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Private Health Insurance Legislation Amendment Bill (No. 2) 2009

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Links: The relevant links to the Bill, Explanatory Memorandum and second reading speech can be accessed via BillsNet, which is at http://www.aph.gov.au/bills/. When Bills have been passed they can be found at ComLaw, which is at http://www.comlaw.gov.au/.

Purpose

The Private Health Insurance Legislation Amendment Bill (No. 2) 2009 (the Bill), proposes to amend the *Private Health Insurance Act 2007* (the Act), to allow for:

- conditional listing of prostheses on the Commonwealth Prostheses List (the List)
- the Minister for Health and Ageing to make rules to specify criteria for listing of prostheses on the List.

Background

Benefits and prostheses

Prostheses are artificial devices attached to the body as an aid, or substitute for body parts that are missing or non-functional. Prostheses can include: cardiac pacemakers and defibrillators, cardiac stents, hip and knee replacements, intraocular lenses, and human tissues such as human heart valves, corneas, bones (part and whole) and muscle tissue.[1]

The Act requires private health insurers to pay benefits for prostheses that are provided as part of an episode of hospital treatment or hospital substitute treatment and for which a Medicare benefit is payable for the associated professional service.[2] Prostheses and human

1. Department of Health and Ageing (DoHA), 'Health Insurance – Prostheses List', DoHA website, viewed 12 October 2009, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

2. See Private Health Insurance Act 2007 subsection 72-1(2).

tissue products that attract benefits are specified in the Commonwealth Prostheses List, contained in the schedule to the Private Health Insurance (Prostheses) Rules (the Rules), which also specify the benefit amount. There are more than 9500 products on the Prostheses List.[3]

The Prostheses List derives from a long-established system for funding of surgically implanted devices by health insurers. In the past, the term 'surgically implanted prosthesis' was used to distinguish the listed products from devices such as artificial limbs, which, while meeting the ordinary meaning of prostheses, are not part of these arrangements.[4]

In order for a new prosthesis to be listed, an application requesting this must be made to the Minister for Health and Ageing. The Minister may take advice from the Prostheses and Devices Committee (PDC) when deciding whether or not to grant an application to list.[5] Applications are assessed against mandatory criteria as specified in the Act, and non-mandatory criteria. Mandatory criteria include:

- the product must registered on the Australian Register of Therapeutic Goods
- the product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment and
- a Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist).[6]

Non-mandatory criteria are set out in administrative guidelines which specify that the product should:

- be surgically implanted in the patient and be purposely designed in order to either replace an anatomical body part; combat a pathological process; or modulate a physiological process or
- be essential to and specifically designed as an integral single-use aid for implanting a product, as described above, which is only suitable for use with the patient in whom that product is implanted or

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3. Department of Health and Ageing, op. cit.
4. Department of Health and Ageing (DoHA), *Prostheses list guide to listing and setting benefits (Part 1) July 2009*, DoHA, Canberra, 2009, p. 44, viewed 12 October 2009, http://www.health.gov.au/internet/main/publishing.nsf/Content/BD94DFD828DDFA6BCA2575EF000F806A/$File/PL%20Guide%20Part%201.pdf
5. Private Health Insurance (Prostheses) Rules subrule 9(1). The PDC comprises 13 members, including clinicians, insurers, hospitals, manufacturers and a consumer representative.
6. As set out in *Private Health Insurance Act 2007* subsection 72-1(1).

- be critical to the continuing function of the surgically implanted product and which is only suitable for use by the patient in whom that product is implanted and
- has been compared to alternate products on the Prostheses List or alternate treatments and:
  - assessed as being, at least, of similar clinical effectiveness and
  - the cost of the product is relative to its clinical effectiveness.[7]

Under current arrangements, it is not clear if additional conditions can be considered or required when granting an application for listing: devices are either listed for 'general use' or not listed at all.[8] Allowing for such a 'conditional' listing may be desirable where a prosthesis is clinically effective in specific circumstances, but where it may not be considered appropriate for 'general use'. For example, while insulin infusion pumps are considered life-saving for some people with diabetes, the current rules only allow for an 'unconditional listing' of these devices. The Minister points out this could lead to health insurers being required to pay benefits for the device, regardless of the clinical circumstances in which it was provided.[9]

The **proposed amendments to subsection 72-1(2)** would permit the Rules to set out additional conditions or circumstances that need to be satisfied in order for a health insurer to provide a benefit for a listed device. The Rules are legislative instruments subject to Parliamentary scrutiny. Further, **proposed subsection 72-10(6)** would allow for the Rules to specify listing criteria that are in addition to those mandatory criteria contained in the Act but not so as to over-ride them, and would also allow for different listing criteria to apply in different circumstances. This would allow for the listing of new kinds of prostheses in a yet to be developed section of the Prostheses List.[10]

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7. Department of Health and Ageing (DoHA), *Prostheses list guide to listing and setting benefits (Part 1) July 2009*, DoHA, Canberra, 2009, p. 13, viewed 12 October 2009, http://www.health.gov.au/internet/main/publishing.nsf/Content/BD94DFD828DDFA6BCA2575EF000F806A/$File/PL%20Guide%20Part%201.pdf

8. N Roxon, 'Second reading speech: Private Health Insurance Legislation Amendment Bill (No. 2) 2009', House of Representatives, *Debates*, 17 September 2009, p. 9887, viewed 13 October 2009, http://parlinfo.aph.gov.au/parlInfo/search/display/display.w3p;query=Id%3A%22chamber%2Fhansardr%2F2009-09-17%2F0013%22

9. Ibid.

10. Explanatory memorandum, 'Private Health Insurance Legislation Amendment Bill (No. 2) 2009', p. 2. The Minister for Health and Ageing has also indicated that she has instructed the PDC to develop a new part of the List to accommodate currently non-compliant devices such as insulin pumps. See N, Roxon, op. cit.

Insulin pumps

In her second reading speech, the Minister highlighted the significance of the proposed amendments for insulin pumps.[11] Although private health insurance companies reimburse the cost of insulin pumps,[12] there has always been some uncertainty about their long-term status on the Prostheses List because they are not surgically implanted, do not require hospital admission for initialisation and are not associated with a Medical Benefits Schedule (MBS) item.[13]

However, insulin pumps for people with type 1 diabetes (T1D) are in effect a prosthetic because they replace the function of pancreatic cells which produce insulin and which are destroyed by an autoimmune process that induces T1D. For people with diabetes, particularly T1D, insulin pumps are an alternative method of insulin delivery which, as a number of studies have substantiated, offer improved glycaemic control and blood glucose stability.[14] Optimum glycaemic control is a clinical goal of diabetes management because of the relationship between poor glycaemic control and the greater risk of diabetes complications.[15]

Given that insulin pump wearers have to calculate insulin doses based on carbohydrate consumption and blood glucose levels and program the pump accordingly, change cannulas and monitor insertion sites, some may question, particularly in relation to young children, the Minister's assertion that: 'Pumps reduce the need for parental supervision in

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11. Ibid.

12. A gap payment may still apply.

13. Australian Government, *Report of the Review of the Prostheses Listing Arrangements*, [report prepared for the Minister for Health and Ageing by R Doyle], 2007, p. 21, viewed 15 October, 2009, http://www.health.gov.au/internet/main/publishing.nsf/Content/A397E63789AE5E5DCA25736B001D59C2/$File/Prostheses%20review%202007.pdf

14. Australian Healthcare Associates (AHA), *Final report: insulin pump review*, AHA, 2008, pp. 25–35, viewed 15 October 2009, http://dpl/Books/2009/AHA_InsulinPumpReview_Final_Report.pdf

15. For further information about diabetes and insulin pumps see: Australian Institute of Health and Welfare (AIHW), *Diabetes: Australian Facts 2008*, AIHW, Canberra, 2008, viewed 15 October 2009, http://www.aihw.gov.au/publications/cvd/daf08/daf08.pdf; and Australian Healthcare Associates, op. cit.

    Current National Diabetes Services Scheme (NDSS) statistics indicate 7938 people are using insulin pumps. Of the 908,837 people with diabetes, 126 128 have type 1 diabetes; 759 277 have type 2 diabetes; 18 095 have gestational diabetes; and the remainder are classified as 'other' or 'unknown'. As advised by the NDSS Team Leader, Diabetes Australia, 14 October 2009.

looking after a child with type 1 diabetes.'[16] A recent Australian insulin pump review highlights the parental management implications for children with T1D:

> In the case of toddlers, preschoolers and primary-school-aged children, the initiation of insulin pump therapy requires the child's parent(s) or caregivers to be committed to being the "pump user" and active participants in diabetes management … young children are cognitively unable to learn nor manipulate the pump functions, and cannot be relied upon to appropriately calculate and administer … doses independently.[17]

It should also be noted that while, as the Minister notes, improved lifestyle can be a benefit for insulin pump users, improved glycaemic control is the paramount goal.

Basis of policy commitment

The Government's Review of the Prostheses Listing Arrangements (2007) acknowledged the ongoing uncertainty surrounding devices such as insulin pumps which were listed on the Prostheses List, but do not meet the listing criteria. While the Review recommended that items not meeting the listing criteria be removed by December 2008—a recommendation accepted and since implemented by the Government[18]—it also suggested separate arrangements to ensure their private health insurance cover:

> There is also the matter of how to deal with high value devices such as replacement speech processors or insulin pumps which do not require hospital admission as part of the provision process and are not associated with an MBS item. Under current arrangements insurers are not required to pay benefits for products provided in these circumstances, even though the items are included on the List. As long as insurers take a sensible approach to paying benefits for these items I see no need to change current regulatory requirements. However, I note that if it proves necessary the Minister could establish arrangements to require insurers to pay benefits through an alternative mechanism, as it is clear that they do not meet the criteria to be a prosthesis. [19]

In relation to insulin pumps, the Bill's provisions complement other government measures, introduced by the current and previous governments, which support insulin pump usage.

16. N Roxon, op. cit.
17. Australian Healthcare Associates, op. cit., p. 24.
18. Prostheses and Devices Committee, *PDC Bulletin*, no. 26, October 2008, p. 3, viewed 15 October 2009, http://www.health.gov.au/internet/main/publishing.nsf/Content/80E1029BEC23CB4FCA2574F9007B85EC/$File/PDC%20Bulletin%2026%20-%20October%2008.pdf
19. *Report of the Review of the Prostheses Listing Arrangements*, op. cit.

In 2004, National Diabetes Services Scheme subsidies were introduced for insulin pump consumables.[20]

More recently, the 2008–09 Budget provided means-tested subsidies of up to $2500 towards the cost of insulin pumps for people under the age of 18 with T1D, where insulin pump therapy is deemed clinically necessary.[21] However, while this measure was welcomed by some stakeholders, there is a question about the adequacy of the subsidy. Those receiving the maximum subsidy of $2500 will need to pay at least that amount again for the most basic model of insulin pump. The low uptake figures would appear to substantiate the inadequacy of the subsidy. Departmental advice provided in response to a Senate Estimates question confirmed that the uptake has been 'lower than anticipated', with total expenditure of around $419 000 up to June 2009, well below the budget estimate of $1 million.[22] The scheme is also a limited one because it does not take into account other people who may have a clinical need for an insulin pump and need support, including young adults with T1D and women with gestational diabetes.

Financial implications

The Explanatory Memorandum states that the Bill has no financial impact.[23]

Main provisions

Schedule 1—Amendments

Item 1 proposes to amend paragraphs (c) and (d) of table item 4 in existing **subsection 72-1(2)** of the Act, in relation to the prosthesis benefit circumstances. **Proposed paragraph (c)** provides that a health insurance benefit would be payable if the prosthesis is provided in circumstances where a Medicare benefit is payable (the same as the current provision)

20. For further information, see the National Diabetes Services Scheme website, viewed 15 October 2009, http://www.ndss.com.au/en/ and its 'Insulin Pump Consumables' website, viewed 15 October 2009, http://www.ndss.com.au/Products--Outlets/Insulin-pump-consumables/

21. Australian Government, *Budget measures: budget paper no. 2: 2008–09*, Commonwealth of Australia, Canberra, 2008, p. 236. See also: Juvenile Diabetes Research Foundation (JDRF), 'Type 1 Diabetes Insulin Pump Program', JDRF website, viewed 15 October 2009, https://www.jdrf.org.au/pumps/

22. Senate Community Affairs Committee, 'Answers to Questions on Notice, Health and Ageing Portfolio, Budget Estimates 2009–10, 3 & 4 June 2009', Question nos. E09-138 and E09-304, viewed 13 October 2009, http://www.aph.gov.au/Senate/committee/clac_ctte/estimates/bud_0910/vol1_doha.pdf

23. Explanatory memorandum, op. cit., p. 2.

and if the Rules specify other conditions that are to be met, that these conditions are satisfied. **Proposed paragraph (d)** provides that a health insurance benefit may also be payable if the prosthesis is provided in circumstances (other than where a Medicare benefit is payable) set out in the Rules, and where the Rules set out conditions, those conditions are satisfied.[24]

Item 2 proposes to **insert new subsections 72-10(6)** and **(7)** into the Act, in relation to the listing of a prosthesis in the Rules. **Proposed subsection 72-10(6)** enables the Rules to specify the listing criteria that must be satisfied in order for an application to list a prosthesis to be granted. This proposed subsection also enables the Rules to provide for different listing criteria to apply in different circumstances. **Proposed subsection 72-10(7)** provides that the Minister would not be able to grant an application for listing if any applicable listing criteria is not satisfied. A **proposed note** to **proposed subsection 72-10(7)** clarifies that the Minister would have discretion to refuse to grant an application, even where the listing criteria are satisfied.

Concluding comments

To date, the proposed measures have not generated significant public commentary from stakeholders,[25] although the surety of private health insurance coverage will no doubt be welcomed by consumers.

However, while the proposed amendments would allow for the conditional listing of devices that do not meet the current criteria for the Prostheses List, the Minister notes that 'with further developments in medical technology there is likely to be a greater need for listing devices on a conditional basis in the future'.[26] In relation to insulin pumps, there is already another challenge with new insulin pumps incorporating continuous glucose monitoring devices. The costs of the transmitter components of these devices are reimbursed through ancillary health insurance by only some private health insurers; the sensor components are not covered nor are they eligible for any government subsidy.[27]

The challenge will be balancing access to these new technologies while containing costs for all stakeholders, including private health insurers and consumers.

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24. Circumstances other than where a Medicare benefit is payable include public hospital outpatient clinics, for example.

25. As at 15 October 2009.

26. N Roxon, op. cit.

27. Personal communication. For information about continuous glucose monitors, see Juvenile Diabetes Research Foundation (JDRF), ''CGMs improve control and reduce hypos', JDRF website, viewed 15 October 2009, http://jdrf.org.au/news/view/cgms-proven-to-improve-control-and-reduce-hypos

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