

EXPLANATORY STATEMENT

Select Legislative Instrument 2012 No. 168

National Health Act 1953
and

National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)

By authority of the Minister for Health

Section 140 of the *National Health Act 1953* (the Act) provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing all matters which 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.

The Pharmaceutical Benefits Scheme (PBS) operates under Part VII of the Act which provides for and regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

The *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) prescribe matters in relation to the operation of the PBS and set out details associated with certain aspects of prescribing and supply under the PBS.

Item 81 of Schedule 1 to the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012* (the amending Act) provides, in part, that the Governor-General may make regulations prescribing matters which are required or permitted by the Schedule to be prescribed, or which are necessary or convenient to be prescribed for carrying out or giving effect to the Schedule.

The purpose of this amendment is to give effect to changes made to the Act by the amending Act, and to prescribe matters relating to the amending Act. The regulation reflects that in the Act (as amended) *approved ex-manufacturer price* replaces *approved price to pharmacists* as the base price for a PBS medicine. The *approved ex-manufacturer price* is the price agreed or determined for a medicine for PBS purposes as defined under the Act (as amended). The Regulation would also prescribe, for a small number of brands of pharmaceutical items, an *approved ex-manufacturer price* for the purpose of transitional provisions in the amending Act.

The changes also reflect amended provisions in the Act which provide for listing of pharmaceutical benefits for supply only via PBS prescriber bags, and separate provisions for those listings for authorised midwives and authorised nurse practitioners.

Details of the regulation are set out in the [Attachment](#).

The amendments in the amending Act and in the regulation regarding PBS pricing and price disclosure reflect agreements made by the Government with Medicines Australia in the September 2010 Memorandum of Understanding (MOU) and with the Consumers Health

Forum, the Generic Medicines Industry Association and Medicines Australia in the September 2011 Statement of principles of commitment between stakeholders (Statement of principles).

A draft of the pricing sections of the Bill for the amending Act was provided to signatories to the Statement of principles in May 2012, prior to introduction of the Bill into Parliament. No changes to the draft Bill were requested or resulted from this consultation process.

Stakeholder briefings regarding the legislative changes for PBS pricing were provided by the Department of Health and Ageing in April and May 2012 for representatives of medicines industry, consumer, pharmacy and wholesaler organisations. The need for consequential changes to the Principal Regulations and other legislative instruments was included in those discussions. Further information, briefings and presentations were provided for pharmaceutical companies and industry organisations in June 2012. No significant issues were raised.

No consultation occurred regarding the listing changes for PBS prescriber bag supplies. These are minor technical changes. They are not relevant to the industry agreements, do not substantially alter existing arrangements, and have no significant impact for consumers, pharmacy, industry or other users of the PBS.

The Act specifies no conditions that need to be met before the power to make the regulation may be exercised.

The regulation is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

The regulation commences on 1 October 2012.

Authority: Section 140 of the *National Health Act 1953* and Item 81 of Schedule 1 to the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2012*

ATTACHMENT**Details of the *National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)*****Section 1 – Name of regulation**

This section provides that the title of the regulation is the *National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)*.

Section 2 – Commencement

This section provides for the regulation to commence on 1 October 2012.

Section 3 – Amendment of *National Health (Pharmaceutical Benefits) Regulations 1960*

This section provides that Schedule 1 amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations).

Schedule 1 – Amendments**Item [1] – Subregulation 5(1), definition of authority prescription**

This item changes a reference to subsection 85B(5) of the Act to a reference to subsection 85B(4) of the Act in line with amendments to section 85B being made by the amending Act. New subsection 85B(4) is identical to the previous subsection 85B(5).

Item [2] – Regulation 15

This item substitutes a new regulation 15. The new regulation contains a reference to section 93AB of the Act, but otherwise is identical to the current regulation. There is no substantive change in the meaning of the regulation.

Both the current regulation and the substituted regulation contain a reference to section 93AA of the Act. Current subsection 93AA of the Act covers supply of pharmaceutical benefits by prescribers for patient use, from supplies obtained and held for that purpose, by both authorised midwives and authorised nurse practitioners. Under amendments contained in Schedule 3 to the amending Act, section 93AA will apply, from 1 October 2012, only to supply by authorised midwives, and new section 93AB to supply by authorised nurse practitioners. Thus, where the current regulation refers to section 93AA, the substituted regulation refers to sections 93AA and 93AB.

This item also substitutes a new more descriptive heading for the regulation.

Item [3] – Regulation 16, heading

This item substitutes a more descriptive heading for regulation 16.

Item [4] – Subregulation 16(1)

This item amends the subregulation by replacing the current reference to section 93AA of the Act with a reference to sections 93AA and 93AB. The amendment reflects the splitting of current section 93AA into two sections, sections 93AA and 93AB, from 1 October 2012. There is no substantive change in the meaning of the subregulation or the regulation.

Item [5] – Regulation 17, heading

This item substitutes a more descriptive heading for regulation 17.

Item [6] – Regulation 18, heading

This item substitutes a more descriptive heading for regulation 18.

Item [7] – Regulation 18

This item amends regulation 18 by replacing the current reference to section 93AA of the Act with a reference to sections 93AA and 93AB. The amendment reflects the splitting of current section 93AA into two sections, sections 93AA and 93AB, from 1 October 2012. There is no substantive change in the meaning of the regulation.

Item [8] – Subregulation 19(6)

This item changes a reference to subsection 85B(5) of the Act to a reference to subsection 85B(4) of the Act in line with amendments to section 85B being made by the amending Act. New subsection 85B(4) is identical to the previous subsection 85B(5).

Item [9] – Paragraph 36(2)(c)

This item amends the paragraph by replacing the current reference to subsection 93AA(2) of the Act with a reference to subsections 93AA(2) and 93AB(2). The amendment reflects the splitting of current section 93AA into two sections, sections 93AA and 93AB, from 1 October 2012. There is no substantive change in the meaning of the paragraph or the regulation.

Item [10] – Subregulation 36(3), note

This item corrects an error in a cross-reference to a subsection of the Act. The correct cross-reference prior to 1 October 2012 was subsection 85B(4); from 1 October 2012 the correct cross-reference is subsection 85B(5).

Item [11] – Regulation 37A, definition of approved price to pharmacists

This item repeals the definition of *approved price to pharmacists*. This term is being removed from the Act from 1 October 2012 and replaced with *approved ex-manufacturer price* under amendments contained in Schedule 1 to the amending Act. The *approved ex-manufacturer price* replaces the *approved price to pharmacists* as the core Pharmaceutical Benefits Scheme (PBS) price in the Act. The Principal Regulations already contain many provisions based on the *approved ex-manufacturer price*. Provisions based on the *approved price to pharmacists* are being omitted or amended by items in this Schedule and the term will no longer appear in the Principal Regulations.

Item [12] – Regulation 37A

This item inserts a definition of a new term, *start day*, in regulation 37DA. A *start day* in relation to a brand of a pharmaceutical item is the day on which the price disclosure requirements under the Act first apply to the brand. The new term *start day* will replace the current term *relevant day* in a number of regulations.

The term *relevant day* is being replaced because *relevant day* will have a defined meaning in the Act from 1 October 2012, which is different from its current meaning in the Principal Regulations. From 1 October 2012, where the term *relevant day* appears in the Principal

Regulations, it will have its new defined meaning in the Act. The term is inserted in regulation 37FA and regulation 37G by items 20 and 24 of this Schedule.

Item [13] – Regulation 37C

This item repeals regulation 37C. As the concept of an *approved price to pharmacists* is being removed from the Act by the amending Act, and would be removed from the Principal Regulations under item 11 of this Schedule, the formula for working out an adjusted approved price to pharmacists is no longer needed.

Item [14] – Regulation 37D

This item repeals regulation 37D. The formula for converting an *approved price to pharmacists* to an *approved ex-manufacturer price* is no longer needed, as the concept of an *approved price to pharmacists* is being removed from the Act and the Principal Regulations. The *approved ex-manufacturer price* replaces the *approved price to pharmacists* in the legislation as the base price for a PBS medicine.

Item [15] – Regulation 37DA

This item omits regulation 37DA. A new regulation (regulation 37FA) with the same purpose as regulation 37DA is being inserted by item 20 of this Schedule.

Item [16] – Subregulation 37ED(1)

This item substitutes a new subregulation 37ED(1). The subregulation uses a new defined term *start day* in place of the term *relevant day* in the existing subregulation. There is no substantive change in the meaning of the subregulation or the regulation. The changes are required because the term *relevant day* will have a defined meaning in the Act from 1 October 2012, which is different from its current meaning in the Principal Regulations, and from that date, the term will have that defined meaning when used in the Principal Regulations.

Other references in regulation 37ED to *relevant day* would be changed to *start day* by an amendment in item [32] of this Schedule.

Item [17] – Subregulation 37ED(6), note

This item omits the note under regulation 37ED. The note concerns brands to which section 99ADJ of the Act applies. Section 99ADJ is repealed by the amending Act on 1 October 2012 and, therefore, the note is no longer needed.

Item [18] – Before subregulation 37EE(1)

This item inserts a new subregulation (1A) into regulation 37EE. New subregulation (1A) replaces existing subregulation (5) which is being omitted by item [19] of this Schedule. These amendments, combined with the amendments to the regulation made by item [32] of this Schedule (the replacement of the term *relevant day* with the defined term *start day*) do not result in any substantive change in the operation of the regulation. The changes are required because the term *relevant day* will have a defined meaning in the Act from 1 October 2012, which is different from its current meaning in the Principal Regulations, and from that date, the term will have that defined meaning when used in the Principal Regulations.

Other references in regulation 37EE to *relevant day* would be changed to *start day* by an amendment in item 32 of this Schedule.

Item [19] – Subregulation 37EE(5)

This item omits the subregulation. It is no longer needed due to the amendments to the regulation being made by items [18] and [32] of this Schedule.

Item [20] – Regulation 37F

This item substitutes a new regulation 37F, and inserts a new regulation 37FA.

New regulation 37F provides the manner in which price disclosure requirements for the first disclosure cycle and data collection period apply to a brand of a pharmaceutical item, if at the time it is listed on the PBS, there are other brands with the same drug and manner of administration already subject to price disclosure. The new brand joins the current price disclosure cycle or cycles for that drug/manner of administration as described in regulation 37EB. There will always be one cycle whose data collection period has not ended, and the new brand is placed in that cycle by subregulation (2). Data collection periods for price disclosure are described in regulation 37EC. There may also be a cycle (a prior cycle) for which the data collection period has ended, but the reduction day prescribed under regulation 37K has not occurred; where this is the case, subregulation (3) places the new brand in the prior cycle also. Some, but not all, brands placed in the prior cycle will be placed in the data collection period for the cycle by subregulation (4).

New subregulations (1) and (2) differ from the existing subregulations in that the term *relevant day* has been replaced by a new defined term *start day*. The changes are required because the term *relevant day* will have a defined meaning in the Act from 1 October 2012, which is different from its current meaning in the Principal Regulations, and from that date, the term will have that defined meaning when used in the Principal Regulations. There are a number of other stylistic changes to the two subregulations. The changes to these subregulations do not result in any substantive change to the meaning of the subregulation or the operation of the regulation.

New subregulation (3) provides to the same effect as existing paragraph (3)(a). New brands which would be placed in a prior cycle by existing paragraph (3)(a) will continue to be placed in the prior cycle by new subregulation (3). *Start day* replaces *relevant day* for the reasons set out above, and other changes are stylistic.

New subregulation (4) provides to the same effect as existing paragraph (3)(b), but its application is more limited. It applies to relevant brands covered by subregulation (3), but only in the circumstances covered by paragraph (4)(b). These circumstances are that there was no other brand of that pharmaceutical item subject to the price disclosure requirements on both the start day for the relevant brand and the day before that day. The subregulation thus applies to a new brand joining a prior disclosure cycle, if there was no other brand of that pharmaceutical item subject to the price disclosure requirements on both the start day for the brand and the day before that day, ie, it applies to new brands of *new* pharmaceutical items joining a prior cycle. It does not apply to new brands of *existing* pharmaceutical items joining a prior cycle; these brands are covered by new subregulation (3), but not subregulation (4).

If a brand of the same pharmaceutical item as the new brand was listed on the PBS on the day before the start day for the new brand, but that brand was not listed on the start day,

subregulation (4) will apply. This is because the criterion in paragraph (4)(b) is satisfied: there is no brand of that pharmaceutical item subject to price disclosure on both the start day for the relevant brand and the day before that day. On the start day, there is no existing brand of that pharmaceutical item and on that day the new brand is, in effect, a new brand of a new pharmaceutical item.

New brands of *existing* pharmaceutical items are placed in the prior disclosure cycle under subregulation (3). However, they are not placed in the data collection period for that cycle under subregulation (4) for the purposes of calculating a weighted average disclosed price for the brand; the reason for this is that it is no longer necessary under the amended Act for there to be a weighted average disclosed price calculated in order for these brands to have a price reduction on the reduction day for the prior cycle. Their prices will be reduced on the reduction day to match the reduced prices of other brands of that pharmaceutical item under new section 99ADHA of the Act, which is being inserted into the Act on 1 October 2012 by the amending Act. The price reductions for these new brands of existing pharmaceutical items under the Act will be the same as those that would occur if the brands were placed in the data collection period and had a weighted average disclosed price calculated; reducing the prices directly under the Act gives the same result and avoids these unnecessary administrative processes.

Thus, the only substantive difference between the current and the substituted regulation 37F (the non-coverage of new brands of existing pharmaceutical items by subregulation (4)) will not lead to a substantively different outcome because of the operation of new section 99ADHA of the Act.

The substituted Note under regulation 37F alerts readers to other relevant regulations. This Note is the same as the existing Note except that the current reference to regulation 37DA has been replaced with a reference to new regulation 37FA. Regulation 37DA is being omitted (see item 15 of this Schedule) and new regulation 37FA is being made for the same purpose (see below).

New regulation 37FA is made for paragraph 99ADB(3B)(c) of the Act and its purpose is to derive an ***approved ex-manufacturer price*** on the ***relevant day*** for certain brands of pharmaceutical items that were not listed on the PBS on that day. ***Relevant day*** has the meaning in subsection 99ADB(1) of the Act as amended.

An ***approved ex-manufacturer price*** on the ***relevant day*** is an ***applicable approved ex-manufacturer price***. An ***applicable approved ex-manufacturer price*** for a brand is needed to perform the price disclosure calculations in regulation 37G.

If, at the time a new brand of a pharmaceutical item is listed on the PBS, its drug and manner of administration are already subject to price disclosure, the new brand joins the current price disclosure cycle or cycles for that drug/manner of administration (regulation 37F applies to these brands). There will always be one cycle whose data collection period has not ended. There may also be a cycle (a prior cycle) for which the data collection period has ended, but the reduction day has not occurred (subregulation 37F(3) applies to brands being placed in a prior cycle). A new brand joining a prior cycle will not have been listed on the relevant day for that cycle. A price on that day for some, but not all, of these brands may be calculated under this regulation.

Subregulation (1) sets out when the regulation applies. The regulation applies to a brand of pharmaceutical item (the relevant brand) to which regulation 37F applies, if the circumstances mentioned in subregulation 37F(4) apply to the relevant brand. The regulation thus applies to a new brand joining a prior disclosure cycle, if there was no other brand of that pharmaceutical item subject to the price disclosure requirements on both the start day for the brand and the day before that day, ie, it applies to new brands of new pharmaceutical items joining a prior cycle. The reason why it does not apply to new brands of existing pharmaceutical items joining a prior cycle was explained in the context of substituted regulation 37F above.

Subregulation (2) provides that the regulation does not apply if both the start day for the brand and the relevant day is 1 October 2012. In the usual case the relevant day is the last day of the data collection period, but if that day is 30 September 2012, the relevant day is 1 October 2012. Thus, in the usual case, a new brand which is listed on the PBS after the end of a data collection period will not have a PBS price on the relevant day and needs to have one calculated for it under regulation 37FA. However, a new brand listing on 1 October 2012 and going into a prior disclosure cycle whose data collection period ended on 30 September 2012 is the exception; its start day is 1 October 2012 and it will have a price on the relevant day (1 October 2012) and thus does not need to have one calculated for it under regulation 37FA.

Subregulation (3) sets out the method for working out the approved ex-manufacturer price of the relevant brand on the relevant day for the prior disclosure cycle where the start day for the brand is after the relevant day. The price is the ex-manufacturer price of the brand on the start day for the brand, plus any amounts that would have been deducted from the ex-manufacturer price of the brand as price reductions under Division 3A of Part VII of the Act had the brand been a listed brand in the period between the relevant day and the start day for the brand. The effect is to ensure the ex-manufacturer price used as the comparison price of the brand for the prior price disclosure cycle is the price that would have been in place on the relevant day had the brand been listed at the time.

Item [21] – Paragraphs 37G(3)(a) and (6)(a)

This item changes the current reference to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the paragraphs or the regulation.

Item [22] – Subregulation 37G(14)

This item changes the current expression ‘every brand of every pharmaceutical item’ to ‘each brand of each pharmaceutical item’. This amendment, together with the amendment in item 23, is being made for the purpose of clarifying the meaning of the subregulation. There is a separate weighted average disclosed price calculated for each brand of each pharmaceutical item, and each brand has an applicable approved ex-manufacturer price.

Item [23] – Subregulation 37G(14)

This item changes the expression ‘brands’ to ‘brand’ for the purpose of clarifying the meaning of the subregulation. See item 22 for a further explanation of this amendment and the related amendment in that item.

Item [24] – Subregulation 37G(15)

This item substitutes a new subregulation (15) setting out a new definition of the term *adjusted volume*. The volume of the brand sold, based on the number of packs of each size, is disclosed under the price disclosure requirements. The adjusted volume is the volume worked out as if the pack sizes were all equivalent to the pricing quantity of the brand. The pricing quantity is the quantity by reference to which the approved ex-manufacturer price of a brand must be agreed or determined under the Act, as amended by the amending Act.

Pricing quantity is defined in subsection 84AK(1) of the amended Act.

Item [25] – Paragraph 37H(1)(i) and (j)

This item changes a reference to ‘given for’ to a reference to ‘given in relation to’. The new wording reflects the wording in section 99ADC of the Act, for the purposes of which the regulation has been made. The change has been made to avoid any uncertainty about the meaning of the subparagraphs.

Item [26] – Paragraph 37J(3)(a)

This item changes the current reference to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the paragraph or the regulation.

Item [27] – Paragraph 37J(3)(b)

This item changes the current reference to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the paragraph or the regulation.

Item [28] – Paragraph 37J(4)(a)

This item changes the current reference to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the paragraph or the regulation.

Item [29] – Subparagraph 37J(4)(b)(ii)

This item changes the current reference to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the subparagraph or the regulation.

Item [30] – After Part 7

This item inserts a new Part 8 into the Principal Regulations. It also inserts two new regulations (regulations 49 and 50) into new Division 1 of Part 8.

New Part 8 of the Principal Regulations provides for transitional provisions. Division 1 contains transitional provisions relating to the amending Act. Item 81 of Schedule 1 to the amending Act contains a regulation-making power under which the regulations in this Division are made.

New regulation 49 provides for *approved ex-manufacturer prices* on 1 October 2012. Subregulation (1) provides that Schedule 7 to the Principal Regulations sets out the approved ex-manufacturer price on 1 October 2012 for each brand of a pharmaceutical item listed in the Schedule.

Subregulation (2) provides that the regulation is made for paragraph 70(a) of the amending Act.

Under the amending Act, the ***approved ex-manufacturer price*** is replacing the ***approved price to pharmacists*** as the base price for a PBS medicine on 1 October 2012. It is necessary for each brand of a pharmaceutical item listed on the PBS to have an approved ex-manufacturer price in place on that day. The amending Act provides for various means by which those prices may be put in place.

The combined effect of items 68 to 72 of Schedule 1 to the amending Act is that:

- if a new price is agreed or determined for a brand of a pharmaceutical item under the amended Act and comes into force on 1 October 2012, this will be the approved ex-manufacturer price of the brand on that day;
- if no new price is agreed or determined, and a price is prescribed for a brand of a pharmaceutical item, this will be the approved ex-manufacturer price;
- if no price is agreed or determined, and no price is prescribed, the approved ex-manufacturer price will be the default ex-manufacturer price provided for in the amending Act.

A price prescribed in Schedule 7 for a brand of a pharmaceutical item will therefore be the approved ex-manufacturer price for the brand on 1 October 2012 only if there is no new price agreed or determined under the amended Act for the brand, which comes into force on that day.

New regulation 50 provides that if a weighted average disclosed price is determined for a brand on or before 30 September 2012, and after that date a new weighted average disclosed price is determined for the brand for the same disclosure cycle, the new price must be determined under the provisions of the Principal Regulations in force immediately before 1 October 2012. A new determination may have to be made if an error affecting the original determination is discovered. This provision ensures that the new price is calculated and determined under the same regulations as the original price was calculated and determined.

Item [31] – After Schedule 6

This item inserts new Schedule 7. Schedule 7 sets out the approved ex-manufacturer prices on 1 October 2012 mentioned in new regulation 49.

Item [32] – Further amendments

This item changes a number of current references to *relevant day* to a reference to *start day*. There is no substantive change in the meaning of the regulations concerned.

Statement of Compatibility with Human Rights

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

National Health (Pharmaceutical Benefits) Amendment Regulation 2012 (No. 4)

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

Overview of the legislative instrument

The legislative instrument amends the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Principal Regulations) regarding procedures and requirements for medicines supplied under the Pharmaceutical Benefits Scheme (PBS).

The amendments relate to PBS pricing and listing arrangements. They are operational and technical changes which provide for improved administration of the PBS. None of the amendments makes any substantive change to the Principal Regulations regarding the availability of, or access to, medicines under the Scheme.

Human rights implications

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

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

Conclusion

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

Tanya Plibersek
Minister for Health