



Submission on MBS Quality Framework Applications and Guidelines

The AMA has reviewed the *Initial Assessment* and *Quality Framework Appraisal* application forms and guidelines from the viewpoint of how the processes will work in practice. Accordingly, we have a number of threshold concerns about the process, as well as concerns about the application requirements.

The concerns listed below are in addition to our concerns provided in an email from Francis Sullivan to Richard Bartlett on 22 December 2009.

Process

Criteria for assessment pathway

At this time the Department's documents only indicate that applications that are not assessed by the Medical Services Advisory Committee (MSAC) will be assessed under the MBS Quality Framework.

The MSAC website states "The principal role of the Medical Services Advisory Committee (MSAC) is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures".

However, it appears that the MBS Quality Framework will also assess *new* medical procedures, and that Departmental officers will decide whether an application for a new medical service is to be submitted to MSAC or the MBS Quality Framework.

The Department must provide stakeholders with the criteria it will use to determine that an application requires assessment by MSAC instead of assessment under the MBS Quality Framework, so that stakeholder are clear about what the differences are between the two assessment processes. At this time, it appears the assessment processes are the virtually same. If that is the case, there seems little need for separate application forms.

These criteria will also ensure applicants clearly understand the differences between the two pathways – which is significantly lacking in the current documentation. It will provide certainty to applicants about the correct pathway to apply to - noting that the guidelines state that if the applicant makes an application to the wrong pathway it will have to make a new application to the other pathway. It may even remove the need for the Initial Assessment process.

These criteria will also go some way to providing transparency of Departmental decisions about the pathway the Department requires an applicant to submit to.

Government initiated services

The AMA would expect that where the Government intends to fund a new service, that service would undergo the same assessment process and that the relevant medical craft groups would be involved.

Timeframe

There is no commitment by the Department to process applications, or the various elements of the assessment, within specified timeframes, or to inform the applicant about the progress of the assessment of the application.

Departmental assessment of Quality Framework Appraisal applications

There are substantial gaps in the guidelines about the way in which applications will be processed within the Department, such as:

- the level and expertise of officials who will review information in applications;
- what will trigger the Department to commission a systematic review – the concern here is that medical craft groups will put substantial effort into gathering, analysing and submitting evidence with their application which will be pointless if the Department then commissions a systematic review anyway;
- will the applicant have input to the research questions for the systematic review that the Department commissions;
- what does the Department intend an “other evaluation of the application” will encompass;
- will the applicant be given a right of reply where the Department has sought external validation of the information provided in the application, particularly against data sources that are not available to the applicant, or where the Department undertakes its own or commissions external research;
- will the Department advise applicants about all the material it submits to the Quality Framework New Listings Advisory Committee that is in addition to the information provided by the applicant.

Development of an Evaluation Plan and Fee prior to Listing

The AMA supports the collection and evaluation of data for new medical services provided in the Australian setting. The proposal for evaluation of time-listed medical services is to systematically collect information on the individuals who are treated with the medical service to monitor the service and its impact on improving healthcare outcomes – essentially a clinical registry.

If the Government is to achieve its objective of ensuring an evidence base to support ongoing Medicare funding of medical services it needs to understand that the gathering and analysis of evidence requires administrative and financial resources. The documentation is silent on how evaluations will be supported and resourced and who will be responsible for them. As past experience has shown, evaluations will not occur if these key elements are not addressed.

In respect of developing the plan, while the guidelines say the Department will work with applicants and clinical endorsers to develop the plan, and that the Quality

Framework New Listing Advisory Committee will consider the final plan, it is not clear whether the Department, the applicant or another entity:

- has primary carriage of development of the evaluation plan;
- will approve the final evaluation plan; and/or
- be responsible for implementing and managing the evaluation.

The value of clinical registries can in fact be limited because of unnecessarily extensive data collection, poor quality control, inadequate governance procedures and lack of funding. If the wrong clinical questions are asked, then the evaluation will be wasted.

The application form requires the applicant to provide the key evaluation criteria, with a focus on collection of evidence for evaluation. The application form should also ask the applicant for their opinion on who should analyse and evaluate the collected evidence.

Time-limited listing and evaluation following time-limited listing

The AMA is interested in why three years has been chosen as the period for time-limited listings that are subject to evaluation – is three years sufficient time to collect a statistically significant, solid evidence base on which to properly evaluate the service?

Further, if the formal evaluation is to take place to coincide with the end of the time-limited listing, we estimate the evaluation will need to commence 12 months before then, which will consequently involve evaluation of only 2 years worth of data. Working backwards we believe the steps will be:

- providers are given at least 3 months notice that MBS funding will cease, to ensure patient treatment plans can be appropriately managed and that patients are aware of prospective out of pocket expenses;
- the Department will advise, and the Minister will decide, on the MBS New Listings Advisory Committee recommendations for permanent, extension of time-limited or cessation of funding;
- the MBS New Listings Advisory Committee will meet and consider the evaluation and make its recommendations to the Department;
- the applicant, clinical endorsers and relevant clinical groups will be advised about the results of the evaluation;
- the responsible entity will undertake the evaluation

Who will evaluate the evidence?

Review of decisions

The AMA notes the proposal for a process for reviewing decisions recommending against time-limited listing will be managed through a process yet to be developed.

However, the documentation is silent about who will be making which decisions throughout the entire process. The Department needs to identify and describe the

various decision-making points in the assessment and recommendation process and who will be making them.

Quality Framework Appraisal application guidelines

General comment

The application guidelines are heavily sprinkled with the word ‘evidence’ when the Department probably means ‘information’. The word ‘evidence’ in these guidelines should only be used when it is intended that the applicant provide evidence as defined by the NHMRC hierarchy of evidence.

In addition, there is usually only one body of evidence to demonstrate the safety, clinical effectiveness and cost effectiveness of a service. There are repeated requests in the guidelines to provide ‘evidence’ that appear to anticipate there will be different bodies of evidence in respect of the provision of the service, the target population, health outcomes and the safety of the service.

Section 2, Question 7

As stated above, there must be clear criteria for applications for the Quality Framework Appraisal Application Process.

It appears from the guidelines (questions 7 and 13) that even minor amendments to existing MBS items to ensure the descriptors reflect current medical practice will require an application to the Quality Framework Appraisal process. Is this what the Department is proposing? If that is the case, then this process is unnecessarily burdensome.

Not every adaptation or evolution of an existing service constitutes a ‘new’ service.

For example, Medicare benefits are not payable for administration of botox for hyperhidrosis by dermatologists, although benefits are payable for other practitioners who rarely see the patient cohort for this service. Will the dermatologists have to apply through this process for their patients to have access to benefits for a service that is clearly within their scope of practice and which has long been funded for other craft groups?

Section 2, Question 8

What is the relevance of a patent number to the assessment?

Section 2, Question 9

Medical craft groups will be able to provide detailed descriptions of the service. Please clarify what is meant by “provide evidence which supports each step” (noting our comment above about the use of the word ‘evidence’).

Section 2, Questions 10 and 19

It is appropriate to ask the applicant to identify when the service is clinically contraindicated. ‘Restriction’ is a term used by the Department when there is a limit

on the circumstances in which Medicare benefits are payable, which often does not correlate with a clinical issue. Restrictions are a matter for the Department and the Minister. Applicants should not be asked to identify when the service should be 'restricted'.

Section 2, Question 11

It is reasonable to ask the applicant to provide a clinical pathway for the treatment of the disease and where in the pathway the service appears. It is not necessary for the applicant to also document here the role the new service will play as this will already be described in the responses to questions 9 and 10. The clinical pathway will illustrate whether the service is first, second or even third line treatment and the indications for which it will be used.

We suggest the words 'clearly documenting what role the new service will play' be substituted with 'to illustrate when the new service will be used in clinical practice'.

Section 2, Question 13

As stated above, there needs to be clarity on the difference between 'adaptation or evolution' and fixing up very old items that no longer adequately reflect current medical practice.

The guidelines call for 'evidence' of the extent of the amendment to an existing item. The medical profession will be able to describe what they do now and show how the item descriptor does not reflect that. Evidence will not be available that compares how the procedure was performed when the item was first introduced with what occurs now.

Section 2, Question 15

In recent times the Department has been keen to regulate the practice of medicine through the MBS. This is rather blunt instrument, and has the unintended consequence of restricting access to benefits for patients who do not have access to a particular specialist but who can obtain treatment from a highly trained and skilled medical practitioner.

Medical practitioners who provide medical services are well aware of the need to be appropriately trained and skilled to perform medical procedures. Further, there are processes that ensure medical practitioners practice within their scope of training and expertise: registration; medical college training and continuing professional development programs; and hospital credentialing. In addition, medical device companies are very active in providing training in the use of their devices.

The AMA considers it is not appropriate to now promulgate a defacto regulatory arrangement whereby MBS items are restricted to particularly described medical practitioners beyond those recognised as appropriate qualifications in the Health Insurance Regulations.

Section 2, Question 17

The information required in this section is a duplication of the information required in question 10 – patients who have the clinical indications for the service will be the target population. Perhaps the questions should simply ask the applicant to provide the number in the target group.

Section 2, Question 18

It will not be possible for the evaluation of time-listed service to encompass an evaluation of the health gains – the time period is too short. The evaluation can only assess the effectiveness of the intervention i.e. if the patient had the treatment did it prevent them from moving to the next expected stage of disease progression within the time period.

Longer-term clinical outcomes such as the example used in the guideline require longitudinal studies.

Part B: Inputs and costings

This section should articulate that the information is sought to justify the proposed MBS fee for the service.

Traditionally, MBS fees have been derived by comparing the time and complexity of the new service with other similar services on the MBS. The guidelines state that complexity is a factor only in exceptional circumstances. What are these circumstances?

Procedure time

There will be very little available information about the time a new service takes – the utilisation of a new service not yet funded under the MBS will be extremely low.

The AMA questions the need for applicants to provide minimum and maximum times, in addition to typical times. The MBS has always worked on the swings and roundabouts principle – that sometimes a procedure will be quick to perform on a patient, and another patient take much longer than the typical time. Similarly, a very experienced practitioner will generally be more efficient than a new practitioner. What does the Department intend to use the information on the range of times for and why will typical time be insufficient to cost the MBS fee?

In addition to questions 23, 24 and 25, the application should include a question seeking information on the usual after care for the service, e.g. how many post-operative consultations are required.

Section 3, Question 27

This question should be clear that it is seeking information on relative complexity to other services with similar time within the relevant craft area. Certain procedural specialties are inherently more risky, and require greater ‘sweat factor’ from the specialist than others. This is professional matter. Similarly, some relatively ‘simple’ procedures provide extremely significant long term clinical and social outcomes for patients – is the professional worth of these services less?

It is not appropriate for complexity comparisons to be made across specialties for the purposes of setting MBS fees.

Section 4, Practice Costs

Practice costs vary considerably for medical services depending on the size of the practice i.e. sole practitioner v. multi-practitioner practice, and the nature of the practice i.e. a niche range of services v. a wide range of services, and the location of the practice. It is likely that the applicant will provide practice costs based on their own practice cost experience, and will not have access to information that represents a wider practice cost experience.

How will the Department evaluate practice cost information?

Indirect costs

Traditionally the amount of MBS fees have been comprised of the professional component, and where the service is provided out-of hospital, the equipment costs associated with providing the service.

The AMA is interested to know what policy decision has been taken in respect of setting MBS fees that requires the Department to collect information about indirect practice costs. How will the Department use the information on indirect costs?

If there has been a new policy decision to include in the MBS fee a component for indirect practice costs, please advise how the Department will manage the tension that will arise when there is disparity with MBS fee relativities between existing and new services.

In terms of completing the application form for new services, it will be difficult for individual practitioners, let alone a craft group, to isolate the indirect costs of providing a new service. These costs would be likely to be underestimated.

Section 6, Question 36

In terms of determining MBS outlays for a new service, the Department can reasonably ask the applicant to provide information about the number of patients who will require the service, how many times they will require the service, and the likely take up. It is not reasonable to ask how many providers. The applicant cannot anticipate the actions of other providers.

Based on the guidelines, the Department is wanting to identify barriers to take up. The question should be re-written on this basis – asking how many providers will take up the service in the first year will not provide information that identifies the barriers.

If barriers are identified in the application, is the Department intending that it will take steps to remove those barriers?

Section 7, Question 40

It is impractical to require the applicant to provide details of clinical pathways for items that the new service is intending to replace or complement, or would generate use of an existing item. The new service may generate more blood tests that have much wider clinical application than that of the new service.

An explanation of the anticipated use of the relevant items should be sufficient to assist the Department to cost the flow ons.

Section 7, Questions 41

We would make the observation that every medical service provided is intended to improve patient outcomes and reduce the need for further intervention. The Department should combine this question with question 18 as both questions go to the same issue.

11 January 2010