
Prostheses List Reforms

***Industry Working Group on Revised Benefit Setting
and Review Framework***

Terms of Reference

and

Operating Guidelines

A. Role of the Industry Working Group on Revised Benefit Setting and Review Framework

To ensure Australian patients have access to safe, effective, and cost-effective innovative medical devices in the private sector by:

- developing a revised framework for benefit setting and benefit review reflecting the use of health technology assessment (HTA) including evaluation of the value, cost-effectiveness and innovation of medical technology.

The Industry Working Group will report to the *Prostheses Reform Governance Group* (the Governance Group)

The Industry Working Group on Revised Benefit Setting and Review Framework (the Benefit Setting IWG) will develop and provide a final report to the Minister for Health and MTAA Chairman by 30 June 2020 on options for a revised framework for setting and reviewing benefits for devices on the Prostheses List that will:

- promote the sustainability of privately insured healthcare to help maintain affordability of private health insurance for all Australians
- minimise patient out-of-pocket costs, thereby protecting the value proposition of private health insurance
- preserve patient access to the device recommended by their physician
- support a viable, innovative and diverse medical technology sector in Australia.

B. Function of the Industry Working Group on Revised Benefit Setting and Review Framework

1. The function of the Benefit Setting IWG is to review the current framework for benefit setting and benefit review for medical devices under the Prostheses List (PL) to ensure the future Prostheses List framework:

- a. is tailored to medical technology
- b. has a structure and associated processes that are simple, administratively efficient, pragmatic and sustainable
- c. is not duplicative of other HTA processes
- d. is informed by robust and relevant evidence, including, for market considerations, credible data
- e. encourages competition
- f. is built on transparent processes with appropriate protections around commercial-in-confidence data
- g. provides flexibility to differentiate between product groups/sub-groups
- h. is compatible with the incorporation of new and cost-effective technologies
- i. recognises improvements in value.

2. In developing options, the IWG will have regard to:
 - a. the strengths and weaknesses of the current benefit setting and review framework
 - b. practicable approaches for demonstrating the cost-benefit of the devices
 - c. the circumstances under which to apply HTA
 - d. how 'value' should be defined in the context of medical devices
 - e. how the following parameters should be assessed:
 - i. validated patient reported outcome measures
 - ii. substantial equivalence for the purposes of benefit setting and review
 - iii. superior efficacy or performance over a comparator at the time of benefit setting and also at the time of benefit review
 - f. how the framework fosters and encourages innovation
 - g. criteria and processes for listing medical technologies that do not fit the definition of Part A of the Protheses List
 - h. the transparency requirements in relation to the assessment of Protheses List applications
 - i. mechanisms for reviewing benefits of devices / technologies on the Protheses List
 - j. an appropriate review timetable
 - k. refining the grouping schemes under the Protheses List to support a more efficient listing process
 - l. transparent review processes for Sponsors
 - m. the role of real world data in benefit setting and benefit review.
3. The options developed by the Benefit Setting IWG should:
 - a. improve the transparency of medical device benefit setting on the Protheses List
 - b. support the building of stakeholder and consumer confidence in Protheses List benefits
 - c. support fair reimbursement to sponsors and suppliers for their products
 - d. support fair reimbursement to hospitals for the costs they incur in providing medical devices to patients
 - e. be manageable and sustainable in terms of costs to operate – the costs will not be disproportionately burdensome for stakeholders
 - f. include a risk assessment, and advise on ease of implementation and potential transition arrangements.
4. Stakeholders will be consulted during the development of the report.

C. Role of members

The individual members of the Benefit Setting IWG will:

- attend meetings as required and actively participate in the group's work
- provide complete, accurate and meaningful information in a timely manner
- participate openly and honestly in discussions
- act in the interests of all stakeholders
- conduct themselves appropriately as representatives of their stakeholder organisations

- demonstrate genuine interest in, and commitment to, the initiatives and the outcomes being pursued.

C1. Disclosure of Information

The business of the IWG is Committee-in-Confidence. Documents such as briefs, minutes and spreadsheets are circulated to Members for the purposes of performing their roles and functions. Members must not disseminate or discuss such documents with others outside the Committee Membership.

Discussions in meetings are also confidential, and Members must not discuss issues raised outside the Committee membership unless the Chair has agreed that the information may be discussed for consultation purposes.

C2. Deed of Undertaking

Prior to commencement of their official duties, committee members are asked to read and sign a *Deed of Undertaking in Relation to Confidential Information and Conflict of Interest* (attached). In signing this Deed Poll, members have agreed to the outlined definitions of Conflict of Interest, as well as to adhere to the confidentiality requirements for the information being handled by the committee.

In particular, members are obliged to keep secret and confidential all Confidential Information and ensure that they do not directly or indirectly disclose Committee-in-Confidence information to any person outside the Committee.

In signing the Deed Poll, members have understood and acknowledged that any unauthorised use or disclosure of Confidential Information may make him or her liable for prosecution under the laws of the Commonwealth.

D. Membership

The Benefit Setting IWG will be comprised of:

- Emeritus Professor Terry Campbell AM (Chair)
- Dr Megan Keaney, Department of Health
- Mr Matt Muscio, LifeHealthcare
- Mr Paul Dale, MTAA
- Mr Andrew Wiltshire, Medtronic
- Mr Ian Noble, Noble Pharma Consulting
- Ms Sarah Griffin, Medtechnique
- Mr Paul Suebwongpat, Cochlear Limited
- Mr George Papadopoulos, AusBiotech
- Mr Craig Moy, Private Healthcare Australia
- Dr Jui Tham, Members Health Fund Alliance
- Ms Emma Bognar, Australian Private Hospitals Association
- Ms Gabrielle Moreland, Day Hospitals Australia
- Ms Andrea Selleck, Australian Regional Health Group
- Dr Janet Wale, Consumers Health Forum

- Mr James Downie, Independent Hospital Pricing Authority
- Ms Cathy Ryan, Catholic Health Australia

The Benefit Setting IWG may invite individuals with appropriate knowledge and expertise, including members of other IWGs to participate as required.

E. Operating Guidelines

E1. Chair

The group will be chaired by Emeritus Professor Terry Campbell (Chair of the Prostheses List Advisory Committee).

E2. Membership appointment

Members will be endorsed by the Prostheses Reform Governance Group.

Members will be appointed by the Assistant Secretary, Office of Health Technology Assessment Branch, Department of Health, as members of a departmental committee for financial management purposes, for the duration of the project.

E3. Frequency of Meetings

Meetings will be held as required. Meetings will be convened by the Department of Health.

E4. Agenda items

All agenda items will be forwarded to the Department of Health by close of business ten working days prior to the next scheduled meeting.

The agenda, with attached meeting papers, will be distributed at least five working days prior to the next scheduled meeting.

E5. Meeting papers

In accordance with departmental policy, papers will be circulated electronically via Office 365. The Department will provide support to members to sign up for access.

E6. Record of meetings

The secretariat will record discussions and outcomes of discussions and produce a draft record of each meeting, to be cleared initially by the Chair and circulated to members for comment.

E7. Proxies to meetings

Members of the Benefit Setting IWG, with the exception of expert members, may nominate a proxy to attend a meeting if the Member is unable to attend.

The Chair will be informed of the substitution as soon as possible before the scheduled meeting.

The nominated proxy will provide relevant comments/feedback about the attended meeting to the Benefit Setting IWG Member they are representing.

E8. Quorum

A quorum will be half the regular membership plus one.

E9. Communications

Members will communicate through the SharePoint site in Office 365, or via email.



Australian Government

Department of Health

DEED OF UNDERTAKING IN RELATION TO CONFIDENTIAL INFORMATION AND CONFLICT OF INTEREST

THIS DEED POLL is made the day of20....
by[insert name of Member]
of[insert address of Member]

WHEREAS

1. The Commonwealth of Australia (the “**Commonwealth**”) as represented by the Department of Health (the “**Department**”) has nominated a group of persons as members of the [insert details of the relevant committee/subcommittee] (the “**Committee**”).
2. The Commonwealth has appointed the Member as a member of the Committee.
3. The Commonwealth requires the Member to undertake to preserve and maintain the confidentiality of information to which the Member will have access by virtue of his/her position on the Committee.
4. The Commonwealth requires the Member to undertake certain actions in relation to any actual or potential conflict of interest.

NOW IT IS HEREBY AGREED AS FOLLOWS:

1. Interpretation

- 1.1 In this Deed Poll unless the contrary intention appears:

“**Approved Person**” means a person:

- (a) who has been appointed by the Commonwealth to be a member of the Committee; or
- (b) who is an officer of the Department of Health.

“**Confidential Information**” means any material made available to the Member by the Department that:

- (a) is by its nature confidential;
- (b) is designated by the Commonwealth as confidential; or
- (c) the Member knows or ought to know is confidential;
but does not include any information which:
 - (d) is in the public domain;
 - (e) becomes public knowledge other than by breach of this Deed Poll; or
 - (f) is required to be disclosed by statute or court order.

“**Conflict of interest**” includes any situation where a Member or the Member’s partner, family member, or close family friend has a direct financial or other interest which influences or may appear to influence

proper consideration or decision making by the Committee on a matter or proposed matter, that Member will be required to declare that interest and will then take no further part in the consideration of that matter.

2. Undertaking

- 2.1 Except as provided in this clause 2, the Member agrees that he/she shall keep secret and confidential all Confidential Information and that he/she will not directly or indirectly disclose to any person, other than an Approved Person, any Confidential Information.
- 2.2 The Member agrees not to make any other use of information contained in the Confidential Information except as it relates to fulfilling their role as a member of the Committee.
- 2.3 The obligations on the Member under this clause 2 will not be taken to have been breached to the extent that confidential information is disclosed by a Member to a person who is not an Approved Person, if the Commonwealth has given prior written consent to disclose such Confidential Information to that person. In giving written consent to the disclosure of Confidential Information, the Commonwealth may impose such reasonable conditions as it thinks fit.
- 2.4 Where a Member discloses Confidential Information pursuant to clause 2.3 the Member must:
- (a) notify the receiving person that the information is Confidential Information;
 - (b) not provide the information unless the receiving person agrees to keep the information confidential;
 - (c) comply with any conditions on disclosure imposed by the Commonwealth
- 2.5 The Member understands and acknowledges that any unauthorised use or disclosure of Confidential Information may make him/her liable for prosecution under the laws of the Commonwealth.

3. Survival of Undertakings

- 3.1 The Member acknowledges that the undertakings given in relation to the Confidential Information shall continue in force after the expiration or termination of this Deed Poll.

4. Return of Materials

- 4.1 The Member agrees to return all Confidential Information, including any copies held in the Member's possession, to the Commonwealth on ceasing to perform his/her duties as a member of the Committee, or as otherwise directed by the Commonwealth.

5. Conflict of Interest

- 5.1 The Member warrants that at the date of this undertaking, and to the best of his or her knowledge and after making diligent inquiry, no conflict of interest exists, or is likely to arise in the performance of his/her duties as a member of the Committee.
- 5.2 If, during the period of the membership on the Committee, a conflict of interest does arise, or appears likely to arise, the Member undertakes to notify the Commonwealth immediately in writing and to take such steps as the Commonwealth may reasonably require to resolve or to otherwise deal with the conflict.

6. Indemnity

- 6.1 The Member agrees to indemnify and hold harmless the Commonwealth against all costs (including legal costs and expenses on a solicitor/own client basis), liability, losses and claims reasonably incurred by the Commonwealth which are caused by or contributed to by the Member's failure to comply with this Deed Poll.

7. Governing Law

- 7.1 This Deed Poll shall be governed by and construed according to the law of the Australian Capital Territory.

Executed as a Deed Poll

SIGNED SEALED AND DELIVERED by

.....
(Printed Name of Member) (Signature)

in the presence of:

.....
(Printed Name of Witness) (Signature)