



Australian Government

**Department of Health
and Aged Care**

COST RECOVERY IMPLEMENTATION STATEMENT

National Joint Replacement Registry (NJRR)

1 July 2023 to 30 June 2024

Version 1.2

Cost recovery involves government entities charging individuals or non-government organisations some or all of the efficient costs of a specific regulatory 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)¹, 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*.

¹ 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 and Aged Care (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 results for the administration of the NJRR and contains financial forecasts for the 2023-24 financial year and three forward years.

The Department will maintain and update the CRIS as required 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 replacements 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.

This 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.²

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).³

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.

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 2015* (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, which has been replaced with the Prescribed List of Benefits for Medical Devices and Human Tissue Products (the Prescribed List), according to its revenue as a proportion of all relevant revenue.

² Orthopaedic Association National Joint Replacement Registry – 2022 Hip, Knee and Shoulder Replacement Lay Summary: <https://aoanjrr.sahmri.com/annual-reports-2022>

³ Australian Government Budget Papers 2009-10: https://www.aph.gov.au/binaries/budget/2009-10/content/bp2/download/bp_2.pdf

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 Prescribed List Advisory Committee (PLAC) who have been replaced by the Medical Devices and Human Tissue Advisory Committee (MDHTAC), 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, MDHTAC and Clinical Advisory Groups;
- provide data to MDHTAC to help inform it in the clinical assessment of joint replacement products on, or seeking listing on, the Prescribed 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 regard to spinal disc replacement; and
- provide on request reports to MDHTAC 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 TGA informing it of failed or faulty joint replacement prostheses; and
 - v. continue to progress the secure database linkage with the Department's Prescribed 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. The NJRR operates on a not-for-profit basis.

The funding provided to the NJRR, and therefore any changes to the total levy amounts, reflects the funding amount agreed between the AOA and the Commonwealth to manage the NJRR for a specified period.

In September 2023, the Commonwealth and AOA agreed to a 12-month extension of the 2019-20 funding agreement to manage the NJRR for the period from 1 July 2023 to 30 June 2024. This includes 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, this funding to the AOA is for the ongoing management of the NJRR for the 2023-24 financial year.

The costs to maintain the NJRR in 2023-24, are summarised in Table 1 below. 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	2023-24 \$'000
Core funding	2,458
Cyber security	114
Indexation	103
Total	\$2,674

[Note: \$ are rounded to nearest '000]

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

The levy is imposed on each NJRR levy day (levy day), which is specified in the NJRR Levy Rule. A levy may also be imposed on a day determined by the Minister for Health and Aged Care, the Hon Mark Butler MP (the Minister), 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.

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. Design of cost recovery charges

The NJRR Levy Rule specify that one levy day will occur each financial year on 30 November. The NJRR Levy Rule 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.

3.4. Prostheses List reforms

The Australian Government's 2021-22 Budget announced the intention to implement reforms to improve and modernise the Prostheses Listing arrangements.

⁴ <https://www.legislation.gov.au/Details/F2023C00701>

The cost recovery arrangements related to the Prescribed List commenced on 1 July 2023. It is not expected that the Prostheses List reforms will have a cost recovery impact on the NJRR cost recovery arrangements.

4. RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken in August 2023. The outcome of this risk assessment was an overall risk rating of 'low'.

5. STAKEHOLDER ENGAGEMENT

The sponsors of joint replacement devices listed on the Prescribed List will be subject to the levy. As of October 2023, there were 45 sponsors.

The annual levy amounts that sponsors pay are expected to increase, these increases are attributed to indexation of core funding to AOA for the operation of the NJRR. Sponsors 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 MDHTAC.

Stakeholder consultation occurs via industry comment on the draft CRIS. Public consultation was undertaken in May 2023 to seek views on levy increases for proposed additional activities for the management of NJRR. Two submissions were received and a summary with departmental responses is at **Attachment A**.

The final 2023-24 CRIS reflects a 12-month extension of the 2019-20 funding agreement to manage the NJRR for the period from 1 July 2023 to 30 June 2024 for existing activities only. Additional consultation was undertaken with the AOA and the Department of Finance prior to finalising the 2023-24 CRIS.

Any future funding agreement will require the development of a new CRIS, which will be informed by stakeholder consultation.

6. FINANCIAL ESTIMATES

Table 2 reflects the forecast expenses of the full cost recovery approach within this CRIS along with the estimated revenue for financial years 2023-24 to 2026-27. Any changes to financial estimates will be updated in this table as part of the regular CRIS updates.

Table 2 – Financial estimates for 2023-24 to 2026-27.

Administration and management of the NJRR	2023-24 \$'000	2024-25 \$'000	2025-26 \$'000	2026-27 \$'000
Expenses = X	2,674	2,741	2,796	2,847
Revenue = Y	2,674	2,741	2,796	2,847
Balance = Y – X	0	0	0	0
Cumulative balance	0	0	0	0

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, an explanation will be provided.

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

Administration and management of the NJRR	2018-19 \$'000	2019-20 \$'000	2020-21 \$'000	2021-22 \$'000	2022-23 \$'000
Expenses = X	2,577	2,376	2,523	2,543	2,571
Revenue = Y	2,368	2,376	2,523	2,543	2,571
Balance = Y – X	(209)	0	0	0	0
Cumulative balance	(217)	(217)	(217)	(217)	(217)
Variance explanation	There were no variances for expenses or revenue in the 2022-23 financial year.				
Balance management strategy	The cumulative deficit of \$217,000 relates to the 2018-19 and prior financial years, which was funded by the Department.				

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.

Activity Work Plan

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

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 Australian Orthopaedic Association National Joint Replacement Registry 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
New Funding Agreement	New funding agreement between the Department and AOA to be finalised	TBA
Update CRIS for 2024-25	Update on financial forecasts from 2024-25 to 2027-28 financial years.	June 2024

9. CRIS APPROVAL AND CHANGE REGISTER

Date of CRIS change	CRIS change	Approver	Basis for change
November 2023	Update of CRIS for 2023-24. Report on financial performance data for 2022-23 (Version 1.2)	First Assistant Secretary, Technology Assessment and Access Division	Update of finance performance for 2022-23 and financial forecasts from 2023-24 to 2026-27 financial years. Updated summary of costs to be recovered and consultation outcome.
May 2023	Consultation draft of CRIS for 2023-24	First Assistant Secretary, Technology Assessment and Access Division	Update of financial forecasts from 2023-24 to 2026-27 financial years. Consultation on proposed increase to levy.
November 2022	Update of CRIS with 2021-22 financial performance data (Version 1.2)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2021-22 financial results.
June 2022	Update of CRIS for 2022-23 (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Update for 2022-23 year.
November 2021	Update of CRIS for 2021-22 (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Update of financial results for 2020-21.
June 2021	Update of CRIS for 2021-22 (Version 1.0)	First Assistant Secretary, Technology Assessment and Access Division	Update for 2021-22 year.
March 2021	Updates of CRIS for 2020-21 from consultation	Minister for Health and Aged Care	Update of CRIS for outcome of consultation and 2019-20 financial outcome.

Date of CRIS change	CRIS change	Approver	Basis for change
November 2020	Consultation draft of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Update of financial results for 2019-20. Consultation on proposed increase to levy amount, including financial estimates Change to levy date for 2020-21 and key forward dates.
June 2020	Update of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Update for 2020-21 year.
November 2019	Update of CRIS for 2019 -20	First Assistant Secretary, Technology Assessment and Access Division	Update of financial results for 2018-19 and key forward dates.
June 2019	Update of CRIS for 2019 -20	First Assistant Secretary, Technology Assessment and Access Division	Update of financial estimates, key dates and events.
June 2018	Update of CRIS for 2018 -19	First Assistant Secretary, Technology Assessment and Access Division	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

ATTACHMENT A – SUMMARY OF STAKEHOLDER VIEWS ON REQUIRED CRIS CONSULTATION AND RELATED DEPARTMENT RESPONSES 2023-24

Consultation information:

Stakeholder Comment	Departmental Response
<i>Levy calculation method used</i>	
<p>Stakeholder feedback noted that the role of the NJRR is clear and its value to Australia and the world is rarely disputed.</p> <p>Stakeholders were concerned the method for calculating the cost recovery levy protects large companies from paying their fair share of any increasing NJRR costs.</p> <p>A suggestion was that subsequent cost recovery implementation should include an increase in the maximum levy per levy category. This would help ensure all companies that benefit from an increasing growth in arthroplasty in Australia pay for their increased cost to the NJRR.</p>	<p>The Department notes the consultation feedback and will continue to monitor the cost recovery arrangements and provide policy advice to Government.</p>
<i>Cost Recovery Arrangements</i>	
<p>Stakeholder feedback illustrated strong support of the registry but suggested that if the scope of AOA data collection activities are to be expanded, then costs for maintaining the registry should be partly offset by Government funding and potentially other beneficiaries such as private health insurers.</p> <p>Feedback suggested that all requests by the AOA are industry funded and it appears that the 2023-24 Federal Budget does not invest in the NJRR.</p> <p>Furthermore, stakeholders consider that any surplus not covered by the states and territories for funding the Patient Reported Outcomes Measures (PROMs) is a government responsibility and do not agree that industry should be charged for the PROMs measures.</p>	<p>The purpose of the NJRR is to improve and maintain the quality of care for individuals receiving joint replacement surgery. The Department notes that the NJRR is used to inform surgeons, health care professionals, governments, orthopaedic companies and the community on the performance of individual joint replacement devices.</p> <p>Provisions under Section 7A of the <i>Private Health Insurance (National Joint Replacement Register Levy) Act 2009</i> state that the National Joint Replacement Register levy imposed in relation to a joint replacement device is payable by the sponsor of the joint replacement device.</p> <p>In the 2023-24 Budget, the Australian Government is investing funding over four years to establish a National Clinical Quality Registry (CQR) Program. This program will support 10 existing national CQRs and establish two new funding streams dedicated especially to CQRs.</p> <ul style="list-style-type: none"> Stream 1 will start from 2024-25. It will provide support for a small number of high

Stakeholder Comment	Departmental Response
	<p>priority national CQRs, which will be selected via an application process.</p> <ul style="list-style-type: none"> Stream 2 will start from 2024-25. It will provide grant funding for short-term projects that boost CQR capacity or help them professionalise (this could include CQRs not in scope of Stream 1). <p>Program implementation details, including the eligibility requirements and selection criteria are being finalised.</p> <p>The Department will continue to monitor the cost recovery arrangements and provide policy advice to Government.</p>