DEPARTMENT OF HEALTH AND AGEING

SUBMISSION TO THE SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE

PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER) LEVY BILL 2009

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1. OVERVIEW OF THE BILL

1.1 Introduction

1.1.1 The Private Health Insurance (National Joint Replacement Register Levy) Bill 2009 (the Bill) will impose a levy on joint replacement prostheses sponsors in order to fund the National Joint Replacement Registry (NJRR). The NJRR collects information about joint replacement surgeries, such as hip, knee, ankle, shoulder, wrist and spinal disc replacement procedures, and reports on the safety and quality of these surgeries and devices used in the surgeries, to ensure patients get the best outcomes.

1.2 Purpose and limits of the Bill (Clauses 1 to 4)

1.2.1 The Bill, on enactment, will be cited as the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*. Other than Sections 1 and 2, which commence on the day the Bill receives Royal Assent, the Bill commences on the later of 1 July 2009 or the date of Royal Assent.

1.2.2 The Bill binds the Crown in each of its capacities, including the executive governments of the Commonwealth, States and Territories, and its application extends to include the Territory of Cocos (Keeling) Islands and to the Territory of Christmas Island.

1.3 Definitions (Clause 5)

1.3.1 The definitions for the Bill establish who is a sponsor, what is a joint replacement prosthesis, the meaning of national joint replacement levy, national joint replacement levy days and supplementary national joint replacement levy days and the Rules – the Private Health Insurance (National Joint Replacement Register Levy) Rules (the Rules) and Private Health Insurance (Prostheses) Rules (the Prostheses Rules) – that are relevant to the new Act.

1.3.2 A person is a *sponsor* for joint replacement prostheses if a joint replacement prosthesis is currently listed in the Prostheses Rules (commonly referred to as the Commonwealth Prostheses List) either as a result of an application made by the person under subsection 72-10(2) of the *Private Health Insurance Act 2007*, or is listed in accordance with section 12 of the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007* and the person was the sponsor of that prosthesis for the purposes of the *National Health Act 1953*.

1.3.3 A *joint replacement prosthesis* is a prosthesis that is listed on the Commonwealth Prosthesis List (the List) and is used in joint replacement.

1.4 National joint replacement register levy (Clauses 6 and 7)

1.4.1 The national joint replacement register levy is imposed on each sponsor of joint replacement prostheses.

1.4.2 The levy is imposed on each day specified in the Private Health Insurance (National Joint Replacement Register Levy) Rules (the Rules) as a national joint replacement register

levy day for a financial year (a maximum of four days per year). Additionally, the Minister may impose one or two further levy days (supplementary national joint replacement register levy days), by legislative instrument, as a supplementary national joint replacement register levy day for a financial year. The levy can therefore be imposed a maximum of six times per financial year.

1.4.3 The rate of levy imposed on a national joint replacement register levy day is the rate specified in the Rules and applies on that day. The rate of levy imposed on a supplementary national joint replacement register levy day is the rate that is determined by the Minister and applies on that day.

1.4.4 The rate must be based on the number of joint replacement prostheses that each sponsor has listed on the Commonwealth Prostheses List on the national joint replacement register census day or supplementary national joint replacement register census day. The rate may differ for the different kinds of joint replacement prostheses sponsored. The rate may be set at zero for one or more kinds of joint replacement prostheses, and the maximum rate must not exceed $5,000.00 for a financial year with respect to any one joint replacement prosthesis sponsored.

1.5 Rules and regulations (Clauses 8 and 9)

1.5.1 This Bill enables the Minister to make Private Health Insurance (National Joint Replacement Register Levy) Rules providing for matters required or permitted by the Bill to be provided, or necessary or convenient to be provided in order to carry out or give effect to the Bill. As described in clause 5, the Rules may provide that one or more kinds of prostheses are taken, or are taken not, to be joint replacement prostheses for the purposes of the definition of *joint replacement prosthesis*.

1.5.2 The Bill also provides that the Governor-General may make regulations prescribing matters required or permitted by the Bill to be prescribed, or necessary or convenient to be prescribed in order to carry out or give effect to the Bill.

2. WHAT IS THE NATIONAL JOINT REPLACEMENT REGISTRY?

2.1 The National Joint Replacement Register

2.1.1 The NJRR collects data on the implantation of prosthetic joint replacement devices and reports revision rates, complications and other outcomes for joint replacement surgery. The NJRR also monitors mortality rates for the NJRR. The information collected provides an accurate measure of the success or otherwise of a procedure. This information is then used to inform surgeons, other health care professionals, governments, sponsors of joint replacement products and the community.

2.1.2 Every hospital in Australia (both public and private) that undertakes joint replacement surgery contributes data to the NJRR. An Information Data Collection document outlining the NJRR and its data collection processes was provided to each hospital. The document was prepared in a manner to allow hospital administrations the choice of presenting the document to an ethics, quality assurance or medical advisory committee. Once approval was granted, procedures were implemented to begin data collection. Each hospital nominates a hospital coordinator (usually a member of theatre nursing staff) to liaise with Registry staff and be responsible for coordinating the completion and submission of data forms to the Registry.

2.1.3 Implementation of the NJRR commenced in nine South Australian hospitals in September 1999. Since that time all hospitals in Australia that undertake joint replacement procedures have agreed to submit data. Currently the NRR receives information on over 6000 procedures per month from almost 300 hospitals.

2.1.4 In addition to the data collection, the NJRR has published a number of reports; for example a report on the demographics of shoulder, elbow, wrist, ankle and spinal disc arthroplasty published in October 2008. The NJRR reports can be found at http://www.dmac.adelaide.edu.au/aoanjrr/publications.jsp

2.2 Joint replacement surgery

2.2.1 Joint replacement surgery is a commonly performed major operation. The rate of joint replacement surgery has continued to increase each year, for many years, and is expected to do so in the future. This is due to improvements in prosthetic devices, the availability of new prostheses, and advancements in medical technology and surgical techniques. Additionally, the combination of an ageing population and a more active lifestyle has lead to an increased need or demand for joint replacement surgery. The Australian Bureau of Statistics reported that the proportion of Australians participating in sporting and recreational activities increased from 62% in 2002 to 66% in 2006. Currently about 70,000 hip and knee replacements are undertaken each year in Australia.

2.2.2 The increased frequency of joint replacement surgery and the lack of knowledge in relation to outcomes were recognised by the Australian Orthopaedic Association (AOA). Prior to the establishment of the NJRR, it was unclear which people were receiving joint replacement surgery, how frequently the surgery was occurring, what types of prostheses were being used or what techniques were being used to implement them. The purpose of the NJRR continues to be to define, improve and maintain the quality of care of patients receiving joint replacement surgery.

3. BENEFITS OF NJRR DATA COLLECTION

3.1 Surgical benefits

3.1.1 Since the NJRR's establishment, the AOA has found that the ability to identify factors important in achieving successful surgical outcomes has resulted in both improved standards and considerable cost savings. The NJRR estimates that the information it has provided has improved surgical practice and changed the use of particular devices, reducing the number of unnecessary revision surgeries by 1,200 Australians per year and saving the health sector and consumers around $44.6 million. (*NJRR Presentation, Nordic Orthopaedic Federation, 10 – 13 June 2008, Amsterdam – Outcomes of Revision Arthoplasty, Graves SE.*) These estimates are based on an analysis of the reductions in the proportion of hip and knee procedures that are revisions during the period of operation of the NJRR.

3.1.2 The average costs for revision procedures are much higher than for standard joint replacements, and the Registry helps in minimising revisions by collecting data indicating which devices are linked to higher revision rates. This assists orthopaedic surgeons in selecting better performing prostheses.

3.1.3 Around 70,000 Australians had joint replacement surgery in the last 12 months. Expenditure on hip and knee prostheses represents around 30% of total expenditure by health insurers on prostheses. Insurers paid $1.039 billion in benefits for prostheses in 2007-08, out of a total $7.4 billion spent on hospital benefits in that year. This means that prostheses expenditure represents around 15% of privately insured hospital benefit outlays.

3.1.4 The NJRR assists in ensuring this funding, and public hospital expenditure, is directed to better performing products with lower revision rates.

3.2 Industry benefits

3.2.1 Suppliers of joint replacement prostheses derive considerable direct financial benefit from the information obtained and reported on by the NJRR, as this forms part of the post-market surveillance of joint replacement prostheses. This monitoring of the safety and quality of devices provides considerable benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices. Any devices showing high failure rates can be identified quickly and promptly removed from the market.

3.2.2 The data produced by the NJRR also assists the industry by informing the development of new prostheses, allowing manufacturers to draw on reliable performance information for existing products and designs.

4. FUNDING ARRANGEMENTS AND IMPLEMENTATION OF THE LEVY

4.1 Funding arrangements

4.1.1 In 1998 the Government agreed to fund the AOA to maintain the NJRR and has continued to fund it since, through annual funding agreements. Each year funding for the NJRR has depended on whether sufficient resources could be identified from within departmental funding allocations.

4.1.2 It is vital that the NJRR continues to have a stable source of ongoing funding. Taxpayers have met the operating costs of the NJRR for over ten years, which are now around $1.6 million a year.

4.1.3 As noted in Chapter 1, the Bill will impose a levy on joint replacement prostheses sponsors in order to fund the NJRR. A joint replacement prosthesis is a prosthesis that is listed on the Commonwealth Prostheses List (the List) and which is used in joint replacement surgery. The List is contained in the schedule to the Private Health Insurance (Prostheses) Rules 2009. A person is a joint replacement prostheses sponsor if a joint replacement prostheses is currently on the List as a result of an application made by the person.

4.1.4 The List provides mandatory benefits that must be paid by private health insurers to policy holders for prosthetic devices on the list. The List is maintained by the Department of Health and Ageing (the Department) and is updated every February and August.

4.1.5 The Private Health Insurance Legislation Amendment Bill 2009 (the PHILA Bill) contains consequential amendments to the *Private Health Insurance Act 2009* (the PHI Act) concerning the imposition of the levy. These consequential amendments have the effect of making the levy a private health insurance levy under the PHI Act.

4.1.6 The amendments in the PHILA Bill also have the effect that the levy is a debt due to the Commonwealth, and that late payment may be subject to a late payment penalty. The Minister will have the power to waive all or part of the late payment penalty where the Minister considers there are good reasons for doing so.

4.1.7 It is appropriate that manufacturers and importers of medical devices used in joint replacement surgery now fund the costs of the NJRR. The new cost recovery arrangements will be similar to the funding arrangements for the United Kingdom's National Joint Registry, which is funded through a levy on joint replacement products.

4.1.8 As noted in Chapter 2, while there are other stakeholders who benefit from the data supplied by the NJRR, suppliers derive considerable direct financial benefit, as this forms part of their post-market surveillance of joint replacement prostheses. This monitoring of the safety and quality of devices provides benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices. Any devices showing high failure rates can be identified quickly and promptly removed from the market.

4.1.9 The data produced by the NJRR also assists the industry by informing the development of new prostheses, allowing manufacturers to draw on reliable performance information for

existing products and designs.

4.1.10 The introduction of cost recovery arrangements will produce $5 million in budget savings over four years. Legislated cost recovery arrangements will ensure the continuing independence of the NJRR from industry as the levy will be mandatory and collected by the Government to fund the NJRR.

4.1.11 The additional costs will not be able to be automatically passed on by device sponsors to private health insurers (resulting in increased premiums) because the benefits that private health insurers must pay for particular devices are set under Commonwealth legislation.

4.1.12 Any increase in benefits for joint replacement products will need to be negotiated between sponsors and insurers and then approved by the Government through changes to the Prostheses List.

4.2 Imposition of the levy

4.2.1 The Bill enables a levy to be imposed in two ways and imposes a maximum of six days in any financial year on which a levy can be imposed.

4.2.2 Sponsors will be levied according to the number of joint replacement prostheses they sponsor on the relevant levy day.

4.2.3 Firstly, sponsors will be levied on each day specified in the Rules, as a national joint replacement register levy day. A maximum of four levy days per financial year are permitted by this method. The levy rate for this method will also be specified in the Rules.

4.2.4 Secondly, the Minister can determine, by legislative instrument, to have supplementary levy days in each financial year. A maximum of two supplementary levy days per financial year are permitted. The rate for the supplementary levy will be determined as part of the legislative instrument.

4.2.5 Currently there are approximately 30 joint replacement sponsors, but this number will change over time as new products are included on the List and older products are withdrawn.

4.2.6 The Bill allows for a single levy to be set for each levy day, or for different levy rates for different kinds of joint replacement prostheses. The Bill also allows for the levy for some or all items to be set at zero, and it prescribes a maximum levy amount of $5,000.00. The maximum rate of levy for each joint replacement prostheses over the financial year has been set to cover increasing costs in the longer term.

4.2.7 If all sponsors are levied an equal amount, the levy will be around $600.00 - $650.00 per listing per year. However, as the Prostheses List benefit range for joint replacement devices is from around $50.00 to $67,000.00 per item, the Government is considering setting a range of levies to reflect different benefit ranges. The Department is consulting with the industry on the benefit ranges for the levy.

4.2.8 Given the wide range of prosthetic devices used in joint replacement surgery and the corresponding variation in benefits for different kinds of joint replacement prostheses, a maximum rate of levy of $5,000.00 is considered reasonable.

5. SUMMARY AND CONCLUSION

5.1 Overview of the NJRR

5.1.1 The NJRR collects information about joint replacement surgeries, such as hip, knee, ankle, shoulder, wrist and spinal disc replacement procedures, and reports on the safety and quality of these procedures and devices used in the operations.

5.1.2 The work of the NJRR is critical to improving health outcomes for many Australians. Around 70,000 people had joint replacement surgery in the last 12 months. The NJRR estimates that the information it has provided has improved surgical practice, reducing the number of unnecessary revision surgeries by 1,200 procedures per year.

5.1.3 In addition to improved patient outcomes, the NJRR estimates that it has saved the health sector and consumers around $44.6 million, based on reductions in the level of hip and knee revision procedures while the NJRR has been operating.

5.1.4 The average costs for revision procedures are much higher than for standard joint replacements, and the NJRR helps in minimising revisions by collecting data indicating which devices are linked to higher revision rates. This assists orthopaedic surgeons in selecting better performing prostheses.

5.1.5 Expenditure on hip and knee prostheses represents around 30% of total expenditure by health insurers on prostheses. Insurers paid over $1 billion in benefits for prostheses in 2007-08, out of a total 7.4 billion spent on hospital benefits in that year. This means that prostheses expenditure represents around 15% of privately insured hospital benefit outlays.

5.1.6 The NJRR assists in ensuring this funding, and public hospital expenditure, is directed to better performing products with lower revision rates.

5.2 Overview of the Bill

5.2.1 The Private Health Insurance (National Joint Replacement Register Levy) Bill 2009 will impose a levy on joint replacement prostheses sponsors in order to fund the NJRR.

5.2.2 Taxpayers have met the operating costs of the NJRR for over ten years, which are now around $1.6 million a year.

5.2.3 It is appropriate that manufacturers and importers of medical devices used in joint replacement surgery now fund the costs of the NJRR. The new cost recovery arrangements will be similar to the funding arrangements for the United Kingdom's National Joint Replacement Registry, which is funded through a levy on joint replacement products.

5.2.4 The NJRR provides invaluable post-market surveillance of joint replacement prostheses, and this monitoring of the safety and quality of devices provides considerable benefit to the industry by improving consumer confidence in the safety and efficacy of joint replacement devices. Any devices showing high failure rates can be identified quickly and promptly removed from the market.

5.2.5 The data produced by the NJRR also assists the industry by informing the development of new prostheses, allowing manufacturers to draw on reliable performance information for existing products and designs.

5.3 Benefits of the Bill

5.3.1 The Bill introduces cost recovery arrangements that will also produce $5 million in budget savings over four years.

5.3.2 Legislated cost recovery arrangements will ensure continuing and stable funding for the critical work of the NJRR, and ensure that it can continue to provide data to improve patient outcomes.

5.3.3 The proposed arrangement will preserve the independence of the NJRR. As levies will be imposed under legislation, and collected by the Government on behalf of the NJRR, there will be no possibility of funding being withdrawn from the NJRR by medical devices sponsors who are not happy with its findings.

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