

Guidelines for the Recognition of Medical Specialties and Fields of Specialty Practice under the Health Practitioner Regulation National Law

May 2018

May 2018

Approval

Australian Medical Council – 12 April 2018
Medical Board of Australia – 2 May 2018

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Part A: Introduction

A1: Summary

New or amended specialties are approved by the COAG Health Council on the recommendation of the Medical Board of Australia.

The recognition of a new or amended specialty by the COAG Health Council is a 'regulatory instrument'. It extends the scope of offences that apply to the unauthorised use of protected specialist titles and to individuals who otherwise hold themselves out as being authorised or qualified to use the titles. Therefore, the process for assessing whether a new or amended specialty should be recognised is rigorous. It includes public consultation and oversight of the regulatory assessment process by the Office of Best Practice Regulation Commonwealth Department of Prime Minister and Cabinet.

The COAG Health Council may approve a new or amended specialty¹ only after a public benefit has been demonstrated. That is, applicants proposing a new or amended specialty for recognition under the National Law² must establish that there is a need for requiring government intervention (regulation) in the interests of the public and that existing arrangements or other alternative non-regulatory options are unsatisfactory. Specialist recognition is not about the interest or prestige of the practitioners who are seeking this recognition.

Applicants for a new or amended specialty submit an initial proposal to the Medical Board of Australia. Attachment A provides a guide to an initial proposal for recognition of a new or amended specialty under the National Law.

If on the basis of the initial assessment of the proposal, the Medical Board decides that there may be a case for the recognition of a new or amended specialty, the applicant will be asked to provide additional information, including the information at Attachment B. The Board will conduct a **detailed assessment** of the case for recognition. This includes seeking advice from the Australian Medical Council.

The Medical Board will recommend that the COAG Health Council approve a new or amended specialty, if on the basis of the assessment processes it has concluded that there is a case for recognition.

The reasonable costs involved in conducting an assessment of an application proposing the recognition of a new or amended specialty will be borne by the applicant.

A2: Background

Under the National Law, a National Board for a profession may recommend that the COAG Health Council approve one or more specialties and associated specialist titles for a profession (section 13 of the National Law). The COAG Health Council has approved the operation of specialist recognition for the medical, dental and podiatry professions.

The Australian Health Workforce Ministerial Council (now operating as the COAG Health Council) approved a *'List of specialties, fields of specialty practice and related specialist titles'* for the medical profession that took effect at the commencement of the National Registration and Accreditation Scheme (the National Scheme). The approved *'List of specialties, fields of specialty practice and related specialist titles'* for medicine is published at <http://www.medicalboard.gov.au/Registration-Standards.aspx>.

¹ Throughout this document, references to new or amended specialties include new or amended fields of specialty practice and all associated titles.

² Health Practitioner Regulation National Law, as in force in each state and territory.

The COAG Health Council has provided guidance³ (the COAG Guidance) to National Boards on submissions for the approval of specialties, for the purposes of specialist registration in a health profession under the National Scheme.

A3: Purpose

This document complements the COAG Guidance. It describes the process for dealing with applications for recognition of a new medical specialty or an amendment to the list of medical specialties and/or fields of specialty practice.

A4: What does specialist recognition mean?

Recognition of a specialty or field of specialty practice means that the COAG Health Council has made a decision under the National Law to recognise a new or revised specialty or field of specialty practice and to amend the list of titles of specialties, fields of specialty practice and titles for the profession.

The National Law protects the public through the 'protection of title'. The National Law contains a list of 'protected titles' and only individuals who are registered in a particular profession and/or specialty can use the titles associated with that profession and/or specialty. For example, under the National Law:

- A person can only use the title 'medical practitioner' if they are a registered medical practitioner.
- A person can only use the title 'medical specialist' if they are registered in a recognised specialty in the medical profession.
- A person can only use a protected specialist title if they are registered in the associated recognised specialty or field of specialty practice. To illustrate, the title 'specialist general practitioner' can only be used by someone who has specialist registration in general practice and the title 'specialist in addiction medicine' can only be used by someone who has specialist registration in addiction medicine.

Therefore, specialist registration means that a person can use the protected title associated with the specialty in which they are registered.

A COAG Health Council approval of a specialty or field of specialty practice is a 'regulatory instrument'. It extends the scope of offences that apply to the unauthorised use of these protected titles and to individuals who otherwise hold themselves out as being authorised or qualified to use them.

Put simply, it is a breach of the National Law for someone to use a protected title if they do not hold the relevant registration. The penalties as at February 2018⁴ for an individual are up to \$30,000 and for a body corporate up to \$60,000.

As stated in the COAG Guidance '...approval by the Ministerial Council [COAG Health Council] of a specialty or specialist registration under the National Law in no way impacts on eligibility for Commonwealth benefit programs such as the Medicare Benefits Schedule or the Pharmaceutical Benefits Schedule. Eligibility for these programs is established under separate Commonwealth Government application and assessment processes.'

Specialist recognition is approved only after a public benefit has been demonstrated. That is, it has to be demonstrated that it is in the public interest to recognise the specialty. Specialist recognition is not about the interest or prestige of the practitioners who are seeking this recognition.

³ COAG Health Council, Approval of specialties under section 13 of the Health Practitioner Regulation National Law Act – Guidance for National Board submissions to the Australian Health Workforce Ministerial Council dated 29 July 2014 accessible at <http://www.ahpra.gov.au/About-AHPRA/Ministerial-Directives-and-Communiques.aspx>

⁴ These penalties are the penalties under the National Law as at February 2018 and are subject to change.

A5: What organisations are responsible for recognition of a new or amended medical specialty or field of specialty practice?

In summary

- **The COAG Health Council** approves new or amended specialties or fields of specialty practice.
- **The Medical Board of Australia** recommends to the COAG Health Council to approve a new or amended specialty or field of specialty practice.
- **The Australian Medical Council** provides advice to the Medical Board on the proposal for recognition of a new or amended specialty, including the education and training impacts of the proposal. The Australian Medical Council also prepares the consultation documents and reports for the Medical Board of Australia.
- **The Office of Best Practice Regulation** of the Commonwealth Department of Prime Minister and Cabinet oversees the regulatory assessment process prior to the COAG Health Council decision.
- **The applicant** is responsible for making a case for recognition of a new or amended specialty or field of specialty practice as defined in these guidelines and the reasonable costs of any assessment work required by the Medical Board.

Role of the COAG Health Council

The COAG Health Council:

- approves a health profession for which specialist registration will operate under the National Law;
- decides whether to approve, on recommendation of the Medical Board of Australia, a list of specialties, fields of specialty practice and specialist titles for the medical profession; and
- provides guidance to the National Boards about the matters they should address in submissions for approval of specialties for the profession.

Role of the Medical Board of Australia

The Medical Board of Australia:

- considers initial applications that propose a new or amended specialty and decides whether there is a sufficient case to assess a detailed application for recognition;
- consults the Office of Best Practice Regulation as required;
- advises the COAG Health Council if it intends to start an assessment of an application for recognition of a new or amended specialty or field of specialty practice;
- consults widely if it decides there may be a case for recognition (in the form of a consultation Regulation Impact Statement if required);
- considers advice from the Australian Medical Council, any specialist college for the profession, and any other relevant submission, and determines whether or not to recommend that the COAG Health Council approve a new or amended specialty;
- makes a submission to the COAG Health Council if it recommends a new or amended specialty be approved; and

- having assessed the case for recognition, informs the COAG Health Council if it has decided not to recommend that a new or amended specialty or field of specialty practice be approved.

Role of the Australian Medical Council (AMC)

The Australian Medical Council:

- has an advisory not a decision making role in the process for recognition of specialties;
- provides advice to the Medical Board of Australia on the proposal for recognition at various stages of assessment. This includes completing the assessment of an application for recognition according to a program agreed by the Medical Board of Australia and preparing a report on its assessment for the Medical Board. It also includes developing consultation documents and reports for the Medical Board of Australia;
- considers applications from relevant education providers for an accreditation assessment of their programs of study after the COAG Health Council makes a decision to amend the approved '*List of specialties, fields of specialty practice and related specialist titles*'.

Role of applicant

It is the responsibility of the applicant to develop and submit an application that addresses the requirements in these guidelines (see Attachments A and B) and to provide the application in the format required.

The applicant:

- submits an initial proposal to the Medical Board of Australia seeking assessment of the case for recognition;
- if the Medical Board of Australia decides that the initial proposal demonstrates there may be a case for recognition of a new or amended specialty, the proposal proceeds to a detailed assessment where the applicant will be required to provide additional information in the format requested by the Australian Medical Council and the Medical Board of Australia. If a regulation impact statement is required, the applicant will provide information required to support this statement; and
- is responsible for paying the reasonable cost of any assessment work required by the Medical Board of Australia (see Attachment E for more information).

Role of the Office of Best Practice Regulation

A decision to approve a new specialty or amended specialty is a 'regulatory instrument' within the meaning of the *Council of Australian Governments Best Practice Regulation: A Guide for Ministerial Councils and National Standards Setting Bodies October 2007* ('the COAG Guide to best practice regulation'). This guide requires a robust regulatory assessment process to be carried out prior to the COAG Health Council decision. The Office of Best Practice Regulation of the Commonwealth Department of the Prime Minister and Cabinet oversees this assessment process. The Office of Best Practice Regulation is responsible for scrutinising Regulation Impact Statement processes on behalf of COAG.

The Office of Best Practice Regulation:

- oversees the assessment processes in relation to the approval of a new or amended specialty to ensure that it is consistent with the COAG Guide to best practice regulation;
- decides whether a Consultation Regulation Impact Statement is required; and
- decides whether a Decision Regulation Impact Statement is required.

The Medical Board will consult the Office of Best Practice Regulation throughout the assessment process.

PART B: The process for seeking recognition of a new or amended specialty under the National Law

Applicants are advised to read the *'Matters to be addressed in submissions to the COAG Health Council recommending a new or amended specialty'* at Attachment B before developing an application for a proposed new or amended specialty. Attachment B is based on the COAG Guidance to National Boards on the matters to be addressed in a submission to the COAG Health Council for a new or amended specialty.

The following process is implemented when an applicant seeks to have a new or amended specialty recognised by the COAG Health Council. The process has a number of key steps which must be completed. Each step may take time to complete, and may result in a request or requests for additional information or clarification.

The recognition process is a two-stage linked process.

Stage 1: Initial assessment of proposal (application): In this stage, the Medical Board of Australia decides whether the proposal demonstrates there may be a case for recognition of a new or amended specialty. If the Medical Board decides there is no case for recognition, the application does not proceed further.

Stage 2: Detailed assessment of proposal: In this stage, the Medical Board conducts a detailed assessment of the case for recognition of a new or amended specialty. This stage leads to the Medical Board deciding whether or not to recommend the COAG Health Council approve the new or amended specialty and the COAG Health Council making its decision.

The process in summary:

- The applicant submits an initial proposal to the Medical Board of Australia.
- The Medical Board seeks advice from the Australian Medical Council on the initial proposal.
- The Medical Board considers the initial proposal and Australian Medical Council's advice and decides whether there may be a case for recognition.
- If the Medical Board decides there may be a case for recognition, it proceeds with a detailed assessment. The Medical Board will:
 - advise the COAG Health Council if it intends to start an assessment of an application for recognition of a new or amended specialty or field of specialty practice;
 - seek advice from the Office of Best Practice Regulation about whether a regulation impact statement (RIS) is required;
 - request that the Australian Medical Council establish a review panel. The review panel will obtain additional information and will develop a consultation document (in the form of a consultation RIS if the Office of Best Practice Regulation has advised that this is necessary).
- If the Office of Best Practice Regulation has advised that a consultation RIS is necessary, the Medical Board will send the Australian Medical Council's consultation RIS to the Office of Best Practice Regulation and will seek advice as to whether or not it meets the requirements of the COAG Guide to best practice regulation.
- The Australian Medical Council review panel considers the results of consultation and writes a report on the proposal. The report will be considered through Australian Medical Council committee processes, resulting in advice to the Medical Board.
- The Medical Board will consider the Australian Medical Council's advice and will decide whether or not to recommend that the COAG Health Council approve the new or amended specialty.
- If the Medical Board decides to recommend that a new or amended specialty be recognised, it will make a recommendation (in the form of a Decision RIS, if required) to the COAG Health Council.
- The COAG Health Council makes its decision.

B1 Initial assessment of proposal

In this stage, the Medical Board of Australia decides whether or not the initial proposal demonstrates there may be a case for recognition of a new or amended specialty.

1. Applicant develops an initial proposal

The applicant develops an initial proposal for recognition of a new or amended specialty and submits the proposal to the Medical Board of Australia.

For details on the content of the proposal, see Attachment A.

2. The Medical Board of Australia seeks advice from the Australian Medical Council regarding the initial proposal

The Medical Board will send the initial proposal for recognition of a new or amended specialty and any additional documentation to the Australian Medical Council with a request for advice.

3. The Australian Medical Council considers the initial proposal and provides advice to the Medical Board

4. The Medical Board considers the initial proposal and the advice from the Australian Medical Council and decides whether there may be a case for recognition of a new or amended specialty

The Medical Board will only decide that there may be a case for recognition of a new or amended specialty if it reaches the conclusion on the basis of the initial assessment that:

- recognition is likely to contribute to one or more of the objectives of the National Law. That is to: enhance protection of the public, facilitate workforce mobility, facilitate access to health services and enable the continuous development of a flexible, responsive and sustainable health workforce and innovation in service delivery; and
- regulation will offer an overall net benefit and alternative, non-regulatory options will not offer the same benefit.

Outcomes of the initial proposal

a. The Medical Board of Australia decides there is not a sufficient case for recognition and will not proceed with a detailed assessment

If the Medical Board decides there is not a sufficient case for recognition of a new or amended specialty, the proposal will not proceed to a detailed assessment. The Medical Board will inform the applicant of the outcome and will provide reasons why the application was unsuccessful.

The Medical Board will not consider a new proposal until 12 months has lapsed since it informed the applicant that the application was not successful.

At Attachment C are some examples of the type of applications that are not likely to be successful.

b. The Medical Board of Australia decides there may be a sufficient case for recognition

If the Medical Board decides there may be a sufficient case for recognition, it will proceed to a detailed assessment of the proposal for a new or amended specialty. The Medical Board will:

- inform the applicant – with advice on the process that the Australian Medical Council will follow in the detailed assessment of the proposal
- inform the Australian Medical Council – so it can proceed with a detailed assessment of the proposal
- liaise with the Office of Best Practice Regulation as to whether or not a consultation RIS is required in the circumstances. The Medical Board will use information in the applicant's initial proposal in its communications with the Office of Best Practice Regulation
- inform the COAG Health Council, each state and territory and the Commonwealth through the Jurisdictional Advisory Committee that it will be conducting a detailed assessment of the case for recognition of the new or amended specialty. The Medical Board will provide the COAG Health Council and the jurisdictions with:
 - its submission to the Office of Best Practice Regulation; and
 - the advice from Office of Best Practice Regulation as to whether or not a consultation RIS is required.

After receiving advice from the Office of Best Practice Regulation, the Medical Board may ask the applicant to provide additional information in support of the application. This application must address the matters defined in Attachment B.

B2 Detailed assessment of proposal

In this stage, the Medical Board decides whether or not to recommend that the COAG Health Council approve the proposed new or amended specialty.

5. The Medical Board of Australia requests the Australian Medical Council conduct a detailed assessment

The Medical Board will write to the Australian Medical Council and will formally request that it undertake a detailed assessment of the application for recognition of a new or amended specialty.

The Australian Medical Council will establish a review panel. The review panel will undertake a detailed analysis of the case for recognition of the new or amended specialty.

The review panel will prepare a consultation document. The review panel's consultation document will be in the form of a consultation RIS if the Office of Best Practice Regulation has advised that this is necessary.

If the Office of Best Practice Regulation advises that a consultation RIS is not necessary, a consultation document will be developed as per the AHPRA guidelines '*Consultation process of National Boards*'.

For further information about the review panel, see Attachment D.

6. The Medical Board of Australia consults the Office of Best Practice Regulation

If the Office of Best Practice Regulation advises that a consultation RIS is necessary, the Medical Board will send the consultation RIS prepared by the Australian Medical Council to the Office of Best Practice Regulation and will seek advice as to whether or not it meets the requirements of COAG Guide to best practice regulation.

7. Consultation

The Medical Board will consult widely on the proposal to approve a new or amended specialty.

The consultation process will be consistent with the COAG best practice regulation requirements if a consultation RIS is required.

If a consultation RIS is not required, the Medical Board will consult in accordance with the Australian Health Practitioner Regulation Agency guidelines '*Consultation Process of National Boards*' which will include to:

- publish the consultation document and proposal on the Medical Board's website;
- email the consultation document and proposal to relevant stakeholders and invite them to provide feedback on the proposal.

The consultation period will usually be eight weeks.

Submissions made in response to the consultation will be published according to AHPRA guidelines '*Consultation process of National Boards*'. The Medical Board publishes submissions received on its website to encourage discussion and inform the community and stakeholders, unless requested otherwise. There may be circumstances under which submissions may not be published.

The Medical Board will provide all the submissions from the consultation to the Australian Medical Council.

8. The Australian Medical Council review panel assesses the feedback from the consultation

The Australian Medical Council review panel will consider the feedback from the consultation. It may also seek additional information in order to complete the detailed assessment. For example, it may:

- interview representatives of the applicant and other relevant stakeholders;
- seek additional information from the applicant or any other person or organisation;
- complete a program of clinical site visits to contribute to understanding of the role and place of clinical practice in the proposed specialty or field of specialty practice within the broader context of the Australian health system. These visits may include interviews with practitioners practising substantially in the field, and other health professionals working in related or associated disciplines. The review panel may seek recommendations from the applicant on who to include in the clinical site visits, but the group will develop its own program; and/or
- undertake any other investigations or inquiry that appears appropriate to the review panel.

In some circumstances, the Australian Medical Council may recommend to the Medical Board that additional work be commissioned by third parties (e.g. academics, health economists), if this work is regarded as essential to the assessment of the case. The Medical Board will consult with the applicant about any such request. The reasonable cost of any work the Medical Board decides should be undertaken will be borne by the applicant.

9. The Australian Medical Council review panel prepares a report on the case for recognition and submits it through the Australian Medical Council committee processes

The Australian Medical Council's Specialist Education Accreditation Committee will oversee the recognition process on behalf of the Australian Medical Council Directors. The Specialist Education Accreditation Committee is a standing committee of the AMC. Its terms of reference are available on the AMC website. The Committee will establish a Recognition of Medical Specialties Sub-Committee to advise it on the recognition processes.

The Australian Medical Council will send the review panel's report to the applicant and will invite comments on the factual accuracy and findings of the assessment. The applicant's comments will be taken into consideration when the review panel's report is considered by the Recognition of Specialties Sub-Committee and subsequently the Specialist Education Accreditation Committee.

10. The Australian Medical Council provides a report to the Medical Board of Australia

The Australian Medical Council's Specialist Education Accreditation Committee will determine the advice to be given to the Medical Board. The Chair of the Specialist Education Accreditation Committee will inform the Australian Medical Council Directors of its advice to the Medical Board. The Australian Medical Council will submit a report of its findings and advice endorsed by the Specialist Education Accreditation Committee to the Medical Board.

11. The Medical Board of Australia decides on its recommendation to the COAG Health Council

The Medical Board considers the Australian Medical Council's report and decides whether or not to recommend a new or amended specialty to the COAG Health Council.

Medical Board of Australia decision on detailed assessment

a. Board decides not to recommend recognition of a new or amended specialty to the COAG Health Council

The Medical Board will inform the applicant and the COAG Health Council of the outcome and will provide reasons for not recommending recognition of the new or amended specialty.

b. Board decides to recommend the COAG Health Council recognise the new or amended specialty

The Medical Board will inform the applicant that it is recommending that the COAG Health Council recognise the new or amended specialty.

If a consultation RIS was required, the Medical Board will ask the Australian Medical Council to prepare a Decision RIS. The Medical Board will provide the Decision RIS to the Office of Best Practice Regulation and will seek advice as to whether or not it meets the requirements of the COAG Guide to best practice regulation.

12. The Medical Board of Australia recommends the COAG Health Council recognise a new or amended specialty

The Medical Board will submit its recommendation for recognition of a new or amended specialty to the COAG Health Council including the Decision RIS (if required) and any feedback from the Office of Best Practice Regulation.

13. COAG Health Council decision

The COAG Health Council will consider the Medical Board of Australia's recommendation (which may be in the form of a Decision RIS if required). The COAG Health Council may:

- request further information from the Medical Board or another body prior to making a decision; or
- decide to approve or not approve the new or amended specialty. If the COAG Health Council decides not to approve the new or amended specialty at this time, it will give the Board the reasons for the decision.

The COAG Health Council, in approving the specialty must be satisfied that:

- there has been sufficient consultation with key stakeholders during development of the proposal for approval of the specialty; and
- the COAG best practice regulation requirements have been met; and
- approval of the specialty provides the greatest net public benefit, compared with alternative options.

14. The Medical Board of Australia will inform the applicant and the Australian Medical Council of the COAG Health Council's decision

The Medical Board will write to the applicant and the Australian Medical Council to inform them of the COAG Health Council's decision. The Medical Board will also publish its recommendation which may be in the form of a Decision RIS and the COAG Health Council's decision on its website.

If the COAG Health Council approves the specialty or amended specialty, the Medical Board will amend the *'List of specialties, fields of specialty practice and related specialist titles'* and will publish the amended list.

Attachment E describes a range of administrative and procedural matters in the recognition of specialties including fees and charges, and confidentiality and access to information.

Part C: Accreditation assessment and approval of education providers

If the COAG Health Council approves the recognition of a new specialty, education providers with programs of study in that specialty may apply to the Australian Medical Council for accreditation of their program of study. The Australian Medical Council assesses programs of study in recognised specialties against the relevant approved accreditation standards for specialist medical training programs.

For a proposed new specialty, a full accreditation assessment of the training and education program is not undertaken until the recognition process has been completed and a decision has been made to recognise the specialty.

Where an existing accredited education provider is delivering a training program in a new or amended field of specialty practice or an amended specialty, the accreditation assessment may be undertaken in the regular cycle of accreditation assessment for that education provider.

The Australian Medical Council assesses the specialist programs of study, including the continuing professional development programs, available for the new or revised specialty. This process is described in detail in the Australian Medical Council documents *Assessment and Accreditation of Specialist Medical Programs and Continuing Professional Development Programs by the Australian Medical Council: Standards and Procedures*.

Only programs of study in a new or amended specialty or field of specialty practice that have been accredited by the Australian Medical Council and approved by the Medical Board of Australia will lead to specialist registration. Approved programs of study for general or specialist registration are published on the Medical Board of Australia's website under 'Accreditation'.

Glossary

AHPRA	Australian Health Practitioner Regulation Agency. AHPRA administers the National Registration and Accreditation Scheme.
Australian Medical Council	The Australian Medical Council is the accreditation authority for the medical profession under the National Law. In the process for recognition of new or amended specialties, the Australian Medical Council has an advisory role to the Medical Board of Australia.
The applicant	The individual or organisation seeking recognition of a medical specialty or field of specialty practice under the National Law.
COAG Health Council	The Council of Australian Governments (COAG) Health Council (formerly operating as the Australian Health Workforce Ministerial Council). The COAG Health Council may give directions to a National Board about the policies to be applied by the National Board in exercising its functions under the National Law. The COAG Health Council decides whether to approve specialties and fields of specialty practice on the advice of a National Board.
Jurisdictional Advisory Committee	<p>The Jurisdictional Advisory Committee (JAC) is convened by the AHPRA at the request of the Australian Health Ministers' Advisory Council (AHMAC). It is a forum for providing authoritative advice and/or direction or agreement on National Registration and Accreditation Scheme matters that require Australian Health Ministers to reach a decision under the National Law.</p> <p>Membership comprises health officials at the deputy secretary/deputy director-general (or equivalent) level from each state and territory and the commonwealth with portfolio responsibility for the National Scheme.</p>
National Law	The Health Practitioner Regulation National Law, as in force in each state and territory.
National Boards	<p>Under the National Law, National Boards are established for regulated health professions. For medicine this is the Medical Board of Australia. The functions of the National Boards include to:</p> <ul style="list-style-type: none">• register health practitioners;• develop standards, codes and guidelines for the health profession;• investigate notifications and complaints about health practitioners;• where necessary, conducts panel hearings and refers serious matters to Tribunal hearings;• assess international health practitioners who wish to practise in Australia; and• approve accreditation standards and accredited programs of study.
National Scheme	The National Registration and Accreditation Scheme (NRAS or the National Scheme) for the health professions is implemented through enactment of the National Law in each state and territory. The National Scheme covers the regulation of certain health professions and includes the accreditation of programs of study for those professions.

Medical Board of Australia or Medical Board	The Medical Board of Australia regulates medical practitioners in the public interest.
Recognition	Recognition of a specialty or field of specialist practice means that the COAG Health Council has made a decision under the National Law to recognise a new or amended specialty or field of specialty practice and amend the approved 'List of specialties, fields of specialty practice and related specialist titles'.
Regulation Impact Statement	Regulation is any law, government rule or direction that requires certain conduct from individuals, businesses and governments. A Regulation Impact Statement (RIS) is a rigorous process for analysing the most feasible (efficient and effective) options available, including the possibility of regulation, to produce the greatest net benefit to society, while simultaneously meeting the needs of government.
Office of Best Practice Regulation.	The Office of Best Practice Regulation of the Australian Government Department of Prime Minister and Cabinet is responsible for scrutinising Regulation Impact Statement processes on behalf of the Council of Australian Governments.
Specialist Education Accreditation Committee	The Australian Medical Council committee responsible for the accreditation of specialist medical programs and their providers, including the initial accreditation, monitoring and any subsequent re-accreditation. In relation to recognition of medical specialties, the Committee oversees the work of its Recognition of Medical Specialties Sub-Committee.
Recognition of Medical Specialties Sub-Committee	A sub-committee of the Australian Medical Council's Specialist Education Accreditation Committee.

Attachment A

Guide to an initial proposal for recognition of a new or amended specialty under the National Law

The initial proposal must describe the objective/s of the proposal in broad terms. The proposal must also:

1. Describe the function of the organisation lodging the preliminary proposal and its interest in the proposal.
2. Present a clear statement of the issue or issues that the proposal for the recognition of a new or amended specialty is intended to address, including:
 - a. How recognition of the proposed new or amended specialty within the National Scheme will advance the objectives of the National Scheme, That is; to:
 - enhance protection of the public, including improvement in the quality of health services;
 - facilitate workforce mobility;
 - facilitate access to health services in the public interest; and
 - enable the development of a flexible, responsive and sustainable health workforce and innovation in service delivery.
 - b. Why the existing arrangements are unsatisfactory.
 - c. How significant the benefits of recognition are in terms of the objectives of the National Scheme.
 - d. The extent to which health services are established in the proposed specialist or field of specialty practice and the demonstrated and/or potential ability of this proposal to improve the provision of the service.
 - e. Describe other ways in which the proposal is in the public interest.
3. Describe alternative options (both regulatory and non-regulatory) for addressing the issues outlined in point 2. In addition to recognition under the National Law, the proposal must present and compare the advantages and disadvantages of:
 - existing arrangements (no change);
 - other regulation that exists that may be used to address the problem listed in point 2;
 - other non-regulatory mechanisms to achieve the desired outcome, for example: self-regulation of practitioners through professional (voluntary) codes of conduct.

Note: The Council of Australian Governments' (COAG) Best Practice Regulation Guide for Ministerial Councils and National Standard Setting Bodies (2007, p. 3) define 'regulation' as referring to: the broad range of legally enforceable instruments which impose mandatory requirements upon business and the community, as well as to those government voluntary codes and advisory instruments for which there is a reasonable expectation of widespread compliance. Other forms of regulation might include: The registration provisions of the Health Practitioner Regulation National Law, therapeutic goods and medicines regulation, health complaints regulation, consumer protection regulation and National Quality and Safety Standards.

4. Describe the existing professional standards that are relevant to training and specialty practice in the specialty:
 - a. If education programs and continuing professional development programs exist, provide a short outline of them and a link to more detailed information.
 - b. Indicate what new standards or requirements are anticipated if the proposal results in recognition of a new or amended specialty or field of specialty practice under the National Law.

Note: The capacity to provide training and education to support specialist practitioners is a key consideration during Stage 1.

Note: Groups representing developing specialties and fields of specialty must identify existing specialties and field of specialty whose scope of practice or training programs are similar.

5. Identify the stakeholder groups likely to be affected by the recognition of the specialty including groups within the regulated profession or segments of the profession, other health professions, health consumers and the community, health service providers, funding bodies, education providers and Aboriginal and Torres Strait Islander Peoples.
6. Describe the consultation which has been undertaken to determine the stakeholders affected by the proposal.
7. Identify extant medical specialties and/or fields of specialty practice that have significant overlap in scope of practice, required knowledge, skills and competencies with the proposed new or amended specialty or field of specialty practice; and describe what differentiates the proposed new or amended specialty from these existing specialties.
8. Identify expected impacts of each option on the various stakeholder groups, including impacts on coordination and continuity of health care and the quality and safety of care, workforce impacts, financial impacts, business impacts and competition impacts.

Attachment B

Matters to be addressed in submissions to the COAG Health Council recommending a new or amended specialty

These matters are based on the COAG Health Council Guidance⁵ to National Boards about the matters that should at least be addressed in a submission to the COAG Health Council for approval of a new or amended specialty.

Applicants must address these matters in their detailed proposal to the Medical Board.

1. The field of practice is distinct and a legitimate area of specialist practice

The applicant must address the following concerning the scope of practice of the specialty or field of practice:

- a. that the specialty or field of practice is based on substantiated concepts in medical science and health care delivery
- b. that the specialty or field of practice is a legitimate and distinctive field of medicine with specialist knowledge and skills that are over and above those required for generalist practice and separate from other existing specialties or fields of practice. This might include, for example, the extent to which the field of practice has:
 - an established and distinct body of knowledge;
 - a comprehensive and developing body of international and local research, literature, practice and innovation;
 - formal recognition as a specialty in comparable countries.

2. The specialty or field of practice is capable of contributing to the standards of medical practice

The applicant must address the following concerning the scope of practice of the specialty or field of practice:

- a. that the specialty or field of practice has structures and governance arrangements in place that demonstrate substantial institutional support for its practice including:
 - professional bodies that represent practitioners in the field of practice;
 - acceptance by government and non-government health service funders, and service delivery bodies.
- b. that there are standards for:
 - medical practice in the specialty or field of specialty practice to ensure high quality health care;
 - guidelines and procedures for determining who will be Foundation Fellows/Members of the professional body (NB the level of knowledge, skills and competence of Foundation Fellows/Members should be no lower than those who will complete its training program); and
 - training, assessment and certification in the specialty or field of practice.
- c. that the Australian professional body or bodies can demonstrate experience in all or some of the following:
 - health policy development;

⁵ COAG Health Council, Approval of specialties under section 13 of the Health Practitioner Regulation National Law Act – Guidance for National Board submissions to the Australian Health Workforce Ministerial Council dated 29 July 2014 accessible at <http://www.ahpra.gov.au/About-AHPRA/Ministerial-Directives-and-Communiques.aspx>

- health promotion and advocacy;
- research facilitation;
- the development and dissemination of the discipline's evidence base;
- the education of other medical and health professionals;
- engagement with health consumers.

3. Regulation in the form of recognition of the specialty or field of specialty practice addresses service delivery, and quality of healthcare in Australia

The applicant must address the following concerning the scope of practice of the specialty or field of practice:

- a. How the recognition of the scope of practice of the specialty or field of specialty through the Health Practitioner Regulation National Law will address service delivery, including one or more of the following:
 - safety of service delivery;
 - quality of service delivery;
 - access to services for consumers;
 - efficiency of the health system.
- b. How the recognition of the scope of practice of the specialty or field of specialty through the Health Practitioner Regulation National Law enhances protection of the public and addresses quality of healthcare in one or more of the following dimensions:
 - effectiveness of health care as defined by improved health outcomes;
 - appropriateness of health care as defined by providing care relevant to the patient's needs and based on established standards;
 - safety of care (e.g. significant reduction of harm experienced as a result of receiving healthcare);
 - public health significance as defined by a significant burden of disease, incidence, prevalence or impact on the community relevant to the proposed specialty coupled with a demonstrated capacity of members of the proposed specialty to influence this at a population level.
- c. That the recognition of the scope of practice of the specialty or field of specialty through the Health Practitioner Regulation National Law will not adversely affect the quality of healthcare in Australia by promoting:
 - the unnecessary fragmentation of medical knowledge and skills (e.g. where this serves to increase the risk of medical errors and/or inefficient or inappropriate care);
 - the unnecessary fragmentation of medical care (e.g. where patients are required to see multiple practitioners for care at a significant coordination cost);
 - the unnecessary deskilling of other medical practitioners (e.g. General Practitioners and other primary health care providers);
 - inequitable access to health care as defined by socioeconomic status, geography or culture.

Attachment C

Proposals not likely to meet the requirements for recognition under the National Law

The objectives of the National Registration and Accreditation Scheme include the following:

- a. To provide for the protection of the public by ensuring that only health practitioners who are suitably trained and qualified to practise in a competent and ethical manner are registered.

The protection of title under the National Law enables recipients of health care to know whether they are dealing with a registered health practitioner, and that a practitioner holding a particular specialist title has the knowledge, skills and professional attributes necessary to offer the specialist medical services associated with that title.

The matters to be addressed in proposals and the process assess whether ongoing developments and innovations in medical care warrant formal recognition of a discipline as a distinct specialty or field of specialty practice within the context of the National Law and the Australian health system recognising that there are costs associated with recognition. The matters to be addressed in proposals have also been designed to distinguish between a distinct medical specialty that is recognised by a distinct title for its practitioners, and a separate specialist medical training program for its practitioners and what more usefully should be regarded as a 'special clinical interest'.

A guiding principle of the recognition process is that the Australian community and health system are better served by avoiding unnecessary fragmentation of medical knowledge, skills and medical care. As is clear from the matters taken into consideration in Attachment B, the onus is placed on the applicant to demonstrate the benefits of specialty in a particular field of medicine and present evidence to this effect.

It follows that it is unlikely that preliminary proposals based on any of the following would be successful:

- an area of practice limited to a specific geographic area or narrow demographic group;
- an area of practice limited to the treatment of a single disease;
- an area of practice based on a single modality of treatment;
- an area of practice not directly involved in clinical care unless evidence is presented that specialisation is providing substantial benefits to the health status of the Australian community;
- an area of practice already recognised (fully or partly) under a different name unless there was a clear case that the new specialty represented major developments. More than one professional body, however, may consider that it fulfils the standard setting and training roles for an already recognised specialty. In such cases, the most appropriate avenue is via the Australian Medical Council's process for accreditation of the program of study and not the recognition process.

Attachment D

The work of the Australian Medical Council review panel

The Australian Medical Council establishes a review panel to undertake a detailed analysis of the case for recognition, working within the recognition guidelines and Australian Medical Council policy on the conduct of panels.

The applicant will be informed of the proposed composition of the review panel and will be provided with a brief biographical summary of each member. The applicant will have an opportunity to comment on whether it considers any of the potential members may have conflicts of interest that would affect their capacity to carry out their task impartially.

The Australian Medical Council selects the review panel having considered any comment from the applicant.

The review panel will:

- read the initial proposal for recognition and the submissions lodged in respect of the application for recognition;
- obtain additional information relevant to support a detailed assessment for recognition;
- develop a consultation document; and
- prepare an assessment report on its findings for the Australian Medical Council. Beyond providing this assessment, the panel is not responsible for the Australian Medical Council's advice to the Medical Board of Australia on recognition of the new or amended specialty or field of specialty practice.

As it starts to consider the application (proposal) for recognition, the review panel will determine whether additional information is required. The Australian Medical Council will determine timelines for information to be provided in consultation with the applicant. If the applicant does not provide the information necessary for the detailed assessment of the case for recognition within these timelines, the Australian Medical Council will advise the Medical Board. The Medical Board may decide to close the application.

When it has all the material required, the review panel completes its assessment of the case for recognition. The review panel works within these guidelines and the Australian Medical Council's policy on the conduct of panels. It assesses the case for recognition against the matters required to be addressed in Attachment B.

Development of a consultation document

The review panel will prepare a consultation document. If a consultation RIS is required, it will follow the COAG guidelines *Best Practice Regulation: A Guide for Ministerial Councils and National Standards Setting Bodies*. If a consultation RIS is not required, the review panel will follow AHPRA guidelines, Consultation process of National Boards.

Other elements of the assessment

The review panel may undertake the following activities in order to complete its assessment:

- interview representatives of the applicant body and other relevant stakeholders;
- seek additional information from the applicant;

- complete a program of clinical site visits to contribute to understanding of the role and place of clinical practice in the proposed specialty or field of specialty practice within the broader context of the Australian health system;

These visits include interviews with practitioners practising substantially in the field, and other health professionals working in related or associated disciplines. The review panel may seek recommendations from the applicant on who to include in the clinical site visits, but the panel will develop its own program.

- consider submissions made in response the Medical Board's consultation document;
- any other investigations or inquiry that appears appropriate to the review panel.

In some circumstances, the Australian Medical Council may recommend to the Medical Board that additional work be commissioned by third parties (e.g. academics, health economists), if this information is regarded as essential to the assessment of the case. The Medical Board will consult with the applicant about any such request. The applicant will bear the cost of any work the Medical Board decides should be undertaken.

Conflict of interest and impartiality of review panels

Proposed members of review panels must declare to the Australian Medical Council any personal or professional interest (of themselves, any family member or any business associate) that may be perceived to conflict with their ability to undertake impartially their duties as a panel member. The Australian Medical Council will disclose all declared interests of the persons recommended to the applicant and seek the applicant's comments on the panel membership. Having considered the interests declared and the applicant's comments, the Australian Medical Council's Specialist Education Accreditation Committee makes a decision on the appointment of the panel, on the advice of the Recognition of Medical Specialties Sub-Committee.

If a conflict of interest emerges for a panel member during a review, the panel member is expected to disclose the nature of the interest as soon as possible after the relevant facts have come to their knowledge. The panel chair and responsible Australian Medical Council staff member will determine an appropriate course of action. Any such conflicts, and the course of action taken, will be reported to the applicant and the Australian Medical Council.

Members of Australian Medical Council committees, expert panel and teams are expected to make decisions responsibly, and to apply standards in a consistent and an impartial fashion. Although members of committees and expert panels are appointed because they have relevant skills and expertise for the task to be completed, a high level of impartiality is required.

Attachment E

Procedural and administrative matters relating to review of applications for recognition under the National Law

Priority order for consideration of applications

While the Medical Board of Australia will generally consider proposals for recognition of a new or amended specialty in the order received, it reserves the right to decide that a particular application should be given priority.

The Medical Board will establish a priority order of applications, and review the priority order every six months.

Fees and charges

The assessment of an application (proposal) for recognition will be undertaken on a cost recovery basis, including recovery of the costs of providing administrative overheads utilised in the process.

There will be costs to the applicant associated with:

- the development of an initial proposal (application) for recognition of a new or amended specialty;
- a fee for a review of the initial proposal;
- the development of a detailed proposal addressing the matters in attachment B (including, if required, the work necessary to support a regulation impact statement);
- a fee for the consultation processes; and
- a fee covering the direct costs of the work of the Australian Medical Council review panel, which will undertake the direct assessment.

As the direct costs of some elements of the work will vary depending on the complexity of the assessment, set fees are paid in advance of the work, and the applicant will be invoiced for any outstanding fees on completion of the work.

All fees must be paid before any advice will be given to the COAG Health Council.

Confidentiality/public access/accessibility

The application process is an open process. The name of the applicant, and the case they put forward to support their application are public.

Applicants are advised to prepare their applications as a public document. The application for recognition will be published. Consultation submissions will also be published according to AHPRA guidelines, '*Consultation process of National Boards*'.

Applicants will receive updates on the status of their applications. As described in these guidelines, the applicant will be provided with the opportunity to review drafts of the report that the Australian Medical Council is preparing for the Medical Board, to correct any errors of fact, and to comment on any recommendations, conclusions or judgements in the draft report of the detailed assessment. At such points, these assessments are confidential to the Australian Medical Council, the Medical Board and the applicant. The applicant should not discuss the draft report with third parties without the consent of the Medical Board.

If the Medical Board needs to confirm material in a draft report with a third party, it will advise the applicant of these plans.

The Medical Board places the Australian Medical Council's report (that may be in the form of a Decision RIS if required) in the public domain following the decision of the COAG Health Council.

Review Process

There is no appeal mechanism in the National Law for a decision of the Medical Board not to recommend to the COAG Health Council that a specialty be recognised.

If the applicant believes that the decision not to recommend that a specialty be recognised is based on incorrect information, they can provide feedback to the Medical Board. The Medical Board will decide whether the additional information/correction would have made a difference to its recommendation.