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THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

PRIVATE HEALTH INSURANCE LEGISLATION AMENDMENT (MEDICAL DEVICE AND HUMAN TISSUE PRODUCT LIST AND COST RECOVERY) BILL 2022

PRIVATE HEALTH INSURANCE (PROSTHESES APPLICATION AND LISTING FEES) AMENDMENT (COST RECOVERY) BILL 2022

PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) AMENDMENT (CONSEQUENTIAL AMENDMENTS) BILL 2022

EXPLANATORY MEMORANDUM
For the Purposes of Exposure Draft Consultation

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OUTLINE

The package of three Bills supports the implementation of the 2021-22 Budget measure, *Modernising and Improving the Private Health Insurance Prostheses List*. This package of Bills is the first tranche of legislative changes to implement this Budget measure. It is anticipated that further tranches of legislative changes and administrative changes will be required to fully implement the Budget measure.

The Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022 (the PHI Bill)

The *Private Health Insurance Act 2007* (**PHI Act**) provides for rules (and a schedule to these rules, known as the Prostheses List) to specify the minimum and maximum benefits that private health insurers are required to pay for items that are included in the Prostheses List.

The Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022 (**PHI Bill**) amends the PHI Act to better define the products that may be eligible for inclusion on the list. The PHI Bill amends the PHI Act to include definitions of medical device and human tissue product that are aligned (where relevant) to the *Therapeutic Goods Act 1989*. The practical effect of these amendments is to clarify that set benefits are only payable for medical devices or human tissue products that meet these definitions (in addition to other criteria which will be set out in the updated legislative instrument).

The measures in the PHI Bill are expected to create an environment that will assist in reducing the prices paid by insurers. This will, in turn, put downward pressure on private health insurance premiums and improve the affordability and attractiveness of private health insurance for consumers.

The PHI Bill also renames the current Private Health Insurance (Prostheses) Rules (current Rules), made under the PHI Act, to the Private Health Insurance (Medical Devices and Human Tissue Products) Rules (renamed Rules) to better reflect its purposes and the types of products eligible for inclusion. It is intended that the renamed Rules will include a schedule to be known as the Prescribed List of Benefits for Medical Devices and Human Tissue Products (Prescribed List) (**PL**).

The PHI Bill also updates the cost recovery arrangements authorised by both the PHI Act and the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* (**PHI Fees Act**). This includes providing for a statutory authority for the Minister for Health and Aged Care to establish fee for service cost recovery arrangements consistent with the Australian Government Charging Framework (**AGC Framework**).

The new cost recovery provisions established by the PHI Bill will include the following:

- The PHI Act will be amended to permit rules which impose fees for activities performed by the Department in relation to listing goods on the PL
- Provide for items to be removed from the PL, and for the Department to cease providing services, where fees or the levy remain unpaid
- Provide for late payment penalty and waivers in relation to fees and levy, and
- Authorise the rules to provide for other matters in relation to fees and levy.

The PHI Bill also amends the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007* to reflect the changes made to the PHI Act that are consequential to the PHI Bill and PHI Fees Bill.

The Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022 (PHI Fees Bill)

The Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022 (**PHI Fees Bill**) amends the PHI Fees Act to rename the Act and update the cost recovery arrangements enabled under this Act.

This Bill provides for the imposition of a cost recovery levy on each kind of medical device and human tissue product on the PL. The amount of the levy will be set by the regulations. The Bill will further authorise the regulations and rules to provide for matters in relation to the levy. The existing application and listing fees will be repealed.

This Bill also renames the legislative instrument that may be made under the PHI Fees Act so it is consistent with the new name of the relevant legislative instrument that may be made under the PHI Act for medical devices and human tissue products.

These cost recovery arrangements are consistent with the AGC Framework.

The Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022 (PHI NJRR Bill)

The Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022 (**PHI NJRR Bill**) amends the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009* (**PHI NJRR Act**) to reflect the renamed Private Health Insurance (Medical Devices and Human Tissue Products) Rules that will made under the PHI Act. This Bill also addresses an incorrect reference in the PHI NJRR Act.

Background

Current Legislation

The PHI Act regulates private health insurance products in Australia. Subsection 333-20(1) of the PHI Act allows for the Minister to make, by legislative instrument, the Private Health Insurance (Prostheses) Rules (current Rules). The Schedule to the current Rules is referred to as the Prostheses List.

Division 72 of the PHI Act provides for the current Rules (and the Prostheses List) to specify the minimum and maximum benefits that private health insurers are required to pay for items that are included in the Prostheses List. These benefits are paid to a hospital when the items included on the Prostheses List are provided to someone with appropriate private health insurance as part of hospital or hospital substitute treatment. These benefits apply where there is a Medicare benefit payable for a service associated with the use of the item.

The PHI Fees Act imposes application fees and listing fees that are a tax, as well as who is liable to pay these fees and when.

The PHI NJRR Act imposes the national joint replacement register levy and provides for the rate of this levy, as well as who is liable to pay this levy.

Prostheses List

In the context of the Prostheses List, the term 'benefit' means the reimbursement to health consumers when they receive treatment. The benefit shown on the Prostheses List is the amount payable by private health insurers for the prosthesis. The Medicare benefit is the amount payable by Medicare for the professional service associated with the provision of the prosthesis and this benefit is independent of the benefits specified in the Prostheses List.

Despite the 'Prostheses List' name, the list does not include devices or products such as external limb prosthetics, external breast prostheses or implants used solely for cosmetic purposes.

Listing on the Prostheses List

Medical device sponsors and suppliers (collectively referred to as 'sponsors') may voluntarily apply to include items on the Prostheses List (known as 'listing') along with the minimum benefit that would be payable by private health insurers for that item. If an application for an item is granted and the relevant fees are paid then the Rules must be varied or remade to list the item when the Rules are next varied or remade. The Prostheses List is then updated to reflect the inclusion of newly listed items. The Rules are remade or varied three times a year.

Policy Issues

Scope of the Prostheses List

Increasing medical costs, increasing utilisation of health services (particularly by older people and people with chronic disease) and declining participation rates (particularly by younger Australians) is challenging the affordability and long-term sustainability of the private health insurance sector.

The cost of products on the Prostheses List has been identified as a factor in the rising price of private health insurance premiums for consumers. It is agreed by all stakeholders that prices paid in the public hospital sector in Australia are, on average, lower than private hospital prices and the benefits paid by insurers.

The current scope of the Prostheses List lacks specificity, meaning there are no distinct or legislated limits on what is included in the Prostheses List. The lack of a legislated definition of a 'prosthesis' (to be remedied by the inclusion of definitions of medical device and human tissue product) can potentially result in items being listed which could be better funded by other avenues or are already funded through other means ('double funded'). The ambiguous scope of the Prostheses List has also led to an increase in complexity. Since 1997, the number of items on the Prostheses List has expanded nearly tenfold. In 2021, there are over 11,600 billing codes and over 1,700 unique groupings.

Fees and Charges

The functions associated with assessing and administering Prostheses List applications are cost-recovered activities. Charges for these activities have remained largely the same since they were introduced in 2007.

The current arrangements are not consistent with the AGC Framework, as the charges do not reflect the minimum efficient costs of delivering the Government services. These existing charges do not reflect the levels of effort, cost, and complexity of current activities such as administration and evaluation associated with the Prostheses List.

Reforms

In the 2021-22 Federal Budget, the Australian Government committed $22 million over four years for the *Modernising and Improving the Private Health Insurance Prostheses List*. These reforms will be given effect through a range of legislative changes and administrative changes. The legislative changes include:

- changes to primary legislation, and
- new or varied legislative instruments (regulations and rules).

It is anticipated that the majority of the reforms will be given effect through new or varied legislative instruments.

The reforms include initiatives to realise savings for insurers, and ultimately consumers, as well as structural reforms to better focus government regulated prices on high cost and innovative medical devices.

Overall, the legislative and administrative changes for the reforms will:

- modernise and improve the Prostheses List
- better align the prices set for medical devices on the Prostheses List for private providers with those paid for devices in the public hospital system
- continue to guarantee that insurers will pay a set benefit for each relevant medical device or human tissue product to ensure that patients continue to have access to safe, clinically effective and cost-effective devices and products
- preserve clinician and patient choice in the private health system
- narrow the gap between benefits payable under the PHI Act and public sector prices
- give the private healthcare sector and medical technology industry a sustainable and predictable environment, and
- support innovation.

Consultation

The measures in the Bills have been developed following extensive consultation. Consultation has included two legislative reform specific consultation papers, a series of webinars, as well as consultation dealing with other related key reform themes.

Following consultation, the measures in the Bills have been refined and, the definitions of ‘medical device and ‘human tissue product’ were amended to include flexibility in their scope to allow for exceptional circumstances and innovative new kinds of devices and products.

PRIVATE HEALTH INSURANCE LEGISLATION AMENDMENT (MEDICAL DEVICE AND HUMAN TISSUE PRODUCT LIST AND COST RECOVERY) BILL 2022

Section 1 – Short Title
Section 1 provides for the short title of the Act to be the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2022*.

Section 2 – Commencement
Section 2 sets out when the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill commences. Sections 1 and 3 commence on the day the Act receives the Royal Assent. Schedules 1 and 2 commence on a day to be fixed by Proclamation. This delayed commencement provides for the orderly introduction of the new requirements, including the making of relevant legislative instruments. However, if a proclamation is not made within 6 months from the day of Royal Assent, then the provisions in Schedules 1 and 2 commence the day after that 6 month period.

Section 3 – Schedule(s)
Section 3 provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms. This is a technical provision which gives operational effect to the amendments contained in the Schedules. Schedule 1 amends the PHI Act and the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007*. Schedule 2 amends the PHI Act.

SCHEDULE 1 — PRIVATE HEALTH INSURANCE ACT 2007 and PRIVATE HEALTH INSURANCE (TRANSITIONAL PROVISIONS AND CONSEQUENTIAL AMENDMENTS) ACT 2007

Amendments in this schedule amend the PHI Act and the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007* to better define the products that may be eligible for inclusion on the list. The PHI Bill includes definitions of medical devices and human tissue products that are aligned (where relevant) to the *Therapeutic Goods Act 1989*. The practical effect of these amendments is to clarify that set benefits are only payable for medical devices or human tissue products that meet the definitions (in addition to other criteria which will be set out in the legislative instrument) (see items 2 and 3 and definitions inserted in item 17).

The PHI Bill also renames the relevant legislative instrument that may be made under the PHI Act to reflect its purposes and the types of products eligible for inclusion in the legislative instrument (see item 18). The name of this renamed legislative instrument is the 'Private Health Insurance (Medical Devices and Human Tissue Products) Rules'.

Item 1 and items 8 to 16
These items are consequential amendments to the PHI Act to reflect the new name of the legislative instrument that may be made for medical devices and human tissue products (see item 18).

Items 2 and 3 – Subsection 72-1(2) (table item 4, column headed "There must be a benefit for…")
Items 2 and 3 amend the requirements that a complying insurance policy (that covers hospital treatment) must meet in relation to benefit requirements under Part 3-3 of Chapter 3 of the PHI Act. These insurance policy requirements relate to where there must be a set benefit (minimum

benefit and if relevant, the maximum benefit) for treatment involving medical devices or human tissue products.

Items 2 and 3 amend item 4 in the table to subsection 72-1(2) to omit references to 'prothesis', replace them with 'medical device' and 'human tissue product', and refer to a renamed legislative instrument. Together with the definitions of 'medical device' and 'human tissue products' (see item 17), the effect of these amendments is to clarify that set benefits are only payable for medical devices or human tissue products (as defined). The amendments make it clear that the set benefits apply only to these specific devices and products that are defined.

The amendments mean that minimum benefits (and if relevant, maximum benefits) continue to apply for the kinds of medical devices or human tissue products in the new Private Health Insurance (Medical Devices and Human Tissue Products) Rules. These benefits apply where the device or tissue product is provided as part of hospital treatment or hospital substitute treatment covered under the policy in circumstances in which a Medicare benefit is payable or in circumstances set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

The amendments in item 3 continue to provide that any relevant conditions in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules must be satisfied for the benefit to be payable in relation to the provision of medical devices or human tissue products.

Items 4, 5 6 and 7 – Subsection 72-1(2) (table item 4, column headed "The amount of the benefit must be…")

Items 4 to 7 also amend item 4 in the table to subsection 72-1(2) to omit references to 'prothesis' and replace them with 'medical device' and 'human tissue product', and to refer to the renamed legislative instrument. These amendments do not affect the amount of the benefit. The benefit payable must continue to be at least the amount set out in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules and no more than the maximum amount (if any) set out in those rules. The amendments align the provisions for benefit amounts with the kinds of devices and products for which benefits may apply (see items 2 and 3).

Item 17 – Sections 72-11 and 72-12

Item 17 inserts new sections 72-11 and 72-12 in the PHI Act to define a 'medical device' and 'human tissue product' for the purposes of the PHI Act.

Together with amending items 2 and 3, the practical effect of the definitions of 'medical device' and 'human tissue product' is to limit the kinds of medical devices and human tissue products to the medical devices or human tissue products that meet these definitions (in addition to other criteria which will be set out in the legislative instrument). It is these devices and products for which benefits are payable by private health insurers.

Item 18 – Subsection 333-20(1) (table item 4)

Item 18 amends the name of the legislative instrument that may be made for medical devices and human tissue products. The new name reflects the kinds of medical devices and human tissue products that would be included in the legislative instrument and that prescribes the payable benefits.

Items 19 to 20

These items are consequential amendments to the PHI Act to reflect the new name of the legislative instrument that may be made for medical devices and human tissue products (see item 18).

Items 21 to 23
These items amend the *Private Health Insurance (Transitional Provisions and Consequential Amendments) Act 2007*. This amendment continues to provide that prostheses under the pre-2007 scheme may be listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules after commencement of the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill, without anyone needing to apply.

Item 24 – Applications made before commencement
Item 24 provides that applications made under subsection 72-10(2) before commencement but not decided by commencement can be dealt with after commencement on the basis of the Act as amended. An application made before commencement meets the requirement in paragraph 72 10(1)(a). If rules in relation to cost recovery fees or cost recovery levy make the person who made an application under subsection 72-10(2) liable for a fee or levy, that would include the person who made an application before the commencement time. This will allow for an orderly transition to the requirements in the new legislation.

Item 25 – Private health insurance arrangement
Item 25 is a savings provision for the definition of a private health insurance arrangement.

SCHEDULE 2 — PRIVATE HEALTH INSURANCE ACT 2007

Amendments in this schedule amend the PHI Act to update the cost recovery arrangements so these arrangements are consistent with the AGC Framework. This includes providing for a statutory authority for the Minister for Health and Aged Care to establish fee for service cost recovery arrangements consistent with the AGC Framework. This includes permitting legislative instruments to impose fees for activities carried out in connection with the Private Health Insurance (Medical Devices and Human Tissue Products) Rules.

The amendments do not impose any levies, as these are imposed under the renamed *Private Health Insurance (Medical Devices and Human Tissue Products Levy) Act 2007* (Levy Act). However, the amendments do provide for:

- Fees to be imposed under the PHI Act (item 4) for cost recovery of Government services provided associated with the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, and
- Matters relating to fees and levies such as liability, timing and means of payment, and circumstances for payment (item 4).

Item 1 – Paragraph 72-10(3)(b)
Item 1 repeals paragraph 72-10(3)(b) and substitutes a new paragraph 72-10(3)(b) to provide that any application for listing is accompanied by any fee that the applicant is liable to pay when the application is made.

Items 2 and 3 – Paragraph 72-10(5)(b)
Item 2 repeals paragraph 72-10(5)(b) and substitutes a new paragraph 72-10(5)(b) to provide that the applicant must pay any cost recovery fee that the applicant is liable to pay for the initial listing of a medical device or human tissue product that is not already on the list. Item 3 inserts a note to refer the reader to matters under section 72-25 that are also relevant.

Item 4 – Sections 72-15 and 72-45
Item 4 repeals sections 72-15 and 72-20 and inserts the following new sections:

- section 72-15 (which deals with fees for certain activities)
- section 72-20 (which deals with delisting because of unpaid fees or levy)
- section 72-25 (which deals with refusing to carry out activities if fee or levy is unpaid)

- section 72-30 (which deals with when fees must be paid)
- section 72-35 (which deals with payment of fees)
- section 72-40 (which deals with recovery of fees)
- section 72-45 (which deals with other matters relating to fees)

Section 72-15 provides for the Private Health Insurance (Medical Devices and Human Tissue Products) Rules to specify cost recovery fees in relation to activities in connection with the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. As well as setting out a number of fees related matters that may be specified in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules, section 72-15 specifies that these cost recovery fees cannot amount to taxation. This addresses the constitutional limitation on the imposition of a tax.

Section 72-20 allows the Minister or the Minister's delegate to remove a kind of medical device or human tissue product from the list when a person is liable to pay a cost recovery fee or levy and fails to pay this cost recovery fee or levy in accordance with the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. This will be a discretionary decision and does not provide that a kind of medical device or human tissue product must be removed from the list if a cost recovery fee or levy is not paid. This discretionary power will allow for the Minister or the Minister's delegate to retain a listing, for example, where it is in the best interests of patients and clinicians.

Section 72-25 allows the Minister or the Minister's delegate to refuse to carry out activities for a person (the debtor) where the person is liable to pay a cost recovery fee or levy and has not paid this cost recovery fee or levy. In practice, this may mean that all requests associated with the debtor for any service related to applications for a new listing of a medical device or human tissue product or administration of an existing listing may be refused until the cost recovery fee is paid. This provision will prevent a ***debtor*** who has unpaid cost-recovery fees from incurring additional liabilities. It will also reduce the likelihood that the Commonwealth will expend further resources in relation to activities for that person where there is an outstanding debt and will encourage those persons to pay a cost-recovery fee or levy for which they are liable.

Section 72-45 provides that matters relating to who is liable to pay a cost recovery fee, methods for payment of cost recovery fees, timing for the payment of cost recovery fees and refunding and remittance of cost recovery fees may be made in Private Health Insurance (Medical Devices and Human Tissue Products) Rules under the PHI Act.

The other matters are standard provisions for imposing and dealing with fees.

Items 5, 6 and 7 – Sections 304-10 and 307-20
These items extend the existing levy related provisions in the PHI Act to include levy imposed under the Levy Act. The amendments provide that these levies are subject to the same requirements for payment and late payment penalties as other levies. Item 7 has the effect of allowing the Minister to waive a late payment penalty in respect of the levy imposed under the Levy Act.

Items 8 and 9 – Section 307-30
These items provide that the Private Health Insurance (Levy Administration) Rules may specify the persons who are liable to pay the levy imposed by the Levy Act.

Item 10 – Clause 1 of Schedule 1
This item inserts references to relevant new definitions.

PRIVATE HEALTH INSURANCE (PROSTHESES APPLICATION AND LISTING FEES) AMENDMENT (COST RECOVERY) BILL 2022

Section 1 – Short Title
Section 1 provides for the short title of the Act to be the *Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Act 2022*.

Section 2 – Commencement
This section sets out when the Private Health Insurance (Prostheses Application and Listing Fees) Amendment (Cost Recovery) Bill 2022 (PHI Fees Bill) commences. The PHI Fees Bill only commences if the *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2022* commences. If that Act commences then the PHI Fees Bill commences on commencement of that Act or the day the PHI Fees Bill receives Royal Assent, whichever is later.

Section 3 – Schedule(s)
This section provides that each Act that is specified in a Schedule to this bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms. This is a technical provision which gives operational effect to the amendments contained in the Schedule. Schedule 1 amends the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*.

SCHEDULE 1 — PRIVATE HEALTH INSURANCE (PROSTHESES APPLICATION AND LISTING FEES) ACT 2007

Amendments in this schedule update the cost recovery arrangements so these arrangements are consistent with the AGC Framework (item 3).

The *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*, prior to these amendments, imposed application fees and listing fees that are a tax, as well as who is liable to pay these fees and when.

Item 1 – Title
This item amends the long title of the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* to reflect the new cost recovery arrangements, and that these arrangements will be more appropriately characterised as levies (rather than fees).

While this Bill amends the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* to more appropriately characterise these arrangements as levies, this remains a taxation Act.

Item 2 – Section 1
This item amends the short title of the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* to rename it to the *Private Health Insurance (Medical Devices and Human Tissue Product Levy) Act 2007* (Levy Act). This reflects the new cost recovery arrangements, that these arrangements are levies and that they apply to medical devices and human tissue products.

Item 3 – Sections 3 to 9
Item 3 repeals sections 3 to 9 and substitutes new sections 3 to 7 in the Levy Act.

Section 3 includes new definitions for the purposes of the Levy Act; these definitions have the same meaning as in the PHI Act.

Section 4 imposes a levy on each item listed in the Private Health Insurance (Medical Devices and Human Tissue Products) Rules. The levy specifically applies to the ongoing listing of each listed item. This means practicably that each listed Billing Code listed will be liable to pay the levy amount. Section 4 provides that the levy is imposed on a levy imposition day specified by the Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules. Subsection 4(3) provides that the levy amount imposed on each Billing Code will be prescribed by regulations made under the Levy Act.

Subsection 4(4) specifies that in prescribing the amount of the levy, the Minister must be satisfied that that the amount is no more than the Commonwealth's costs in connection with ongoing listing. Practicably, this ensures that the levy amount reflects the costs of cost-recovered activities. This amount is prescribed by regulations made by the Governor-General under the Levy Act.

Section 5 details the different levy amounts that may be prescribed in regulations made under the Levy Act, including the amount or method for calculating the levies. Section 5 provides that the amount of a levy may be nil. Section 5 provides that regulations made under the Levy Act may provide exemptions from the levy.

A note has been included under section 5 to advise readers of the legislation that some matters relating to levies are set out in the rules made under the PHI Act, specifically the Private Health Insurance (Levy Administration) Rules. This includes matters such as who is liable to pay the levy.

Section 6 provides that rules, specifically Private Health Insurance (Medical Devices and Human Tissue Products Levy) Rules, may be made for the purposes of the Levy Act, for example matters relating to a levy imposition day (subsection 4(2)).

Section 7 provides that the Governor-General may make regulations prescribing matters relating to the Levy Act. This section provides for levy amounts to be set out in regulations, consistent with subsection 4(3).

PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) AMENDMENT (CONSEQUENTIAL AMENDMENTS) BILL 2022

Section 1 – Short Title
Section 1 provides for the short title of the Act to be the *Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Act 2022*.

Section 2 – Commencement
This section sets out when the Private Health Insurance (National Joint Replacement Register Levy) Amendment (Consequential Amendments) Bill 2022 (Consequential Amendments Bill) commences. The Consequential Amendments Bill only commences if the *Private Health Insurance Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2022* commences. If that Act commences then the Consequential Amendments Bill commences on commencement of that Act or the day the Consequential Amendments Bill receives Royal Assent, whichever is later.

Section 3 – Schedule(s)
This section provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms. This is a technical provision which gives operational effect to the amendments contained in the Schedule. Schedule 1 amends the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*.

SCHEDULE 1 — PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) ACT 2009

Amendments in this schedule are consequential amendments arising from the change of the name of the legislative instrument made under the PHI Act as set out in the Private Health Insurance Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022 (see item 18 of that Bill). The new name of this legislative instrument is the 'Private Health Insurance (Medical Devices and Human Tissue Products) Rules'.

The *Private Health Insurance (National Joint Replacement Register Levy) Act 2009* imposes the national joint replacement register levy and provides for the rate of this levy, as well as who is liable to pay this levy.

Item 1 – Subsection 5(1) (definition of joint replacement prosthesis)
Item 1 repeals the definition of 'joint replacement prosthesis' as this is replaced with a new definition of 'joint replacement device' (see item 2).

Item 2 - Subsection 5(1)
This item inserts new definitions for 'joint replacement device' and 'Private Health Insurance (Medical Device and Human Tissue Product) Rules' in the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*. These new definitions reflect the new name of the legislative instrument made under the PHI Act for medical devices and human tissue products, and the items that may be included in that instrument, namely medical devices.

The new name of the legislative instrument is set out in the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022 (see item 18 of that Bill).

Item 3 - Subsection 5(1) (definition of Private Health Insurance (Prostheses) Rules)
This item is a consequential amendment to repeal the definition of the previous name of the legislative instrument made under the PHI Act.

Item 4 - Subsection 5(1) (definition of supplementary national joint replacement register levy day)
Item 4 addresses an incorrect reference to a determination. The definition of 'supplementary national joint replacement register levy day' incorrectly refers to a Ministerial determination under section 6. These determinations are made under section 8A and the amendment addresses and rectifies this error.

Item 5 – Subsection 5(2)
Item 5 replaces the expression 'joint replacement prosthesis' with 'joint replacement device' in the provision specifying the person that is a sponsor for a prosthesis. These amendments are necessary to reflect the new definition (see item 2) and the items that may be included in the legislative instrument made under the PHI Act, namely medical devices.

Item 6 – Paragraphs 5(2)(a) and (b)
Item 6 replaces the expression 'prosthesis' with 'device' in the provision that specifies the 'sponsor' for a prosthesis. The item also substitutes the new name of the legislative instrument made under the PHI Act for medical devices and human tissue products. These amendments are as a consequence of the amendments in the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022, specifically the items that may be included in the legislative instrument made under the PHI Act, namely medical devices.

Item 7 – Paragraph 5(2)(b)
Item 7 replaces the expression 'prosthesis' with 'device' in the provision specifying the 'sponsor' for a prosthesis. This amendment is also as a consequence of the amendments in the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022.

Item 8 – Subsection 5(3)
Item 8 replaces the expression 'prosthesis' with 'medical device' as a consequence of the new definition of 'joint replacement device' (item 2) and amendments to the PHI Act in the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022.

This provision provides that the Private Health Insurance (National Joint Replacement Register Levy) Rules may provide that one or more classes of medical devices are taken, or are taken not, to be joint replacement devices for the purposes of the definition of joint replacement device. Consistent with the previous provision, this amended provision provides flexibility in specifying those joint replacement devices on which levy is imposed.

Items 9 to 13 – Subsections 6(1), 7(2), 7(3) and Section 7A
Items 9 to 13 replace the expression 'prosthesis' with 'medical device' in the provisions that impose the levy, the rate of that levy and who must pay the levy. These amendments are as a consequence of the amendments to the PHI Act in the Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Bill 2022.