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

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 26 November 2020

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

OPC64612 - B

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1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 2) Regulations 2020*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 January 2021.	1 January 2021

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the *National Health Act 1953*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2009

1 Regulation 1.3 (after the heading)

Insert:

Note: A number of expressions used in this instrument are defined in the Act, including the following:

(a) designated vaccine;

(b) Secretary;

(c) vaccine.

2 Regulation 1.3

Insert:

cost-effectiveness test, in relation to an application referred to in subregulation 2.1(1), means an assessment of:

(a) the extent (if any) to which the efficacy and toxicity of the therapy proposed in the application for a disease or disorder differs from the efficacy and toxicity of any alternative therapy for the disease or disorder; and

(b) the cost of the proposed therapy relative to the cost of the alternative therapy.

evaluation category means any of the following categories that Division 2.1 indicates an application is in:

(a) Category 1;

(b) Category 2;

(c) Category 3;

(d) Category 4;

(e) Committee Secretariat category;

(f) new brand of existing pharmaceutical item category;

(g) standard re-entry pathway category;

(h) early re-entry pathway category;

(i) early resolution pathway category;

(j) facilitated resolution pathway category.

high added therapeutic value: a drug, medicinal preparation or vaccine has ***high added therapeutic value*** if the drug, preparation or vaccine:

(a) addresses a high and urgent unmet clinical need; and

(b) is expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over any alternative therapy.

MSAC means the body known as the Medical Services Advisory Committee.

3 Regulation 1.3 (paragraphs (b), (c), (d), (e) and (f) of the definition of *notification*)

Repeal the paragraphs, substitute:

(b) for a meeting application—subregulation 1A.10(2) or (3); or

(c) for an application under Part 2—whichever one of subregulations 2.17(1), (3) and (4) is relevant to the application or prior notice of the application; or

(d) for a pricing application—whichever one of subregulations 3.12(1), (3) and (4) is relevant to the application or prior notice of the application; or

4 Regulation 1.3 (definition of *Secretary*)

Repeal the definition.

5 Regulation 1.3 (definition of *submission services*)

Omit "subregulation 2.2(1)", substitute "regulation 2.2".

6 Regulation 1.3

Insert:

Therapeutic Goods Administration means the part of the Department known as the Therapeutic Goods Administration.

7 Regulation 1.3 (definition of *therapy*)

Repeal the definition.

8 Subregulation 1A.1(2)

Omit "(if the notification for the person's ATAGI application is given during the financial year starting on 1 July 2020)".

9 Subregulation 1A.1(2) (note)

Repeal the note.

10 Subregulation 1A.2(3)

Omit "(if the notification for the person's ATAGI application is given during the financial year starting on 1 July 2020)".

11 Subregulation 1A.2(3) (note)

Repeal the note.

12 Paragraph 1A.4(1)(b)

Omit "5.1", substitute "includes in the application reasons why regulation 5.1 applies to provide a fee exemption".

13 Subregulation 1A.4(2)

Omit "to the Department".

14 Paragraph 1A.7(b)

Omit "in Schedule 1", substitute "of Schedule 1".

15 Regulation 1A.7 (table)

Repeal the table, substitute:

Fee for providing the service of holding a pre-submission meeting		
Item	**Category of pre-submission meeting**	**Fee ($)**
1	First meeting	15,580
2	Second or later meeting	21,180

16 Regulation 1A.7 (note)

Repeal the note.

17 Regulation 1A.9

Omit "and briefing papers".

18 Subregulation 1A.10(1)

Omit "both a meeting application and briefing papers", substitute "a meeting application".

19 Paragraph 1A.10(1)(a)

Omit "and briefing papers".

20 Subregulations 1A.10(2) and (3)

Repeal the subregulations (not including the note), substitute:

(2) If the Secretary agrees to the Department holding a pre-submission meeting with the applicant on a day less than 30 business days after the Secretary notifies the applicant under subregulation (1), the notice under that subregulation must also state the matters mentioned in subregulation (4).

(3) If the Secretary agrees to the Department holding a pre-submission meeting with the applicant on a day (the ***meeting day***) at least 30 business days after the Secretary notifies the applicant under subregulation (1), the Secretary must notify the applicant in writing of the matters mentioned in subregulation (4) not more than 20 business days before the meeting day.

(4) The matters to be included in a notice mentioned in subregulation (2) or (3) are as follows:

(a) the category of the pre-submission meeting (see regulation 1A.7);

(b) the amount of the fee that is payable for the service of holding the pre-submission meeting (see regulation 1A.7);

(c) the manner for paying that fee.

21 Subregulation 1A.11(2)

Repeal the subregulation, substitute:

(2) If the meeting application is withdrawn before the end of the last business day before the pre-submission meeting applied for is to be held, the Department must refund any fee paid for the service of holding the meeting.

22 Regulation 2.1A (paragraph beginning "Submission services are provided")

Repeal the paragraph, substitute:

Submission services are provided in response to a person's submission to the Committee or Minister (also known as an application for those services). The amount of the fee payable for providing the submission services depends on the evaluation category of the person's application, which in turn depends on what the application is for. If the application is for more than one thing, the evaluation category is generally determined by the first provision of this Part about evaluation categories to apply to the application.

23 Regulation 2.1A

After "If the person's application is to the Committee, the person will", insert "generally".

24 Subdivision 1 of Division 2.1 (heading)

Repeal the heading.

25 Paragraph 2.1(1)(a)

Omit "in Schedule 1", substitute "of Schedule 1".

26 At the end of subregulation 2.1(1)

Add:

Note: For details about how to apply, see regulation 2.16.

27 Subregulation 2.1(2) (note)

Repeal the note, substitute:

Note: If an application includes 2 or more requests, the evaluation category of the application depends on the request that is covered by the earliest of the following regulations of this Division (unless the application has been resent after an earlier application was unsuccessful because it did not resolve all issues that needed to be resolved).

28 Subregulation 2.2(1)

Omit "(1) For", substitute "For".

29 Subregulation 2.2(1) (table)

Repeal the table, substitute:

Fees and deposits for providing submission services

Item	Column 1 Evaluation category of application in response to which submission services are provided	Column 2 Fee ($)	Column 3 Deposit included in fee ($)
1	Category 1	223,340	430
2	Category 2	168,700	430
3	Category 3	43,020	430
4	Category 4	33,710	430
5	Committee Secretariat category	12,730	430
6	New brand of existing pharmaceutical item category	6,450	0
7	Standard re-entry pathway category	166,650	430
8	Early re-entry pathway category	41,680	430
9	Early resolution pathway category	41,830	430

Fees and deposits for providing submission services			
Item	**Column 1** **Evaluation category of application in response to which submission services are provided**	**Column 2** **Fee ($)**	**Column 3** **Deposit included in fee ($)**
10	Facilitated resolution pathway category	238,660	72,440

Note 1: The evaluation category of an application generally depends on what the application requests or is for (see the rest of this Division). However, the evaluation category of a resent application may depend on matters not resolved by the previous application.

Note 2: The following provisions of this Division are arranged so that only the first of them (in order of appearance in this Division) to apply to an application determines the evaluation category of the application (unless the application has been resent after an earlier application was unsuccessful because it did not resolve all issues that needed to be resolved).

Note 3: The deposit in column 3 of the table may be withheld from a refund of a fee paid for an application if the application, or prior notice of it, is withdrawn soon after it is sent (see regulation 2.18).

30 Subregulation 2.2(2)

Repeal the subregulation (including the note).

31 Subdivisions 2, 3 and 4 of Division 2.1

Repeal the Subdivisions, substitute:

2.3 Applications in Category 1

(1) An application referred to in subregulation 2.1(1) is in Category 1 if:

(a) the application includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in an item of Schedule 1; and

(b) any of subregulations (2), (3), (4) and (5) of this regulation apply in relation to the request or the application.

Drug, medicinal preparation or vaccine first in class for new population or disease

(2) This subregulation applies to a request if it relates to:

(a) a drug or medicinal preparation whose intended effect is achieved by a distinct pharmacological, chemical, immunological or metabolic means that has not been considered before by the Committee; or

(b) a vaccine whose intended effect is achieved by a distinct immunological means that has not been considered before by the Committee; or

(c) a drug, medicinal preparation, or vaccine, that is for the treatment or prevention of a disease or disorder that has not been considered before by the Committee.

Drug, medicinal preparation or vaccine covered by a provisional determination

(3) This subregulation applies to a request if it relates to a drug, medicinal preparation, or vaccine, that is a medicine, within the meaning of the *Therapeutic Goods Act 1989*, in relation to which a provisional determination under section 22D of that Act is in force when the application including the request is received by the Department.

Codependent application relating to testing

(4) This subregulation applies to an application relating to a drug, medicinal preparation or vaccine if:

(a) determining the existence of:

(i) the proposed circumstances for writing a prescription for supply of the drug or medicinal preparation under Part VII of the Act; or

(ii) the proposed circumstances for provision of the vaccine under section 9B of the Act;

will depend on provision of a medical service using technology before administration of the drug, medicinal preparation or vaccine starts or is continued; and

(b) it is proposed that there be an item of the table, within the meaning of the *Health Insurance Act 1973*, for the medical service; and

(c) the application includes a request for MSAC to recommend that such an item be included in the table (as well as the request mentioned in paragraph (1)(a) for the Committee); and

(d) in considering their respective requests, both the Committee and MSAC need to do a cost-effectiveness test (whether or not the Committee or MSAC needs to assess anything else).

Codependent application relating to administration

(5) This subregulation applies to an application relating to a drug or medicinal preparation if:

(a) administration of the drug or medicinal preparation proposed to be provided under the Act will involve the provision of a medical service; and

(b) it is proposed that there be an item of the table, within the meaning of the *Health Insurance Act 1973*, for the medical service; and

(c) the application includes a request for MSAC to recommend that such an item be included in the table (as well as the request mentioned in paragraph (1)(a) for the Committee); and

(d) in considering the request for the Committee, the Committee needs to do a cost-effectiveness test (whether or not the Committee needs to assess anything else); and

(e) in considering the request for MSAC, MSAC needs to assess the cost of the therapy proposed in the application for a disease or disorder relative to the cost of any alternative therapy for the disease or disorder (whether or not MSAC needs to assess anything else).

2.4 Applications in Category 2

An application referred to in subregulation 2.1(1) is in Category 2 if:

(a) it includes a request that the Committee:

(i) recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 1.1, 1.2, 1.3, 2.1, 2.2, 2.3, 2.5, 2.5A or 2.10 of Schedule 1; or

(ii) advises the Minister in relation to a power mentioned in item 2.15 of Schedule 1; and

(b) in considering the request the Committee needs to do a cost-effectiveness test; and

(c) if the request relates to a drug or medicinal preparation—the drug or preparation is not a medicinal food the patient population for which is too small for the applicant to be able to provide a meaningful economic evaluation for the application; and

(d) the application is not in Category 1.

2.5 Applications in Category 3

(1) An application referred to in subregulation 2.1(1) is in Category 3 if:

(a) subregulation (2), (3), (4) or (5) of this regulation applies to the application; and

(b) the application is not in Category 1 or Category 2.

Applications including certain requests

(2) This subregulation applies to an application if it includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 1.4, 2.4, 2.6, 2.9, 2.11, 2.15 or 2.17 of Schedule 1.

Applications involving assessment of clinical need and effectiveness

(3) This subregulation applies to an application if:

(a) it includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 1.2, 2.2 or 2.5A of Schedule 1; and

(b) in considering the request, the Committee needs to assess the applicant's claim about the clinical need for, and clinical effectiveness of, the drug, medicinal preparation, or vaccine, to which the request relates; and

(c) the application does not:

(i) propose any change to the unit price of a listed drug or designated vaccine; or

(ii) need the Committee to assess any implications arising from the request for the cost of supplying or providing the drug, medicinal preparation or vaccine.

Applications for determination of brand of medicinal preparation with somatropin

(4) This subregulation applies to an application if it:

(a) is for the Minister to exercise a power mentioned in item 3.1 of Schedule 1 in relation to a medicinal preparation including somatropin; and

(b) includes a claim about the therapeutic benefit derived from the relationship between ingredients in the preparation.

Applications relating to medicinal food

(5) This subregulation applies to an application if it includes a request relating to a drug, or medicinal preparation, that is a medicinal food the patient population for which is too small for the applicant to be able to provide a meaningful economic evaluation for the application.

2.6 Applications in Category 4

(1) An application referred to in subregulation 2.1(1) is in Category 4 if:
  (a) any of subregulations (2), (3), (4), (5) and (6) of this regulation apply to the application; and
  (b) the application is not in Category 1, Category 2 or Category 3.

Manner of administration of listed drugs and equivalent pharmaceutical items

(2) This subregulation applies to an application if it includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 2.5 of Schedule 1 so as to determine, or vary a determination of, the manner of administration of a form of a listed drug.

Changes to maximum quantity or number of repeats

(3) This subregulation applies to an application if it includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 2.6 of Schedule 1 so as to vary a determination of a maximum described in paragraph 85A(2)(a) or (b) of the Act.

Determinations affecting who may prescribe pharmaceutical benefits or pharmaceutical items

(4) This subregulation applies to an application if it includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 2.6A or 2.6B of Schedule 1 so as to:
  (a) specify, or vary a specification of, persons who may prescribe pharmaceutical benefits or pharmaceutical items; or
  (b) determine, or vary a determination of, a pharmaceutical benefit for whose supply a PBS prescriber of a kind mentioned in any of subsections 88(1), (1A), (1C), (1D) or (1E) of the Act is authorised to write a prescription.

Prescriber bag supplies

(5) This subregulation applies to an application if it includes a request that the Committee recommends to the Minister that the Minister exercise a power mentioned in item 2.8 of Schedule 1.

Exempt items

(6) This subregulation applies to an application if it includes a request that the Committee advises the Minister that the Minister exercise a power mentioned in item 2.16 of Schedule 1.

2.7 Applications in Committee Secretariat category

(1) An application referred to in subregulation 2.1(1) is in the Committee Secretariat category if:
  (a) subregulation (2), (3) or (4) of this regulation applies to the application; and
  (b) the application is not in Category 1, Category 2, Category 3 or Category 4.

New or varied listed drugs and designated vaccines that pose no greater risk

(2) This subregulation applies to an application if the application:

(a) includes a request that the Committee recommends to, or advises, the Minister that the Minister exercise a power mentioned in item 1.2, 2.2, 2.5 or 2.5A of Schedule 1; and

(b) demonstrates that there is no increase in risk to a patient associated with using a listed drug or designated vaccine as a result of the proposed exercise of the power.

Pharmaceutical benefits that can no longer be supplied early

(3) This subregulation applies to an application that includes a request that the Committee recommends to the Minister that the Minister exercise the power mentioned in item 2.7 of Schedule 1.

New brand of glucose indicator pharmaceutical item

(4) This subregulation applies to an application for the Minister to exercise a power mentioned in item 3.1 of Schedule 1 in relation to a medicinal preparation that is a pharmaceutical item that either includes a glucose indicator or has the form of a glucose indicator.

2.8 Applications in new brand of existing pharmaceutical item category

An application for the Minister to exercise a power mentioned in item 3.1 of Schedule 1 is in the new brand of existing pharmaceutical item category if the application is not in Category 3 or the Committee Secretariat category.

2.9 Evaluation categories of certain resent applications

(1) This regulation applies to an application (the ***current application***) if:

(a) the current application is a remaking and resending, under regulation 2.19, of an amended form of an application (the ***previous application***) that was the last sent before the current application; and

(b) the previous application was not in:

(i) the Committee Secretariat category; or

(ii) the new brand of existing pharmaceutical item category; and

(c) the Committee declined to take, or was of the view that the Minister should not take, the action sought by the previous application, because of issues (the ***outstanding issues***) arising from the previous application.

(2) This regulation has effect in relation to the current application despite whichever of regulations 2.3, 2.4, 2.5, 2.6, 2.7 and 2.8 applies to it.

Standard re-entry pathway category

(3) The current application is in the standard re-entry pathway category if:

(a) after considering the previous application, the Committee either:

(i) considered that the outstanding issues could not be resolved easily and identified the outstanding issues in a communication to the applicant; or

(ii) made a suggestion described in paragraph (4)(a), (5)(a) or (6)(a); and

(b) either:

(i) the prior notice (given under regulation 2.15) for the current application; or

(ii) if prior notice was not required for the current application—the current application;

states that the current application is likely to be in the standard re-entry pathway category.

Early re-entry pathway category

(4) The current application is in the early re-entry pathway category if:

(a) after considering the previous application, the Committee:

(i) considered that the drug, medicinal preparation, or vaccine, to which the application related does not have high added therapeutic value; and

(ii) considered that the outstanding issues could be resolved easily; and

(iii) suggested to the applicant that the applicant remake and resend the application, as an application in the early re-entry pathway category, to resolve the outstanding issues; and

(iv) identified the outstanding issues in the suggestion; and

(b) the only material differences between the current application and the previous application are to address the outstanding issues; and

(c) the resending of the current application occurs after the suggestion and no later than the second submission due day after the suggestion for applications in the early re-entry pathway category; and

(d) either:

(i) the prior notice (given under regulation 2.15) for the current application; or

(ii) if prior notice was not required for the current application—the current application;

states that the current application is likely to be in the early re-entry pathway category.

Early resolution pathway category

(5) The current application is in the early resolution pathway category if:

(a) after considering the previous application, the Committee:

(i) considered that the drug, medicinal preparation, or vaccine, to which the application related has high added therapeutic value; and

(ii) considered that the outstanding issues could be resolved easily; and

(iii) suggested to the applicant that the applicant remake and resend the application, as an application in the early resolution pathway category, to resolve the outstanding issues; and

(iv) identified the outstanding issues in the suggestion; and

(b) the only material differences between the current application and the previous application are to address the outstanding issues; and

(c) the resending of the current application occurs after the suggestion and no later than the second submission due day after the suggestion for applications in the early resolution pathway category; and

(d) either:

(i) the prior notice (given under regulation 2.15) for the current application; or

(ii) if prior notice was not required for the current application—the current application;

states that the current application is likely to be in the early resolution pathway category.

Facilitated resolution pathway category

(6) The current application is in the facilitated resolution pathway category if:

(a) after considering the previous application, the Committee:

(i) considered that the drug, medicinal preparation, or vaccine, to which the application related has high added therapeutic value; and

(ii) considered that a workshop involving the applicant and one or more members of the Committee is desirable to discuss the outstanding issues; and

(iii) suggested to the applicant that the workshop be held and that the applicant later remake and resend the application, as an application in the facilitated resolution pathway category, to resolve the outstanding issues; and

(b) the workshop is held at which the outstanding issues are discussed; and

(c) the resending of the current application occurs after the workshop and no later than the second submission due day after the workshop for applications in the facilitated resolution pathway category; and

(d) either:

(i) the prior notice (given under regulation 2.15) for the current application; or

(ii) if prior notice was not required for the current application—the current application;

states that the current application is likely to be in the facilitated resolution pathway category.

32 Subregulation 2.15(1)

Omit "in item 1, 2 or 4 of the table in subregulation 2.2(1)", substitute "other than the new brand of existing pharmaceutical item category".

33 Paragraph 2.15(1)(b)

Repeal the paragraph, substitute:

(b) at least:

(i) 20 business days before the submission due day for the application; or

(ii) if the application is to be in the early re-entry pathway category or the early resolution pathway category—5 business days before the submission due day for the application; or

(iii) if the application is to be in the facilitated resolution pathway category because a workshop is to be held as described in subregulation 2.9(6)—10 business days before the workshop is to be held.

34 Subparagraph 2.16(1)(c)(i)

Repeal the subparagraph, substitute:

(i) for an application that is likely to be in an evaluation category because of subregulation 2.5(4) or regulation 2.8—the office of the Department administering applications about item 3.1 of Schedule 1; or

35 Subregulation 2.16(3)

Omit "meeting that is".

36 Subregulation 2.16(3) (note)

Repeal the note.

37 Subregulation 2.16(4)

Omit "meetings", substitute "consideration of applications".

38 After regulation 2.16

Insert:

2.16A Economic evaluations to support applications in Category 1 or Category 2

An application in, or likely to be in, Category 1 or Category 2 must be accompanied by an economic evaluation for the application.

39 Subregulation 2.17(1)

Omit "The fee for the submission services is payable to the Department.".

40 Subregulation 2.17(1) (note 2)

Repeal the note.

41 Subregulations 2.17(2) and (3)

Repeal the subregulations (including the note), substitute:

Notices relating to applications if fee exemption or waiver sought

(2) However, subregulation (1) does not apply if the notice received by the Department under subregulation 2.15(1) includes either of the following relating to the fee for providing submission services in response to the proposed application:

(a) reasons why regulation 5.1 is expected to apply to provide an exemption from the fee;

(b) a request for waiver of the fee.

In that case, subregulation (3) of this regulation applies instead.

(3) Within 15 business days after the Department receives the application to which the notice under subregulation 2.15(1) relates, the Secretary must notify the applicant in writing:

(a) that the Department has received the application; and

(b) whether the fee exemption applies, or whether the fee is waived; and

(c) if the request was for waiver and the fee is not waived—of the applicant's review rights under Part 6; and

(d) if the fee exemption does not apply and the fee is not waived:

(i) of the amount of the fee that is payable for providing submission services in response to the application; and

(ii) of the manner for paying that fee.

Notices relating to applications for which prior notice is not required

(4) Within 15 business days after the day the Department receives an application referred to in subregulation 2.1(1) for which prior notice is not required under subregulation 2.15(1), the Secretary must notify the applicant in writing:

(a) that the Department has received the application; and

(b) if the application includes either reasons why regulation 5.1 applies to provide a fee exemption or a request for waiver of the fee for providing submission services in response to the proposed application:

(i) whether the fee exemption applies, or the fee is waived; and

(ii) if waiver was requested but the fee is not waived—of the applicant's review rights under Part 6; and

(c) if the fee exemption does not apply and the fee is not waived:

(i) of the amount of the fee that is payable for providing submission services in response to the application; and

(ii) of the manner for paying that fee.

Fee specified in notification under this regulation is payable

(5) The amount of the fee (if any) specified in a notification under this regulation is payable.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

42 After regulation 2.17

Insert:

2.17A Declining to accept incomplete application sent to Department

(1) The Secretary may decline to accept an application referred to in subregulation 2.1(1) that is sent to the Department if the application is so incomplete that it does not provide an adequate basis for:

(a) preparing a recommendation or advice requested by the application; or

(b) deciding whether to exercise a power as applied for.

(2) If the Secretary declines to accept an application:

(a) the Secretary must, within 10 business days, notify the applicant in writing of the declining of the application; and

(b) the Commonwealth may refuse to provide any submission services relating to the application; and

(c) the Department must refund any fee paid for providing submission services in response to the application except for the deposit included in the fee.

43 Subregulation 2.18(2)

Repeal the subregulation, substitute:

When a withdrawal will result in a refund

(2) If:

(a) a notification is given under subregulation 2.17(1) in response to prior notice of a proposed application; and

(b) the prior notice or the application is withdrawn:

(i) before the later of the end of the tenth business day after the notification is given and the end of the last business day before the submission due day for the application; or

(ii) if the proposed application is likely to be in, or the application is in, the early re-entry pathway category, the early resolution pathway category or the facilitated resolution pathway category—within 10 business days after the notification is given;

the Department must refund any fee paid for providing submission services in response to the application except for the deposit referred to in column 3 of the table in regulation 2.2.

(2A) If:

(a) a notification is given under subregulation 2.17(3) about an application; and

(b) the application is withdrawn within 10 business days after the notification is given;

the Department must refund any fee paid for providing submission services in response to the application except for the deposit referred to in column 3 of the table in regulation 2.2.

44 Paragraph 2.18(3)(b)

Omit "subregulation 2.17(2)", substitute "subregulation 2.17(4)".

45 At the end of regulation 2.18

Add:

(4) Despite subregulations (2), (2A) and (3), the Department need not make a refund under any of those subregulations relating to a proposed application in the facilitated resolution pathway category if the withdrawal mentioned in that subregulation occurs after the last business day before the workshop mentioned in subregulation 2.9(6) in connection with the application.

46 Subregulation 2.19(1)

Omit "(1)".

47 Subregulations 2.19(2) and (3)

Repeal the subregulations.

48 After subregulation 2.20(1)

Insert:

(1A) To avoid doubt, the Secretary may determine under subregulation (1) that the application is in an evaluation category (the ***determined category***) other than the category that the application, or prior notice (under subregulation 2.15(1)) of the application, states the application to be likely to be in, even if the determined

category is an evaluation category described in regulation 2.9 (about evaluation categories of certain resent applications).

49 Paragraph 2.20(3)(a)

Omit "payable for the submission services that relate to each of those evaluation categories", substitute "for the submission services that applied when the notification for the application was given (under regulation 2.17)".

50 Subregulation 2.20(3)

Omit "to the Department".

51 Subregulation 2.20(4)

Repeal the subregulation.

52 Regulation 3.1 (paragraph beginning "The pricing application")

Omit "42 days", substitute "30 business days".

53 At the end of regulation 3.1

Add:

> Six months after a pricing application is sent, the Commonwealth may cease to provide the pricing services applied for if the Secretary is satisfied that negotiations relevant to the pricing services have not concluded successfully and are not continuing because of the applicant. If the ceased services relate to a proposed deed, a partial refund of fees is available.

54 Subregulation 3.3(1) (table)

Repeal the table, substitute:

Fees for providing pricing services		
Item	**Pricing services provided in response to pricing application in this category**	**Fee ($)**
1	Pricing Pathway A category	141,410
2	Pricing Pathway B category	111,920
3	Pricing Pathway C category	74,090
4	Pricing Pathway D category	20,300
5	Pricing Secretariat category	13,170

55 Subregulation 3.3(2)

Repeal the subregulation (including the note), substitute:

(2) For the purposes of subregulations 3.11(2) and 3.13(2) and (2A) (about refunds excluding deposits), each of these fees includes a deposit of $430.

(3) For the purposes of subregulations 3.13(4) and 3.16(2) (about a refund excluding a deposit if a deed is not entered into):

(a) the fee relating to Pricing Pathway A category includes a deposit of $133,135; and

(b) the fee relating to Pricing Pathway B category includes a deposit of $103,645; and

(c) the fee relating to Pricing Pathway C category includes a deposit of $65,815.

56 Subregulation 3.12(1)

Omit "The fee for the pricing services is payable to the Department.".

57 Subregulation 3.12(1) (note 2)

Repeal the note.

58 Subregulations 3.12(2) and (3)

Repeal the subregulations (including the note), substitute:

Notices relating to pricing applications if fee exemption or waiver sought

(2) However, subregulation (1) does not apply if the notice received by the Department as described in paragraph 3.10(1)(a) includes either:

(a) reasons why regulation 5.1 is expected to apply to provide an exemption from; or

(b) a request for waiver of;

the fee for providing pricing services in response to the proposed application. In that case, subregulation (3) of this regulation applies instead.

(3) Within 15 business days after the Department receives the application to which the notice described in paragraph 3.10(1)(a) relates, the Secretary must notify the applicant in writing:

(a) that the Department has received the application; and

(b) whether the fee exemption applies, or whether the fee is waived; and

(c) if the request was for waiver and the fee is not waived—of the applicant's review rights under Part 6; and

(d) if the fee exemption does not apply and the fee is not waived:

(i) of the amount of the fee that is payable for providing pricing services in response to the application; and

(ii) of the manner for paying that fee.

Notices relating to applications for which prior notice is not required

(4) Within 15 business days after the day the Department receives a pricing application for which prior notice is not required under subregulation 3.10(1), the Secretary must notify the applicant in writing:

(a) that the Department has received the application; and

(b) if the application includes either reasons why regulation 5.1 applies to provide a fee exemption or a request for waiver of the fee for providing submission services in response to the proposed application:

(i) whether the fee exemption applies, or the fee is waived; and

(ii) if waiver was requested but the fee is not waived—of the applicant's review rights under Part 6; and

(c) if the fee exemption does not apply and the fee is not waived:

(i) of the amount of the fee that is payable for providing submission services in response to the application; and

(ii) of the manner for paying that fee.

Fee specified in notification under this regulation is payable

(5) The amount of the fee (if any) specified in a notification under this regulation is payable.

Note: Part 4 deals with the payment of fees, including the time for payment (see paragraph 4.1(1)(b)).

59 After subregulation 3.13(2)

Insert:

(2A) If the pricing application is withdrawn within 10 business days after the day a notification is given under subregulation 3.12(3) about the pricing application, the Department must refund any fee paid for providing pricing services in response to the pricing application except for the deposit referred to in subregulation 3.3(2).

60 Paragraph 3.13(3)(b)

Omit "3.12(2)", substitute "3.12(4)".

61 At the end of regulation 3.13

Add:

(4) If:

(a) the prior notice or pricing application is withdrawn after the period described in whichever of subregulations (2), (2A) and (3) is relevant; and

(b) the application or proposed application was or would have been for pricing services relating to the entering into of a deed under section 85E of the Act (whether or not other pricing services were or would have been applied for);

the Department must refund any fee paid for providing pricing services in response to the application or proposed application except for the deposit referred to in subregulation 3.3(3).

62 Subregulation 3.14(3)

Omit "to the Department".

63 At the end of Part 3

Add:

Division 3.5—Cessation of pricing services 6 months after pricing application is sent

3.15 Cessation of pricing services 6 months after pricing application is sent

Six months after a pricing application is sent, the Commonwealth may cease to provide the pricing services applied for if the Secretary is satisfied that:

(a) an agreement or understanding has not been reached with the applicant in relation to the assistance for the Minister to consider whether to exercise a power to which the pricing services relate; and

(b) negotiations relevant to the pricing services are not proceeding because of the applicant's inaction.

3.16 Refund if deed not made within 6 months after pricing application is made

(1) This regulation applies if:

(a) a pricing application applies for pricing services relating to the entering into of a deed under section 85E of the Act; and

(b) under regulation 3.15, the Commonwealth ceases to provide the pricing services; and

(c) when the Commonwealth ceased to provide the pricing services, the deed had not been entered into.

(2) The Department must refund any fee paid for providing the pricing services except for the deposit referred to in subregulation 3.3(3).

64 Paragraph 3A.1(1)(b)

Omit "under a provision of Part VII of the Act set out in that item of the table", substitute "described in the item".

65 Subregulation 3A.1(1) (table)

Repeal the table, substitute:

Fee for providing list management services		
Item	**List management services provided in assisting the Minister to consider whether to exercise this power**	**Fee ($)**
1	A power under: (a) subsection 85AD(1) (about price agreements) of the Act; or (b) section 85B (about price determinations) of the Act; relating to a listed brand of a pharmaceutical item if subregulation (2) applies	5,040
2	A power under subsection 85E(1) of the Act (as affected by subsection 33(3) of the *Acts Interpretation Act 1901*) to vary a deed entered into under subsection 85E(1) of the Act	1,970
3	A power under subsection 85E(1) of the Act to enter into a deed with a person replacing an expired deed made with the person under that subsection	10,330
4	A power under any of the following provisions of the Act (relating to pricing): (a) subsection 99ACB(6A); (b) subsection 99ACB(6B); (c) subsection 99ACBA(1); (d) subsection 99ACD(7A); (e) subsection 99ACD(7B); (f) subsection 99ACE(5); (g) subsection 99ACE(5A); (h) subsection 99ACEA(1); (i) subsection 99ACF(3); (j) subsection 99ACF(3AA); (k) subsection 99ACF(3AB)	7,040

66 Subregulation 3A.1(1) (note)

Repeal the note.

67 Subregulation 3A.3(1)

Omit "10", substitute "15".

68 Paragraph 3A.3(1)(c)

Repeal the paragraph, substitute:

(c) if the application includes either reasons why regulation 5.1 applies to provide a fee exemption or a request for waiver of the fee for providing list management services in response to the application:

(i) whether the fee exemption applies, or the fee is waived; and

(ii) if waiver was requested but the fee is not waived—of the applicant's review rights under Part 6; and

69 Subregulation 3A.3(2)

Omit ", or any part of the fee that has not been waived, is payable to the Department", substitute "is payable".

70 Subregulation 3A.4(2)

Omit "notice about", substitute "notification for".

71 At the end of Part 3A

Add:

3A.5 Partial refund if replacement for expired deed not made

(1) This regulation applies if:

(a) a list management application by a person sought the exercise of a power, described in item 3 of the table in subregulation 3A.1(1), to enter into a deed (the ***replacement deed***) with the person replacing an expired deed with the person entered into under subsection 85E(1) of the Act; and

(b) the fee set out in that item is paid (in full or in part) for list management services in response to the application; and

(c) the Department becomes aware of a decision (whether by the Minister, the person or an agreement between them) not to enter into the replacement deed.

(2) The Department must refund $8,275 to the person.

72 Paragraph 4.1(1)(b)

Repeal the paragraph, substitute:

(b) before the end of 28 days starting on the day that the Department gives notice under these Regulations to the applicant that the fee is payable.

73 Subregulation 4.1(4) (note)

Omit "subregulation 2.17(2) of a decision under subregulation 5.2(1) to waive all or part of", substitute "subregulation 2.17(3) or (4) of a decision under subregulation 5.2(1) to waive".

74 Paragraph 4.3(3)(a)

Omit "an application under Part 2 that is in the major evaluation category (see table item 1 in subregulation 2.2(1))", substitute "an application referred to in subregulation 2.1(1) that is in the Category 2 evaluation category".

75 Regulation 4.7

Repeal the regulation.

76 Subparagraph 5.1(1)(m)(i)

Omit "the Human Services Department", substitute "Services Australia".

77 Subregulation 5.1(6)

Repeal the subregulation, substitute:

Including reasons for exemption in application or prior notice

(6) An applicant for services who considers that subregulation (1) or (3) applies to provide a fee exemption for the services must include in the application the reasons why that subregulation applies to provide a fee exemption, unless the applicant has complied with subregulation (7).

(7) A person who:

(a) proposes to make and send an application for services in relation to which the person expects subregulation (1) or (3) of this regulation to apply to provide a fee exemption; and

(b) is required by regulation 2.15 or 3.10 to give the Department prior notice of the application;

must include in the notice the reasons why that subregulation is expected to apply to provide a fee exemption.

78 Subregulation 5.2(1)

Omit "on request, decide whether or not to waive all or part of", insert "on request made in accordance with subregulation (1A), decide whether or not to waive".

79 Subregulation 5.2(1)

Omit "The request must be included in the person's application under Part 2 or 3 for any of the services referred to in paragraph (b).".

80 Subregulation 5.2(1) (note)

Repeal the note.

81 After subregulation 5.2(1)

Insert:

(1A) The request must be made:

(a) in the person's application under Part 2 or 3 for any of the services referred to in paragraph (1)(b); or

(b) if, under regulation 2.15 or 3.10, prior notice of the application is required—in the prior notice.

Note: A request to waive fees payable under Division 1A.1 for ATAGI advice would need to be included in a related application for services under Part 2 or a prior notice of that application.

82 Subregulation 5.2(2)

Omit "all or part of".

83 Paragraph 5.2(4)(a)

Omit "subregulation (1), a person requests the Secretary to waive all or part of", substitute "subregulation (1A), a person requests the Secretary to waive".

84 Subregulation 5.2(4)

Omit "all or part of" (last occurring).

85 Subregulations 5.2(5) and (7)

Omit "all or part of".

86 Subregulation 6.2(3)

Repeal the subregulation, substitute:

(3) A person authorised under subregulation (6) must, within 10 business days after receiving the application:

(a) review the reviewable decision; and

(b) make a decision (the ***initial review decision***):

(i) to affirm or vary the reviewable decision; or

(ii) to revoke the reviewable decision, and make any other decision that the person thinks appropriate; and

(c) give the applicant written notice of the initial review decision.

87 Subregulation 6.2(4)

Omit "paragraph (3)(d)", substitute "paragraph (3)(c)".

88 Subregulation 6.2(7)

Repeal the subregulation, substitute:

(7) However:

(a) disregard a person's authorisation for the purposes of subregulation (3) if the person was involved in making the reviewable decision; and

(b) disregard a person's authorisation for the purposes of subregulation (5) if the person was involved in making:

(i) the initial review decision; or

(ii) the reviewable decision from which the initial review decision was made.

89 Paragraph 6.4(a)

Omit "6.2(3)(c)", substitute "6.2(3)(b)".

90 In the appropriate position in Part 7

Insert:

Division 4—Application and transitional provisions relating to amendments commencing on 1 January 2021

7.4 Scope of this Division

This Division applies to amendments of these Regulations made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 2) Regulations 2020*.

Note: The *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (2020 Measures No. 2) Regulations 2020* commenced on 1 January 2021.

7.5 Application of new fees

The amendments involving the following provisions apply in relation to applications, notification for which is given on or after 1 January 2021:

(a) regulation 1A.7;
(b) Division 2.1;
(c) subregulation 2.20(1A);
(d) paragraph 2.20(3)(a);
(e) subregulation 2.20(4);
(f) regulation 3.3;
(g) regulations 3A.1 and 3A.5.

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

The amendments of regulations 1A.9, 1A.10 and 1A.11 apply in relation to meeting applications sent on or after 1 January 2021.

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

(1) The amendments involving the following provisions apply to applications sent, or proposed to be sent, on or after 1 January 2021:
  (a) regulation 2.15;
  (b) regulation 2.16A;
  (c) subregulations 2.17(2), (3) and (4);
  (d) regulation 2.18;
  (e) subregulations 2.19(2) and (3).

(2) Regulation 2.17A applies to applications sent on or after 1 January 2021.

7.8 Application of amendments about procedure for making pricing applications

The amendments involving the following provisions apply to pricing applications sent, or proposed to be sent, on or after 1 January 2021:

(a) subregulations 3.12(2), (3) and (4);
(b) regulation 3.13.

7.9 Cessation of pricing services 6 months after pricing application sent

Division 3.5 applies in relation to pricing applications sent on or after 1 January 2021.

7.10 Application of amendment about time for payment of fees

The amendment involving paragraph 4.1(1)(b) applies to notifications given on or after 1 January 2021.

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

The amendment involving subregulations 5.1(6) and (7) applies to applications sent, or notices given, on or after 1 January 2021.

7.12 Application of provisions about requests for waiver of fees

The amendments involving regulation 5.2 apply to requests made on or after 1 January 2021.

7.13 Application of provisions about internal review

The amendment involving subregulation 6.2(3) applies to applications made under subregulation 6.2(1) on or after 1 January 2021.

91 After item 2.6 of Schedule 1

Insert:

2.6A To specify, or vary the specification of, a class of persons in a determination made under subsection 85A(1) or (2) of the Act

2.6B To determine for the purposes of subsection 88(1), (1A), (1C), (1D) or (1E) of the Act a pharmaceutical benefit for whose supply a PBS prescriber mentioned in that subsection is authorised to write a prescription, or to vary such a determination

92 Item 2.8 of Schedule 1

Omit "or 93AA", substitute ", 93AA or 93AB".

93 Schedule 2

Repeal the Schedule.