



Private Health Insurance (National Joint Replacement Register Levy) Bill 2009

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Private Health Insurance (National Joint Replacement Register Levy) Bill 2009

Date introduced: 28 May 2009

House: House of Representatives

Portfolio: Department of Health and Ageing

Commencement: Everything other than sections 3-9: on Royal Assent
Sections 3-9: the later of 1 July 2009 or on Royal Assent

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 purpose of the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009 (the Bill) is to establish the National Joint Replacement Register Levy (the levy) to fund the National Joint Replacement Registry (the Registry).¹

Background

The Australian Orthopaedic Association (AOA) established the Registry in 1999 to improve the results of joint replacement surgery in Australia through detailed information about joint replacement surgery. Another aim of the Registry is to reduce the number of redo operations. The Registry provides information about the types of joints available and surgical techniques. It also includes information about factors known to influence the outcome of joint replacement surgery such as the health concerns of the patient and their overall health status, the type of joint replacement used and the way the operation is conducted.

The Registry collects information on each joint replacement surgery in Australia, except in instances where the patient does not consent. The following details are collected; details of the patient, the reason for the surgery, which joint was replaced and the side of the

1. Explanatory Memorandum, Private Health Insurance (National Joint Replacement Register Levy) Bill 2009, p. 1.

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operation, type of joint replacement and all the individual components used in the operation.

The Registry also records information if a joint replacement is redone (known as a revision procedure). This procedure is recorded as it relates to the first (or primary) operation. This enables the Registry to determine how many of the initial primary procedures have been revised, the reason why it was redone, how long after the original surgery the revision occurred and which of the components (if any) was replaced.

As all hospitals which undertake joint surgery (around 300) in Australia participate in the Registry, comprehensive information about joint replacement surgery is collected. This allows for comparative analysis to be undertaken about types of surgery done and the joints that are replaced. The Registry does not recommend what is the best joint replacement for a particular patient.

The Registry has been funded by the Australian Government since its inception in 1999. Additional funding was granted in 2007 to expand the role of the Registry to collect information on other types of joint replacements such as shoulder, elbow, wrist, ankles and spinal disc.²

Basis of policy commitment

Although not expressly stated, it appears that the decision to cost recover expenditure associated with the Registry is consistent with the broader government agenda to cost recovery generally. Since its election, the government has also sought to introduce cost-recovery arrangements for consideration by the Pharmaceutical Benefits Advisory Committee (PBAC) for products to be listed on the Pharmaceutical Benefits Scheme (PBS).³

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2. T Abbott (Minister for Health and Ageing), *National Joint Replacement Registry – increased data collection*, media release, Budget 2007-08, viewed 11 June 2009, [http://www.health.gov.au/internet/budget/publishing.nsf/Content/4E7457965553B382CA2572D40029BDF6/\\$File/hfact48.pdf](http://www.health.gov.au/internet/budget/publishing.nsf/Content/4E7457965553B382CA2572D40029BDF6/$File/hfact48.pdf).
 3. See Rebecca de Boer, *National Health Amendment (Pharmaceutical and Other Benefits-Cost Recovery) Bill 2008*, Bills Digest, no. 125, 2007-2008, Parliamentary Library, Canberra, viewed 16 June 2009, <http://www.aph.gov.au/library/pubs/bd/2007-08/08bd125.pdf>; Rebecca de Boer, *National Health Amendment (Pharmaceutical and Other Benefits-Cost Recovery) Bill 2008 [No. 2]*, Bills Digest, no. 170, 2008-2009, Parliamentary Library, Canberra, viewed 16 June 2009, <http://www.aph.gov.au/library/pubs/bd/2008-09/09bd170.pdf>.

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This measure was introduced in the context of the 2009-10 Budget. The Budget papers note that Government has funded the Registry since 1998 and that it is considered 'appropriate' for 'significant stakeholders in this sector to meet the cost of the Registry'.⁴

In its submission to the Senate inquiry, the Department of Health and Ageing (DoHA) noted that the Registry effectively performs a post-marketing surveillance role which provides financial benefit to manufacturers of joint replacement prostheses as well as providing information about safety, quality and efficacy. The United Kingdom's National Joint Registry was provided in support of the proposal as it operates on a levy which is applied to all joint replacement products. It also argued that the levy was required to ensure stability of funding for the Registry.⁵

Committee consideration

The Bill has been referred to the Senate Standing Committee on Community Affairs (the Committee) for review. The report is due on 16 June 2009. The Committee conducted two public hearings that are discussed elsewhere in this Digest.

Position of significant interest groups

Although this measure has failed to generate significant media commentary, the submissions to the Senate inquiry indicated a wide range of views. Most stakeholders were opposed to the introduction of the levy. The AOA did not have 'specific comments' on the proposal, but noted that the introduction of the levy would have no impact 'on the continued independence, integrity and world-renowned quality of the NJRR'.⁶ The Australian Health Insurers Association (AHIA) was in favour of the proposal.

There were several recurring themes raised in the submissions and public hearings. The perceived lack of consultation about implementation and limited timeframes to respond to

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4. Australian Government, *Budget measures: budget paper no. 2:2009-10*, Commonwealth of Australia, Canberra, 2009, p. 298.
 5. Department of Health and Ageing (DoHA), Submission to the Senate Community Affairs Legislation Committee, Inquiry into the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009, 9 June 2009, viewed 12 June 2009, http://www.aph.gov.au/Senate/committee/clac_ctte/private_hth_nat_joint_replace_reg_09/submissions/sub18.pdf
 6. Australian Orthopaedic Association (AOA), Submission to the Senate Community Affairs Legislation Committee, Inquiry into the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009, 3 June 2009, viewed 12 June 2009, http://www.aph.gov.au/Senate/committee/clac_ctte/private_hth_nat_joint_replace_reg_09/submissions/sub01.pdf

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the inquiry were strongly criticised. Other stakeholders focused on the inequity of the arrangements, suggesting that the full cost of the levy should not be borne by the industry but other stakeholders (or beneficiaries) who should also contribute.⁷ Some considered it to be no more than a tax and another additional cost for the industry to bear (especially for sponsors with products listed on the Prostheses List, which is also subject to cost recovery arrangements).⁸ It was suggested that this may result in low volume products being withdrawn from the Australian market with significant implications for patient access.⁹ There was also concern that this Registry would serve as a model for future registries and that further consultation was required to ensure the best possible approach.¹⁰

Another issue raised in the submissions was the appropriateness of cost recovery arrangements for an outcome that could essentially be considered a 'public good'.¹¹ The information provided by the Registry ultimately offers significant benefits to patients (and clinicians) as it provides information about safety, quality and efficacy of joint replacement procedures. It also provides benefits to government, taxpayers and insurers as it may reduce overall health expenditure.

Although there was much commentary about the imposition of additional cost to the industry, only one submission considered the appropriateness of the levy amount. Medtronic argued that 99% of the Registry (around 9,000 items) attracted a benefit of less than \$8,000, rather than the \$67,000 that was quoted in the Explanatory Memorandum.¹² Other submissions also suggested that the levy should be applied by volume rather than listing, so companies with several low volume products on the Registry are not penalised and do not ultimately withdraw products from the Australian market.¹³

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7. This was a dominant theme of the submissions. See, for example, [submissions](#) from Smith & Nephew, Medical Technology Australia Association (MTAA), Advanced Surgical Therapies, Austofix, Global Orthopaedic Technology and Medtronics.
 8. See, for example, [submissions](#) from St Jude Healthcare, Smith & Nephew, Stryker, MTAA, Advanced Surgical Therapies and Zimmer.
 9. See, for example, submissions from Boston-Scientific, Medtronics, Global Orthopaedic Technology, LifeHealthCare and Advanced Surgical Therapies.
 10. See, for example, [submissions](#) from Johnson & Johnson, Boston Scientific, Medtronics, MTAA.
 11. See, for examples, [submissions](#) from LifeHealthCare, St Jude Healthcare, Zimmer and Catholic Healthcare Australia.
 12. Medtronic, *Submission to the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009*, submitted 5 June 2009, viewed 12 June 2009, http://www.aph.gov.au/Senate/committee/clac_ctte/private_hth_nat_joint_replace_reg_09/submissions/sub13.pdf
 13. See, for example, Global Orthopaedic Technology, Submission to the Senate Community Affairs Legislation Committee, Inquiry into the Private Health Insurance (National Joint

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Financial implications

According to the Government, the Bill will result in estimated budget savings of \$5 million dollars over four years.¹⁴

Main provisions

Clause 5 contains definitions of terms used in the Bill.

Importantly, under **subclause 5(2)**, a *sponsor* of a joint replacement prosthesis is defined as:

(a) a joint replacement prosthesis is currently listed in the Private Health Insurance (Prostheses) Rules as a result of an application made by the person under subsection 72-10(2) of the *Private Health Insurance Act 2007*; or (b) if a joint replacement prosthesis is currently listed in the Private Health Insurance (Prostheses) Rules in accordance with section 12 of the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007*—the person was, immediately before the commencement of the *Private Health Insurance Act 2007*, the sponsor of that prosthesis for the purposes of the *National Health Act 1953*.

In addition, *joint replacement prosthesis* is defined in **subclause 5(1)** as a prosthesis listed in the Private Health Insurance (National Joint Replacement Register Levy) Rules (the Rules), and used in joint replacement.

Clause 6 of the Bill provides for the imposition of the levy.

Subclause 6(1) provides that the levy will be imposed on each sponsor for joint replacement prostheses on days specified:

- in the Rules, and
- by the Minister, by legislative instrument,¹⁵ as a supplementary levy,

during each financial year.

Subclauses 6(2) and **(3)** have the effect that the levy and supplementary levy would not be imposed on more than four and two occasions respectively in each financial year.

Replacement Register Levy) Bill 2009, 5 June 2009, viewed 12 June 2009,
http://www.aph.gov.au/Senate/committee/clac_ctte/private_hth_nat_joint_replace_reg_09/submissions/sub12.pdf

14. Explanatory Memorandum, p. 2.

15. Therefore, it is subject to parliamentary scrutiny: see *Legislative Instruments Act 2003* Part 5.

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Under **clause 7**, the rate of the levy imposed on a particular day will be specified in the Rules, while the supplementary levy rate for a particular day will be determined by the Minister, also by legislative instrument, both of which would apply on that specific day.

Subclause 7(2) provides that the rate of the levies must be based on the number of joint replacement prostheses sponsored as follows:

- the levy—the census day as specified in the Rules, and
- the supplementary levy—the census day as the Minister determines by legislative instrument.

In addition, the rate of levies may differ depending on the type of joint replacement prosthesis sponsored, ranging from \$0 (for one or more types of prostheses) to not more than \$5000 (for sponsorship of any one prosthesis).

Clause 8 empowers the Minister to make the Rules.

Clause 9 contains a standard regulation making power.

Please note that these proposed amendments should be considered together with amendments proposed in relation to the levy in the Private Health Insurance Legislation Amendment Bill 2009 (the PHI Bill).¹⁶ The PHI Bill was introduced by the Government on 3 June 2009. According to the Government, the amendments proposed in the PHI Bill are consequential to the amendments proposed in this Bill, allowing for the administration of the levy.¹⁷

Concluding comments

The joint replacement prostheses industry has expressed significant concern about implementation of this measure, particularly in relation to equity, stakeholder consultation, and access to low volume products. This proposal also raises questions about the appropriateness of cost recovery arrangements for government procurement process and processes (such as Registries) that offer a ‘public good’. These questions have not been sufficiently addressed in the Explanatory Memorandum and the submission to the inquiry by DoHA.

16. See [Private Health Insurance Legislation Amendment Bill 2009 items 4-10](#) and **14**.

17. [Explanatory Memorandum](#), Private Health Insurance Legislation Amendment Bill 2009, p. 2.

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