

Public Consultation

24 February 2023

Application for recognition of a new field of specialty practice: Genetic Pathology

Summary

The Medical Board of Australia is consulting on the application by the Royal College of Pathologists of Australasia to have Genetic Pathology recognised as a new field of specialty practice within the specialty of Pathology, under the Health Practitioner Regulation National Law (National Law).

Under section 13 of the National Law, a National Board for a profession may recommend that Health Ministers approve one or more specialties and associated specialist titles for a profession.

The recognition of a new or amended specialty by the Health Ministers 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 Impact Analysis (formerly the Office of Best Practice Regulation) Commonwealth Department of Prime Minister and Cabinet.

Health Ministers may approve a new or amended specialty only after a public benefit has been demonstrated. That is, applicants proposing a new or amended specialty for recognition under the National Law must establish that there is a need for 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.

Further details about the Genetic Pathology application and recognition process are contained in the consultation documents.

The consultation is open until **26 April 2023**.

Consultation process

The Australian Medical Council's (AMC's) review panel assesses and provides advice to the Board on proposals for the recognition of new or amended medical specialties. Stakeholder feedback received by the Board will be forwarded to the AMC for analysis and advice.

On behalf of the Board, the AMC may also seek additional information in order to complete its detailed assessment of the proposal based on stakeholder feedback. 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 AMC 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.

Making a submission

The Medical Board of Australia (the Board) is inviting comments on the application by the Royal College of Pathologists of Australia for Genetic Pathology to be recognised as a new field of specialty practice under the Health Practitioner Regulation National Law. There are also specific questions which you may wish to address in your response.

Please provide written submissions by email, marked: '*Consultation on the recognition of Genetic Pathology*' to medboardconsultation@ahpra.gov.au by close of business on **26 April 2023**.

Submissions for publication on the Board's website should be sent in Word format or equivalent¹.

Submissions by post should be addressed to the Executive Officer, Medical, Ahpra, GPO Box 9958, Melbourne 3001.

Publication of submissions

The Board publishes submissions at its discretion. The Board generally publishes submissions on its website to encourage discussion and inform the community and stakeholders. Please let us know if you do not want us to publish your submission or want us to treat all or part of it as confidential.

We will not place on our website, or make available to the public, submissions that contain offensive or defamatory comments or which are outside the scope of the subject of the consultation.

Before publication, we may remove personally-identifying information from submissions, including contact details.

¹ You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you supply a text or word file. As part of an effort to meet international website accessibility guidelines, Ahpra and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx

The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the Board.

The Board accepts submissions made in confidence. These submissions will not be published on the website or elsewhere. Submissions may be confidential because they include personal experiences or other sensitive information. Any request for access to a confidential submission will be determined in accordance with the *Freedom of Information Act 1982* (Cth), which has provisions designed to protect personal information and information given in confidence.

Please let us know if you do not want us to publish your submission or want us to treat all or part of it as confidential.

Published submissions will include the names of the individuals and/or the organisations that made them, unless confidentiality is requested.

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Background

Health Ministers have approved a range of specialties for medicine under section 13 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law). Some specialties also have specialty fields. The approved list of specialties, specialty fields and specialist titles for medical practitioners is available on the Board's website [here](#).

Under the National Law, a National Board for a profession may recommend that Health Ministers approve new or amended medical specialties.

Health Ministers will only consider a recommendation for a new or amended specialty if a public benefit has been demonstrated. That is, applicants proposing a new or amended specialty must establish that there is a need for government intervention (regulation) in the interests of the public and that existing arrangements, or other regulation or non-regulatory options are unsatisfactory. For this reason, the application process involves a robust regulatory assessment, with extensive stakeholder consultation.

The recognition process is a two-stage, linked process. The Australian Medical Council (AMC), as the accreditation authority for medicine under the National Law, provides advice to the Medical Board of Australia having undertaken detailed assessments of the applicant seeking recognition.

Stage 1: Initial assessment of proposal: In this stage, applicants for a new or amended specialty submit an initial proposal to the Board. The Board decides whether the proposal demonstrates there may be a case for recognition of a new or amended specialty. If it decides there is no case for recognition, the application does not proceed further.

Stage 2: Detailed assessment of proposal: In this stage, the Board conducts a detailed assessment of the case for recognition. This includes seeking advice from the AMC. This stage leads to the Board deciding whether or not to recommend that Health Ministers approve the new or amended specialty and Health Ministers making a decision.

[Guidelines for the Recognition of Medical Specialties and Fields of Specialty Practice under the Health Practitioner Regulation National Law](#) outlines the process for organisations to apply for recognition of new or amended medical specialties under the National Law.

Genetic Pathology Proposal

The Royal College of Pathologists of Australasia (RCPA) submitted an initial (Stage 1) application to the Board in 2019.

In line with the *Guidelines*, the AMC has assessed the proposal and provided advice to the Board. The Board has determined that the information presented in the initial proposal indicated that there may be a case for the recognition of Genetic Pathology as a new field of specialty practice, and agreed to progress the proposal to the detailed (Stage 2) assessment.

The Office of Impact Analysis (formerly the Office of Best Practice Regulation) has determined a Regulatory Impact Statement (RIS) is not required to support the public consultation on this proposal. Therefore, the public consultation is being conducted in accordance with the Board's consultation process.

The RCPA has also provided additional information to the Board to support the matters which must be addressed in the Stage 2 detailed assessment process.

The full application by the RCPA, and the additional information to support the Stage 2 assessment process is provided on the RCPA website and can be accessed here:

<https://www.rcpa.edu.au/Education/Submission-for-Recognition>

Options

The AMC will be undertaking the Stage 2 assessment of the application for Genetic Pathology to be recognised as a new field of specialty practice. At this early stage, two options have been identified for consideration by the Board. As outlined in the *Guidelines*, the AMC will thoroughly investigate the detailed case for and against the recognition of Genetic Pathology, and report on its assessment to the Board.

Option 1 – Recognition of Genetic pathology as a distinct field of specialty practice

The College states that approval of Genetic Pathology as a distinct field of specialty practice will ensure referring general practitioners, patients and employers have timely access to appropriately qualified pathologists with knowledge and skills in:

- a. recognition of the availability of genetic tests relevant to patient diagnosis and treatment, their uses and limitations, and in the case of hereditary disorders, the implications for other family members
- b. the supervision, quality assurance and correct interpretation of the right tests
- c. maintenance of appropriate continuous professional development to ensure continuity of safe patient care.

Genetics and genomics are areas of practice that are expanding and rapidly changing, and it is important for public safety that there is access to skilled people who can analyse genetic material and doctors who can integrate this with clinical information.

The RCPA states that approval of Genetic Pathology for the purposes of specialist registration will ensure visibility of the current workforce and may incentivise more medical practitioners to take up training in Genetic Pathology. Overseas specialists with comparable qualifications will also be able to be registered as specialists in this field. Specialist recognition will ensure patients have timely access to a qualified workforce.

If Genetic Pathology were approved as a new field of specialty practice, the title 'Specialist Genetic Pathologist' would become a protected title under the National Law. This is an administrative change that will enable medical practitioners with the RCPA qualification in Genetic Pathology to have Genetic Pathology added to their record on the Register of Specialists.

The RCPA currently provides a program of education and training for medical practitioners in Genetic Pathology. If Genetic Pathology is recognised as a field of specialty practice, the AMC will invite education providers with programs of study in Genetic Pathology to seek accreditation of their program.

Option 2 – Retain the status quo

The RCPA program of education and training for medical practitioners in Genetic Pathology will continue. The AMC currently accredits programs of study in the speciality of pathology and the recognised pathology fields of specialty practice. It provides comments about Genetic Pathology in its accreditation reports, however, Genetic Pathology is not an accredited program of study.

Under this option, medical practitioners who have completed the RCPA Genetic Pathologist training program will not be recognised as specialist Genetic Pathologists as the title is not protected. They will continue to be recognised as specialist pathologists. It is possible for other Pathologists to call themselves a 'Genetic Pathologist' but without completing the genetic pathology program of study. The College states that these pathologists may not provide a comprehensive range of genetic testing services, and that it may make it difficult for other medical practitioners and the public to recognise individuals with the expertise to provide specialist level advice.

The National Pathology Accreditation Advisory Council (NPAAC) advises the Australian Government, state and territory health ministers on matters relating to the accreditation of pathology laboratories. It sets the standards and requirements that laboratories must meet in Australia for safe and quality laboratory practice in order to be accredited providers of Medicare. The NPAAC standards require laboratories

conducting genetic testing to be accredited and be under the direction, control and full-time clinical supervision of a designated supervising pathologist who has relevant qualifications, competency and experience in genetic testing.

While this is a different regulatory process to the process for recognition of medical specialties, it is relevant in that the RCPA trains and certifies Pathologists as being competent to supervise laboratories performing genetic testing where applicable. Laboratories which are primarily concerned with testing in other disciplines of pathology, for example Anatomical Pathology, may carry out a limited range of less complex genetic tests associated with that discipline. These laboratories may be supervised by Pathologists who are not Genetic Pathologists, but who have demonstrated competence in the specific range of genetic tests concerned. Specialised genetic pathology laboratories, on the other hand, carry out a full range of complex genetic testing and must be supervised by a doctor who is specifically trained as a Genetic Pathologist.

The RCPA states that if the specialty is not recognised, it may be more difficult to encourage medical practitioners to undertake the necessary training program resulting in potential workforce shortfalls at a time when the technologies involved in genetics and genomics are rapidly expanding.

Issues for consultation

Assessment of the impact of recognition

Wide ranging consultation with stakeholders is a part of the assessment of the application for Genetic Pathology to be recognised as a field of specialty practice. The assessment will consider the information, submissions and evidence concerning the impact of the recognition of a new field of specialty practice including:

- How recognition of the proposed new field of specialty practice will advance the objectives of the National Registration and Accreditation Scheme
- The existing arrangements, whether these are unsatisfactory, and the net benefit of the proposed change
- The extent to which health services are established in the proposed field of specialty practice and the demonstrated and/or potential ability of this proposal to improve the provision of the service
- Stakeholder groups likely to be affected by recognition and the likely impacts on these groups
- The specialty is distinct and a legitimate area of specialist practice
- The specialty is capable of contributing to the standards of medical practice
- Regulation in the form of recognition of the field of specialty practice addresses service delivery, and quality of healthcare in Australia.

Potential impacts of recognition of Genetic Pathology identified by the Royal College of Pathologists of Australasia

The RCPA application for recognition of genetic pathology as a field of specialty practice outlines the College's assessment of the potential impacts. This consultation is seeking submissions on the potential impacts identified by the RCPA, as well as other impacts that should be considered.

This consultation also invites comments on alternative options (both regulatory and non-regulatory) for addressing the problem identified.

A summary of the College's application is provided below. **Please refer to the documents on the RCPA website for the full application – <https://www.rcpa.edu.au/Education/Submission-for-Recognition>**

- *Specialist Genetic Pathologist Recognition - Initial proposal for recognition of a new medical specialist title under the Health Practitioner Regulation National Law*
- *Recognition of a new field of specialty practice under the Health Practitioner Regulation National Law – Stage 2 Assessment Request for detailed information: Specialist Genetic Pathologist*

In summary, the College states:

Costs impacts are expected to be small for Government and for medical practitioners seeking to use the protected title 'Specialist Genetic Pathologist'.

If the proposal is approved, other than protection of title, no significant changes to existing arrangements are expected. The following would continue:

- The RCPA education and training program in Genetic Pathology for medical practitioners
- Under National Pathology Accreditation Advisory Committee requirements, individuals who have undertaken the RCPA Genetic Pathology program will continue to supervise accredited laboratories.

Stakeholder groups likely to be affected by recognition of Genetic Pathology are included below. The College's assessment of the likely impacts on these groups has also been included. The consultation aims to investigate these impacts thoroughly with all stakeholders.

- **Medical practitioners with the RCPA qualification in Genetic Pathology**

If this group of practitioners wanted to use the proposed protected title, there would be a small administrative fee to add them to the Register of Specialists in the field of Genetic Pathology. The fee is currently set at \$215. There are twenty-six Pathologists with the qualification. In addition, there are currently fourteen Genetic Pathology trainees in Australia who are expected to qualify and be registered as specialists over the next five years.

Medical practitioners with specialist registration are currently required to complete CPD. This requirement would continue if the proposal was approved. There would be no additional CPD requirements.

- **Royal College of Pathologists of Australasia**

If the proposal is approved, the current RCPA training program in Genetic Pathology would need to be accredited by the AMC and approved by the Board for the purposes of providing an approved qualification for specialist registration. The AMC currently accredits the other training programs of the RCPA in approved specialties. Training in Genetic Pathology is considered in the AMC process although it is not an accredited training program. A full assessment of the training program would not be a significant impost to the RCPA.

If the specialist title was added to the Medical Board of Australia's list of specialties, there may be a greater demand for training positions. The increase is expected to be small, perhaps a few additional positions each year, but not likely to be noticeable in the short term. The RCPA has advised that there exists internal capacity for this and it will not impact significantly on the operations of the RCPA. The

costs of accrediting training sites will be absorbed into existing infrastructure and processes. Specialists will continue to contribute to accreditation and training in an honorary capacity.

- **Other medical practitioners and scientists working in genetics**

Competition amongst other medical practitioners and scientists working in genetics is not expected. The training requirements, scopes of practice and skill sets of other medical practitioners and scientists working in genetics are different to medical practitioners qualified as Genetic Pathologists.

The only possible exception is in relation to some Pathologists who have undertaken additional training in genetic technologies, but not the full RCPA specialised program in Genetic Pathology. These pathologists supervise a limited range of low complexity tests using genetic technologies in laboratories that are not primarily concerned with genetic testing. It is possible that fully qualified Genetic Pathologists will be preferred.

Genetic Pathologists will always be required to supervise full-scope genetic pathology laboratories covering a comprehensive range of complex genetic tests. It is expected that this will remain unchanged, if the proposal for the recognition of Genetic Pathology as a field of specialty practice is approved. It is about the qualification rather than the title.

- **Businesses (including pathology laboratories and research laboratories)**

Changes to existing arrangements are not expected to be significant. Laboratories conducting genetic testing are currently required to meet National Pathology Accreditation Advisory Council (NPAAC) accreditation standards, which require appropriately qualified pathologists for clinical supervision of laboratories to receive Medicare benefits for patients. This is not expected to change with specialty recognition.

Employers currently employ medical practitioners with a qualification in Genetic Pathology as de-facto Genetic Pathologists. If the proposal is approved, and if that results in more doctors doing the genetic pathology training, employers may have less difficulty finding specialist Genetic Pathologists who can supervise laboratories. Given that the training program is five years in length, this is a long-term potential consequence.

- **Consumers**

If the proposal is approved, referring General Practitioners, particularly in rural and regional areas, will have enhanced access to Genetic Pathologists to support genetic diagnosis of patients. They would have easier access to a resource that can help them to discuss the needs of their patients, reducing inappropriate or unnecessary testing, reducing delays in diagnosis and potentially reducing referrals to the wrong types of specialists. This may save patients time and money and reduce delays to receiving treatment.

Costs to consumers from approval of this proposal are not expected to change. This proposal is not expected to impact on access to Medicare benefits for genetic testing conducted in accredited laboratories.

While there may be increases in costs through advances in genetic testing and technology, this is not related to the proposal to add the field of specialty to the list of specialties.

- **Governments**

Minimal additional costs are expected to government. There could be a very small increase in the number of training positions over time, limited to the few sites that have the capacity to train Genetic Pathologists. Genetic testing currently occurs and some genetic testing is funded by Medicare. As noted, any increasing costs to consumers and government would be a result of advances in genetic testing and technology and this would occur regardless of whether or not the proposal is approved.

Some unnecessary costs might potentially be reduced if Genetic pathologists provide advice on the use of appropriate tests and there is more timely referral of patients to the right specialists.

Questions for consideration

The Board is inviting general comments on the proposal for Genetic Pathology to be recognised as a new field of specialty practice with reference to the criteria for recognition (see Part A), as well as feedback on the following questions.

General questions

1. Has the claim that regulatory action is necessary to recognise genetic pathology as a field of specialty practice been substantiated?
2. Have the positive consequences of recognition of Genetic Pathology as a field of specialty practice under the National Law been stated? Are there additional positive consequences that should be considered?
3. Have the potentially negative consequences of recognition of Genetic Pathology as a field of specialty practice under the National Law been stated? Are there additional negative consequences that should be considered?
4. Are there specific issues that should be the focus of the AMC assessment of the proposal?
5. Are there any impacts for patients and consumers, particularly vulnerable members of the community, that have not been considered in the application for the recognition of Genetic Pathology as a new field of specialty practice?
6. Are there any impacts for Aboriginal and Torres Strait Islander People that have not been considered in the application for the recognition of Genetic Pathology as a new field of specialty practice?
7. Are there specific stakeholder groups that should be consulted further as the proposal is assessed and what would that add to understanding of the proposal? (please see Attachment B for the stakeholder groups for this consultation)

The Board is also interested in your views on the following specific questions.

8. What are the interactions now between genetic pathologists and other medical and health practitioners? How are these likely to change if Genetic Pathology is recognised as a medical specialty?
9. Your views on how the recognition of Genetic Pathology will impact on the following:
 - balance of the workforce to undertake genetic testing
 - unnecessary fragmentation of health care knowledge and skills
 - unnecessary deskilling or restrictions in the scope of practice of other practitioners
 - flexibility in the deployment of the pathology, other medical and health workforce
 - provision of care and increase and/or decrease in the volume of genetic testing

Relevant sections of the National Law

The relevant section of the National Law is section 13.

The full application from the RCPA can be accessed here:

<https://www.rcpa.edu.au/Education/Submission-for-Recognition>

Part A: Recognition of new medical specialties and fields of specialty practice

What does specialist recognition mean?

Recognition of a specialty or field of specialty practice means that the Health Ministers have 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 '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.

Health Ministers 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.

Approved specialties

The current approved '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) is published at <http://www.medicalboard.gov.au/Registration-Standards.aspx>.

Organisations responsible for recognition of a new or amended medical specialty or field of specialty practice

- **Health Ministers** approve new or amended specialties or fields of specialty practice.
- The **Medical Board of Australia** recommends to Health Ministers 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 Impact Analysis** of the Commonwealth Department of Prime Minister and Cabinet oversees the regulatory assessment process prior to the Health Ministers decision.
- The **applicant** is responsible for making a case for recognition of a new or amended specialty or field of specialty practice and the reasonable costs of any assessment work required by the Medical Board.

Criteria for proposals seeking recognition

Initial proposal

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
 - 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.
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 of field of specialty practice under the National Law.
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

Detailed (Stage 2) assessment of the proposal

These matters are based on the COAG Health Council Guidance to National Boards about the matters that should at least be addressed in a submission for approval of a new or amended specialty. Applicants must address these matters as part of the detailed assessment of the proposal to the Medical Board.

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

Recognition process

Responsibility Key:

Applicant



Medical Board of Australia (the Board)



Australian Medical Council (AMC)



Health Ministers



Initial assessment process (Stage 1)

Step 1

Applicant submits an initial proposal to the Board

Step 2

The Board seeks advice from the AMC on the initial proposal

Step 3

The AMC prepares advice on the initial proposal

Step 4

The Board considers the initial proposal and AMC's advice.

If there is not a sufficient case for recognition

- the application process closes
- the applicant unable to reapply for recognition for 12 months

If there may be a case for recognition

- the Board informs the Office of Impact Analysis (OIA), Health Ministers, applicant and AMC
- the Board liaises with OIA if a Consultation Regulatory Impact Statement (RIS) is needed in the detailed assessment (Stage 2)
- the Board advises applicant on information for Stage 2 based on OIA advice and requirements in Guidelines for Recognition

Detailed assessment process (Stage 2)

Step 5

The Board requests the AMC commence the detailed assessment of the proposal

Step 6

Applicant submits the information requirements for the detailed assessment

Step 7	AMC sets up review panel to complete assessment. (Review panel considers the application and decides on the activities necessary to assess the case e.g. meetings, site visits)
Step 8	Review panel prepares consultation documents (a consultation RIS if needed) which is sent to the Board
Step 9	<p>Stakeholder consultation: The Board will:</p> <ul style="list-style-type: none"> • consult OIA on document if consultation RIS was required. • seeks submissions using the consultation document prepared by the AMC • provides consultation submissions to AMC and publishes submissions on website
Step 10	AMC Review Panel assesses the consultation feedback, and completes assessment. It may seek additional information through: site visits, stakeholder discussions, and/or asking the Board to commission additional work
Step 11	The AMC review panel prepares a report on the case for recognition
Step 12	Applicant comments on report's accuracy and findings
Step 13	The AMC Recognition of Medical Specialties Sub Committee considers report and provides advice to Specialist Education Accreditation Committee, which finalises AMC's advice to the Board. If a consultation RIS was required, AMC prepares report in the form of a Decision RIS
Step 14	The AMC provides a report to the Board
Step 15	<p>The Board considers the report and decides: Not to recommend recognition.</p> <p>The Board will then:</p> <ul style="list-style-type: none"> • inform the applicant • inform Health Ministers <p>Assessment ends</p>

	<p>To recommend recognition.</p> <p>The Board will then:</p> <ul style="list-style-type: none"> inform the applicant if Decision RIS was required it seeks OIA advice on whether document meets Guide to Best Practice Regulation requirements <p>Assessment continues to Step 16-19</p>
Step 16	<p>Health Ministers make a decision. In approving the specialty, Health Ministers must be satisfied that:</p> <ul style="list-style-type: none"> there has been sufficient consultation with key stakeholders during development of the proposal for approval of the specialty approval of the specialty provides the greatest net public benefit, compared with alternative options
Step 17	<p>The Board publishes its advice to Health Ministers and their decision on its website</p>
Step 18	<p>If Health Ministers approve the specialty, the Board updates the List of specialties, fields of specialty practice and related specialist titles and will publish the amended list</p>
Step 19	<p>AMC calls for applications for accreditation of programs of study in the new specialty or field of specialty practice. Only programs of study that have been accredited by the AMC and approved by the Board will lead to specialist registration.</p>

Accreditation assessment and approval of education providers

If Health Ministers approve the recognition of a new specialty, education providers with programs of study in that specialty may apply to the AMC for accreditation of their program of study. The AMC 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 AMC 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'.

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

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. 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 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 AMC's process for accreditation of the program of study and not the recognition process.

Attachment A

Statement of assessment

The Medical Board of Australia's statement of assessment against Ahpra's Procedures for the development of registration standards, codes and guidelines

Proposal by the Royal Australasian College of Pathologists (RCPA) for the approval of Genetic Pathology as a new field of specialty practice

The Australian Health Practitioner Regulation Agency (Ahpra) has *Procedures for the development of registration standards, codes and guidelines* which are available at: www.ahpra.gov.au

These procedures have been developed by Ahpra in accordance with section 25 of the Health Practitioner Regulation National Law as in force in each state and territory (the National Law) which requires Ahpra to establish procedures for the purpose of ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice.

Below is the Medical Board of Australia's (the Board) assessment of the RCPA proposal for the approval of Genetic Pathology as a new field of specialty practice.

1. The proposal takes into account the National Scheme's objectives and guiding principles set out in section 3 of the National Law

Board assessment

The RCPA has outlined in its proposal how it believes recognition of Genetic Pathology as a new field of specialty practice within the National Scheme will advance the objectives of the National Scheme.

The proposal will:

- protect the public by ensuring only medical practitioners qualified in Genetic Pathology are granted specialist registration and can call themselves a 'Specialist Genetic Pathologist'
- facilitate the provision of high quality education and training of health practitioners by ensuring that Genetic Pathology training is accredited against national standards facilitate access to services provided by health practitioners in accordance with the public interest by ensuring medical practitioners with expertise in Genetic Pathology are easily identified through the public Specialists Register, thereby enabling timely access to experts who can apply the right genetic tests.

The Board's consultation and assessment of the RCPA proposal will consider the information, submissions and evidence concerning the impact of the recognition of Genetic Pathology, including how recognition will advance the objectives of the National Scheme, and whether the claims made in the application have been substantiated.

2. The consultation requirements of the National Law are met

Board assessment

The National Law requires wide-ranging consultation on proposed standards, codes and guidelines, including consulting on applications for recognition of new medical specialties and fields of specialty practice.

The Board will ensure that there is public exposure of the RCPA proposal for the approval of Genetic Pathology as a new field of specialty practice and the opportunity for public comment by undertaking

an eight-week public consultation process. The public process will include the publication of the consultation paper on the Board's website and informing medical practitioners via the Board's electronic newsletter sent to more than 95% of registered medical practitioners.

Key stakeholders will also be invited to comment on the proposal including, specialist medical colleges, Commonwealth and State and Territory Governments, professional organisations, patient safety organisations, consumer groups, and Aboriginal and Torres Strait Islander groups.

The Board will take into account the feedback it receives during the consultation process in deciding whether to recommend to Health Ministers that Genetic Pathology be approved as a new field of specialty practice.

3. The proposal takes into account the principles set out in the Ahpra procedures

The Board makes the following assessment specific to the principles expressed in the Ahpra procedures.

A. Whether the proposal is the best option for achieving the proposal's stated purpose and protection of the public

Board assessment

The proposal aims to protect the public by ensuring referring general practitioners, patients and employers have timely access to appropriately qualified pathologists with knowledge and skills in:

- the recognition of the availability of genetic tests relevant to patient diagnosis and treatment, their uses and limitations, and in the case of hereditary disorders, the implications for other family members
- the supervision, quality assurance and correct interpretation of the right tests
- the maintenance of appropriate continuous professional development to ensure continuity of safe patient care.

B. Whether the proposal results in an unnecessary restriction of competition among health practitioners

Board assessment

The proposal is not expected to restrict competition amongst other health practitioners and scientists working in genetics. The Board understands the training requirements, scopes of practice and skill sets of other medical practitioners, health practitioners and scientists working in genetics are different to medical practitioners qualified as Genetic Pathologists.

C. Whether the proposal results in an unnecessary restriction of consumer choice

Board assessment

The proposal aims to enhance patient access to Genetic Pathologists, particularly in rural and regional areas. Referring general practitioners will have support in the genetic diagnosis of patients. They will have easier access to a resource that can help them to discuss the needs of their patients, reducing inappropriate or unnecessary testing, reducing delays in diagnosis and potentially reducing referrals to the wrong types of specialists. This may save patients time and money and reduce delays to receiving treatment.

D. Whether the overall costs of the proposal to members of the public and/or registrants and/or governments are reasonable in relation to the benefits to be achieved

Board assessment

The proposal is not expected to have any significant cost impacts for members of the public, registrants or governments.

The RCPA currently delivers training in Genetic Pathology to medical practitioners. If the proposal is approved, medical practitioners with the approved qualification in Genetic Pathology will need to pay a small application fee to obtain specialist registration in Genetic Pathology.

Patients will continue to access Medicare benefits for genetic tests conducted in accredited laboratories.

The proposal may incentivise more medical practitioners to take up training in Genetic pathology. There could be a very small increase in the number of training positions over time, limited to the few sites that have the capacity to train Genetic Pathologists. Genetic testing currently occurs and some genetic testing is funded by Medicare. The costs to governments is expected to be minimal.

- E. [Whether the proposal's requirements are clearly stated using 'plain language' to reduce uncertainty, enable the public to understand the requirements, and enable understanding and compliance by registrants](#)

Board assessment

The proposal is an application by the RCPA for the recognition of Genetic Pathology as a new field of specialty practice. The consultation document is written in plain language and outlines the RCPA's proposal and what are the perceived consequences of the recognition of Genetic pathology as a new field of specialty practice. Based on the advice of the Australian Medical Council (AMC), the Board believes that there may be a case for the approval of Genetic Pathology as a new field of specialty practice however, the Board is consulting widely with stakeholders to seek feedback on whether the consequences have been identified and stated clearly before making a decision on whether to recommend that the Ministerial Council approves Genetic pathology as a new field of specialty practice. If the proposal is approved, the title Specialist Genetic Pathologist will become a protected title and only qualified pathologists who have been granted specialist registration in Genetic Pathology will be able to use the protected title.

- F. [Whether the Board has procedures in place to ensure that the proposed registration standard, code or guideline remains relevant and effective over time](#)

There is a process for recognising new medical specialties and fields of specialty practice but there is no legislated process for reviewing the list of recognised medical specialties and fields of specialty practice.

The AMC assesses programs of study, including the continuing professional development programs in recognised specialties, against the approved [accreditation standards](#). If this proposal is approved, education providers and their programs of study in Genetic pathology are expected to meet the accreditation standards.

These accreditation standards require educational outcomes for programs to address community needs, and that education providers relate their training and education functions to the health care needs of the community, ensuring the promotion of health and safety of the public including Aboriginal and Torres Strait Islander Peoples. If certain standards are not met, the AMC applies accreditation conditions to the program, and continuing accreditation is subject to satisfying these conditions. The AMC may decide not to grant accreditation if programs do not meet the standards.

Once the AMC has accredited programs and their providers, under the National Law it must monitor the program and provider to ensure that they continue to meet the accreditation standards. The AMC seeks annual submissions from accredited education providers to satisfy this monitoring requirement.

National Boards' Patient and Consumer Health and Safety Impact Statement

24 February 2023

Statement purpose

The National Boards' Patient and Consumer Health and Safety Impact Statement (Statement)² explains the potential impacts of the proposal by the Royal Australasian College of Pathologists (RCPA) for the approval of Genetic Pathology as a new field of specialty practice (the proposal), on the health and safety of the public, vulnerable members of the community and Aboriginal and Torres Strait Islander Peoples.

The four key components considered in the Statement are:

1. The potential impact of the proposal for the approval of Genetic Pathology as a new field of specialty practice on the health and safety of patients particularly vulnerable members of the community including approaches to mitigate any potential negative or unintended effects
2. The potential impact of approval of Genetic Pathology as a new field of specialty practice on the health and safety of Aboriginal and Torres Strait Islander Peoples including approaches to mitigate any potential negative or unintended effects
3. Engagement with patients, particularly vulnerable members of the community, about the proposal
4. Engagement with Aboriginal and Torres Strait Islander Peoples about the proposal.

The National Boards' Health and Safety Impact Statement aligns with the *National Scheme's Aboriginal and Torres Strait Islander Cultural Health and Safety Strategy 2020-2025*, *the NRAS engagement Strategy 2020-25*, the *NRAS Strategy 2020-25* and reflect key aspects of the revised consultation process in the [Procedures for developing registration standards, codes and guidelines and accreditation standards](#).

² This statement has been developed by Ahpra and the National Boards in accordance with section 25(c) and 35(c) of the *Health Practitioner Regulation National Law* as in force in each state and territory (the National Law). Section 25(c) requires AHPRA to establish procedures for ensuring that the National Registration and Accreditation Scheme (the National Scheme) operates in accordance with good regulatory practice. Section 35(c) assigns the National Boards functions to develop or approve standards, codes and guidelines for the health profession including the development of registration standards for approval by the COAG Health Council and that provide guidance to health practitioners registered in the profession. Section 40 of the National Law requires National Boards to ensure that there is wide-ranging consultation during the development of a registration standard, code, or guideline.

Below is our initial assessment of the potential impact of the proposal by the RCPA for the approval of Genetic Pathology as a new field of specialty practice on the health and safety of patients, particularly vulnerable members of the community, and Aboriginal and Torres Strait Islander Peoples. This statement will be updated after consultation feedback.

1. How will this proposal impact on patient and consumer health and safety, particularly vulnerable members of the community? Will the impact be different for vulnerable members compared to the general public?

The RCPA has made an application for Genetic Pathology to be approved as a recognised field of specialty practice. If the proposal is approved by Ministers for Health, medical practitioners who hold an approved qualification in Genetic Pathology can apply for specialist registration and use the protected title 'Specialist Genetic pathologist'. The names of Genetic Pathologists will be published on the Specialists Register.

The proposal aims to ensure that referring General Practitioners, patients and employers have timely access to appropriately qualified pathologists with knowledge and skills in:

- d. recognition of the availability of genetic tests relevant to patient diagnosis and treatment, their uses and limitations, and in the case of hereditary disorders, the implications for other family members
- e. the supervision, quality assurance and correct interpretation of the right tests
- f. maintenance of appropriate continuous professional development to ensure continuity of safe patient care.

Specialist registration will enable referring General Practitioners, particularly in rural and regional areas, to easily identify appropriately qualified Pathologists through the online public Register of Specialists to support genetic diagnosis of patients. General Practitioners and other doctors will have easier access to a resource that can help them to discuss the needs of their patients, reducing inappropriate or unnecessary testing, reducing delays in diagnosis and potentially reducing referrals to the wrong types of specialists. This may save patients time and money and reduce delays to receiving treatment.

Engagement through the stakeholder consultation will help to better understand possible outcomes and to meet the Board's responsibilities to protect patient safety and health care quality.

2. How will consultation engage with patients and consumers, particularly vulnerable members of the community?

In line with our consultation processes, the Medical Board of Australia (the Board) is undertaking wide-ranging public consultation for a minimum of eight weeks. During the public consultation phase, the Board will engage with patient and consumer organisations, peak bodies and other relevant organisations to get input and to identify any issues for vulnerable consumers and for Aboriginal and Torres Strait Islander Peoples.

Stakeholders who have been invited to comment on the proposal are:

- Specialist medical colleges
- National Health Practitioner Boards
- Commonwealth and State and Territory Governments
- Australian Medical Schools
- Australian Postgraduate Medical Councils
- Consumer health and safety organisations

- Aboriginal and Torres Strait Islander groups
- Medical professional associations
- Specialist medical trainee associations
- Health complaints entities
- Health quality and safety entities
- Hospital Associations
- Pathology associations
- Allied health professional associations
- Registered medical practitioners
- Genetic scientists and their professional bodies

3. What might be the unintended impacts for patients and consumers particularly vulnerable members of the community? How will these be addressed?

The Board is not aware of any unintended impacts for patients and consumers, particularly vulnerable members of the public. The proposal aims to improve access to qualified Genetic pathologists.

The consultation is part of the Board's and the Australian Medical Council's (AMC) assessment process of the RCPA's proposal and aims to investigate the likely impacts with relevant organisations and consumer groups, and will also help to identify any potential impacts.

The Board will fully consider any potential impacts that are raised during the consultation process in making a decision of whether to recommend to Health Ministers that Genetic Pathology be approved as a new field of specialty practice.

4. How will this proposal impact on Aboriginal and Torres Strait Islander Peoples? How will the impact be different for Aboriginal and Torres Strait Islander Peoples compared to non-Aboriginal and Torres Strait Islander Peoples?

The Board is not aware of any impacts that will be different for Aboriginal and Torres Strait Islander Peoples compared to non-Aboriginal and Torres Strait Islander Peoples. As previously noted, the proposal aims to improve access to qualified Genetic Pathologists, particularly in rural and remote areas.

Stakeholder engagement through wide-ranging consultation will help to identify any potential impacts and to meet the Board's responsibilities to protect the safety and health care quality for Aboriginal and Torres Strait Islander Peoples.

The Board will fully consider any potential impacts that are raised during the consultation process in making a decision of whether to recommend to Health Ministers that Genetic Pathology be approved as a new field of specialty practice.

5. How will consultation about this proposal engage with Aboriginal and Torres Strait Islander Peoples?

The Board is committed to the National Scheme's [Aboriginal and Torres Strait Islander Cultural Health and Safety Strategy 2020-2025](#) which focuses on achieving patient safety for Aboriginal and Torres Strait Islander Peoples as the norm, and the inextricably linked elements of clinical and cultural safety.

As part of the consultation process, there will be engagement with relevant Aboriginal and Torres Strait Islander organisations and stakeholders to ensure there are no unintended consequences for Aboriginal and Torres Strait Islander Peoples.

6. What might be the unintended impacts for Aboriginal and Torres Strait Islander Peoples? how will these be addressed?

The Board does not expect there to be any adverse impacts for Aboriginal and Torres Strait Islander Peoples as a result of the proposal.

The consultation aims to investigate the likely stated impacts with relevant organisations and Aboriginal and Torres Strait Islander Peoples, and will also help to identify any unintended impacts.

The Board will fully consider any potential negative impacts for Aboriginal and Torres Strait Islander Peoples that may be raised during consultation when making a decision on whether or not to recommend to Health Ministers that Genetic Pathology be approved as a new field of specialty practice.

7 How will the impact of this proposal be actively monitored and evaluated?

If Health Ministers approve the recognition of Genetic Pathology as a new field of specialty practice, education providers with programs of study in this specialty may apply to the AMC, as the accreditation authority for medicine under the National Law, for accreditation of their program of study. The AMC assesses programs of study, including the continuing professional development programs in recognised specialties, against the approved [accreditation standards](#).

Education providers and their programs of study are required to meet the accreditation standards. These standards require educational outcomes for programs to address community needs, and that education providers relate their training and education functions to the health care needs of the community, ensuring the promotion of health and safety of the public including Aboriginal and Torres Strait Islander Peoples. If certain standards are not met, the AMC applies accreditation conditions to the program, and continuing accreditation is subject to satisfying these conditions. The AMC may decide not to grant accreditation if programs do not meet the standards.

Once the AMC has accredited programs and their providers, under the National Law it must monitor the program and provider to ensure that they continue to meet the accreditation standards. The AMC seeks annual submissions from accredited education providers to satisfy this monitoring requirement.