



**Australian Government**  
**Department of Health**

**COST RECOVERY IMPLEMENTATION STATEMENT**

National Joint Replacement Registry (NJRR)

**Version 1.2**

**1 July 2020 to 30 June 2021**

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific government activity. This may include goods, services or regulation, or a combination of them. The Australian Government Charging Framework, which incorporates the Cost Recovery Guidelines (the CRGs)<sup>1</sup>, sets out the framework under which government entities design, implement and review regulatory charging activities, consistent with the *Public Governance, Performance and Accountability Act 2013*.

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<sup>1</sup> The CRGs are available on the Department of Finance website Cost Recovery Guidelines

## **1. INTRODUCTION**

### **1.1. Purpose of the CRIS**

This Cost Recovery Implementation Statement (CRIS) provides information on how the Department of Health (the Department) manages cost recovery to provide Commonwealth funding to the Australian Orthopaedic Association (AOA) for its administration of the National Joint Replacement Registry (NJRR). It also reports financial and non-financial performance information and contains financial forecasts for the 2020-21 financial year and three forward years.

The Department will maintain the CRIS until the activity or cost recovery for the activity has been discontinued.

### **1.2. Description of the activity**

The purpose of the NJRR is to improve and maintain the quality of care and health outcomes for individuals receiving joint replacement surgery. Information on hip, knee, shoulder, elbow, wrist, ankle and spinal disc replacement is collected from all hospitals in Australia undertaking joint replacement surgery. This information is then used to inform surgeons, other health care professionals, governments, orthopaedic companies and the community.

The continual monitoring process inherent in the NJRR's function has been beneficial to joint replacement surgery. The number of revision surgeries has declined significantly as a result of the increased use of the type and class of prostheses shown by NJRR data to have better outcomes; and a decline in use of certain prostheses types with less satisfactory performance data<sup>2</sup>.

## **2. POLICY AND STATUTORY AUTHORITY TO COST RECOVER**

### **2.1. Government policy approval to cost recover the activity**

In the 2009-10 Budget, the Australian Government announced that expenses associated with maintaining the NJRR would be recovered from the manufacturers and importers of joint replacement prostheses (collectively referred to as sponsors).<sup>3</sup>

The NJRR provides valuable post-market surveillance of joint replacement prostheses, which benefits industry through improved consumer confidence in the safety and efficacy of joint replacement devices. The data produced by the NJRR informs the development of new prostheses, enabling manufacturers to draw on reliable performance information for existing devices and designs.

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<sup>2</sup> <https://aoanjrr.sahmri.com/annual-reports-2019>

<sup>3</sup> [https://www.aph.gov.au/binaries/budget/2009-10/content/bp2/download/bp\\_2.pdf](https://www.aph.gov.au/binaries/budget/2009-10/content/bp2/download/bp_2.pdf)

## **2.2. Statutory authority to charge**

The *Private Health Insurance (National Joint Replacement Register Levy) Act 2009* (NJRR Levy Act) and the *Private Health Insurance (National Joint Replacement Register Levy) Rule 2019* (NJRR Levy Rule) established the mechanism to enable the costs of the NJRR to be recovered through a levy imposed on each joint replacement prosthesis sponsor for each relevant item on the Prostheses List according to its revenue as a proportion of all relevant revenue.

## **3. COST RECOVERY MODEL**

### **3.1. Outputs and business processes of the activity**

The NJRR Levy ensures that funding is available to develop, maintain and administer the NJRR which includes but is not limited to the following activities:

- create quality demographic information on the practice of hip, knee, ankle, shoulder, wrist, elbow and spinal disc replacement surgery and provide relevant performance reports on these to clinicians and hospitals;
- develop and manage effective systems to monitor hip, knee, ankle, shoulder, wrist, elbow and spinal disc replacement prostheses outcomes both generally and in relation to specific surgical techniques;
- maintain a system to assess new implantable device technologies used following introduction into Australian clinical practice;
- maintain a system for tracking of implanted joint replacement prostheses and a system for regular reporting to the Prostheses List Advisory Committee (PLAC), the Therapeutic Goods Administration (TGA), clinicians, hospitals and medical device companies;
- monitor joint replacement prostheses which have been subject to recall;
- maintain and consider further development to the established audit systems for hospitals and surgeons;
- maintain an algorithm to identify any joint replacement prosthesis not performing to the level of others in its class and provide this advice to suppliers, TGA, PLAC and Clinical Advisory Groups (CAG);
- provide data to PLAC to help inform it in the clinical assessment of joint replacement products on, or seeking listing on, the Prostheses List;
- provide utilisation data to the Department from the NJRR based on billing code usage separated by private/public hospitals;
- produce the Annual and Supplementary Reports by the end of September each year, to be publicly available on the NJRR website;
- continue and maintain a formal reporting system between the NJRR and TGA for joint replacement prostheses identified as having possible safety issues;
- continue the collaborative approach with the Neurosurgical Society of Australasia to ensure quality of data and analysis in regards to spinal disc replacement; and
- provide reports on request to PLAC regarding joint replacement prostheses data and the performance of listed joint replacement prostheses, including, but not limited to:
  - i. information on the usage of hip, knee, ankle, shoulder, wrist, elbow and spinal disc replacement prostheses twice during a year;
  - ii. information on the relative effectiveness of joint replacement prostheses for which data is collected;
  - iii. advice on clinical issues;

- iv. advice on NJRR notifications to the Therapeutic Goods Administration informing it of failed or faulty joint replacement prostheses; and
- v. continue to progress the secure database linkage with the Department's prostheses list database.

### 3.2. Costs of the NJRR

The sum of all levies collected from relevant prostheses sponsors is intended to be commensurate with the costs of Commonwealth funding provided to the AOA to administer and manage the NJRR.

In October 2019 a new funding agreement was signed with the AOA covering the period from 2019-20 to 2022-23. The amount of the funding was \$2.376 million each year to 2022-23, with no indexation. The funding provided by the Commonwealth under the funding agreement included funding for AOA personnel, activities undertaken by subcontracted providers, information technology and equipment support, the costs associated with the activities of the NJRR in collecting data on joint replacement prostheses in accordance with the funding agreement, and administrative costs. The NJRR operates on a not-for-profit basis.

In August 2020 a review of the current funding agreement was undertaken, as outlined in section 3.3 of this document.

The costs to maintain the NJRR, as outlined in the funding agreement, are summarised in Table 1 below, with the proposed increase in costs to be recovered for 2020-21 added below with an asterisk. The remaining proposed changes in costs to 2022-23 are summarised in section 6 of this document. Further information on past costs recovered are summarised in section 7.1 of this document.

**Table 1 - Summary of costs to be recovered**

| Cost type                 | 2020-21<br>\$'000 |
|---------------------------|-------------------|
| Data services             | 1,656             |
| Other personnel           | 500               |
| Other costs and equipment | 220               |
| Data security upgrade*    | 110               |
| Indexation applied*       | 37                |
| <b>Total</b>              | <b>2,523</b>      |

*\*Increase in cost for 2020-21, with the entirety of proposed changes in costs further discussed in Section 3.3 and summarised in Section 6*

The formula for determining the rate of levy on each sponsor is set out in the NJRR Levy Rule.<sup>4</sup>

The levy is imposed on each NJRR levy day (levy day), which is specified in the NJRR Levy Rules. A levy may also be imposed on a day determined by the Minister for Health, by legislative instrument, as a supplementary NJRR levy day (supplementary levy day). There can be no more than four levy days in a financial year and the Minister cannot specify more than two supplementary levy days in a financial year. Accordingly, the NJRR Levy restricts the number of times a levy may be imposed to a maximum of six levies in a financial year.

<sup>4</sup> <https://www.legislation.gov.au/Details/F2015L017>

Section 8(2) of the NJRR Levy Act provides that different rates may be set for different kinds of joint replacement prostheses. The rate may be set at zero but must not exceed \$5,000 for a financial year.

### **3.3. Changes to cost recovery arrangements**

The NJRR Levy Rules specify that one levy day will occur each financial year on 30 November. The NJRR Levy Rules also specify that the census day on which the rate of levy to be imposed is calculated is 30 September. No supplementary levy days have been determined. Invoices are delivered to sponsors following levy days.

The Minister for Health, the Hon Greg Hunt MP (the Minister), has agreed that in 2020-21 only, the levy date will be deferred to 31 March 2021. This allowed time for engagement with stakeholders on the proposed increase to the levy amount and ensures that sponsors are prepared for the new levy date. The census date for the 2020-21 financial year remained as 30 September 2020.

In line with requirements under the grant agreement, in August 2020 the Department (in consultation with the AOA) conducted a review of the current funding to AOA for core activities to administer and maintain the NJRR. The review found that the current funding levels were inadequate to ensure important cybersecurity measures, vital for protecting confidential data, were able to be maintained effectively on an ongoing basis. An outcome of the review was a proposal to increase funding to the AOA for ongoing contemporary cybersecurity measures at a cost of \$110,000 per annum. It also found that annual indexation should be incorporated into the levy formula.

These changes equate to approximately a 6% increase from the previous levy amount as paid in 2019-20.

## **4. RISK ASSESSMENT**

A Charging Risk Assessment was undertaken in February 2021. The outcome of this risk assessment was an overall risk rating of 'medium'.

## 5. STAKEHOLDER ENGAGEMENT

The key stakeholders relevant to the imposition of the NJRR levy are the sponsors of medical devices listed on the Prostheses List that will be subject to the levy. As at 15 September 2020, there were 37 sponsors.

The proposed levy arrangements result in additional costs to sponsors of joint replacement prostheses. These costs may be passed on to purchasers of devices including public hospitals and consumers receiving private services. Although the levy results in extra costs for sponsors, they obtain substantial benefits from the continued operation of the NJRR, including commercial benefits.

Other stakeholders who derive benefits from the NJRR include surgeons who perform joint replacement surgery, patients, public and private hospitals, the TGA, private health insurers and the PLAC.

The consultation was held for a 2 week period from 25 November to 8 December 2020. Stakeholders did not raise any issues with the proposed changes in levy arrangements (outlined in Section 3.3 of this CRIS) that will go ahead for both the 2020-21 financial year and the remaining years of the agreement with AOA.

One stakeholder provided comments in regards to the maximum cap use for the calculation on what individual companies had to pay. The Department intends to consult with all the relevant stakeholders at the earliest opportunity to ensure that this program continues to serve the needs of stakeholders, as well as revisit the issue raised.

The Department will also continue its regular meetings with the AOA.

## 6. FINANCIAL ESTIMATES

Table 2 reflects the forecast expenses of the full cost recovery approach within this CRIS along with the estimated revenue from 2019-20 until 2022-23 as the current agreement with the AOA expires on 30 June 2023. Any changes to financial estimates will be updated in this table as part of the regular CRIS updates.

Subject to the outcomes of consultation, the Minister for Health has agreed to a proposed increase in the grant amount to the AOA by \$110,000 per annum for enhanced cybersecurity, plus the application of indexation to the total NJRR funding envelope.

**Table 2 – Financial estimates for 2020-21 to 2022-23**

| <b>Administration and management of the NJRR</b> | <b>2020-21<br/>\$'000</b> | <b>2021-22<br/>\$'000</b> | <b>2022-23<br/>\$'000</b> |
|--|---------------------------|---------------------------|---------------------------|
| Expenses = X                                     | 2,523                     | 2,543                     | 2,571                     |
| Revenue = Y                                      | 2,523                     | 2,543                     | 2,571                     |
| Balance = Y – X                                  | 0                         | 0                         | 0                         |
| Cumulative balance                               | (217) <sup>4</sup>        | (217)                     | (217)                     |

<sup>4</sup> This cumulative balance is carried over from previous years as this is mostly due to the Department providing extra one-off funding to the AOA for ICT security purposes in 2018-19 (~\$209k). Those expenses were funded by the Australian Government and was not recovered from sponsors.

## 7. PERFORMANCE

### 7.1. Financial Performance

The following table will be updated after each financial year to report on actual financial performance.

Any year where there is a significant variance (such as in 2018-19), an explanation will be provided.

**Table 3 – History of NJRR levy revenue and funding provided to the AOA**

| <b>Administration and management of the NJRR</b> | <b>2015-16<br/>\$'000</b>  | <b>2016-17<br/>\$'000</b> | <b>2017-18<br/>\$'000</b> | <b>2018-19<br/>\$'000</b> | <b>2019-20<br/>\$'000</b> |
|--|--|---------------------------|---------------------------|---------------------------|---------------------------|
| Expenses = X                                     | 2,243  | 2,286                     | 2,329                     | 2,577                     | 2,376                     |
| Revenue = Y                                      | 2,238  | 2,286                     | 2,326                     | 2,368                     | 2,376                     |
| Balance = Y – X                                  | (5)  | 0                         | (3)                       | (209)                     | 0                         |
| Cumulative balance                               | (5)  | (5)                       | (8)                       | (217)                     | (217)                     |
| Variance explanation                             | There was no variance for 2019-20 for expenses or revenue.   |                           |                           |                           |                           |
| Balance management strategy                      | The cumulative balance is carried over from previous years. This is mostly attributable to the Department providing extra funding to the AOA for ICT security purposes in 2018-19 (~\$209k). These expenses were funded by the Australian Government and were not recovered from sponsors. |                           |                           |                           |                           |

## **7.2. Non-Financial Performance**

The AOA is required to produce the following documents to the Department in order to execute its performance requirements:

### **Performance Reports**

A comprehensive review of the operation of the core activities of the NJRR in the reporting period, provided to the Department of Health.

### **Activity Work Plan**

Detailing the activities planned for the NJRR for the coming financial year, provided to the Department of Health.

### **Final Report**

- A comprehensive review of the operation of the core activities of the NJRR in the reporting period;
- An evaluation of the performance, benefits and outcomes of the entire Activity;
- A discussion of any issues, problems or delays; and
- The extent to which the Activity achieved the Aim of the Activity and the Program's Objectives as specified in this Schedule.

### **Annual Report**

- Information on the methodology used by the NJRR, particularly in relation to its data collection and management protocols;
- All notifications made to orthopaedic companies, clinicians and the TGA on products that the AOANJRR has identified as having possible safety issues; and
- Comprehensive data on joint replacements covered by the NJRR, including demographics, usage, revision and mortality rates, using data on joint replacement procedures performed from the commencement of data collection to the end of the previous calendar year.

### **Other Reports**

As requested or as required.



## 8. KEY FORWARD DATES AND EVENTS

| Activity        | Information to be included and requirements | Due Date         |
|-----------------|---|------------------|
| Levy Imposition | Levy applied and invoices raised            | 31 March 2021    |
| CRIS update     | Update for 2021-22 financial year           | 30 November 2021 |

## 9. CRIS APPROVAL AND CHANGE REGISTER

| Date of CRIS change | CRIS change                                   | Approver  | Basis for change   |
|---------------------|---|---|--|
| March 2021          | Updates of CRIS for 2020-21 from consultation | Minister for Health                             | Update of CRIS for outcome of consultation and 2019-20 financial outcome.  |
| November 2020       | Consultation draft of CRIS for 2020-21        | First Assistant Secretary, Department of Health | Update of financial results for 2019-20. Consultation on proposed increase to levy amount, including financial estimates<br>Change to levy date for 2020-21 and key forward dates. |
| June 2020           | Update of CRIS for 2020-21                    | First Assistant Secretary, Department of Health | Update for 2020-21 year.   |
| November 2019       | Update of CRIS for 2019 -20                   | First Assistant Secretary, Department of Health | Update of financial results for 2018-19 and key forward dates.   |
| June 2019           | Update of CRIS for 2019 -20                   | First Assistant Secretary, Department of Health | Update of financial estimates, key dates and events.   |
| June 2019           | Update of CRIS for 2018 -19                   | First Assistant Secretary, Department of Health | Update of financial results for 2017-18, financial estimates, key dates and events.  |
| February 2018       | Update of 2016-17 financial performance       | Secretary, Department of Health                 | Update of financial results for 2016-17.   |
| December 2016       | Certification of the CRIS                     | Secretary, Department of Health                 | New cost recovered activity  |
| April 2016          | Agreement to the CRIS                         | Minister for Health                             | New cost recovered activity  |