of a single submission date;
- introduction of solution focussed pathways for PBAC reconsideration following a ‘not recommended’ PBAC outcome (resubmission pathways);
- revised cost recovery arrangements; and
- further expansion of the Department’s Health Products Portal.

The Department has consulted on Stage 2 process changes since November 2019.

Revised submission categories

The revised submission categories have been established to:

- Provide greater transparency on the complexity and activities required to assess the different application types coming forward for PBAC consideration.
- Align work effort and resourcing with the cost recovery fees and further reduce cross-subsidisation of evaluation fees via more granular categories.
- Ensure continued effective handling of submissions, focussing resources on the more complex PBAC submissions.

Categories 1 and 2 replace the ‘major’ evaluation category; and Categories 3 and 4 replace the ‘minor’ evaluation category.

- Category 2 will apply for all ‘major’ applications, unless an applicant clearly justifies how their application meets one or more of the Category 1 criteria.
- Category 3 will apply for all ‘minor’ applications unless an applicant clearly justifies how their application meets one or more of the Category 4 criteria.

PBAC (Committee) Secretariat and New Brand (Generic) submission categories remain unchanged. The Department will continue to validate applications to ensure the correct fee is charged.

This item removes Subdivisions 2, 3 and 4 of Division 2.1 from the Principal Regulations and replaces with the following:

Regulation 2.3 - Applications in Category 1

This regulation prescribes the definition of when a person’s application is in the ‘Category 1’ evaluation category. An application is in this category if the application includes a request in relation to one or more of the three following criteria:

- A first in class medicine or vaccine for a new population [defined by subregulation (2)]; or
- A drug or designated vaccine with a TGA Provisional determination related to the proposed population [defined by subregulation (3)]; or
- A drug with a codependent technology that requires an integrated codependent submission to the PBAC and Medical Services Advisory Committee (MSAC) [defined by subregulations (4) and (5)].

Category 1 applications require the Committee to apply the ‘cost-effectiveness test’. The definition of ‘cost-effectiveness test’ was added to the Principal Regulations by item 2. This definition aligns with the ‘health advantage test’ previously provided for in subregulation 2.4(2) of the Principal Regulations.

These submission types are expected to require additional interaction between the PBAC Secretariat and either TGA representatives or MSAC Secretariat and the PBAC.

Regulation 2.4 - Applications in Category 2

This regulation prescribes the definition of when a person’s application is in the ‘Category 2’ evaluation category. An application is in this category if a request in the application relates to specified items of Schedule 1, requires the Committee to apply the ‘cost-effectiveness’ test, and is not in Category 1.

Evaluation Category 2 generally reflects the wording of ‘Subdivision 2 – Applications that are major’, previously provided for in the Principal Regulations.

Regulation 2.5 - Applications in Category 3

This regulation prescribes the definition of when a person’s application is in the ‘Category 3’ evaluation category. An application is in this category if request in the application:

- relates to specified items of Schedule 1 and is not in evaluation Category 1 or 2 [as defined by subregulations (1) and (2)]; or
- requires the Committee to assess the clinical need and effectiveness of a drug, medicinal preparation or vaccine [as defined by subregulation (3)]; or
- relates to an exception to the new brand of an existing pharmaceutical item category because the application includes a claim about the therapeutic benefit or relates to Somatropin [subregulation (4)]; or
- is in relation to a medicinal food [subregulation (5)].

Evaluation Category 3 generally reflects the wording of ‘Subdivision 3 – Applications that are minor’, previously provided for in the Principal Regulations.

Regulation 2.6 - Applications in Category 4

This regulation prescribes the definition of when a person’s application is in the ‘Category 4’ evaluation category. An application is in this category if the application is not in Category 1, Category 2 or Category 3 and includes a request in relation to one of the six following criteria:

- Listing of a new pharmaceutical item of a listed medicine [as defined by subregulation (2)]; or
- A change/new manner of administration of a listed drug [as defined by subregulation (2)]; or

- A change to the maximum quantity and/or number of repeats of a listed medicine [as defined by subregulation (3)]; or
- A change or addition to the prescriber type(s) of a listed medicine [as defined by subregulation (4)]; or
- Including a listed medicine on the prescriber bag, or varying an existing prescriber bag listing [as defined by subregulation (5)]; or
- Consideration as an exempt item (exempt items are dealt with in s 84AH of the A) [as defined by subregulation (6)].

These application types are expected to require minimal evaluation. Category 4 applications are considered by the PBAC Executive, and ratified by the PBAC to streamline the process for these submission types.

Regulation 2.7 - Applications in Committee Secretariat category

This regulation prescribes the definition of when a person's application is in the 'Committee secretariat' evaluation category. This definition reflects the wording of Regulations 2.12 and 2.13 previously provided for in the Principal Regulations.

Regulation 2.8 - Applications in new brand of existing pharmaceutical item category

This regulation prescribes the definition of when a person's application is in the 'Committee secretariat' evaluation category. This definition reflects the wording of Regulations 2.14 of the Principal Regulations.

This definition reflects the wording of regulation 2.14 of the Principal Regulations.

Proposed regulation 2.9 – Evaluation categories of certain resent applications

Summary

Resubmission Pathways

Initial submissions that have not been recommended by the PBAC, are eligible to return to the PBAC for further consideration, these submissions and are considered a resubmission. Currently there is no clear delineation between an initial submission and a resubmission. In returning to the PBAC for further consideration, four resubmission pathways have been established to:

- Support the PBAC's decision-making process and provide a framework for the PBAC to assist applicants in the development of their resubmission;
- Support access to medicines through solution-focused pathways where issues can be easily resolved;
- Enable efficient use of PBAC time by focusing on more complex resubmissions; and
- Align work effort, resourcing and cost recovery fees.

Following PBAC consideration, all submissions with a 'not recommended' outcome are able to lodge a resubmission via the Standard Re-entry Pathway.

The PBAC may nominate an Early Resolution Pathway, Early Re-entry Pathway or Facilitated Resolution Pathway based on their independent assessment of:

1. the issues for resolution; and
2. whether the medicine or vaccine represents High Added Therapeutic Value (HATV) for the proposed population:
 - the medicine or vaccine addresses a high and urgent unmet clinical need; and

- the medicine or vaccine is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapies.

The definition of ‘high added therapeutic value’ was added to the Principal Regulations by item 2.

This regulation defines the four pathways available for PBAC reconsideration:

1. *Standard Re-entry Pathway* is the sponsor-determined (default) resubmission pathway and also applies where:
 - an applicant chooses not to accept the PBAC nominated resubmission pathway; or
 - an Early Re-entry Pathway or Early Resolution Pathway has been nominated by the PBAC and an applicant decides to address issues other than those identified by the PBAC (including a subset of issues); or
 - an applicant decides to lodge later than the allowable timelines for the other pathways.
2. *Early Re-entry Pathway* may be nominated by the PBAC, where the PBAC considers that the remaining issues could be easily resolved; and the medicine or vaccine does not represent HATV for the proposed population. Applicants who accept this pathway must only address the issues as outlined by the Committee. To ensure early reconsideration, two lodgement deadlines apply for this pathway.
3. *Early Resolution Pathway* may be nominated by the PBAC, where the PBAC considers the medicine or vaccine represents HATV for the proposed population; and that the remaining issues could be easily resolved. Applicants who accept this pathway must only address the issues as outlined by the Committee. To ensure early reconsideration, two lodgement deadlines apply for this pathway.
4. *Facilitated Resolution Pathway* may be nominated by the PBAC, where the PBAC considers the medicine or vaccine represents HATV for the proposed population and where the PBAC can determine specific matters that need discussion and could be resolved through a workshop. Applicants who accept this pathway will have the opportunity to attend a solution-focussed workshop with one or more members of the PBAC to explore feasible options to address the issues identified by the Committee. To ensure the reconsideration in a timely manner following the workshop, two lodgement deadlines apply for this pathway.

The Department will also validate resubmission pathway applications to ensure the correct evaluation fee is charged.

Item [32] – Subregulation 2.15(1)

This item amended the wording of this subregulation within the Principal Regulations to require lodgement of prior notice for all applications to the PBAC. Prior notice is not required for new brand applications; or where an urgent public health exception applies.

Item [33] – Paragraph 2.15(1)(b)

This item replaced paragraph (b) within the Principal Regulations to specify the timeframes in which a person must give the Department the required period of notice prior to lodgement. Prior notice lodgement timeframes vary depending on which evaluation category applies.

For evaluation categories 1 to 4 and Committee secretariat, prior notice is required at least 20 business days prior to lodgement. This maintains the process currently provided for in the Principal Regulations.

For evaluation categories Early Re-entry Pathway and Early Resolution Pathway, prior notice is required at least 5 business days before lodgement. For the Facilitated Resolution Pathway evaluation category, prior notice is required at least 10 business days before the workshop is held.

Item [34] – Subparagraph 2.16(1)(c)(i)

This item amended the references in subparagraph (i) of the Principal Regulations.

Item [35] – Subregulation 2.16(3)

This item removed the words ‘meeting that is’ from the Principal Regulations to allow for out-of-session consideration by the PBAC for Early Resolution Pathway applications.

Item [36] – Subregulation 2.16(3) (note)

This item removed this note from the Principal Regulations as it is no longer necessary.

Item [37] – Subregulation 2.16(4)

This item replaced the word ‘meeting’ with ‘consideration of applications’ in the Principal Regulations to allow for out-of-session consideration by the PBAC for Early Resolution Pathway applications.

Item [38] – After regulation 2.16

This item inserted a new provision into the Principal Regulations to require an economic evaluation for Category 1 and 2 applications.

Item [39] – Subregulation 2.17(1)

This item removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [40] – Subregulation 2.17(1) (note 2)

This item removed this note from the Principal Regulations – refer item 41.

Item [41] – Subregulations 2.17(2) and (3)

This item replaced these subregulations and the note currently provided for in the Principal Regulations to provide for lodgement of a fee waiver or exemption application with prior notice (where applicable). This amendment reflects the changes made by items 77 and 81.

The Department is required to issue a notification within 15 days after lodgement of the application (to the PBAC), where a fee waiver or exemption is requested; and/or where prior notice is not required.

This item also inserted a note to clarify that Part 4 deals with payment of fees. This note was removed by item 40.

Item [42] – After regulation 2.17

This item inserted a new provision into the Principal Regulations to allow the Department to not accept an application to the PBAC on the basis it is incomplete and does not contain the information required for PBAC consideration. In these circumstances, the Department will notify the applicant within 10 business days after lodgement of their application and refund any fee paid except for the non-refundable deposit amount.

The Department's online Health Products Portal assists applicants to provide the required submission documents. The decision to not accept an incomplete application is not a reviewable decision under Part 6 of the Principal Regulations.

Item [43] – Subregulation 2.18(2)

This item expanded the refund withdrawal window within the Principal Regulations to provide for the later of – 10 business days after the notification is given by the Department; or the submission due day.

For Early Re-entry Pathway, Early Resolution Pathway or Facilitated Resolution Pathway applications, the refund withdrawal window is within 10 business days after the Department gives the notification.

Item [44] – Paragraph 2.18(3)(b)

This item replaced the reference in paragraph (b) within the Principal Regulations to reflect the changes made by item 41.

Item [45] – At the end of regulation 2.18

This item inserted a new provision into the Principal Regulations to provide the Department with the discretion to provide a refund in relation to the fee paid for the Facilitated Resolution Pathway evaluation category where an applicant withdraws their prior notice after the last business day before the workshop.

Item [46] – Subregulation 2.19(1)

This item removed the number '(1)' from the Principal Regulations as it is no longer required.

Item [47] – Subregulations 2.19(2) and (3)

This item removed subregulations (2) and (3) from the Principal Regulations as prior notice exceptions for resent applications are no longer be required.

Item [48] – After subregulation 2.20(1)

This item inserted a new subregulation into the Principal Regulations to clarify that an evaluation category may change because of the Department's validation process. There is no change to the validation of evaluation categories process provided for in the Principal Regulations.

Item [49] – Paragraph 2.20(3)(a)

This item amended the wording of paragraph (a) within the Principal Regulations to clarify the fee that will be payable as a result of the Department's validation of an evaluation category. The fee that applies is in the same financial year as the notification was originally given by the Department.

Item [50] – Subregulation 2.20(3)

This item removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [51] – Subregulation 2.20(4)

This item removed this subregulation from the Principal Regulations as it is no longer required.

Item [52] – 3.1 (paragraph beginning “The pricing application”)

This item replaced the words ‘42 days’ with ‘30 business days’ within the Principal Regulations.

Item [53] – At the end of regulation 3.1

This item inserted a new paragraph into the Principal Regulations to provide a simplified outline for the changes made to Part 3.

Item [54] – Subregulation 3.3(1) (table)

This item replaced the fee table within the Principal Regulations to reflect the revised 2020-21 fees approved by Government in the 2020-21 Budget. This amendment reflects the costs incurred by the Department in providing pricing services.

Pricing Pathway A, B and C fees outlined in the table include the \$8,275 ‘rebate management fee’. This fee covers rebate management activities undertaken by the Department, required over the five-year deed term for an applicant to maintain their PBS listing arrangements.

To support implementation of the second stage of PBS process improvements, the Department further reviewed and updated the 2018-19 cost model. New activities were identified because of the changes to submission evaluation categories. In addition, there have been changes to all fees because of parameter changes, which include changes to IT costs, depreciation, salary and wage costs to meet whole-of-Government requirements.

Item [55] – Subregulation 3.3(2)

This item replaced this subregulation within the Principal Regulations to specify the non-refundable deposit amounts that apply for pricing services.

This item also removed the note related to indexation of fees by CPI from the Principal Regulations to reflect the change made by item 75.

Item [56] – Subregulation 3.12(1)

This item removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [57] – Subregulation 3.12(1) (note 2)

This item removed this note from the Principal Regulations – refer item 58

Item [58] – Subregulations 3.12(2) and (3)

This item replaced these subregulations and the note within the Principal Regulations to provide for lodgement of a fee waiver or exemption application with prior notice (where applicable). This amendment reflects the changes made by items 77 and 81.

This item also requires the Department to give notice within 15 days as to whether the waiver or exemption is approved.

This item also inserted a note to clarify that Part 4 deals with payment of fees. This note was removed by item 58.

Item [59] – After subregulation 3.13(2)

This item inserted a provision into the Principal Regulations to provide for a refund of any fee paid (except for the non-refundable deposit amount); where an applicant withdraws their pricing application within 10 business days after a notification is given.

Item [60] – Paragraph 3.13(3)(b)

This item replaced the reference in paragraph (b) within the Principal Regulations to reflect the amendments made by item 58.

Item [61] – At the end of regulation 3.13

This item inserted a new provision into the Principal Regulations to specify the refund that applies for Pricing Pathway A, B or C applications where a deed arrangement between the applicant (‘responsible person’) and the Commonwealth has not been entered into.

Where an applicant withdraws their prior notice or pricing application within 10 business days from the date the notice is given, the Department is required to refund any fee paid except for the non-refundable deposit amount.

In addition, where an applicant withdraws their pricing application and has not entered into a deed arrangement (under Pricing Pathway A, B or C), including where the Department ceases to provide pricing services after 26 weeks (see item 63), the Department is required to refund the \$8,275 rebate management fee.

Item [62] – Subregulation 3.14(3)

This item removed the reference to ‘the Department’ from the Principal Regulations to align with section 99YBA of the Act which specifies that fees are payable to the Commonwealth.

Item [63] – At the end of Part 3

This item inserted a new Division, Division 3.5 into the Principal Regulations to allow the Department to cease pricing services after 6 months (26 weeks) and to provide for a refund of the in circumstances where a deed arrangement between the applicant (‘responsible person’) and the Commonwealth has not been entered into.

The ability to cease pricing services after 6 months (26 weeks):

- allows the Department to formally end pricing services where there is no ongoing (active) negotiation between the applicant and the Department; and
- provides increased transparency in relation to the expected timeframe for pricing services – from lodgement of a pricing application to in-principle agreement to listing arrangements. There is currently no timeframe for the provision of pricing services.

To recommence pricing services where pricing services had ceased, an applicant is required to lodge a new prior notice and pricing application and a new fee is payable dependent on the listing arrangements sought.

As pricing services can only be ceased where an applicant is not actively negotiating with the Department to reach in-principal agreement on listing arrangements, the decision to cease pricing services after 6 months in these circumstances, is not a reviewable decision under Part 6 of the Principal Regulations.

Item [64] – Paragraph 3A.1(1)(b)

This item amended the wording of the paragraph (b) within the Principal Regulations to reflect wording in the replacement fee table – refer item 65.

Item [65] – Subregulation 3A.1(1) (table)

This item replaced the fee table within the Principal Regulations to reflect the revised 2020-21 fees approved by Government in the 2020-21 Budget.

This amendment reflects the costs incurred by the Department in providing PBS list management services. New fees were introduced to cost recover existing deed management activities undertaken by the Department in response to an applicant's request to renew or vary their deed arrangement.

Deed renewal fee: This fee is charged in response to an applicant's request to enter into a new deed, at the end of the original deed term. Applicants request deed renewal services via an Application for List Management Services. The deed renewal fee also includes the rebate management fee to account for ongoing management of the deed.

Deed variation fee: This fee is charged in response to an applicant's request to vary the terms of an existing deed, within the existing deed term. Applicants request deed variation services via an Application for List Management Services. Applicants may seek to vary deed arrangements to support more beneficial terms and conditions (i.e. the PBAC has amended allowable risk share arrangements or widened the subsidy cap).

To support implementation of the second stage of PBS process improvements, the Department further reviewed and updated the 2018-19 cost model. New activities were identified because of the changes to submission evaluation categories. In addition, there have been changes to all fees because of parameter changes, which include changes to IT costs, depreciation, salary and wage costs to meet whole-of-Government requirements.

Item [66] – Subregulation 3A.1(1) (note)

This item removed this note from the Principal Regulations to reflect the change made by item 75. Indexation of fees by CPI is no longer provided for in the Principal Regulations.

Item [67] – Subregulation 3A.3(1)

This item amended wording of this subregulation within the Principal Regulations to allow the Department 15 business days to issue a notification in response to an application for PBS list management services.

Item [68] – Paragraph 3A.3(1)(c)

This item amended the wording of paragraph (c) within the Principal Regulations to ensure consistency with Regulation 5.1.

Item [69] – Subregulation 3A.3(2)

This item removed the reference to a partial fee waiver from the Principal Regulations as it is no longer required.

Item [70] – Subregulation 3A.4(2)

This item replaced the words 'notice about' with 'notification for' in the Principal Regulations.

Item [71] – At the end of Part 3A

This item inserted new provisions into the Principal regulations to provide for a partial refund of the ‘deed renewal fee’ where an applicant withdraws their list management application, and a deed arrangement (between the applicant (‘responsible person’) and the Commonwealth) has not been entered into.

This is in addition to the refund of list management fees paid if an application is withdrawn within 10 business days after the notification is given.

Item [72] – Paragraph 4.1(1)(b)

This item replaced paragraph (b) within the Principal Regulations, to specify the Department’s 28-day payment terms.

Item [73] – Subregulation 4.1(4) (note)

This item amended the wording of this note within the Principal Regulations to update the subregulation references and remove the reference to a partial fee waiver as it is no longer required.

Item [74] – Paragraph 4.3(3)(a)

This item amended the wording of paragraph (a) within the Principal Regulations, to specify the fee payable for an independent review aligns with the evaluation Category 2.

Item [75] – Regulation 4.7

This item removed this regulation from the Principal Regulations. Indexation by CPI is inconsistent with the current Australian Government Charging Framework. Under the Framework, fees are reviewed and updated annually in line with the Government agreed charging model.

Item [76] – Subparagraph 5.1(1)(m)(i)

This item replaced the reference to ‘the Human Services Department’ with ‘Services Australia’ in subparagraph (m)(i) within the Principal Regulations.

Item [77] – Subregulation 5.1(6)

This item removed this subregulation and inserted new provisions to require a person to give reasons as to why they are eligible for a fee exemption.

Where prior notice is required, an applicant must provide the reasons a fee exemption applies with their prior notice. Where prior notice is not required, an applicant must provide the reasons a fee exemption applies with their application to the PBAC.

This amendment aligns invoicing with fee exemption decision notices, and allows applicants the opportunity to withdraw an application (without penalty) following receipt of their decision notice.

Fee exemptions are available for applications that meet the eligibility criteria.

Item [78] – Subregulation 5.2(1)

This item removed partial fee waivers from the Principal Regulations to reflect the Department’s cost recovery administrative processes. Where an applicant meets the eligibility criteria for a fee waiver, the fees are waived in full.

Item [79] – Subregulation 5.2(1)

This item amended the wording of this subregulation within the Principal Regulations to reflect the change to fee waiver lodgement timing made by item 81.

Item [80] – Subregulation 5.2(1) (note)

This item removed this note from the Principal Regulations – refer item 81.

Item [81] – Subregulation 5.2(1)

This item inserted a new subregulation into the Principal Regulations to change the lodgement timing for fee waiver applications.

This item also inserted a note into the Principal Regulations to advise that a request to waive ATAGI fees need to be included in the related application for submission or pricing services. This note was removed by item 80.

Where prior notice is required, an applicant must provide their fee waiver application with their prior notice. Where prior notice is not required, an applicant must provide their fee waiver application with their application for submission, pricing or list management services.

This amendment aligns invoicing with fee waiver decision notices and allows applicants to withdraw an application (without penalty) following receipt of their decision notice.

Fee waivers are available for applications that meet the eligibility criteria.

Item [82] – Subregulation 5.2(2)

This item amended the wording of this subregulation within the Principal Regulations to align with the change made by item 78.

Item [83] – Paragraph 5.2(4)(a)

This item amended the wording of paragraph (a) within the Principal Regulations to align with the change made by item 78.

Item [84] – Subregulation 5.2(4)

This item amended the wording of this subregulation within the Principal Regulations to align with change made by item 78.

Item [85] – Subregulations 5.2(5) and (7)

This item amended the wording of these subregulations within the Principal Regulations to align with the change made by item 78.

Item [86] – Subregulation 6.2(3)

This item amended the internal review provision within the Principal Regulations so that the delegates for a reviewable decision and an initial review decision are not the same person.

Item [87] – Subregulation 6.2(4)

This item removed the reference to ‘paragraph (3)(d)’ and replaced with ‘paragraph (3)(c)’ in this subregulation within the Principal Regulations to align with the changes made by item 86.

Item [88] – Subregulation 6.2(7)

This item replaced this subregulation to align with the changes made by item 86.

Item [89] – Paragraph 6.4(a)

This item removed the reference to ‘6.2(3)(c)’ and replaced with ‘6.2(3)(b)’ in paragraph (a) within the Principal Regulations to align with the changes made by item 86.

Item [90] – In the appropriate position in Part 7

This item inserted a new heading ‘Division 4—Application and transitional provisions relating to amendments commencing on 1 January 2021’ and the following application provisions into the Principal Regulations:

7.4 Scope of this Division

This regulation specifies that the application provisions be made in relation to the proposed Regulations.

7.5 Application of new fees

This regulation specifies that new fees apply to applications for pre-submission services, submission services, pricing services and list management services where the notification is given by the Department on or after 1 January 2021.

7.6 Application of amendment of provisions about applications for pre-submission meetings

This regulation specifies that the amendments given effect by items 17 to 21 apply to meeting applications sent on or after 1 January 2021.

7.7 Application of amendments about procedure for making applications under Part 2

This regulation specifies that the amendments given effect by items 22 to 52 apply to applications for submission services sent (or proposed to be sent) on or after 1 January 2021.

7.8 Application of amendments about procedure for making pricing applications

This regulation specifies that the amendments given effect by items 53 to 63 apply to applications for pricing services sent (or proposed to be sent) on or after 1 January 2021.

7.9 Cessation of pricing services 6 months after pricing application sent

This regulation specifies that the amendment given effect by item 63 apply to applications for pricing services sent (or proposed to be sent) on or after 1 January 2021.

7.10 Application of amendment about time for payment of fees

This regulation specifies that the amendment given effect by item 72 apply to notifications given on or after 1 January 2021.

7.11 Application of provisions about including reasons for fee exemptions in application or prior notices

This regulation specifies that the amendment given effect by item 77 apply to applications sent or notices given on or after 1 January 2021.

7.12 Application of provisions about requests for fee waivers

This regulation specifies that the amendment given effect by items 78 to 85 apply to requests made on or after 1 January 2021.

7.13 Application of provisions about internal review

This regulation specifies that the amendment given effect by items 86 to 89 apply to applications made [under subregulation 6.2(1)] on or after 1 January 2021.

Item [91] – After item 2.6 of Schedule 1

This item inserted two new sub-items into Schedule 1 of the Principal Regulations to give effect to the amendments made by item 31 (in relation to the Category 4).

Item [92] – Item 2.8 of Schedule 1

This item amended the wording of Schedule 1 of the Principal Regulations to also include reference to section 93AB of the Act, to give effect to the amendments made by item 31 (in relation to the Category 4).

Item [93] – Schedule 2

This item removed Schedule 2 from the Principal Regulations. This schedule is no longer required as the two items referred to in Schedule 2 (Somatropin and a glucose indicator) are now referred to by name in the relevant evaluation category.

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. 2) Regulations 2020

The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 2) 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 would implement part of a 2020-21 Budget measure, which includes revised Pharmaceutical Benefits Scheme (PBS) processes and fees.

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 the 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 provide for 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 for pharmaceuticals to be included 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. In addition, allowing the Commonwealth to recover its costs associated with PBS listing and improving the efficiency of processes, aids in creating a viable and well-functioning PBS. This in turn assists Australians to more easily access necessary medicines which, in turn, promotes the various rights to health in the Conventions.

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