

RADIATION ONCOLOGY HEALTH PROGRAM GRANTS (ROHPG) SCHEME Administrative Guidelines

Effective 1 January 2020

Acknowledgement: This document has been drafted in consultation with public and private radiotherapy providers.

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1 PURPOSE OF THIS DOCUMENT

The purpose of this document is to provide information about the Radiation Oncology Health Program Grant Scheme (ROHPG Scheme) and the assessment criteria used to make decisions under Part IV of the *Health Insurance Act 1973 Act* (the Act) in respect of applications for funding. This document also outlines the standard conditions which will be applied in relation to approved applications.

2 BACKGROUND

The ROHPG Scheme provides a capital contribution to the cost of linear accelerators (linacs) to assist in patient access to high-cost radiotherapy treatment.

The ROHPG Scheme is open to public and private sector providers who are recognised under Sections 40-41 of the Act as an 'approved organisation' providing an 'approved health service' at a specific location, with specified equipment.

Funding under the ROHPG Scheme is separate from, but complementary to the Medicare Benefits Schedule (MBS). Medicare pays benefits to patients for the professional and operating costs of radiation oncology services provided to them and does not include funding to organisations for the cost of equipment used in providing these services.

The ROHPG Scheme provides funding for both public and private providers of radiation oncology services to establish new facilities in locations across Australia that have been identified as priority areas (refer to Clause 4 – Priority Areas), and purchase replacement equipment when appropriate.

To apply for funding under the ROHPG Scheme, providers must first be an approved organisation under Section 40 of the Act. Details on how to apply to be an approved organisation and for approval of a health service to be funded under the ROHPG Scheme are at Clause 5 - Application Process.

Through the ROHPG Scheme, the Commonwealth Government aims to assist in:

- improving health outcomes for cancer patients;
- increasing access to radiation oncology services;
- improving equity of access for cancer patients; and
- ensuring the highest quality and safety of radiation oncology services.

Further, the ROHPG Scheme aims to encourage and steer:

- utilisation of radiation as a treatment of cancer noting that radiation is a highly effective form of treatment:
- high quality, safe radiation oncology services; and
- access (investment in areas of need).

3 LEGISLATIVE ARRANGEMENTS

The following provisions in Part IV of the Act are relevant for the ROHPG Scheme. A reference to the Minister in these Guidelines refers to the Minister for Health for the Commonwealth of Australia or an officer who has been delegated some or all of the powers conferred on the Minister under Part IV of the Act.

Section 40 of the Act provides for the approval of an organisation, whether public or private, as an 'approved organisation' by the Minister.

Section 41 of the Act provides for the approval by the Minister of an 'approved health service' provided, or to be provided, by an 'approved organisation'. For the ROHPG Scheme, approval is granted for a health service using specified equipment at a specified location.

Section 42 of the Act allows the Minister to determine an approved organisation's entitlement to be paid all or a proportion of the costs incurred in providing an approved health service.

Subsection 43(1) of the Act allows the Minister to specify any conditions attached to those payments.

Subsection 45(1) of the Act allows the Minister to direct an organisation to make claims for payment in a specified way.

Section 46 allows the Minister to make, and apply conditions to, advances on payments.

4 PRIORITY AREAS

It is recognised that the planning of radiotherapy services properly rests with States and Territories. For the purposes of the ROHPG Scheme, the provision of funding for radiation oncology services is based on health planning regions. Health planning region boundaries are determined by each State and Territory Government.

The Australian Government Department of Health (the Department) will seek advice from the States and Territories in December each year regarding health planning regions identified as priority areas for the purposes of radiation oncology services. It is assumed that in making this assessment factors such as cancer incidence, population and existing services will be taken into consideration.

Identified priority areas will be published in February of each year on the Department's website.

5 APPLICATION PROCESS

The types of application that can be made are:

- approval of an organisation
- New facility or additional equipment at an existing approved facility ("expansion of capacity")
- Replacement of existing equipment
- Relocation of an approved facility
- Transfer of ownership or control of an existing facility

Applications <u>must</u> be made using the appropriate ROHPG prescribed application form. Application forms can be downloaded from the Department's website at the following link:

https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-roi-hpg-overview-index.htm#guidelines

Application forms can also be requested by emailing radiation.oncology@health.gov.au.

All ROHPG applications can be mailed to:

Director
Radiation Therapy and Medical Indemnity Section
MBS Policy and Specialist Services Branch
Medical Benefits Division
Department of Health
MDP 861, GPO Box 9848

CANBERRA ACT 2601

Alternatively, applications can be emailed to <u>radiation.oncology@health.gov.au</u>.

5.1 State/Territory notification of application

All providers, both private and public, will need to demonstrate that they have notified the relevant state or territory of their ROHPG application. This is to assist States and Territories in the planning of radiation oncology services.

Where significant cross-border flows of patients are expected, the applicant should also consult with the other relevant States or Territories and provide information showing that this has occurred.

This notification is required for <u>all</u> ROHPG applications.

Notification can be in the form of email correspondence, for example copying in the Department's Radiation Oncology mailbox (radiation.oncology@health.gov.au) with correspondence to the relevant State or Territory.

5.2 Applications for newly identified priority areas

The Department will update identified priority areas and publish timelines for applications for new priority areas on it's website in February of each year.

The process for applications for new priority areas (NPAs) will be as follows:

- Applications for NPAs will open eight weeks after being published on Health website.
- Applications for the NPAs will be accepted for a period of four weeks then close until further notice.
- Applications for a NPA will be considered together and assessed against the criteria at Clause 6.2 of these Guidelines.
- When the Minister, or their Delegate, has made a decision to approve a ROHPG funding application for a health service in a NPA, the applicants will be notified of the decision and the newly approved facility will be added to the list of ROHPG funded facilities on the Department's website.
- Applications for the NPA will then reopen and be accepted at any time on an ongoing basis throughout the year.
- In the event that no applications are received for a NPA in the initial four week application period, applications will be assessed on a "first come, first served" basis.

6 ASSESSMENT CRITERIA

This clause sets out relevant criteria for the Minister to take into account when making decisions under the Act and information that applicants will be required to provide. The Minister will consider the merits of each particular case and may also consider other relevant factors or issues that arise on a case-by-case basis.

Competing applications from different organisations for approval of a health service, or expansion of capacity, in the same priority area will be assessed based on their relative ability to meet the assessment criteria.

In the interests of achieving the best health and financial outcome for patients, particular focus will be on affordability and multidisciplinary integrated patient care and applicants may be asked to provide additional information on these aspects of their application.

6.1 Approval of an organisation

To apply to be an approved organisation under section 40 of the Act, applicants must complete and submit the appropriate ROHPG Scheme application form i.e. "Application for approval of an organisation under section 40 of the *Health Insurance Act 1973*".

6.2 Assessment Criteria for a new facility and new equipment at an existing approved facility

The assessment criteria set out in this clause will be applied in relation to:

- applications for approval of a health service that has not previously been approved under Section 41; and
- applications to vary an existing approved health service to include additional specified equipment ("expansion of capacity").

Criterion 1: Eligible equipment

The Minister will consider whether the equipment covered by the application is within the scope of the ROHPG Scheme. This means:

- it must be a linac; and
- it must <u>not</u> have been funded through other Commonwealth budget measures for external beam radiotherapy.

Criterion 2: Patient access

The Minister will consider whether the service locations covered by the application are consistent with supporting patient access to radiation oncology services, based on identified priority areas.

Applications for a new health service, expansion of service or relocation where the health service will not be located in an identified priority area may be considered but must provide evidence of need and have the support of the relevant State/Territory.

Criterion 3: Services must be affordable

The Minister will consider whether the services which will constitute the approved health service are affordable, having regard to billing practices and the extent of out-of-pocket costs.

The <u>minimum</u> requirement under ROHPG conditions of funding is that the approved organisation must offer Medicare bulk-billing arrangements for concessional patients.

To support their application, applicants are required to provide information demonstrating that the fees charged for services that form part of the approved health service will not result in substantial out-of-pocket costs that may affect patient access to radiation oncology services.

Criterion 4: Multidisciplinary and patient-centred care

The Minister will consider whether the radiation oncology services to be provided as part of the approved health service are integrated with other cancer treatments and other medical services. This will help ensure the best possible treatment for patients.

Applicants will be required to provide information demonstrating that the proposed approved health service will form part of an integrated cancer management system including, but not limited to, medical oncology, surgery and allied health services i.e. multidisciplinary care. This includes information regarding:

- arrangements and referral basis, if any, with the relevant specialists;
- clinical oncologists and surgeons networked into services;
- details of links to other centres, particularly for on-referral or discussion on complex cases;
- access to in-patient care; and
- access to other associated follow-up care for patients.

Criterion 5: Commencement Date

The Minister will consider the proposed commencement date for treating patients under the approved health service, and whether this timeframe is realistic and reasonable. The maximum period within which the Department would expect facilities and equipment which form part of an approved health service to become operational is within two years from the date of the approval under Part IV of the Act. The Minister may revoke an approval of a facility or equipment if it does not become operational within 2 years.

6.3 Assessment criteria for replacement of existing equipment

The assessment criteria in this clause will be applied in relation to applications by approved organisations for variation of an approved health service to <u>replace</u> an ROHPG funded linac.

An application to replace an approved health service (i.e. ROHPG funded linac) must demonstrate that:

- there is an ongoing need for the health service;
- the health service will continue to meet Criteria 2 and 3 above; and
- they have complied with the ROHPG conditions of funding.

If an application for replacement is successful, ROHPG payments for new equipment will be made as follows:

- if the linac that is being replaced has received an annual payment in the financial year that new linac commences services, the new linac will not receive a payment in that financial year.
- if the linac that is being replaced has not received an annual payment in the financial year that the new linac commences services, the new linac will be entitled to the full annual payment on receipt of an audit certificate in the financial year it commences services.

6.4 Assessment criteria to relocate an existing approved facility

The assessment criteria in this clause will be applied in relation to applications by approved organisations for variation of an approved health service to relocate a specified service location to a different location.

The Minister will consider the reasons for the proposed relocation and applicants will be required to provide information addressing this.

Relocation of an approved health service should take into consideration existing services. Relocation should be within the same area or to an area of need (identified priority area) and should not create an area of need by withdrawal of the service.

Applications for relocation will be considered against the same criteria as an application for a new facility.

The applicant must notify the Department when the health service ceases to operate in its approved location. ROHPG funding will be suspended from the date operations cease and, if the application is successful, recommence when all conditions of funding are met for the new location, including evidence of an appropriate dosimetry audit at the new location.

6.5 Assessment Criteria for facility transfer of ownership or control of an existing health service Ownership transfers occur where an organisation takes ownership or control of a health service, or part of a health service, that is subject to an existing approval under Section 41 held by a different organisation. This may arise where, for example, a provider acquires a radiation oncology practice from another provider which is an approved organisation. The Department may facilitate continuing ROHPG funding in such circumstances.

To enable continued ROHPG funding when an ownership transfer occurs:

- if the organisation taking ownership or control is not already an approved organisation, they must obtain approval under section 40; and
- the approved organisation taking ownership or control must apply and subsequently obtain approval of a
 health service or variation of their existing approved health service under section 41 to include the
 locations and specified equipment which have been acquired.

To facilitate a transfer applicants for approval or variation of a health service will be required to provide the following information:

- documentation which demonstrates agreement to the transfer of ownership or control;
- expected date of completion of the planned transfer of ownership or control;
- details of the equipment to be transferred; and
- ROHPG numbers of the equipment to be transferred.

The Minister will consider whether there is agreement from all relevant parties to the transfer of ownership or control, when the transfer will occur, and the service locations and/or equipment that will be included in the transfer.

Consideration will also be given to the extent to which the criteria for approval of a new facility continue to be met.

The Department will consult with the existing approved organisation regarding the proposed transfer, and may vary or revoke that organisation's approval of a health service under Section 41 as necessary to facilitate the transfer of approval and ROHPG funding to the new organisation.

Applications relating to transfer of ownership/control are not granted automatically and will be considered in accordance with the relevant ROHPG assessment criteria.

7 PROCEDURAL FAIRNESS FOR APPLICANTS

If, after taking into account all the relevant information for an application, the Minister does not intend to approve an application, or intends to revoke an application, the applicant will be informed prior to a decision being made and be provided with the opportunity to provide additional information in support of its application.

8 FUNDING

In order to receive Government funding under the ROHPG Scheme, providers must:

- be an approved organisation under Section 40 of the Act;
- hold an approval for provision of a health service under Section 41 of the Act; and
- meet the conditions of funding of grants that apply in relation to the approved health service under Sections 43 and 46 of the Act.

8.1 Funding Arrangements

The ROHPG Scheme will provide a contribution of up to \$3 million towards the capital costs of each linac approved as part of the approved health service. The make, model and any optional add-on configurations required for the linac will be at the discretion of the organisation applying for the approval of the health service.

Each approved piece of equipment as part of a health service will be provided with a unique ROHPG identification number for the purpose of administering ROHPG payments.

Arrangements made under the Act for new and replacement linacs will provide for capital contribution grant payments of \$300K per year for 10 years for public sector providers and \$375K per year for 8 years for private sector providers. Payments will be made annually.

In the case where an approved organisation proposes to decommission a linac and seek new capital funding for a replacement linac, a variation to the approved health service can be sought to enable a capital contribution of up to \$3 million over 10 years for public providers and \$3 million over 8 years for private providers for the replacement linac. If approval is granted for funding in relation to the replacement linac the relevant legal instrument under the Act will be varied so that no further payments will be provided in relation to the replaced linac.

8.2 Conditions of funding

Under Sections 43 and 46 of the Act, health program grant payments (including advances) may be made subject to conditions determined by the Minister. Payments may be recovered as a debt due to the Commonwealth if the approved organisation fails to comply with conditions.

The Minister will determine conditions that apply to payments when they approve a health service under Section 41 or vary an approval, and specify those conditions in the legal instrument. This will include standard conditions relating to the matters outlined below. The Minister may also impose additional conditions.

8.2.1 General conditions

The Minister will apply conditions requiring that:

- the approved organisation must provide Medicare eligible services;
- the approved organisation and its employees must not misrepresent their relationship with the Commonwealth;
- the approved organisation must indemnify the Commonwealth in respect of certain matters;
- the approved organisation must offer Medicare bulk-billing arrangements for concessional patients; and
- where possible, the approved organisation must advise the Commonwealth of any planned publicity in relation to an approved health service.

8.2.3 Public Providers

For approved organisations which are public providers, the Minister will apply conditions requiring that the approved organisation have a bank account, under its sole control, into which all advance payments of ROHPG funding are to be deposited and used for radiation oncology purposes at the specified service locations for the approved health service. This condition will minimise the risk of funding being used for general hospital expenses rather than for the purchase of high-value capital equipment to support the delivery of radiotherapy services.

8.2.4 Private Providers

For approved organisations which are private providers, the Minister will apply conditions requiring the approved organisation must adhere to the Australian Privacy Principles in the *Privacy Act 1988* and comply with any relevant privacy legislation and/or guidelines.

8.2.5 Dosimetry auditing

All approved service locations must undergo ongoing independent dosimetry auditing. The independent dosimetry audit must be from an independent organisation with accreditation from the National Association of Testing Authorities (NATA), Australia to ISO 17025. The audit will be consistent with the approach adopted by the Australian Clinical Dosimetry Service (ACDS) which supports a four-year cycle with different audit levels across the cycle.

All ROHPG payments are dependent on evidence of a dosimetry audit from a NATA accredited organisation conducted within the last financial year.

9 REVOCATION OF APPROVALS

The Minister is able to revoke approvals granted under the Act.

Circumstances in which the Minister may consider revocation include, but is not limited to, when an organisation is unable to commence delivery of patient services by the date specified in its application and cannot demonstrate that strategies have been put in place for commencement within a reasonable period. In such circumstances, an organisation may be asked to provide regular progress reports to the Department prior to a decision to revoke.

GLOSSARY

TERM DEFINITION

Act The Health Insurance Act 1973

Approved health service A health service provided by an approved

organisation and approved under subsection 41(3) of the Act. For the ROHPG Scheme, approvals will be given in relation to the provision of radiation oncology services at specific locations using

identified equipment

Approved organisation An entity that has been approved by the Minister for

Health or their delegate as an approved organisation

under subsection 40(3) of the Act

Capital balance The maximum proportion of the cost of providing

the approved health service to be funded by the Commonwealth determined for each type of radiation oncology equipment at the time an application for ROHPG funding is approved

Concessional Patient A person who is a concessional beneficiary for the

purposes of Part VII of the National Health Act 1953,

as in force from time to time

Department The Department of Health

Legal instrument The instrument(s) made by the Minister or Delegate

approving a health service, determining entitlement to payment, determining conditions and giving

to payment, actermining conditions and gr

directions about claims for payment

Linear accelerator

Minister for Health for the Commonwealth of

Australia or an officer who has been delegated some or all of the powers conferred on the Minister under

Part IV of the Act

Priority area As defined in Clause 4

ROHPG Radiation Oncology Health Program Grant