Australian Government

Department of Health and Ageing

Ministerial Determination on the Formal Qualifications and Experience Needed to Become an Approved Pathology Practitioner

Discussion Paper

May 2008

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1. Introduction

Under the *Health Insurance Act 1973* (the Act), with the exception of certain prescribed pathology services, a Medicare benefit is payable for a pathology service only if it is performed at an accredited pathology laboratory (APL) by or on behalf of an approved pathology practitioner (APP). The intent of this approved provider arrangement is to ensure that patients receive pathology services that are conducted by medical practitioners who have the necessary skills. All APPs are required to apply for this status annually and, as part of the application and approval process, are also required to sign a set of undertakings with Medicare Australia that sets out their responsibilities in that role. The current undertakings are at **Attachment A.**

In the version of the Act that was in place until 29 February 2008, although the Minister is required to consider an APP applicant's formal qualifications and experience as well as his or her general fitness for the role (as a "fit and proper person"), the necessary qualifications and experience were not clearly defined beyond requiring an APP to be a medical practitioner. Amendments to the Act, which took effect on 1 March 2008, have given the Minister for Health and Ageing the power to determine the formal qualifications and experience that are needed to become an APP. These amendments are designed to provide the opportunity to remedy a current lack of clarity on what constitutes appropriate competencies for performance as an APP. This is intended to form one of the key assurances available to the Australian public that pathology testing will be conducted safely.

The change to the Act provides for the first time a specific mechanism for clearly defining the Government's policy intention that APPs should hold the relevant expertise to ensure safe patient care associated with the pathology testing for which they are responsible, by specifying the formal qualifications and experience that should be held by applicants for APP status. The detail will be set out in a Ministerial Determination, which is a legislative instrument that is tabled in Parliament. This legislative instrument will provide the basis for decision-making by Medicare Australia, as the Minister's delegate, and guidelines will be developed to support this decision-making process.

This discussion paper proposes that the formal qualifications and experience required to become an APP will vary according to the scope of testing for which each APP applicant applies. This scope of testing indicates the APP applicant's proposed scope of practice in relation to Medicare billing for pathology services. The scope of testing would also be linked to the category of laboratory in which the applicant intends to practise, as per the existing pathology accreditation assessment framework.

2. Purpose

The Department of Health and Ageing has developed this discussion paper to invite feedback from interested parties on the proposed content of the Ministerial Determination.

3. APL categories

Medicare Australia allocates a category to an APL in accordance with the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* (the APL Principles). The current APL Principles, a Ministerial Determination made under section 23DNA of the Act, is provided at **Attachment B.**

The APL Principles define and describe five categories of APL for Medicare Benefits Scheme (MBS) billing purposes – categories GX, GY, B, S and M – including the skills and

experience required to undertake clinical supervision duties within those laboratories. The categories differ in terms of the scope of services they offer and the referred patient population for whom they perform testing. The allocation of category governs the types of pathology testing for which each laboratory is accredited to bill against under the MBS.

For the laboratory categorisation process, Medicare Australia relies upon an assessment undertaken by the National Association of Testing Authorities Australia (NATA) of the laboratory's capacity to safely undertake the range of testing for which it intends to provide services. To ensure that the laboratory will be able to meet the accreditation requirements associated with supervision of pathology testing, as set out in the APL Principles, NATA review includes an advisory visit, which includes a desktop review of the qualifications and experience of the nominated supervising pathologist. The review process occurs prior to access to MBS billing and then routinely at least every three years, according to the scheduled accreditation assessment undertaken by NATA. Laboratories are also required to inform NATA and Medicare Australia if a change to supervision arrangements is proposed, prompting an additional review of the skills and experience of the proposed supervisor.

For supervision purposes in categories GX, GY and B laboratories, where a broad and/or complex range of services may be provided, NATA and Medicare Australia currently require evidence of specialist qualifications in pathology along with the specified additional expertise and experience that are required for the purposes of supervising these categories of laboratories, as required by the National Pathology Accreditation Advisory Council (NPAAC) *Requirements for Supervision of Pathology Laboratories 2007.* These requirements currently state that these laboratories must be "under the direction, control and full-time supervision of a supervising pathologist, or senior scientist, who is expert in the group, or groups, concerned". Pathologists are defined as those specialist pathologists who are recognised by Medicare Australia under the definitions and operation of the Act. Senior scientists are defined as those who have had "not less than 10 years full-time relevant laboratory experience and who possesses one of (a number of specified, relevant higher qualifications)".

In the case of categories M and S laboratories, where the relevant pathology skills and experience are not clearly defined for supervision purposes, NATA currently undertakes a case-by-case assessment of the proposed supervising clinician's skills and experience and usually seeks advice from the specialist professional groups relevant to the proposed scope of testing. This would normally include the Royal College of Pathologists of Australasia (RCPA) but may also include other relevant bodies such as the Royal Australian College of General Practice and the Fertility Society of Australia.

4. Proposed new requirements for APPs

As outlined above, from 1 March 2008 the Minister for Health and Ageing has a new power to determine the formal qualifications and experience required to be an APP. This discussion paper proposes that, for the first time, clearly defined categories of APP approvals will be created, each relating to the category of the laboratory in which APPs practise. For each proposed APP category application, the following criteria would form the basis of assessment of the appropriateness of the APP applicant for their proposed scope of testing:

- training or experience in laboratory management and supervision;
- an understanding of quality and safety issues in the laboratory;
- competence in test performance, test methodology, and test result interpretation for the range of testing proposed;

- an understanding of error in results at pre-analytical, analytical and post-analytical levels;
- an understanding of the interface between laboratory practice and the clinical application of tests; and
- membership of a professional society involved in appropriate standards, quality assurance and continuing professional development activities.

The Department accepts that these criteria are met by all current and potential APPs who are recognised by Medicare Australia as a specialist pathologist. For all other existing or potential APPs, these assessment criteria would need to be applied according to the relevant level of complexity associated with the applicant's proposed scope of testing and category of laboratory for practice, as outlined below.

The existing arrangements for assessing the safety of supervision practices in laboratories provide a useful example of how a tiered arrangement for qualifications and experience can operate but it is not directly equivalent to the model being proposed for APP categorisation. The key difference is that the Act currently sets a baseline qualification of "medical practitioner" for access to APP status.

4.1 Categories GX, GY and B

It is proposed that the appropriate qualifications for persons applying for APP status to practise in categories GX, GY and B laboratories must be a specialist pathologist for the purposes of the HIA and that this would be assessed according to the established Medicare Australia mechanisms for this recognition process. Overseas trained pathologists wishing to have their qualifications recognised as comparable would need to contact the RCPA and the Australian Medical Council for details of this recognition process.

Where Medicare Australia has previously recognised an APP as having specialist qualifications comparable to the FRCPA, those practitioners will continue to be eligible for APP status in relation to all of these categories. For example, anyone who has been recognised as a specialist pathologist for the purposes of the Patient Episode Initiation items under the MBS will also be considered to have qualifications comparable to the FRCPA, and therefore meet the required qualifications and experience to become an APP. Existing APPs who will not be able to meet these revised requirements will need to be considered as part of a proposed transitional arrangement outlined below in **section 5**.

It is anticipated at this stage that APPs approved for categories GX, GY and B would also be eligible to provide services in categories M and S laboratories if the relevant requirements were met for that category and scope of service provision.

4.2 Categories S and M

Both category S and category M laboratories perform limited ranges of testing for a limited client base, although the complexity of testing in category S laboratories may be quite high (for example, in laboratories performing fertility-related testing). Due to the nature of categories S and M laboratories, the APP will in most cases also be the laboratory's testing supervisor for accreditation purpose. For the supervisors of categories S and M laboratories, there are currently no clearly defined, recognisable, formal pathology-related qualifications relevant to the approved scope of testing. The Department considers that there is not usually the same need to require that APP applicants hold formal specialist pathology qualifications for activity in these categories of

laboratory. However, it is still very important from a public health and safety perspective that the APPs responsible for the testing undertaken in these laboratories should have an adequate understanding of the key elements that contribute to the provision of quality pathology services.

It is proposed that individuals applying for APP status for use in category S or category M laboratories would need to clearly identify to Medicare Australia:

- the scope of pathology testing for which they wish to take responsibility; and
- that they have the qualifications and experience necessary for ensuring safe and effective pathology practice relevant to the proposed scope of testing.

This demonstrated capability would be in addition to the base requirement of being a qualified and registered medical practitioner. The Department will work with relevant professional groups over time to develop agreed competency benchmarks and to identify and develop the education and/or training that would provide a good indication of competency that might form an acceptable "formal" pathology-related qualification for a limited range of testing, and which could be relied upon as the basis of assessment in the future.

4.3 Assessment of applicants

It is proposed that Medicare Australia would:

- for categories GX, GY and B laboratories, ensure that applicants are recognised specialist pathologists according to the existing recognition processes; and
- for categories M and S laboratories, seek advice from NATA and other relevant professional bodies as required in order to assess the suitability of each new APP applicant's experience and qualifications for their proposed scope of testing, in accordance with transparent guidelines that will need to be developed.

At present, as part of the laboratory accreditation process, and in accordance with the supervision accreditation standards developed by NPAAC, NATA confirms that the qualifications of individuals supervising and working in APLs are appropriate for supervising the range and complexity of testing undertaken in those laboratories. In the absence of currently available and readily identifiable "formal" qualifications to indicate competencies relevant for testing in categories M and S laboratories, it is proposed that this existing assessment process would be used as a basis for determining suitability for medical practitioners applying for APP status in a specified category.

Where an APP applicant's competency for category M or S scope of testing has already been assessed as adequate by NATA for supervision purposes, it is proposed that this assessment would inform Medicare Australia's decision about whether to accept an APP undertaking. This process would need to be clearly outlined in the form of guidelines for implementation by Medicare Australia and interested stakeholders would be consulted in the development of those guidelines.

Where NATA holds doubt about the capability of an applicant to safely undertake a proposed scope of testing, it would seek advice from the relevant specialist body or bodies in accordance with the established practices associated with the laboratory categorisation assessment processes. This assessment process would take into account the criteria outlined at the start of this section.

The Department proposes to work together with Medicare Australia, RCPA, NATA and other parties with clearly defined professional interests (such as relevant peak sub-specialty professional groups) to develop protocols that will ensure that this process assessment is as clearly defined and timely as possible. The use of such protocols would ensure that all interested parties understand their respective roles and would in turn serve to assure applicants of the existence and application of procedural fairness.

5. Current APPs

The Department proposes that any medical practitioner who was granted APP status prior to these changes will retain it for the duration of their current annual approval period. They will not need to demonstrate any further qualification in order to retain that APP status for their current approval period, regardless of which type of laboratory they operate in. From the time of their next annual application for APP status, all APPs will need to include their proposed scope of testing as part of the application and statement of undertaking. A transition period will need to be agreed for those APPs who do not hold a clearly defined and relevant qualification as outlined above. The Department of Health and Ageing will work with all relevant stakeholders to outline the qualifications and experience required for those groups where there is a lack of clarity, and the timing of the expiry of the transition period will be determined once the appropriate procedures are in place. The Department wishes to commence work on this activity in the near future in order to effectively implement the intent of the revised arrangements as quickly as possible.

For those individuals who already hold an APP approval but do not hold recognised specialist pathologist qualifications, a transition period will also be necessary. This would allow time for appropriate transparent procedures and guidelines to be put in place to enable those practitioners to be assessed to determine whether they have adequate skills and experience in laboratory practice for the scope of testing to which they wish to continue to gain access. The development of these procedures would occur in a similar way to that outlined for the assessment of APP qualifications and experience in categories M and S. It is anticipated that the majority of individuals in this situation would be specialists in other related fields of medicine but with a particular interest in laboratory medicine and, in those cases, it should be possible to establish an appropriate outline of competence for the scope of testing that is applied for. It will be important for these individuals to ensure that the Department is aware of their circumstances so that they can be taken into account.

6. Future APP approval processes

It is proposed that, on initial application or upon renewal of their approvals, all APPs would need to:

- nominate the class/classes of laboratory in which they propose to initiate MBS billing;
- indicate their proposed scope of testing (for categories M and S laboratories); and
- have their qualifications checked by Medicare Australia according to either existing mechanisms for checking registration as a medical practitioner or recognised specialist or according to the standards and guidelines for assessment of other formal qualifications and experience that are still to be developed.

For APPs wishing to be responsible for billing pathology services in category GX, GY or B laboratories, Medicare Australia will rely upon its existing process of ensuring that an applicant has a recognised specialist pathologist qualification.

For APPs in category S or category M laboratories, in addition to the above and where there has not yet been an appropriate qualification defined, Medicare Australia would seek:

- a statement of claims against the criteria set out above; and
- evidence of any current assessment by NATA of their relevant skills and experience for supervision of testing in the requested scope of testing.

For applicants who have not already been subject to NATA assessment as part of a laboratory assessment process and who do not hold a pathology specialist qualification, Medicare Australia would seek NATA's and the relevant professional body's or bodies' assistance in determining the suitability of the applicant's experience for the proposed scope of testing in the nominated laboratory/laboratories. The detail of this proposed process requires further consultation and would need to be subject to the development of transparent guidelines for implementation.

Once approved by Medicare Australia, APP status will remain valid for one year as per the current approval arrangements. In line with current arrangements, APPs will be able to move between pathology laboratories (as long as this is within the classes and/or groups of tests for which they have been approved) and will still need to notify Medicare Australia of these movements.

The revised arrangements outlined above would apply to all new APP applicants from the time that the Ministerial Determination is made.

7. APP annual undertakings

Individuals wishing to become APPs would continue to be required to sign an undertaking for this purpose and to meet all other existing requirements. Modifications will be made to the APP application form and associated undertakings to reflect the revised requirements.

8. Links to the pathology accreditation scheme and associated standards

The current process of assessing the capability of a laboratory to undertake a requested scope of testing for the purpose of accreditation of the laboratory will remain in place. The proposed changes to the requirements around formal qualifications and experience for APPs will augment the current quality assurance processes. The proposed new arrangements would ensure that:

- for the purpose of laboratories conducting a broad and complex range of pathology testing, APPs would be required to hold recognised specialist pathology qualifications or the equivalent degree of competence for a defined scope of testing, as assessed according to the criteria outlined above and the guidelines that will be developed for implementation by Medicare Australia in consultation with stakeholders; and
- all APPs hold the relevant qualifications and/or experience to safely take responsibility for pathology testing they undertake on behalf of consumers and their requesting medical practitioners.

9. Submissions

The Department would be interested to receive feedback on:

- the existence of any qualification/s that a prospective APP could potentially obtain that would cover the relevant pathology competencies for category M and/or category S laboratories;
- whether there are any other identifiable objective criteria that could reasonably be used to assess whether a prospective APP has appropriate experience and/or qualifications; and
- the workability of the criteria and procedures as proposed above where there are currently no appropriate agreed, identifiable formal qualifications.

Stakeholders are also invited to provide submissions on any other issues raised in this paper, including:

- any areas where they agree or disagree with the Department's reasoning; and
- comments on the potential cost to business of these changes where relevant.

Early responses are encouraged but submissions should be received by cob **20 June 2008**. Submissions should be provided to:

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or

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