



**Australian Government**  
**Department of Health and Ageing**

## **DEVELOPMENT OF A QUALITY FRAMEWORK FOR THE MEDICARE BENEFITS SCHEDULE**

### **DISCUSSION PAPER**

This paper has been prepared by the Department of Health and Ageing (the Department) as a basis for further consultation with stakeholders on the implementation of the Medicare Benefits Schedule (MBS) Quality Framework (the Framework). The Framework was announced in the 2009-10 Budget and these consultations will inform the development of advice to the Minister for Health and Ageing, the Hon Nicola Roxon MP, on the long term structure of the Quality Framework. This paper does not reflect the Minister or the Government's views on the proposals outlined within.

This discussion paper has been developed to provide ideas to guide consultation and discussion by providing an overview of some of the issues identified in respect of the implementation of the Framework and to seek feedback on key elements of the Framework. Subject to the views of stakeholders, a paper outlining options for the future development of the Framework will be developed.

Any queries in relation to the contents of this discussion paper can be directed via email to the Medical Benefits Reviews Task Group at [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au)

**Medical Benefits Reviews Task Group**  
**Department of Health and Ageing**  
**April 2010**

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# DEVELOPMENT OF A QUALITY FRAMEWORK FOR THE MEDICARE BENEFITS SCHEDULE

## Background

1. The Medicare Benefits Schedule (MBS) lists rebates payable to patients for private medical services provided on a fee-for-service basis. It is a cornerstone of the Australian health care system, which facilitates patient access to general practice, specialist medical services, and allied health.
2. In the 2009-10 Budget, the Australian Government announced that it would provide \$9.3 million over two years to develop and implement a new evidence-based framework for managing the MBS into the future – the MBS Quality Framework. The Quality Framework will establish new listing, fee setting and review mechanisms that ensure that prospective and already listed items are effective and safe, likely to lead to improved health outcomes for patients and represent value for money. The Australian Government will consider the future of the program in the 2011-12 Budget.
3. The Quality Framework is consistent with international efforts which have focused on exploring innovative approaches to maximise health outcomes for patients, whilst promoting the most efficient use of limited health care resources.
4. The development of the Quality Framework is aligned with other Australian reform and review agendas including the review of Health Technology Assessment, the Primary Care Strategy and the National Health and Hospitals Reform Commission.
5. This discussion paper will be circulated to stakeholders for comment and input with the aim of refining the Quality Framework. A second paper outlining options for progressing the Quality Framework will be provided to stakeholders later in 2010.
6. The new MBS listing process, which is a component of the Quality Framework, commenced on 1 January 2010 and the Department will be actively seeking feedback on its operation with a view to improving and refining the process over time. The process described in this paper for listing new MBS items and the accompanying documentation is current at the time of circulation but it is anticipated that it will be modified on a continuous improvement basis, as the first new listings are processed and feedback is received. For the most current information on the new listing process please monitor the Department's website at <http://www.health.gov.au/mbrtg> .
7. The proposed reforms of the MBS inherent in the Quality Framework will provide greater transparency and a stronger evidence-base for services listed on the MBS. If this vision is to be achieved then it is important that a wide range of stakeholders, including health consumers and their representatives, clinicians, allied health providers, and academics participate in the development of the Quality Framework over the next twelve months.
8. The Australian Government has also requested detailed reviews of diagnostic imaging and pathology funding arrangements to ensure that the Government is paying the right amount to support access for patients to quality diagnostic imaging and pathology services. Where relevant, links will be made between these reviews and the broader Quality Framework initiative. Further details are provided on other current review activities at [Appendix A](#).

## Definitions

9. There are several terms used throughout this paper that have meanings specific to the MBS.
10. *Cost of MBS items* (as distinct from specific costs discussed in the fee section of the paper) is a broad term that encompasses but is not exclusive to:
- the rebate cost of the item for Government;
  - the amount spent by the Government on the item per episode of service (including safety net costs); and
  - the amount spent by the Government over a forward estimates period.
11. *Fit-for-purpose* means structuring the size and type of a review or evaluation to fit the type, complexity and cost of the item or items involved.
12. *Schedule fee* means the amount the Government considers appropriate as a recommended fee for an MBS item. Rebates are paid to patients receiving the service described in an MBS item at a proportion (75%, 85% or 100%) of the Schedule fee. A Schedule fee does not determine the amount a health professional can charge for providing the service.

## Overview of the Quality Framework

### Why is a Quality Framework needed?

1. Like other areas of health expenditure, the MBS has expanded over time as new medical services and technologies emerged and as care models have broadened to include other health services. Currently, 5,703 items are listed on the MBS<sup>1</sup>.
2. Since it was introduced in the 1980s, the basic structures of the MBS – the listing, fee setting and review processes – have changed little. The most significant recent change to the MBS was the introduction of the Medical Services Advisory Committee (MSAC) in 1997-98 to strengthen the evidence-base of the Schedule by providing advice on the safety, effectiveness and cost-effectiveness of emerging technologies and procedures. The MSAC assessments have built a degree of rigour into MBS system architecture. However, only about three per cent of all MBS items have been formally assessed against contemporary evidence of safety, effectiveness and cost-effectiveness through the MSAC assessment process.
3. Prior to the introduction of the Quality Framework on 1 January 2010, there has been no formal process for listing or evaluating MBS items that were not considered by the MSAC. Without formalised reviews or a built-in method to update MBS items as clinical practice has changed, parts of the MBS have grown outdated. Some patients may receive treatments that have not been proven to be clinically effective, and financial incentives within the MBS may not always be aligned with clinical best practice.
4. Key issues for managing the MBS into the future are:
  - the need for a process to establish a robust evidence-base for those items not considered by the MSAC;
  - the need to institute processes for systematic and rolling reviews of MBS items to examine the evidence-base for existing items and cater for changes in clinical practice;
  - the need to develop processes to review Schedule fees to ensure that they represent value for money; and
  - the need to maintain the fiscal sustainability of the MBS.
5. The MBS Quality Framework has been developed in response to these needs.

### What is the Quality Framework?

6. The MBS Quality Framework involves four key elements:
  - introducing a time-limited listing for new MBS items that do not undergo an assessment through the MSAC;
  - requiring an evaluation process for all time-limited items at the end of the time-limited period and before items can be approved for long-term MBS listing, as well as evaluation of amendments made to MBS items;
  - strengthening arrangements for appropriately setting fees for new MBS services; and
  - establishing systematic MBS monitoring and review processes to inform appropriate amendment or removal of existing MBS items.

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<sup>1</sup> As at 20 January 2010

7. At its core, the MBS Quality Framework will strengthen the listing, fee setting and review processes that underpin the MBS by ensuring that services are aligned with contemporary clinical evidence, represent best value for money and improve health outcomes for patients.

8. Interim processes for achieving these aims have been and will continue to be put in place starting from 1 January 2010, and the Australian Government will consider the future of these processes and the broader Quality Framework in the 2011-12 Budget. In the period from now until the Department of Health and Ageing reports to the Government in late 2010, there will be opportunities for continuous improvement of the interim processes.

9. The Quality Framework is being developed around the following principles:

- processes will focus on using evidence to support best outcomes for patients;
- processes will be timely, transparent and offer opportunity for stakeholder participation;
- conflicts of interest will be addressed and actively managed;
- continuous improvement techniques will be applied, and feedback mechanisms will be embedded in processes to foster a quality improvement culture.

### **Overview of new MBS time-limited listing process**

10. From 1 January 2010, all new MBS items that do not undergo assessment through the MSAC, as well as amendments to existing MBS items, will be assessed through a more formal process. The following is a brief overview of the seven stages of the new MBS time-limited listing process.

#### ***Stage 1: Item submissions***

Applicants for new MBS items will have the option of a pre-meeting with the Department and/or completing an initial application which will allow the Department to determine whether an MSAC evaluation is needed or whether a time-limited listing is appropriate. If an application is eligible for MBS listing, advice will be provided to applicants on which assessment pathway the application will proceed through.

For those applications that go directly to the Quality Framework, an initial assessment of the application will be undertaken by the Department to determine eligibility for MBS listing and to confirm the appropriate assessment pathway. The Department reserves the right to redirect the application to MSAC if it disagrees with the applicant's choice of pathway.

Applicants will then be asked to complete a more comprehensive application, providing information and evidence to inform the Department's advice to the Government on potential listings or changes.

#### ***Stage 2: Quality Framework assessment of application***

The Department will conduct a full assessment and review all the information provided to determine if the proposed service is suitable for time-limited listing. The assessment process will look at the safety, quality and potential benefits of the proposed service, including the evidence of a gap in the current arrangements that the proposed service is expected to fill.

#### ***Stage 3: Development of an evaluation plan and Schedule fee prior to listing***

The Department will work with applicants, including clinical endorsers, to develop the evaluation plan. Information provided by the applicant will be used by the Department to set a preliminary fee based on professional service and practice costs identified, which is relative to fees for other services provided by the specialty.

***Stage 4: Appraisal of evaluation plan and fee***

The MBS Quality Framework Expert Advisory Committee (MQFEAC) will appraise the final evaluation plan and proposed Schedule fee in addition to the application form.

***Stage 5: Formulation of advice to the Minister for Health and Ageing***

The Department will make a submission to the Minister for Health and Ageing that combines the MQFEAC's advice with policy advice from the Department.

***Stage 6: Time-limited listing***

On Government approval for time-limited listing of a new service through the MBS, the service will usually be listed for a three to four year time-limited period, which will include time for an evaluation to be conducted.

***Stage 7: Evaluation following time-limited listing***

An evaluation will be undertaken to determine whether the service has met its pre-determined objectives.

11. Further detail about these stages is provided in the section on the [New MBS Time-limited Listing Process](#).

**Overview of proposed review system**

12. It is proposed that MBS Reviews follow a consistent six stage process as outlined below.

***Stage 1: Environmental scanning***

A comprehensive and systematic review of MBS data, supplemented by international research findings and qualitative inputs will be undertaken, covering all MBS items, to identify review candidates.

***Stage 2: Prioritisation and scoping***

Review candidates identified through the environmental scanning process will be assessed against agreed criteria to determine a quarterly review work plan.

***Stage 3: Review***

A fit-for-purpose review of agreed topics will be undertaken. The MQFEAC will oversee the reviews.

***Stage 4: Advice to the Minister for Health and Ageing***

Based on the outcomes of the review, the Department will provide advice to the Minister for Health and Ageing regarding relevant amendments, where appropriate, to the MBS.

***Stage 5: Government decision***

The Minister for Health and Ageing will consider the Department's advice and make a decision on review recommendations.

***Stage 6: Implementation***

Following approval by the Minister or Government, endorsed MBS amendments will be implemented in consultation with key stakeholders.

13. Further detail on these stages is provided in the section on the [Framework for reviewing existing MBS items](#).

## **Overview of proposed input-based Schedule fee setting process**

14. It is proposed to develop an input-based Schedule fee setting process identifying the individual components of a service and which generates fees relative to those of other services provided by the specialty. The components recognised in this process include both:

- the time involved in providing the service (a professional component); and
- the direct and indirect costs of providing a service (a practice cost component).

15. The inputs used in the process will be those which can define and measure these broad components.

16. While it is anticipated that this area of work will be informed by the MBS Fee Advisory Committee, in this part of the discussion paper the Department proposes in general terms a process which would make explicit the professional and practice components of cost for new and revised services and outlines a preliminary methodology for generating a fee.

## Consultations

1. The Department will work collaboratively with stakeholders to finalise a robust MBS Quality Framework for the Government to consider in the 2011-12 Budget process.
2. The Department has begun an extensive consultation process. Stakeholders can contribute to the development and implementation of the Quality Framework through bilateral meetings, participating in advisory committee meetings, and/or providing written submissions. Specialty areas will be invited to any committee meetings that consider an issue or MBS item that is relevant to their work.
3. Stakeholders can formally respond to this discussion paper either in writing or by organising a bilateral meeting with the Department. All responses will inform the development of the Quality Framework.
4. The Department may also hold meetings with a range of relevant stakeholders for more specific issues which flow from this paper. If a stakeholder group has specific concerns about any aspect of this paper they can be raised directly with the Department in a bilateral meeting.
5. Stakeholders are encouraged to provide feedback and expertise where possible including on committee membership, and items or groups of items for review under the new process. Issues, views, and suggestions regarding the MBS Quality Framework can be raised through the formal routes outlined above or informally by contacting Mr Craig Rayner at [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au) or on (02) 6289 9034.
6. The Department views consumer perspectives as integral to the MBS Quality Framework and wants these satisfactorily represented in the consultations and on the advisory committees. Suggestions are welcomed on ways the Department can effectively engage with consumers and consumer organisations. The Department wants the finalised Quality Framework to incorporate mechanisms which ensure consumer involvement in managing the MBS in the future.

## Written submissions

7. All stakeholders are invited to provide written submission addressing all, or selected issues, raised in this discussion paper, by **25 June 2010**. Submissions received will be made publicly available via the Medical Benefits Review Task Group website unless confidentiality is specifically requested and justified. Submissions will be considered by one or more of the advisory committees and taken into account as part of the development of the Quality Framework. Written submissions should be sent to the following address:

Quality Framework  
Medical Benefits Reviews Task Group  
Department of Health and Ageing  
MDP 153  
GPO Box 9848  
CANBERRA ACT 2601

8. For further information regarding this discussion paper or to arrange a bilateral meeting to discuss any aspect of the MBS Quality Framework please contact the Medical Benefits Reviews Task Group at [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au).

## **Website**

9. The website <http://www.health.gov.au/mbrtg> has been developed to provide background information on the development of the Quality Framework, provide updates on progress and, where appropriate, provide access to consultant reports commissioned for the Quality Framework and access to submissions as referred to at paragraph 7.

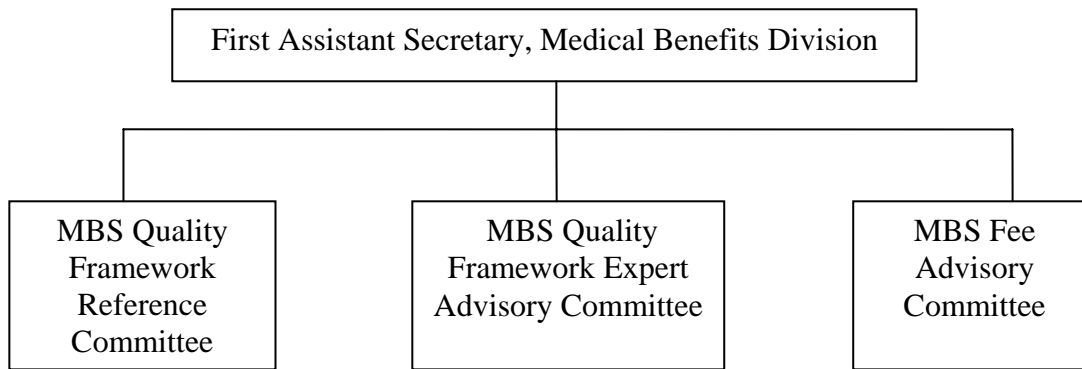
## **Advisory Committees**

### **Key issues raised during consultations to date**

1. The Department of Health and Ageing has undertaken a number of consultations on the Quality Framework, which have involved discussion about all aspects of the Framework. Key stakeholder issues are listed in each section of the paper.
2. Stakeholders were interested in how the committees would be structured, and were supportive of the concept of new committee structures being put in place for managing the MBS. Some stakeholders expressed a desire to provide input to the formation of the committees and there was broad interest in the membership.

### **Advisory committees**

3. Formal advisory mechanisms will be an important part of ensuring that stakeholder input is facilitated and utilised. Advisory mechanisms will need to be flexible, to allow for the range of advice potentially required in relation to MBS listings. The proposed structures outlined below are aimed at providing this flexibility. Over the period of the initiative there will be two Departmental advisory committees and one reference committee that will provide advice and guidance. They are:
  - MBS Quality Framework Reference Committee;
  - MBS Quality Framework Expert Advisory Committee; and
  - MBS Fee Advisory Committee.
4. The MQFEAC will be tasked with providing expert advice on relevant new listings and reviews of MBS items.
5. Each committee will consist of an appropriate range of stakeholders. Members will contribute to developing and refining each component of the Quality Framework. This will ensure a comprehensive and effective overall approach to managing the MBS can be considered by the Government in the 2011-12 Budget context. Advice on the long-term committee structure will be included in the Department's submission to the Government.
6. The MBS facilitates rebate arrangements for patients and as such, consumers have a significant role to play in developing new MBS structures and providing advice on specific MBS issues. The creation of new committees and structures provides the opportunity to explore constructive and broad consumer involvement. To help ensure consumer perspectives are actively considered, a consumer representative will be included in the membership of each committee.
7. The advisory committees and the Reference Committee will be created as individual distinct committees and will directly report to the Department. All members will be appointed for the period of the Quality Framework initiative (until 30 June 2011).



### **MBS Quality Framework Reference Committee**

8. This committee will be a reference point for the Department as the various components of the initiative merge into a longer-term management structure for the MBS. The Reference Committee will play a key role in considering changes to the policies and processes identified for the Quality Framework.

9. Given the breadth of the role for the Reference Committee, its membership will need to be broadly based to bring to the discussions the range of views required to progress the initiative. The membership of this committee will therefore be larger than the other advisory committees and is expected to comprise 15-20 standing members plus Departmental staff.

10. The following organisations and committees will be asked to nominate a member:

- Allied Health Professionals Australia;
- Australian College of Rural and Remote Medicine;
- Consumers Health Forum;
- Royal Australian College of General Practice;
- The Australian Medical Association;
- The Australian Health Insurance Association;
- The Royal Australian College of Physicians; and
- The Royal Australian College of Surgeons;

11. Each of the Quality Framework advisory committees will also nominate a member.

12. The remaining positions on the Reference Committee will be filled after consideration of nominations from interested organisations and relevant Departmental committees associated with the MBS. This committee will be chaired by the First Assistant Secretary, Medical Benefits Division.

13. The Reference Committee is expected to meet twice between May and October 2010, as follows:

- The first meeting will consider this discussion paper, work to date on the components of the Quality Framework initiative and the Committee will provide advice to the Department on the direction of the initiative and any issues that need to be considered.
- The second meeting will be held to consider advice from the Department on the options identified for inclusion in longer-term arrangements for management of the MBS.

## **MBS Quality Framework Expert Advisory Committee**

14. This committee will provide expert advice to the Department regarding new MBS listings and reviews of existing MBS items.

15. Members will be appointed on the basis of their expertise and not as representatives of organisations or colleges. The committee may comprise between 10 to 12 standing members. Members will have expertise, for example, in the areas of evidence-based medicine, clinical medicine, health economics, evaluations or consumer matters.

16. For the establishment of the Committee, the Department is looking to include the following:

- two experts with a background in procedural services;
- one expert in the field of physicians;
- one general practitioner expert;
- one allied health expert;
- one Departmental medical officer;
- one consumer representative; and
- two academics or health economists.

17. The Australian Medical Association, Royal Australasian College of Surgeons and Royal Australasian College of Physicians will be invited to recommend experts for the Committee.

18. The Committee's responsibilities are to:

- advise and make recommendations to the Department on the development and refinement of the components of the MBS time-limited listing process including the evaluation plan framework, guidelines, templates and forms (including the fee setting);
- assess evaluation plans;
- make recommendations to the Department on suitability for time-limited listing;
- liaise with relevant clinical experts and refer appropriate new listings issues to the Department for advice;
- advise on development of the framework for reviewing existing MBS services, including:
  - data sources and criteria for prioritising review activity;
  - review methodologies; and
  - translation of review findings into improvements in clinical practice;
- liaise with relevant clinical experts and identify potential candidate items for review;
- prioritise individual topics for review; and
- provide informed clinical, consumer and evidence-based comment in relation to specific reviews.

## **MBS Fee Advisory Committee**

19. Members will be appointed on the basis of their expertise and not as representatives of organisations or colleges.

20. In addition to Departmental Officers, the committee will consist of:

- two experts with a background in procedural services;
- one experts in the field of physicians;

- one general practitioner expert;
- one allied health expert;
- one health practice management expert;
- one Departmental medical officer;
- one consumer representative; and
- one academic or health economist.

21. The Australian Medical Association, Royal Australasian College of Surgeons and Royal Australasian College of Physicians will be invited to recommend experts for the Committee.

22. In addition, a representative of the sponsoring or specialty group providing the item will be permitted to attend as a non-voting member for the duration of consideration of the proposed item. There may be more than one representative attending the meeting for different items.

23. Representatives from existing Departmental committees will be invited to participate when discussions are relevant to their area of responsibility.

24. The committee will assist in the development of an input-based fee setting methodology for MBS item Schedule fees. Where possible and appropriate, this methodology will inform the relevant parts of the new listing and reviews activities.

### **Expectations for committees**

25. Committee members on all committees will generally be expected to:

- attend meetings whenever possible;
- participate fully in all committee work and provide technical input where relevant;
- actively play a role in reaching consensus on the item/s;
- be impartial and broadly represent Government interests;
- declare any vested or financial interests in the subject matter;
- be prepared to provide, when casting a vote, clearly expressed technical and scientific reasons for that vote; and
- work towards alignment with existing international evidence, wherever practical and relevant.

26. All committee members will be required to adhere to agreed levels of confidentiality in relation to meeting discussions.

27. Expert committees will be chaired by the First Assistant Secretary, Medical Benefits Division or a nominated Departmental officer. Secretariat support for all committees will be provided by the Medical Benefits Reviews Task Group within the Department.

28. Members of committees may be eligible to be paid a sitting fee and have their incidental expenditure and travel arranged and paid for by the Department.

### **Key questions for stakeholders**

- |   |
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| <p>1. Are there comments or suggestions on the proposed roles, committee structures and level of representation or expertise of the committees?</p> |
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## Establishment of committees

29. The Department will shortly establish these committees. The Department is seeking suggestions from stakeholders on particular groups or individuals who would be suitable to participate on these committees.

30. When considering suggestions for any of the committees, the following should be taken into consideration:

- the committees will require consistent representation for the period of the initiative;
- members will be appointed to the MBS Quality Framework Reference Committee only as representatives of a particular organisation;
- members will be appointed to the other two committees as individual experts;
- members of expert committees must have a background in evidence-based medicine, clinical medicine, health economic evaluations or consumer matters; and
- members must be:
  - conversant with relevant technical matters pertaining to a particular committee;
  - able to effectively represent the views of the organisation (in the case of the Reference Committee) or particular area of expertise and be able to make decisions at meetings without referring all matters back to the nominating organisation; and
  - be able to competently and actively participate in committee meetings and contribute to the development and implementation of the Quality Framework.

31. Stakeholders are invited to provide suggestions for participants for the advisory committees by **21 May 2010**. The Department will consider suggestions and is keen to appoint a range of members that will enable the committees to cover a broad range of views and function effectively.

32. If you would like to make a nomination, the following details are required:

- name;
- contact details;
- evidence of nominee's agreement to the nomination;
- the relevant advisory committee to participate on; and
- evidence to support nomination for a particular committee, for example their curriculum vitae.

33. Suggestions or nominations can be emailed to [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au) .

## **New MBS Time-limited Listing Process**

### **Background**

1. From 1 January 2010, all new MBS items that do not undergo assessment through the MSAC and amendments to existing MBS items will be assessed through a more formal process that will determine eligibility for MBS listing.
2. New items that receive MBS funding will be listed on a time-limited basis, which will normally be three to four years, with evaluation to be completed by the end of the interim listing period. In certain cases, this will be shorter or longer, depending on the results of early evaluation activities. For example, there may be items for which it is possible to determine within the first 12 months whether the service meets the required criteria for ongoing listing. Similarly, there may be items for which more than three years will be required to gather sufficient evidence to consider ongoing listing.
3. The new listing process will strengthen the gateway onto the MBS. It will assist in ensuring that future MBS services are aligned with contemporary clinical evidence, represent value for money and improve health outcomes for patients.

### **Key issues raised during consultation to date**

4. Key issues for stakeholders in relation to the time-limited listing process so far have included:
  - how the process will be set up to be robust and transparent;
  - how the new listings process will tie in with the Budget process; and
  - whether all new listings and amendments will be required to go through the new listing process.

### **MBS Time-limited Listing Process**

5. The new MBS time-limited listing process involves seven stages from application to possible listing. The process, as currently proposed, is set out below. It is likely to be refined in response to stakeholder feedback and experience with particular applications.

#### ***Stage 1: Item submissions***

6. There are two processes for assessing applications for MBS listing; the MSAC or the Quality Framework. MSAC will assess medical services that involve new medical technologies and procedures and will maintain the capacity to recommend interim funding for new items to facilitate the collection of evidence for later review. It remains the key committee for the evaluation of the safety, effectiveness and cost-effectiveness of new items – the Quality Framework provides initial rigour for all other potential new listings.
7. A criteria-based approach will be used to determine the appropriate assessment pathway. The assessment pathways are:
  - the MSAC, generally for medical services involving new technologies or procedures, including diagnostic tests; or
  - Quality Framework Appraisal Process, for services not considered by the MSAC.
8. A key area that the Quality Framework new listing process will seek to address is the listing of new consultation and consultation-related items. The Quality Framework process may also be

used for medical services involving technologies or procedures if these are specifically referred to it by MSAC or its secretariat.

9. In assessing possible new consultation items, the Department is aware that clinical trial evidence of the kind expected by PBAC or MSAC is unlikely to be available. The initial assessment of these items will focus on the need for the service, the evidence of a gap in the current arrangements that the service is expected to fill, and the benefits that are anticipated to flow from the availability of the service. The evaluation process will offer an opportunity to validate the initial assessment and to quantify the benefits more accurately.

10. The criteria to determine the appropriate assessment pathway and the assessment process that will be used are continuing to be developed and as new versions become available, they will be put on the website and comments will be sought from interested parties.

11. The Government has recently released the Review of Health Technology Assessment in Australia report (December 2009). A key recommendation endorsed by the Government was the introduction of a new, single entry point for all applications for subsidy under the MBS, Pharmaceutical Benefits Schedule (PBS) and Prostheses List, to be developed by July 2010. Long-term processes for new listings developed under the Quality Framework will be consistent with this approach.

12. Applicants are encouraged to meet with the Department prior to submitting an application to better understand the appropriate process and the kinds of information most relevant for the particular service. Applicants can directly submit an application to the MSAC or the Quality Framework. If applicants are uncertain which pathway they should submit the application through, it is recommended that they submit the Initial Assessment Application Form. This form will allow the Department to determine the appropriate pathway for listing. If applicants choose to apply directly to either the MSAC or the Quality Framework, the Department reserves the right to redirect the application if it disagrees with the applicant's choice of pathway, and to request a new application.

13. Applications for new MBS time-limited items will require a range of information including the description of the service, patient target group, indications, therapeutic claim, clinical need, current evidence, and information to inform setting the fee.

14. Application forms are now available from the Department's website:  
<http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Applications> .

#### *Clinical Endorsement*

15. Each new application will require robust clinical support for the proposed item by a relevant health professional organisation (for example, medical colleges as distinct from an individual clinician). The endorsement extends the role that applicants play in the process by ensuring a level of commitment from relevant health professional organisations.

16. Consideration should also be given to joint endorsement of the service if it is likely to be provided by more than one type of practitioner. The Department encourages all relevant groups to be involved throughout the application process.

17. Endorsing an application for a new service will indicate that group's support for the proposed service, and certify that it is clinically relevant and accepted as part of modern medical practice.

## ***Stage 2: Quality Framework assessment of application***

18. The Department will initially assess the application to determine if the proposed service is eligible for MBS listing, and if applicable, the appropriate pathway for listing.

### *Eligibility*

19. When an application is received by the Department, its eligibility for assessment is checked by seeking input from relevant program areas of the Department to ascertain the following:

- whether the proposed service is a professional service covered by the MBS as generally defined by the *Health Insurance Act 1973*;
- whether the proposed medical service meets the Government's current policy parameters for funding professional services under Medicare; and
- where required, whether any medical devices, diagnostic kits or pharmaceutical products used in providing the service have been included on the Australian Register of Therapeutic Goods (ARTG), or are being considered by the Therapeutic Goods Administration (TGA) for inclusion.

20. To the extent possible, an initial assessment of the application will be conducted within one month of receiving the application. If the application is deemed eligible, the Department will advise applicants in writing whether their application is eligible and, if applicable, where the application has been directed, either to the MSAC or the Quality Framework process. Applicants can also seek updates at any stage.

### *Review of decisions*

21. Applicants who are dissatisfied with decisions concerning eligibility or the appropriate assessment pathway are able to make a request for review to the First Assistant Secretary of the Medical Benefits Division.

22. If eligible, the Department will conduct a full assessment and review all the information provided to determine if the proposed service is suitable for time-limited listing.

### *Full assessment of the application*

23. The Department will review the information provided by the applicant in the application form, as well as any additional relevant data that might have been provided. The Department may commission a systematic review of the relevant literature, including cost-effectiveness evaluation or other evaluation of the application. The Department may also seek to externally validate any/all of the information provided in the application against other data sources, or may seek its own research to validate the information provided. This will involve expert clinical input to the assessment process as required. Assessment of applications will utilise appropriate expertise in evidence-based medicine, clinical medicine, health economics and evaluations.

24. One of the key considerations for new items to be listed on the MBS will be an assessment of cost-effectiveness. The process for consideration of cost-effectiveness will be developed in conjunction with the MSAC<sup>2</sup>. Where there are gaps in data on cost-effectiveness for new items, the evaluation of the item will be designed to fill these gaps.

25. To the extent possible, a full assessment of the application will be conducted within three months. Applicants will be advised in writing of the outcome of the full assessment.

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<sup>2</sup> The following link -

[http://www.msac.gov.au/internet/msac/publishing.nsf/Content/D81BE529B98B3DB6CA2575AD0082FD1B/\\$File/guidelines.pdf](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/D81BE529B98B3DB6CA2575AD0082FD1B/$File/guidelines.pdf) - goes to the MSAC application guidelines, and discussion on cost-effectiveness can be found on page 26

26. The Department will use strict criteria to determine whether the proposed service is:
- suitable for direct listing on the basis that it is not a new item or revises an existing item with no or very limited expected clinical or financial impact;
  - suitable for time-limited listing for a fixed period with an agreed fee and evaluation process over the period; or
  - not suitable and rejected for MBS listing.
27. These criteria are currently being developed and will be available for discussion with stakeholders in the coming months.
28. Assessment of proposed new items will also include consideration of potential offsets or savings, taking into consideration the need for long-term sustainability of MBS expenditure. Potential changes to existing items as a result of introducing the new item could include (over an agreed time-frame):
- de-listing an MBS item that (with the introduction of the new item) is not considered best practice;
  - reducing MBS fees for existing items that relate to the new item; and/or
  - amending existing MBS item descriptors to reflect the impact of introducing the new item, for example restricting the target patient group or restricting access to MBS items on a sequential basis along a clinical pathway.
29. Where an applicant identifies an impact to a different specialty or area within the MBS, to that of the proposed service (such as savings), the affected specialties must be involved in the application process.
- Stage 3: Development of an evaluation plan and Schedule fee prior to listing***
30. Before services are listed for a time-limited period, an approved evaluation plan must be developed. The Department will have primary carriage of the development of the evaluation plan and will work with applicants, including clinical endorsers, during its development. The evaluation plan will be structured to suit the service that is being listed and to address the principles and criteria outlined in the broad evaluation framework.
31. To the extent possible, the development of an evaluation plan will be conducted within one month, but this will ultimately depend on the type of proposed service.
32. The applicant will be invited to comment in the first instance on the draft evaluation plan and then again on the final plan before it proceeds to the next stage.
33. Key elements of the evaluation plan will include:
- key evaluation question/s;
  - key performance indicators for meeting the objectives of the item/s;
  - data and information collection and analysis methods (for example, through qualitative research methods such as literature reviews, or quantitative research methods such as data analysis); and
  - timeframes for evaluation including interim reporting.
34. Information provided by the applicant will be used by the Department to set a Schedule fee based on the time and practice costs identified as included in the service, relative to fees for other

services provided by the specialty. The MBS Fee Advisory Committee may provide advice to the Department, when necessary, on the proposed Schedule fee.

***Stage 4: Appraisal of evaluation plan and Schedule fee***

35. The assessment of the evaluation plan and fee forms the basis of the MQFEAC's final consideration of the application as a whole. The Department will present the evaluation plan and proposed MBS fee to the committee which will consider the final evaluation plan and MBS fee in addition to the application form. The Committee will then formulate recommendations to the Department, which generally fall into one of the following categories:

- recommend the service for time-limited listing; or
- not recommend the service for time-limited listing.

36. Applicants will be advised in writing of the outcome.

***Review of decisions***

37. Applicants or other stakeholders who are dissatisfied with MQFEAC recommendations concerning time-limited listing are able to make a request for a review.

***Stage 5: Formulation of advice to the Minister for Health and Ageing***

38. The Department will make a submission to the Minister for Health and Ageing that combines the MQFEAC's appraisal advice with policy advice from the Department. The Minister will then consider and make decisions on the recommendations in the submission.

***Stage 6: Time-Limited Listing***

39. On Government approval the service will typically be listed on the MBS for a three to four year time-limited period. The monitoring and evaluation requirements and timeframes will be clearly communicated with the applicant.

40. The default position for a time-limited listing at the end of the listing period will be non-continuation of Government funding, unless the formal evaluation of the evidence gathered during the listing period merits otherwise.

***Stage 7: Evaluation following Time-Limited Listing***

41. The formal evaluation at the end of the time-limited listing period is a significant element in the new listing arrangements. The outcomes of the evaluation will be assessed to determine whether the service has met its stated objectives.

42. The Department is responsible for the formal evaluation at the end of the time-limited listing period. Input may be sought from relevant experts, clinical groups as well the applicant and clinical endorser.

43. Following consideration of the final evaluation report and discussion with the applicant and relevant clinical groups, the MQFEAC will formulate recommendations to the Department, which will generally fall into one of the following categories:

- listing does not continue, that is the item be no longer funded;
- the time-limited listing period be extended to collect more evidence (subject to a clear evaluation plan being agreed that will produce the required evidence within the agreed listing extension period);
- the item descriptor or fee be amended for ongoing listing; or
- the item proceed to full listing without amendment.

Any of these outcomes may also entail changes to MBS listings for related items.

44. The applicant, clinical endorser, and relevant clinical groups will be advised of the outcome of the evaluation following time-limited listing and the MQFEAC recommendation prior to it being considered by the Minister for Health and Ageing.

45. The Department will make a submission to the Minister for Health and Ageing that combines the MQFEAC's assessment advice with policy advice from the Department. The Government will then consider and make decisions on the recommendations in the submission.

## **Evaluation of MBS new time-limited items**

### **Background**

1. Prior to the introduction of the Quality Framework on 1 January 2010, there has been no formal process for listing or evaluating MBS items that were not considered by the MSAC. While the majority of currently funded services are likely to be effective, it is important to ensure that all MBS services represent best value for money and improve health outcomes for patients.
2. From 1 January 2010 all new MBS items not assessed through the MSAC will be time-limited, and require an evaluation during the time-limited listing. Amended items will be evaluated where appropriate over the same period (normally three to four years). The evaluation plan will be completed prior to the introduction of a new item or amendment. This part of the discussion paper outlines some of the views on evaluation raised during consultations, some principles for consideration and raises questions for stakeholder feedback.

### **Key issues raised during consultations to date**

3. Key issues for stakeholders in relation to evaluations so far have included:
  - how items specific to certain groups will be evaluated;
  - availability of data;
  - the amount of funding and length of time available for evaluations;
  - ensuring a cohesive approach to evaluation activities (i.e. streamlining evaluations across sector such as pathology or across the MBS); and
  - whether there will be standard objectives assessed as part of any evaluation.

### **Evaluation requirements and principles**

4. There will be significant variation in the evaluation requirements for MBS items, based on the type of service provided and the complexity and cost of the item. The majority of new items and amendments will most likely require only minor evaluations, with a small number of items or groups of items requiring larger or more complex evaluations. Similarly, the methodologies and datasets for evaluations will differ depending upon the objectives being evaluated.
5. The Department provides the following key principles for consideration. Evaluations will be:
  - designed to protect patients' rights to privacy;
  - designed to be fit-for-purpose, with the aim of ensuring that MBS items are evaluated in an efficient and robust manner;
  - flexible, allowing sufficient time to gather data and for appropriate evaluation activities to be undertaken, and taking into account further questions raised or modifications identified during post implementation reviews or the final evaluation;
  - clear and consistent in terms of criteria for evaluation and methodologies to be applied for data extraction and analysis;
  - managed by the Department of Health and Ageing, and developed in close consultation between the Department and the clinical sponsor or clinical group promoting the item/s; and
  - continuously improved, which will be informed by the development of evaluation methodologies over time.

## **Standard objectives for assessment**

6. At a minimum, it is expected that the usage of the item will be compared to Government estimates as part of an evaluation. Evaluations may also assess the following:

- cost-effectiveness;
- safety of the service (in terms of risk of mortality or increased or decreased morbidity); and
- effectiveness of the service, particularly in comparison to other current services for the treatment of the same condition.

## **Data capture**

7. There are a variety of sources for quantitative and qualitative data. Where datasets do not currently exist or are not available, the Department will work with clinical groups to develop methodologies for both capturing and analysing data. These methodologies will be clearly articulated in the evaluation plan by the Department with input from the clinical sponsor or clinical group promoting the item/s.

## **Creation of evaluation plans for new and amended items from 1 January 2010**

8. The Department is currently tendering for a panel of providers of health services evaluations. When this panel is in place, it is expected that experts will provide input as needed to both individual evaluation plans and to a broader evaluation framework that can be used in planning for evaluations. A draft evaluation framework will be included in the options paper.

9. If there are listings considered prior to the panel being established, the Department will work directly with clinical groups to create evaluation plans for new or amended MBS items.

10. The Department holds limited funds to finance evaluations set up during the life of the Quality Framework initiative (to 30 June 2011). For items listed or amendments made after that date, the cost of the evaluation will need to be considered alongside the costs to the MBS in deciding whether to proceed with the new MBS item.

11. Recommendations about evaluations will be made by the Department with input from stakeholders and relevant experts as appropriate; however, the final decision on the evaluation plan rests with the Minister for Health and Ageing.

## ***Key questions for stakeholders***

- |   |
|---|
| <ol style="list-style-type: none"><li>1. Are there further principles or ideas the Department should consider in developing a long-term evaluation framework for MBS items?</li><li>2. Do you have experience or expertise you can contribute to the development of a long-term evaluation framework for MBS items?</li></ol> |
|---|

## Framework for reviewing existing MBS items

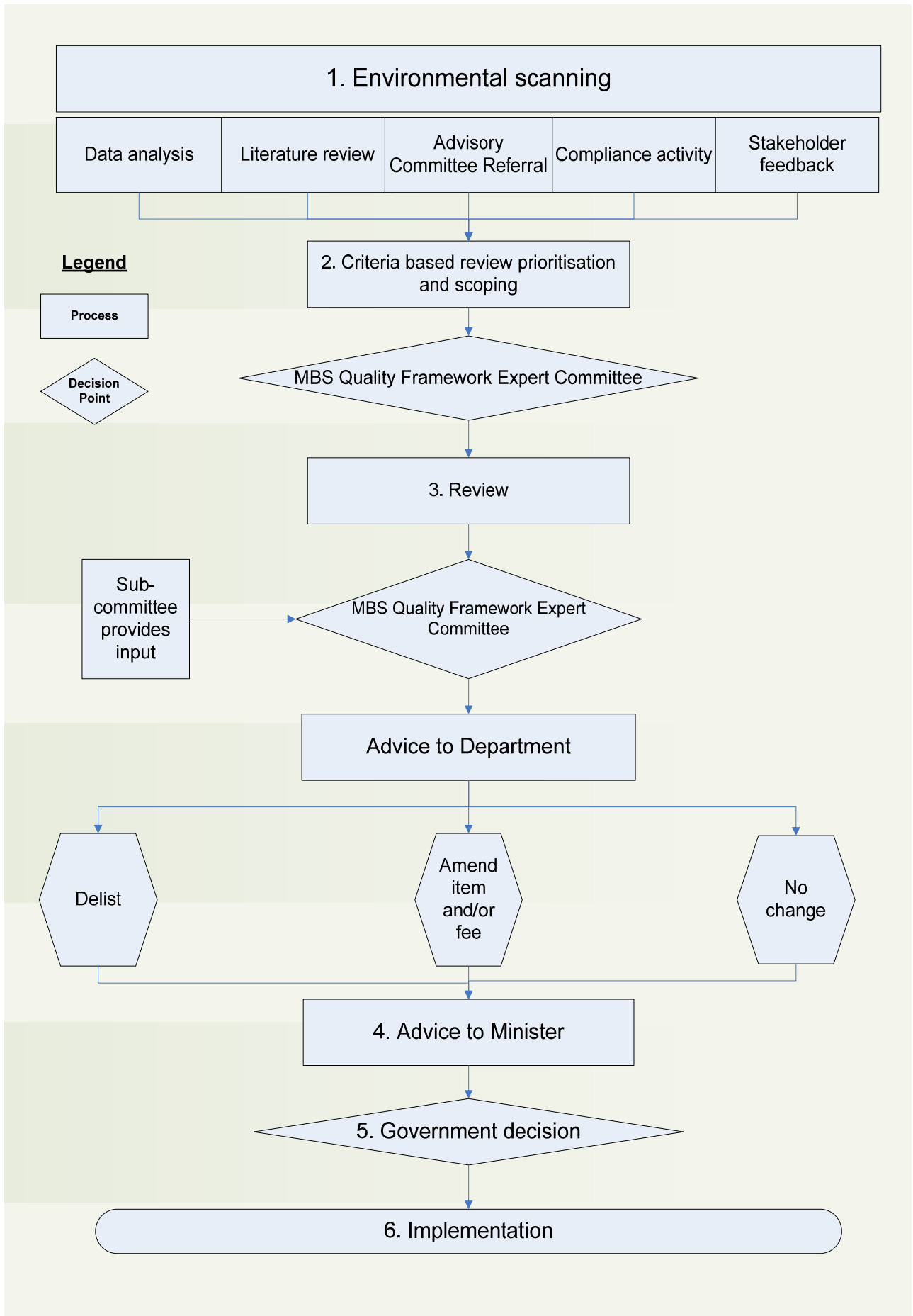
### Background

1. As at January 2010 the Medicare Benefits Schedule (MBS) contains 5,703 items. The majority of these items are longstanding with only a very small proportion (around 3%) of items (accounting for around 1% of total MBS expenditure), having been formally assessed against contemporary evidence of safety, effectiveness and cost-effectiveness.
2. A key component of the 2009-10 Budget measure *Medicare Benefits Schedule – A quality framework for reviewing services*, is the implementation of a systematic approach to reviewing existing MBS items to ensure they reflect contemporary evidence, offer improved health outcomes for patients and represent value for money. The primary focus of the reviews framework will be on quality-related issues with the key objective of identifying and evaluating current MBS services which are potentially unsafe, ineffective, or inappropriately used. This policy initiative represents a significant move by the Government to ensure the sustainability of the MBS into the future.
3. There is general consensus internationally that gaps exist between clinical evidence and current practice that need to be better understood and addressed to improve the quality and effectiveness of health care provision.
4. The Quality Framework Budget measure builds on a Government funded project undertaken by the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) in 2007-08, which included the development of a framework for identifying and reviewing surgical items, evidence-based assessment of five identified surgical items, and development of action plans in relation to the reviewed items. The project resulted in a set of broad criteria to identify and prioritise items for further assessment, and made a number of evidence-based recommendations.
5. The outcomes of the ASERNIP-S project have informed the development of the proposed review approach discussed below. The approach will continue to be refined with stakeholder input, and as consultative committees become established and initial ‘demonstration’ reviews get underway.

### Key issues raised during consultation to date

6. Key issues raised during consultation in relation to reviews so far included:
  - how reviews of MBS items will be triggered;
  - availability of data to inform reviews; and
  - how often reviews will occur.

# MBS Quality Framework approach to MBS reviews



7. Reviews of existing MBS items will initially focus on the quality and safety of medical services currently provided for within the MBS and will also consider cost-effectiveness, where data permits. Reviews focusing primarily on the appropriateness of the MBS fee will be conducted in the longer term following thorough stakeholder consultation on review parameters, principles and methodology, informed by the new Schedule fee setting process being developed.

8. Ultimately, methodologies will be developed to enable review of current MBS fees relative to other MBS fees for services provided within a specialty.

### **Principles to guide MBS Reviews**

9. It is proposed that MBS reviews would be underpinned by the following key principles:

- reviews have a primary focus on improving health outcomes and the financial sustainability of the MBS, through consideration of areas potentially representing:
  - patient safety risk;
  - limited health benefit,
  - inappropriate use (under or over use); and/or
  - intentional misuse of MBS services;
- reviews are evidence-based, fit-for-purpose and consider all relevant data sources;
- reviews are conducted in consultation with key stakeholders including, but not limited to, the medical profession and consumers;
- review topics are made public, with identified opportunities for public submissions and outcomes of reviews published;
- reviews are independent of Government financing decisions and may result in recommendations representing costs or savings to the MBS, as appropriate, based on the evidence;
- secondary investment strategies to facilitate evidence-based changes in clinical practice are considered; and
- review activity represents efficient use of Government resources.

### **MBS Reviews process**

10. The new MBS Reviews process involves several stages from identification to decision implementation. The process, as currently proposed, is set out below. It is likely to be refined in response to stakeholder feedback and experience with particular reviews.

#### ***Stage 1: Environmental scanning***

11. The Department intends to utilise a range of information sources to identify items for review through an 'Environmental Scanning' approach. This approach is expected to comprise the following elements:

- periodic and systematic quantitative analysis of MBS, and other relevant data to identify geographic, provider or temporal variations in MBS service provision or benefits paid;
- regular and comprehensive review of the literature to identify robust and significant developments in the evidence-base supporting currently funded MBS services;
- referral of items or services from advisory committees (e.g. Medical Services Advisory Committee, Pharmaceutical Benefits Advisory Committee, Australian Commission on Safety and Quality in Health Care) on the basis of safety or effectiveness uncertainty;
- identification of potential inappropriate use (under or over use) or misuse of items identified through compliance and surveillance activities undertaken by Medicare Australia;

- referral of items or services identified through stakeholder consultation or public nomination processes; and
- routine consideration of potential item substitution (often called up-coding) prompted by a new MBS listing.

12. For candidate review topics identified through stakeholder referrals, a systematic analysis of the relevant MBS data will also be undertaken to ensure a consistent and rigorous approach to identifying services for review.

### ***Key questions for stakeholders***

1. What other mechanisms could be used to identify existing MBS services for further evaluation under the reviews framework?
2. What additional quantitative data analysis might be appropriate?
3. What issues should be considered in the public nominations process and is it appropriate for this process to be anonymous?

### ***Stage 2: Prioritising and scoping review activity***

13. Once review candidates have been identified through the environmental scanning process, potential reviews will be prioritised using transparent and agreed criteria, and the size and type of review will be scoped. This will ensure that high priority issues receive foremost attention, and that review activities are balanced against available resources. It will also assist in developing fit-for-purpose methodologies for individual reviews. A more detailed discussion of proposed prioritisation and scoping activities is below.

### ***Criteria for prioritising reviews***

14. Given the large number of items currently listed on the MBS, a standardised method for prioritising review activity will be required to enable the Quality Framework to deliver against policy objectives and manage stakeholder expectations in an open and transparent manner. Transparent criteria will be established through a consultative and iterative process to assess the relative need for assessment, and rank reviews in order of priority. The following draft criteria are proposed (which are not presented in any particular order):

- clinical impact – burden of disease/condition to be treated, disease incidence and prevalence, availability of effective alternate treatment options;
- quality and safety impact – potential to address possible quality and safety issues to improve clinical outcomes for patients;
- MBS impact – annual MBS services and benefits paid, potential to address apparent item creep (use has altered beyond the original item intent), redirect service provision to more evidence-based treatment options and/or reduce Schedule complexity or duplication;
- evidence impact – availability of robust evidence or data on which decisions can be made; or
- stakeholder impact – the potential impact of changing MBS arrangements on specific vulnerable sub-populations (for example children, the disabled, elderly or provider groups), and likely stakeholder support for the review.

15. The prioritisation of review candidates will be agreed by the MQFEAC following assessment against the agreed prioritising criteria.

### ***Development of a Scoping Document***

16. Prior to initiating individual evaluations, the Department will prepare a scoping document in consultation with relevant experts to be agreed by the MQFEAC. The scoping document will

provide sufficient information to determine the priority for review and is expected to include the following information:

- purpose of the review;
- review classification (individual item, item group or sub-group, disease group or patient cohort review);
- relevant MBS items;
- information to enable assessment against the following prioritisation criteria:
  - clinical impact;
  - quality and safety impact;
  - MBS impact;
  - evidence impact;
  - stakeholder impact; and
- relevant key stakeholder groups and experts to consult in conducting the review.

17. This work will inform the MQFEAC in determining the most appropriate review methodologies for evaluations.

### ***Key questions for stakeholders***

1. What other criteria could be used to prioritise assessments?
2. Do you consider any of the listed criteria to be more important than the others?
3. What other information should be included in the scoping document?

### ***Stage 3: Review***

18. Reviews will be either of single items, groups of items within a specialty, or related to a specific condition or disease or identified patient episode.

19. The broad process for the reviews is outlined below, noting that it is expected this will be refined over time and with stakeholder input.

#### *Clinical appropriateness reviews*

20. Clinical appropriateness reviews will be overseen by the MQFEAC. The methodology for each review will be fit-for-purpose and appropriate to the service/s and issues identified in the scoping document.

21. Each evaluation will be conducted in a two stage process, involving:

- development of the review protocol; and
- evidence-based evaluation of the service.

22. In most cases, it is expected that an external, independent organisation with demonstrated expertise in health services evaluation, including health technology assessments, will be engaged to conduct the evaluation.

23. A clinical expert/s with experience relevant to the service or services being reviewed will be engaged by the MQFEAC to provide appropriate input to the review process, to ensure that the review reflects an understanding of current Australian clinical practice and draws valid conclusions from the available evidence.

### *Development of review protocol*

24. The evaluator will initially develop a review protocol that outlines the methodology for the particular review. This document will be informed by the preliminary scoping document agreed by the MQFEAC. The draft protocol will be available on the website for stakeholder comment via a submission process.

25. The review protocol will outline the objective, scope and methodologies for each review and will include the following information:

- background information on the MBS service;
- research questions and assessment strategy, including clinical flowchart and types of evidence relevant to the review;
- methods to identify and appraise the evidence;
- additional data sources and analysis methods;
- key stakeholder groups and experts to consult in conducting the review; and
- review timeframes.

### *Review*

26. Appropriate fit for purpose methodologies will be developed for each evidence-based review. For individual service reviews (an individual service may be more than one MBS item), in most cases a rapid review of the scientific literature will be conducted to appraise the strength and quality of the evidence relating to safety and clinical effectiveness, and possibly cost-effectiveness.

27. Reviews of item groups or disease groups are likely to require alternate methodologies which may include analysis of clinical guidelines, qualitative analysis (for example focus groups), consultation with stakeholders and comparisons with international practice.

28. In all cases a draft assessment report will be developed, which will be publicly available for stakeholder comment prior to consideration by the MQFEAC.

29. There will be a number of challenges and complexities in reviewing existing MBS items, particularly associated with the generally poor evidence-base for some items. This will necessitate a broader and more pragmatic approach to the consideration of “evidence”, including consideration of alternate data sources (such as clinical registers) and analysis methods, and where this does not unduly affect the rigour of reviews.

### *Key questions for stakeholders*

- |  |
|--|
| <ol style="list-style-type: none"><li>1. What other methods could be used to review existing MBS services?</li><li>2. What alternate data sources (qualitative and quantitative) could inform reviews of existing MBS items?</li></ol> |
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### **Review outcomes**

30. Reviews are expected to result in primary and supplementary review outcomes as shown below.

### ***Primary review outcomes***

31. Where an evaluation suggests that an item under review is supported by the evidence, the likely recommendation will be that the MBS listing will be retained in its current form. However, should an evaluation suggest that listed MBS items or services are inconsistent with contemporary evidence in relation to its clinical use or effectiveness, direct amendments to the MBS may be recommended. These may include one or more of the following changes:

- addition or removal of MBS items;
- changes to the Schedule fee;
- refinement of MBS item descriptors to better target patient groups, clinical indicators and/or promote the use of optimal clinical pathways; and/or
- potential for interim-listing pending the collection of item-specific data.

32. Potential amendments to the MBS arising from reviews will be undertaken through consultation with the relevant stakeholder groups.

### ***Supplementary review outcomes - initiatives to facilitate evidence-based changes in clinical practice***

33. In addition to primary review outcomes relating to MBS reimbursement, reviews may indicate the need for secondary investment strategies aimed at bridging the divide between current evidence, including clinical guidelines and current clinical practice. To achieve this, a number of strategies may be implemented following the evaluation of individual items or services. These may include, but are not limited to, the following:

- development or revision of clinical practice guidelines for evaluated services where there is an identified need;
- strengthening or targeting of auditing/compliance activities;
- education and training initiatives for practitioners and/or consumers;
- exploring incentive-based initiatives to promote improved clinical practices or linking education and training programs to access incentives; and
- the development of research opportunities where gaps in effective service provision are evident.

34. The identification of mechanisms to support evidence-based best practice will complement and reinforce any primary outcome MBS amendments to help improve health outcomes for patients, whilst ensuring the most efficient use of limited resources.

### **Review of decisions mechanisms**

35. Stakeholders that are dissatisfied with a review outcome will be given the opportunity to lodge a request for review. A process for receiving and managing these requests will be developed in consultation with stakeholders and the MQFEAC.

### ***Key question for stakeholders***

1. What other strategies might be useful in facilitating evidence-based changes in clinical practice?
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## Stakeholder input

36. Stakeholders will have a range of opportunities for input and involvement in the review process including:

- participation on the MQFEAC;
- participating and providing input to specific reviews;
- nominating review candidates;
- commenting on proposed review protocol for each review; and
- commenting on the draft evaluation report including outcomes and implementation strategies prior to the MQFEAC consideration.

37. A dedicated website has been developed to support the implementation of the MBS Quality Framework, [www.health.gov.au/mbrtg](http://www.health.gov.au/mbrtg), which is also linked through [www.mbsonline.gov.au](http://www.mbsonline.gov.au).

38. A range of information will be available through the website about the reviews, including:

- list of reviews that are in progress;
- review protocols; and
- final evaluation reports.

39. In addition, a website portal is being developed to provide a mechanism for stakeholders to nominate review topics, having regard to the proposed prioritising criteria.

40. Stakeholders can provide input or raise issues about reviewing existing MBS items through either the MBS online website ([www.mbsonline.gov.au](http://www.mbsonline.gov.au)) or [www.health.gov.au/mbrtg](http://www.health.gov.au/mbrtg).

### *Key question for stakeholders*

1. What other ways could stakeholders provide input or participate in the process to review existing items?
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## **Input-based Schedule Fee Setting – Measures and Methodology**

### **Introduction**

1. The move to a new MBS fee setting process reflects an increased emphasis on quality of services, expenditure and decision making. It provides an opportunity to examine services and set a MBS fee for new and existing services relative to MBS fees for other services provided within a particular specialty.
2. Currently, the Schedule fees for new services listed on the MBS are predominantly set by comparison and negotiation, with many existing fees being historical. This does not mean that the Schedule fees are unreasonable or incorrect, but does mean that there is not an explicit basis for understanding fee relativities within a specialty. It also risks the cementing of inequities in the fee structures.
3. The new Quality Framework will include an improved evidence-based listing process and Schedule fee setting process and will provide opportunities to review existing services provided by individual specialties. This includes services which might be provided by allied health service providers.
4. The new fee setting process is intended to move the MBS toward making explicit the components of fees for new and revised services included on the MBS. It will also provide a basis for judging the relative value of new and existing services within a specialty.
5. This is consistent with the ongoing intent of MBS fee setting processes. The MBS has always had processes in which fees have been set in relation to the other services included on the MBS. The proposed process does not remove elements like comparison and negotiation, but it does change the role and level at which they can influence the outcome. The new process aims to formalize and make more transparent the inputs, measurements and calculations going into a recommendation for an MBS fee.
6. Once established, the new Schedule fee setting process will be used within the Quality Framework for two broad purposes:
  - i) cost-neutral reviews of existing services within identified service groups, most likely by specialty, in which services within the service group can be reviewed in relation to each other. This may reduce some of the inequities of payment between services, including cross-subsidisation, so that the MBS funding of services becomes more equitable and incentive-neutral than is currently the case (that is, that there are no perverse incentives to provide particular services); and
  - ii) within the evidence based MBS Time-Limited Listing process this MBS fee setting mechanism will provide a recommendation for a schedule fee which is related to the fees of existing services, so that this service is remunerated according to its time and cost components consistently with the broad range of MBS fees for services offered within the specialty.
7. It is intended that, once developed, the Schedule fee setting process will:
  - provide a more objective and consistent approach to setting Schedule fees;
  - allow specific elements of a service to be considered;
  - be as clear and simple as possible, but allow for differences to be taken into account where necessary; and

- focus on reallocating resources within particular specialty areas where necessary to better reflect costs and remove distortions.

8. As well as considering the fees for different MBS items used by a specialty, fee setting may also need to consider related issues such as the impact of the Medicare Safety Net and MBS rules that might vary rebates.

9. An MBS Fee Advisory Committee will be established and it is envisaged that their first task will be to provide advice about further development, refinement and application of the fee-setting process. Some preliminary work has been undertaken on the fee setting process which would meet the stated goals and this is discussed in this section of the paper.

## **Research**

10. During the preliminary work investigating fee setting mechanisms, the Department looked at countries around the world with significant private medical systems including several provinces of Canada, the United States, South Africa, Germany and Switzerland.

11. Most of the countries examined already had input based systems and the Department (where possible) examined the inputs and measurements used in their methodologies.

12. There were commonalities between the systems in each country. All but the United States had compulsory health insurance for citizens, although some provided compulsory insurance publicly and some privately. In most countries, payments for health services were made through a variety of payment mechanisms, as is the case in Australia.

13. All systems were designed to provide remuneration for the professional work involved in the service and for the cost of providing the service.

14. In all cases there was an emphasis on co-operative processes between the Government and specialties.

15. While no one of the systems adopted elsewhere is appropriate to directly import to Australia, at a high level the system introduced could draw on their experiences and methods.

## **Key issues raised during consultations to date**

16. Key issues for stakeholders in relation to fee setting so far included:

- How Schedule fees will be structured, in terms of relativities; and
- Whether new fee-setting approaches will be considered.

17. In general, most stakeholders were interested in the approach to setting Schedule fees under a new process.

## **Fee Setting**

18. The Department's view is that Schedule fees currently include a professional component (reflecting the service provider's time) and a practice component (reflecting the physical costs of providing services). An input-based Schedule fee should make these components explicit.
19. These components could be expressed as units, based primarily on time. Conversion factors could then be used to put a dollar value on the time-based professional and practice components.
20. The conversion factors should be specific to specialties and be based on the services currently provided to ensure that new and reviewed fees maintain relativity with those provided by a specialty.
21. A time based process, using existing services for each specialty as a basis, can deliver results based on an average for each specialty. Variations in both practice and professional costs within and between specialty groups may also arise and a capacity to reflect differential costs and complexity within services needs to be included in the process. This could include, for example, the introduction of complex items in circumstances where there is significant variation in inputs, or the use of complexity modifiers.
22. Each of these elements is discussed below.
23. The preliminary methodology proposed in this paper is one which could establish a likely MBS fee based on set inputs. There could be other factors, such as policy issues, which are beyond the definable inputs discussed in this paper and that might be taken into account in a final decision on the Schedule fee for an MBS item.
24. As with the relative value systems introduced in other countries, establishing an input based process will rely on the co-operation of clinicians and specialty groups in providing information and advice. The Government will need the assistance of stakeholders to ensure that any new MBS fee setting process is developed appropriately and provides results which meet the ongoing needs of clinicians and facilitate the provision of safe, high quality, services for the public which are financially sustainable over time. Overseas experiences indicated that establishing an input based fee setting process is a lengthy process, and we anticipate that this system will take time to establish. Comment is invited on all aspects of this process for the purpose of establishing a transparent framework which provides clear and fair results.

## **Professional Time**

25. The professional component of the calculation is intended to provide payment for the direct work of a provider on a service. A professional cost unit is therefore proposed to be principally based on the time a provider spends on delivering a service.
26. The assumption underlying this approach to fee setting is that the complexity of an item is directly related to the time taken to provide the service and the broader mix of services provided by the specialist group.
27. For a new service the information gathered for this component should include:
  - The time required to provide the service for a reasonably experienced and skilled service provider;
  - The applicants' views about whether the service time reflects the complexity of the service;

28. It is in the context of the items provided by a specialty group that a claim of additional complexity for a specific item would need to be demonstrated – that an item is harder to provide than those that specialists normally have to provide and that the length of the service does not account for that. There might also be other factors that influence complexity, such as heightened medico-legal risk, patient complexity, or other special issues. It would need to be shown that the factor making the item more complex creates a demonstrable and significant impact on the costs of providing an item.

29. Information about hours of operation across a year and the time spent on other services provided by the applying specialty is also necessary for this type of time-based approach to be robust.

30. A conversion factor to convert time units into the professional component of the fee could then be set for each specialty based on current Medicare information about existing MBS fees and service times for services provided by the particular specialty.

31. Initially, services which are clearly “owned” by that specialty could be identified. By “owned” it is meant that the specialty which predominantly provides these services will have that service included in their calculation of the conversion factor. In following this approach the proportion required for ‘ownership’ to be established would be determined by the MBS Fee Advisory Committee.

32. For ‘owned’ services, the average Schedule fee per time unit for services provided by that specialty could be derived, then applied to the time for the new service. This would in principle give a dollar value for the professional component of the new service which is based on time and fees for other services provided by the specialty, maintaining intra-specialty relativity.

33. The Department accepts that moving toward a time-based approach will require information and data that are not currently available from existing Medicare sources. In this light, the Department will be looking to work with stakeholders on both the detail of the methodology and the development of appropriate datasets. In the short-term, however, existing but imperfect sources of information (such as the original Relative Values Study, international experience, AIHW or ABS datasets) may need to be utilised to ensure timely consideration of new applications and progression of reviews. In addition, new item applications may continue to utilise a comparator (to an existing service provided by a specialty) as well as input based pricing methodologies.

### ***Key questions for stakeholders***

1. Does an approach in which a base of time which may be modified for additional complexity, coupled with a conversion factor which is specific to the specialty providing the service, provide an adequate measure of the professional component of the service?
2. Are there other factors you would wish to be taken into account? Why and how could these factors be reflected?
3. Are there factors which you consider should not be taken into account? Why?

### **Practice Cost Units**

34. The practice cost component of the assessment is intended to reflect the direct and indirect costs of providing the service.

35. The indirect practice cost unit apportionment would, as with the professional measurement, be based on time. With the exception of some services with significant direct costs because of consumables or other direct expenditure, this component could be applied on a consistent basis to all services provided by a particular specialty.
36. An indirect practice cost conversion factor could be established for a specialty using a reasonably efficient practice as the base and assuming a full time workload. The cost of the practice would be divided up by time and number of practitioners in an efficient practice.
37. The average indirect practice costs for the specialty providing the service and length of time taken to provide the service are therefore the primary drivers of this element of the fee setting process.
38. The direct costs could include consumables, capital equipment specific to the service that it would not be equitable to amortise across the overall practice, or any significant specific cost which can be directly linked to providing this service.
39. As with the professional component, there must be sufficient flexibility to accommodate variations within specialties.
40. The evidence required to develop this type of practice cost approach would include information about the indirect practice cost structure and evidence about how these costs are handled by practices providing services within that specialty (for example, whether major equipment is purchased or leased and over what period). Other factors such as the tax treatment of costs may need to be taken into account. Direct costs associated with specific services would also require an evidentiary basis.
41. As with professional time, the Department understands that this information is not available from current Medicare datasets and will be looking to work with stakeholders to both refine the methodology and develop appropriate data. Again, in the interim existing but imperfect sources of information (such as the original Relative Values Study, international experience, AIHW or ABS datasets) may need to be utilised.

***Key questions for stakeholders***

1. Does an approach in which time and a base practice cost which may be modified, provide an adequate measure of the practice component of the service?
2. Are there other factors you would wish to be taken into account? Why and how could these factors be reflected?
3. Are there factors which you consider should not be taken into account? Why?
4. The Department has no recommendation at this time for the handling of services for which there would be no dominant professional group providing the service. Do you have a view of how this might be managed, noting that it is intended that there will be a single fee for a given service and this would not be varied according to who provides the service?
5. Are there other factors you would wish to be taken into account in this calculation? Why and how could these factors be reflected?
6. Are there factors which you consider should not be taken into account? Why?

## **Data Sources and Intent**

42. This process will lead to a detailed understanding of time and cost for existing services. The process is one in which relativities within a specialty could be established on a cost-neutral basis, and will aim to ensure that new services fit consistently within the framework of services currently provided by each specialty group.

43. The process outlined should allow specialties to evaluate their own services leading to MBS fees that are more consistent with service delivery costs.

- While we expect indirect practice costs to be proportional to service time, there are additional direct costs involved with providing some services and these need to be taken into account.
- We expect the professional remuneration attracted by the different services provided by individual specialties to vary, even when the length of the service is taken into account.
- Managing practice and professional components on the basis of time should assist the specialty and government to consider the weight of components included in a fee and judge their materiality.

44. While some variation in values is to be expected, and can be justified, significant variations between services might show where a service is relatively higher or lower paid than it should be. Creating relativities within a specialty might allow unreasonable variations to be modified on a basis which is cost-neutral, once utilisation is taken into account.

## **Drawing the Components Together**

45. Between the individual elements noted, the time-based professional component, the time-based practice component, and the conversion factors, the methodology outlined will enable MBS fees to be set with relative values which are directly related to the service mix provided within a specialty.

46. It provides a tool to allow a specialty to review the services they provide and the recompense those services provide relative to each other. This provides an opportunity to reduce cross subsidisation and perverse incentives and to ensure the MBS fees better reflect the relative costs and work involved in them.

47. A hypothetical example of how the fee setting process may work is provided at [Appendix B](#).

## **APPENDIX A**

### ***Review of Diagnostic Imaging Services***

The Australian Government has requested a detailed review of diagnostic imaging arrangements to ensure that the Government is paying the right amount to support access for patients to quality diagnostic imaging services.

The review of diagnostic imaging has four key tasks:

1. To establish appropriate fee relativities for MBS items across and within different diagnostic imaging modalities;
2. To explore alternatives to fee-for-service and establish whether there are areas of diagnostic imaging that would be more appropriately funded through a different mechanism;
3. Review current funding arrangements for MRI, particularly restrictions around Medicare eligible/ineligible units; and
4. To review current funding arrangements for PET, particularly around what capital arrangements should apply.

In addition, within these four key tasks the review will consider the long-term viability of diagnostic imaging services in rural, regional and outer-metropolitan areas.

The Department has commenced initial consultations with key stakeholders and this consultation will continue through 2010. These consultations are seeking to gather information about how current arrangements operate in practice and to invite stakeholders to propose options for the future sustainability for diagnostic imaging services. A discussion paper has been distributed to stakeholders and is available on the Department's website, along with the full Terms of Reference, at [www.health.gov.au/mbrtg](http://www.health.gov.au/mbrtg).

### ***Review of Pathology Services***

The Australian Government has requested a detailed review of pathology funding arrangements to ensure that the Government is paying the right amount to support access for patients to quality pathology services.

The review of pathology has three key tasks:

1. To establish appropriate fee relativities for MBS items for different disciplines;
2. To identify groups of pathology tests that might be appropriate for different funding arrangements; and
3. To explore detailed options for implementing tendering for selected pathology services.

The Department has commenced initial consultations with key stakeholders and this consultation will continue through 2010. These consultations are seeking to gather information about how current arrangements operate in practice and to invite stakeholders to propose options for the future funding arrangements for pathology services. A discussion paper has been distributed to stakeholders and is available on the Department's website, along with the full Terms of Reference, at [www.health.gov.au/mbrtg](http://www.health.gov.au/mbrtg).

### *Review of Health Technology Assessment (HTA Review)*

On 27 February 2010, the Minister for Health and Ageing, Nicola Roxon, and the Minister for Finance and Deregulation, Lindsay Tanner, released the report on the Review of Health Technology Assessment (HTA Review). The report recommended improvements to the way new health products, procedures and services are assessed for public funding, in line with international best practice.

The report on the HTA Review can be found at: <http://www.health.gov.au/htareview>

## APPENDIX B – example of proposed fee setting approach

A new minor procedure is proposed.

The procedure can be completed on in-patients at a licensed day-facility by a qualified service provider.

Evidence is given that the direct service time is between 20 and 35 minutes to complete, but on average takes 25 minutes. In addition, the provider must spend 10 minutes with the patient explaining the service before it is undertaken and then 3 minutes of observation after the service is finished. Including this time in the service is consistent with other services provided by the specialty.

Conversion factors are then used to turn the time of the service into an MBS fee. Conversion factors are dollar amounts which provide us with a base cost per minute for the two components of services – indirect practice cost and professional cost. The conversion factors are calculated for each specialty group based on the MBS fee and time (length) of service for existing items which are currently provided by the specialty. The result is weighted for current utilisation.

For this specialist group, we establish that they provide a range of 60 items (worth around \$20 million in MBS rebates per annum) which take between 15 and 60 minutes to provide. The indirect practice cost conversion factor is stable at \$1.08 per minute. The professional component of the services range between \$0.95 and \$1.88 per minute for these services. The professional cost conversion factor is \$1.42 after being weighted for current utilisation.

The service is of average difficulty for services provided by the specialty, so there is no variation for additional complexity. There are no direct costs, because equipment and consumables are covered by the facility fee, so there is no variation to the indirect practice cost. This means that time, the primary driver of the MBS fee, will be unchanged for both the practice and professional components of the service.

The MBS fee for the service is:

Practice cost is: 38 minutes x \$1.08 = \$41.04

Professional cost is: 38 minutes x \$1.42 = \$53.96

Total fee is: \$41.04 + \$53.96 = \$95.00

This is consistent with other fees for services provided by the specialty.