Australian Government

Department of Health, Disability and Ageing

COST RECOVERY IMPLEMENTATION STATEMENT

Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

1 July 2025 to 30 June 2029

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 which ensures the transparency and accountability for the level of charging and to demonstrate that the purpose for charging, as decided by Government, is being achieved.

Contents

1 INTRODUCTION

1.1 Purpose

This CRIS provides information on how the Department of Health, Disability and Ageing (the Department) implements cost recovery for Commonwealth funding provided to the Australian Orthopaedic Association (AOA) to administer the National Joint Replacement Registry (NJRR) (herein referred to as the AOANJRR). The CRIS reports actual financial and non-financial performance information, outlines legislative changes (and proposed legislative changes) and contains financial and demand forecasts for 2025-2026. 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 AOANJRR 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 AOANJRR'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 AOANJRR data to have better outcomes and a decline in the use of medical device types with less satisfactory performance data[1].

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 AOANJRR is appropriate because:

- it ensures that funding is available to develop, maintain and administer the AOANJRR
- charging 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.

[1] AOANJRR Annual Report 2025

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, regulation, or a combination of these.

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 1 July 2025, there were 40 sponsors.

Sponsors obtain substantial benefits from the continued operation of the AOANJRR, including commercial benefits. Other stakeholders who derive benefits from the AOANJRR 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 AOANJRR would be recovered from the manufacturers and importers of joint replacement medical devices (collectively referred to as sponsors)[2]. The AOANJRR 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 AOANJRR informs the development of new prostheses, enabling manufacturers to draw on reliable performance information for existing devices and designs.

In the 2024-25 Budget, the Government announced:

- additional funding for the AOANJRR that was agreed in 2023-24 ($1.249 million) to be cost recovered over four years from 2024-25 to 2027-28
- additional funding for the AOANJRR in 2024-25 ($1.561 million) to temporarily increase the core operating funding that would not be cost recovered, and
- the Department would undertake a full cost review of the grant and levy arrangements, with the outcomes to inform future funding arrangements for the AOANJRR.

[2] 2009-10 Budget Paper No. 2, p298

The full cost review of the AOANJRR provided recommendations to improve fiscal governance and financial management and included advice on alternate levy options. These options included: increasing the levy base; increasing the levy cap; and removing the levy cap entirely.

In the 2025-26 Budget, the Government announced ongoing funding for the AOANJRR over the four years until 2028-29, to be cost recovered through a levy to sponsors.

Further information about the outputs and cost of the regulatory activity is provided in sections 3.1 and 3.2 of this document.

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 AOANJRR to be recovered through a levy imposed on each joint replacement device sponsor for each relevant item on the Prescribed List, according to that sponsors' revenue as a proportion of all relevant revenue.

Legislative Amendments

The NJRR Levy Rule has been amended to specify the levy amount for 2025-26 and to change the levy date to 28 February 2026.

A grant has been provided to the AOA to administer the AOANJRR over four financial years (2025-26 to 2028-29).

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 AOANJRR, 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 AOANJRR 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 AOANJRR website
- continue and maintain a formal reporting system between the AOANJRR 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 AOANJRR 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 for the data management costs of the AOANJRR are recovered through the sum of all levies collected from joint replacement device sponsors.

Additional funding of $1.249 million was provided to the AOA in 2023-24, to be cost recovered over four years from 2024-25 ($312,000 per year until 2027-28^). This funding was due to increased costs for supporting core activities including operating costs (9%) and associated staffing costs (91%), to manage data and maintain IT systems to administer the AOANJRR.

One-off additional funding of $1.561 million was also provided to the AOA in 2024-25 to temporarily further increase the core operating funding, which is not being cost recovered.

From 2025-26, funding has increased by $2.4 million over the four years to 2028-29 (approximately $600,000 per annum) to cover the data management component of the AOANJRR and ensure that the AOANJRR can continue to monitor the effectiveness of implantable devices and keep the revision rate for surgeries to a minimum. The total cost recovered funding for AOANJRR ranges between around $3.3 million and $3.4 million per annum (GST exclusive + indexation).

In December 2025, the Commonwealth and AOA signed a 4-year grant for the administration of AOANJRR from 1 July 2025 to 30 June 2029. Any additional funding required to administer the AOANJRR is to be sourced by the AOA and no additional ongoing contribution from Government is proposed.

Table 1 below summarises funding to be provided to the AOA for 2025-26 to 2028-29.

Table 2 below summarises the total levy amount for cost recovery for 2025-26 to 2028-29 including the additional funding provided in 2023-24.

Further information on costs recovered in prior financial years is summarised in section 6.2 of this document.

Table 1 – Funding provided to the AOA

Cost type	2025-26	2026-27	2027-28	2028-29
Grant Funding	$3,259,000	**$3,326,000**	**$3,391,000**	**$3,405,000**
Total	$3,259,000	**$3,326,000**	**$3,391,000**	**$3,405,000**

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

Cost type	2025-26	2026-27	2027-28	2028-29
Grant Funding	$3,259,000	$3,326,000	$3,391,000	$3,405,000
Additional funding^	$312,000	$312,000	$312,000	-
Total levy amount	$3,571,000	$3,638,000	$3,703,000	$3,405,000

3.3 Design of the regulatory charge

The formula for determining the levy rate for 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. There is a wide range of medical devices used in joint replacement surgery. The benefits joint replacement devices listed on the Prescribed List receive vary considerably. The formula for determining the levy rate considers the device benefit amount, utilisation, and the AOANJRR funding amount. The maximum rate of levy of $5,000 was considered reasonable when the levy was introduced.

The NJRR Levy Rule specifies one levy day i.e. the day the levy will be charged. For 2025-26 the levy day is 28 February 2026 to align with the implementation of the new grant agreement. For 2026-27 and each future year the levy day would be 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 each year.

If required, a levy may also be imposed on a day determined by the Minister for Health and Ageing (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 2025-2026. Invoices are sent to sponsors following the levy day.

The overall increase in the levy amount in 2025-26 is 21.80% compared to the levy amount in 2024-25. In 2025-26, there are 40 sponsors liable to pay the levy, and 22 sponsors that have devices subject to the $5,000 cap.

The levy amount payable by sponsors each year is calculated based on utilisation rate of devices, device benefit amount and total levy amount. To determine the levy amount to be charged to each sponsor, the calculation is run multiple times to remove devices as they hit the $5,000 cap until the total levy amount is achieved.

Following the full cost review and stakeholder feedback, the Government is proposing to remove the $5,000 cap as small and mid-sized companies currently pay a disproportionate share of the total levy and, in effect, are subsidising larger companies. Removing the cap would result in more equitable arrangements with a proportional decrease in the levy for small and mid-sized companies and an increase in the levy for larger companies.

Further, the Government is proposing to no longer exclude hand and foot articulation devices from the levy. The financial impact of including hand and foot articulation devices in the levy calculation will be detailed in an updated CRIS.

Legislative amendments are required to remove the levy cap and to no longer exclude hand and foot articulation devices from the levy. Implementation is therefore proposed from the 2026-27 financial year (and based on 2025-26 utilisation rate of devices and device benefit amount).

4 RISK ASSESSMENT

A Charging Risk Assessment (CRA) was undertaken in January 2025. The overall risk rating is ‘medium’ because the charging method is a levy. The change in total revenue and the percentage increase for payors received a high rating primarily due to the increased levy amount. All other implementation risks considered as part of the CRA were assessed as low. The overall charging risk is anticipated to decrease as the confirmation of four-year funding reduces financial and implementation uncertainty.

5 STAKEHOLDER ENGAGEMENT

The revised cost recovery arrangements follow the full cost review of the grant and levy arrangements undertaken during 2024-25, which included targeted stakeholder consultations in November 2024. Based on the outcomes of the review, the Government provided additional funding for the data management component of the registry.

Stakeholders will have the opportunity to provide feedback on the proposed changes to the levy for 2025-26 over a 2-week consultation period from 22 January 2026 to 5 February 2026. A summary of consultation

feedback with responses from the Department will be published in **Attachment A** when the 2025-26 CRIS is finalised.

6 FINANCIAL PERFORMANCE

Table 3 outlines the forecast expenses and estimated revenue for the 2025-26 to 2028-29 financial year. Any changes to financial estimates will be updated in this table as part of the regular CRIS updates.

6.1 Financial Estimates

Table 3 below provides the total expenses (i.e. the grant provided to AOA) and the total revenue (i.e. levy amount to be recovered consistent with Government policy decisions) for 2025-26 to 2028-29.

Table 3 – Financial estimates for cost recovered activities

Financial Item	2025-26 ($'000)	2026-27 ($'000)	2027-28 ($'000)	2028-29 ($'000)
Total expenses	3,259	3,326	3,391	3,405
Total revenue	3,571	3,638	3,702	3,405
Balance = revenue - expenses	312	312	312	0
Cumulative balance	-2,186	-1,874	-1,562	-1,562

6.2 Financial Outcomes

Table 4 below is updated after each financial year to report on actual financial performance. i.e. the actual revenue (the levy amount recovered) with actual expenses (grant funding provided to AOA). An explanation will be provided for any year with a significant variance.

Table 4 – Financial outcomes for cost recovered activities

Financial Item	2021-22 ($'000)	2022-23 ($'000)	2023-24 ($'000)	2024-25 ($'000)
Estimates				
Revenue = X	2,543	2,571	2,674	2,932
Expenses = Y	2,543	2,571	2,674	4,181
Balance = X – Y	0	0	0	-1,249
Actuals				
Revenue = X	2,543	2,571	2,674	2,932
Expenses = Y	2,543	2,571	3,923	4,181
Balance = X – Y	0	0	-1,249	-1,249
Cumulative balance	0	0	-1,249	-2,498
Variance explanation	In the 2024-25 Budget, the Government announced additional funding of $1.249 million to be provided to the AOA in 2023-24. The $1.249 million is to be cost recovered over four years from 2024-25. The Government also announced additional funding of $1.561 million to be provided to the AOA in 2024-25 to temporarily further increase the core operating funding, which was not cost recovered.			

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 AOANJRR for the coming financial year.

Performance Reports

Final Report

- A comprehensive review of the operation of the core activities of the AOANJRR 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 the grant agreement.

Annual Report

- Information on the methodology used by the AOANJRR, 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
- comprehensive data on joint replacements covered by the AOANJRR, 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
28/02/2026	Publish final CRIS for 1 July 2025 to 30 June 2029
30/11/2026	Update 2025-2029 CRIS with 2025-26 financial and non-financial performance

9 CRIS APPROVAL AND CHANGE REGISTER

Date of change	CRIS change	Approver	Basis for change
21/01/2026	Approval of draft 2025-26 CRIS for stakeholder consultation	First Assistant Secretary, Technology Assessment and Access Division	Annual CRIS consultation for 2025-26 and financial results for 2024-25.
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.

Date of change	CRIS change	Approver	Basis for change
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
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

Date of change	CRIS change	Approver	Basis for change
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