



COST RECOVERY IMPLEMENTATION STATEMENT

National Joint Replacement Registry

1 July 2024 to 30 June 2025

Version 1.1

Charging for regulatory activity involves government entities charging individuals or organisations in the non-government sector some or all of the minimum efficient costs of a specific government activity. The Cost Recovery Policy along with the Australian Government Charging Framework (the Charging Framework) sets out the policy under which Government entities design, implement and review charging for regulatory activities. The Cost Recovery Implementation Statement (CRIS) is the public document to ensure the transparency and accountability for the level of charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

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1 INTRODUCTION

1.1 Purpose

This CRIS provides information on how the Department of Health and Aged Care (the Department) implements cost recovery for Commonwealth funding provided to the Australian Orthopaedic Association (AOA) to administer the National Joint Replacement Registry (NJRR). The CRIS reports actual financial and non-financial performance information, outlines legislative changes and contains financial and demand forecasts for 2024-2025. This CRIS provides financial forecasts for 2024-25 only as the Department is undertaking a full cost review of the grant and levy arrangements. Following the review and government decisions, a new CRIS will be provided for 2025-26 with financial forecasts for the term of the funding agreement with AOA. The Department will maintain the CRIS while the regulatory activity, or cost recovery for the activity, continues.

1.2 Description of the regulatory charging activity

1.2.1 What is the regulatory activity being cost recovered?

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 of the performance of the individual prostheses.

This continual monitoring process inherent in the NJRR's function has been beneficial to joint replacement surgeries. The number of revision surgeries has declined significantly due to an increase in the use of the type and class of medical devices shown by NJRR data to have better outcomes and a decline in the use of medical device types with less satisfactory performance data¹.

1.2.2 What policy outcomes will the activity achieve?

The regulatory activities contribute to achieving Outcome 2 (Program 2.4) outlined in the Health Portfolio Budget Statements.

Outcome 2: Individual Health Benefits

Ensuring improved access for all Australians to cost-effective and affordable medicines, medical, dental and hearing services; improved choice in health care services, through guaranteeing Medicare and the Pharmaceutical Benefits Scheme; supporting targeted assistance strategies and private health insurance.

Program 2.4: Private Health Insurance

Promote affordable, cost-effective, quality private health insurance and choice for consumers.

1.2.3 Why is charging appropriate for the regulatory activity?

Charging for the administration of the NJRR is appropriate because:

- it ensures that funding is available to develop, maintain and administer the NJRR
- charging of the levy sends price signals to individuals or groups about the cost or value of the regulatory activity
- charging is an important means of improving the efficiency and equity of the regulatory activity.

Cost recovery involves Government entities charging individuals or non-government organisations some or all the efficient costs of a specific Government activity. This may include goods, services, regulation, or a combination of these.

¹ <https://aoanjrr.sahmri.com/annual-reports-2022>

The Charging Framework applies to non-corporate and corporate Commonwealth entities as defined in the *Public Governance, Performance and Accountability Act 2013*. The Department is a non-corporate Commonwealth entity.

The Cost Recovery Policy is that, where appropriate, non-government recipients of specific Government activities should be charged some or all of the cost of those activities.

There are two types of cost recovery charges. The characteristics of a government activity determine the type of cost recovery charge used.

Cost recovery fees will be charged where a direct relationship exists between the regulatory activity and the individual or organisation requesting that specific activity. All regulated entities are charged the same fee for the same activity. Under these circumstances, the activities performed, and their associated costs, are driven by a specific need and demand created by the applicant. For example, applications for new listings on the Prescribed List of Medical Devices and Human Tissue Products (the Prescribed List) will be charged a cost recovery fee.

Cost recovery levy will be charged when the cost of the activity can be reasonably attributed to a broader group of organisations (or individuals) rather than a single entity. In these instances, the level of demand for Government activity or intervention is collectively driven by the industry rather than a single entity within it. For example, ongoing management of already-listed items on the Prescribed List will be funded through a levy payable by the medical devices industry.

1.2.4 Who will pay the regulatory charges?

The sponsors of joint replacement devices listed on the Prescribed List are subject to paying the levy. As of 31 October 2024, there were 43 sponsors.

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 Therapeutic Goods Administration (TGA), private health insurers and the Medical Device and Human Tissue Advisory Committee (MDHTAC).

2 POLICY AND STATUTORY AUTHORITY TO CHARGE (COST RECOVER)

2.1 Government policy approval to charge for this regulatory 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 medical devices (collectively referred to as sponsors)². 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.

The Department is undertaking a full cost review of the grant and levy arrangements. Outcomes of the review will inform funding arrangements from 2025-26. Following the review, a new CRIS will be provided for 2025-26 onwards based on Government decisions.

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

² https://www.aph.gov.au/binaries/budget/2009-10/content/bp2/download/bp_2.pdf

device sponsor for each relevant item on the Prescribed List, according to its revenue as a proportion of all relevant revenue.

Legislative Amendments

The NJRR Levy Rule will be amended to specify the levy amount for 2024-25.

The funding amount for the 2025-26 financial year and future financial years are subject to the outcomes from a full cost review of the administration of the NJRR and Government decisions. The NJRR Rule will be amended in 2025-26 to reflect the terms of any new funding arrangements and amounts for upcoming financial years.

3 CHARGING (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 devices and a system for regular reporting to the MDHTAC, TGA, clinicians, hospitals and medical device companies
- monitor joint replacement devices 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 devices not performing to the level of others in its class and provide this advice to suppliers, TGA, MDHTAC and Expert 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 devices 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
- provide on request reports to MDHTAC regarding joint replacement device data and the performance of listed joint replacement devices, including, but not limited to:
 - information on the usage of hip, knee, ankle, shoulder, wrist, elbow and spinal disc replacement devices twice each year
 - information on the relative effectiveness of joint replacement devices for which data is collected
 - advice on clinical issues
 - advice on NJRR notifications to the TGA informing it of failed or faulty joint replacement devices
 - continue to progress the secure database linkage with the Department's Prescribed List database

3.2 Costs of the regulatory activity

The costs of Commonwealth funding provided to the AOA to administer the NJRR are recovered through the sum of all levies collected from joint replacement sponsors.

In the 2024-25 Budget, the Australian Government agreed to provide additional funding of \$1.249m in 2023-24, to be cost recovered over four years from 2024-25 (this would be \$312,000 per year). This funding is due to increased costs for supporting core activities including operating costs (9%) and associate staffing costs (91%) to manage data and maintain IT systems to administer the NJRR (see details in section 3.1 of this document for key business activities). The Government also announced additional funding of \$1.561m to be provided to the AOA in 2024-25 to temporarily further increase the core operating funding. The additional funding in 2024-25 will not be cost recovered. The 2024-25 financial year is an exception to the full cost recovery approach.

In August 2024, the Commonwealth and AOA signed a Deed of Variation to the existing funding agreement to manage the NJRR for the period from 1 July 2024 to 30 June 2025. Funding provided to the AOA is summarised in Table 1 below.

Further information on past costs recovered are summarised in section 7.1 of this document.

Table 1 – Funding provided to the AOA

Cost type	2024-25
Core Funding	\$2,619,880
Additional funding	\$1,561,000
Total	\$4,180,880

Table 2 - Summary of costs to be recovered by the NJRR levy

Cost type	2024-25
Core Funding	\$2,619,880
Additional funding [^]	\$312,000
Total	\$2,931,880

[^] Additional funding of \$1.249 million was provided to the AOA in 2023-24 to be recovered over 4 years commencing in 2024-25.

3.3 Design of the regulatory charge

The formula for determining the rate of levy on each sponsor is set out in the NJRR Levy Rule. Section 7(2) of the NJRR Levy Act provides that different rates may be set for different kinds of joint replacement devices. The rate may be set at zero but must not exceed \$5,000 for a financial year. The wide range of medical devices used in joint replacement surgery correspond to a great variation in benefits for different kinds of joint replacement devices listed on the Prescribed List. The formula for determining the rate of levy considers the device benefit amount, utilisation, and the NJRR funding amount. The maximum rate of levy of \$5,000 was considered reasonable at the time the levy was introduced, given the variation in benefits for different kinds of joint replacement devices.

The NJRR Levy Rule specifies that one levy day will occur each financial year on 30 November. The NJRR Levy Rule also specifies that the census day on which the rate of levy to be imposed is calculated is 30 September.

If required, a levy may also be imposed on a day determined by the Minister for Health and Aged Care (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. No supplementary levy days have been determined for 2024-25. Invoices are sent to sponsors following the levy day.

The overall increase in the amount of the levy in 2024-25 is 9.64% compared to the amount of the levy in 2023-24. In 2024-25, there are 43 sponsors that will be paying the levy, with 27 sponsors that have devices subject to the \$5,000 cap.

The levy amount payable by sponsor each year is calculated based on utilisation rate of devices, device benefit amount and total levy amount.

For sponsors that are on the NJRR in both 23-24 and 24-25:

- 27 sponsors have devices subject to the \$5,000 cap. For these sponsors, a change in levy to be paid is expected to be between -\$4,579 - \$79,604.
- 13 sponsors do not have devices meeting the cap. For these sponsors, a change in levy to be paid is expected to be between -\$5,154 - \$9,352.

4 RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken in October 2024. The overall risk rating is 'medium' due to the significant changes in the charging arrangements for 2024-25 including the impact that the levy increase may have on some sponsors and additional funding that will not be cost recovered. All other implementation risks considered as part of the CRA were assessed as low risk, including the change in total annual revenue, if legislative changes are required, and if consultation occurred.

5 STAKEHOLDER ENGAGEMENT

Stakeholder consultation occurs through the publishing of a draft CRIS. Public consultation was undertaken from 23 October to 6 November 2024 to seek stakeholder feedback on the levy increases from the additional funding for AOA and partial cost recovery approach in 2024-25. Two submissions were received, and a summary of the feedback and departmental responses is at Attachment A. The Department is undertaking a full cost review of the grant and levy arrangements. Outcomes from the review will include options for the Department to present to Government on funding arrangements from 2025-26. Any proposed changes resulting from Government decision will be informed by stakeholder consultation.

6 FINANCIAL PERFORMANCE

Table 3 outlines the forecast expenses and estimated revenue for the 2024-25 financial year. 2024-25 is an exception to the standard full cost recovery approach. Any changes to financial estimates will be updated in this table as part of the regular CRIS updates. Financial forecasts for 2025-26 will be provided through a new CRIS following completion of the cost review of the grant and levy arrangements.

6.1 Financial Estimates

Table 3 – Financial estimates for cost recovered activities

Financial Item	2024-25 (\$'000)
Total expenses	4,181
Total revenue	2,932
Balance = revenue - expenses	-1,249
Cumulative balance	-2,498

6.2 Financial Outcomes

The following table is updated after each financial year to report on actual financial performance. An explanation will be provided for any year with a significant variance.

Table 4 – Financial outcomes for cost recovered activities

Financial Item	2020-21 (\$'000)	2021-22 (\$'000)	2022-23 (\$'000)	2023-24 (\$'000)
Estimates				
Revenue = X	2,523	2,543	2,571	2,674
Expenses = Y	2,523	2,543	2,571	2,674
Balance = X – Y	0	0	0	0
Actuals				
Revenue = X	2,523	2,543	2,571	2,674
Expenses = Y	2,523	2,543	2,571	3,923
Balance = X – Y	0	0	0	-1,249
Cumulative balance	0	0	0	-1,249
Variance explanation	In the 2024-25 Budget, the Government announced additional funding of \$1.249m to be provided to the AOA in 2023-24. The \$1.249m is to be cost recovered over four years from 2024-25.			

7 NON-FINANCIAL PERFORMANCE

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

Activity Work Plan

Detailing the activities planned for the NJRR for the coming financial year.

Performance Reports

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
- the extent to which the activity achieved its aim 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 NJRR has identified as having possible safety issues
- 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 by the Department or as required.

8 KEY FORWARD DATES AND EVENTS

Date	Activity
30/06/2025	Update CRIS for 2025-26

9 CRIS APPROVAL AND CHANGE REGISTER

Date of change	CRIS change	Approver	Basis for change
28/11/2024	Update of CRIS for 2024-25. Report on financial performance data for 2023-24 (Version 1.1)	Minister for Health and Aged Care	Updated summary of costs to be recovered and consultation outcome. Update of financial performance for 2023-24 and financial forecast for 2024-25.
23/10/2024	Approval of draft 2024-25 CRIS for stakeholder consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation for 2024-25 and financial results for 2023-24.
30/11/2023	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

Date of change	CRIS change	Approver	Basis for change
07/05/2023	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
30/11/2022	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
30/06/2022	Update of CRIS for 2022-23 (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2022-23 year
30/11/2021	Update of CRIS for 2021-22 (Version 1.1)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2020-21 financial results
30/06/2021	Update of CRIS for 2021-22 (Version 1.0)	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2021-22 year
01/03/2021	Update 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
30/11/2020	Consultation draft of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2019-20 financial results. Consultation on proposed increase to levy amount, including financial estimates. Change to levy date for 2020-21 and key forward dates.
30/06/2020	Update of CRIS for 2020-21	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2020-21 year
30/11/2019	Update of CRIS for 2019 -20	First Assistant Secretary, Technology Assessment and Access Division	Updated for 2018-19 financial results and key forward dates
30/06/2019	Update of CRIS for 2019 -20	First Assistant Secretary, Technology Assessment and Access Division	Updated of financial estimates, key dates and events
30/06/2018	Update of CRIS for 2018 -19	First Assistant Secretary, Technology Assessment and Access Division	Updated of financial results for 2017-18, financial estimates, key dates and events
01/02/2018	Update of 2016-17 financial performance	Secretary, Department of Health	Updated for 2016-17 financial results
1/12/2016	Certification of the CRIS	Secretary, Department of Health	New cost recovered activity
01/04/2016	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
Levy calculation method used	
<p>Stakeholders 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 remove the maximum levy cap per product or to charge a fixed rate per registry entry.</p>	<p>The Department notes the consultation feedback.</p> <p>The Department notes the full cost review of the grant and levy arrangements, including the maximum levy cap being undertaken will include options for the Department to present to Government on funding arrangements of the NJRR from 2025-26. Any proposed changes resulting from a government decision will be informed by stakeholder consultation.</p>
Cost Recovery Arrangements	
<p>Stakeholder feedback showed strong support of the registry and the levy for the historical funding level of the NJRR.</p> <p>Feedback acknowledged the Government funding over and above the industry levy in the context of multiple beneficiaries from the output of the NJRR.</p> <p>The appropriateness of the current cost recovery arrangements was queried. Feedback suggested the NJRR is not cost recoverable under the Charging Framework with the view that it is not a regulatory activity undertaken by Government nor an activity generated by the joint replacement device industry.</p>	<p>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>Sponsors obtain substantial benefits from the continued operation of the NJRR, including commercial benefits from improved consumer confidence in the safety and efficacy of joint replacement devices.</p> <p>When and how to apply the Charging Framework is a decision of Government. The Department has implemented the levy on sponsors of joint replacement devices consistent with the Charging Framework and relevant Government policy decisions including that taken in the 2024-25 Budget.</p> <p>The Department notes the full cost review of the grant and levy arrangements being undertaken will include options for the Department to present to Government on funding arrangements from 2025-26.</p>
Full cost review	
<p>Stakeholder feedback welcomed the full cost review of the grant and levy arrangements being undertaken by the Department.</p> <p>Stakeholders noted the impact of inflation and other significant cost pressures and expressed the view that alternate sources of funding beyond current cost recovery arrangement from sponsors should be considered.</p>	<p>The Department acknowledges this feedback and notes that the full cost review of the grant and levy arrangements being undertaken will include options for the Department to present to Government on future funding arrangements of the NJRR from 2025-26.</p>

Stakeholder Comment	Departmental Response
<i>NJRR governance structure</i>	
Stakeholder feedback noted a request to establish a NJRR governance structure including other significant stakeholder groups and for greater transparency of financial expenditure and budget.	The Department acknowledges the feedback in relation to NJRR governance and transparency. The AOA is in the process of establishing a Consultative Committee to provide a forum for industry, government and consumer representatives to provide feedback on the overall strategic direction of the functions and operations of the NJRR.