

Responsible Authority Core Performance Standards Review Report

Authority Name	Te Pou Whakamana Kaimatū o Aotearoa Pharmacy Council of New Zealand (NZ)
Date of Review Report	16 December 2021
Name of reviewing Designated Auditing Agency	BSI Group New Zealand Limited

Executive Summary

Te Pou Whakamana Kaimatū o Aotearoa | Pharmacy Council of New Zealand (NZ) is the responsible authority under the Health Practitioners Competence Assurance Act (the HPCA Act), for the regulation of the pharmacy profession.

The Council regulates over 4,000 health practitioners. Approximately 80% are community pharmacists and 15% hospital pharmacists.

The Pharmacy Council has a core team (13 plus FTEs) that are based in a joint office with the Dental Council team in Wellington. They are supported by a recently established Māori Advisory Group, various operational committees and a number of contract advisors (HR support, chief information technology support, assessment centre advice, professional conduct committees, etc.)

The Council membership (governance) consists of eight members with six pharmacists and two lay people (an advisor is appointed to support the board and is the Chair of the Finance Assurance and Risk Management Committee). Progressively, Council has been moving to enhance and delineate its governance board functions away from those that are operational in nature or focused on the organisation (i.e., committees reporting at a management level rather than governance). Hence, the composition of its Competence and Fitness to Practice Committee and the Intern Advisory Assessment Committee will in time no longer include governors as members.

The Council has three scopes of practice; Intern Pharmacist, Pharmacist and Pharmacist Prescriber. Accreditation occurs against accreditation standards that are specific to the type of programme. For the Intern training programme, the Pharmaceutical Society of New Zealand delivers EVOLVE. The Bachelor of Pharmacy is by the University of Otago and University of Auckland. The Pharmacist Prescriber qualification is one programme jointly developed by both universities and delivered in 2021 by the University of Auckland.

Processes and systems are well established to register applicants, issue practising certificates, review and improve competence, and respond to complaints, conduct and health notifications.

There is a public website that is structured around three audiences: public, potential pharmacists and registered pharmacists. It contains key information on its role, functions and the core regulatory processes that includes policies, newsletters, annual reports, and the strategic plan.

The Council demonstrates the principles of right-touch regulation through its policies, processes, systems, consultations, plans and how it works with the profession and stakeholders.

The Council's approach is to focus 90% on core work and 10% on development enhancement. This is reflected in the current strategic priorities based on the '*Strategic Plan 2019 and Beyond*'. The plan is driving improvements while maintaining public safety. Council reviews its strategic plan annually, principally to test what changes may have occurred environmentally that may suggest some enhancement in the direction of their activities.

Key development initiatives have been prioritised to include: in-house service development of the accreditation process, health equity and cultural safety addressed through two core streams: (a) the pharmacy profession, and (b) organisational, clinical governance and quality improvement, unified prescribing standards, ongoing business intelligence (BI) and implementation of the revamped recertification programme. All pharmacy programmes are currently fully accredited. The in-house process is intended to be in place before accreditation considerations are required in 2023.

Recommendations for improvement identified from this performance review include building on the current initiatives:

- continuing to complete (currently part way through) setting up its own accreditation standards, structures, processes, and policies,
- further evolve the clinical and cultural standards via the projects for Clinical Governance (CG) & Quality Improvement (QI), Cultural Safety and health equity and the Prescriber Standards,
- completing the recruitment of a specific health equity and cultural safety lead and continue the journey for improvement of health equity and cultural safety.

This performance review identified a need to update references to privacy legislation in identified policies to refer to the Privacy Act 2020 and continue to implement an ongoing and timely policy and SOP review process.

Recommendations

The below table summarises the areas for improvement identified from this review with associated timeframes. Refer to the next section of the report for the full reviewer's comments associated with the recommendation.

Ref #	Related core performance standards	Rating	Risk Level	Recommendation	Timeframe (months / date)
1.3	The RA has timely, proportionate, and transparent accreditation and monitoring mechanisms to assure itself that the education providers and programmes it accredits deliver graduates who are competent to practise the relevant profession	PA	L	To continue to complete (currently part way through) setting up its own accreditation standards, structures, processes, and policies. This work will include cultural safety and an ongoing monitoring framework for annual reporting.	9 months (up to 31 August 2022)
6.1	The RA sets standards of clinical and cultural competence and ethical conduct that are: <ul style="list-style-type: none"> • Informed by relevant evidence • Clearly articulated and accessible 	PA	L	To continue to evolve the clinical and cultural standards via the projects for Clinical Governance (CG) & Quality Improvement (QI), Cultural Safety and health equity and the Prescriber Standards.	6 – 9 months (up to 31 August 2022)
10.1	The RA: <ul style="list-style-type: none"> • Ensures that the principles of equity and of te Tiriti o Waitangi/ the Treaty of Waitangi (as articulated in Whakamaua: Māori Health Action Plan 2020-2025) are followed in the implementation of all its functions 	PA	L	To complete the recruitment of a specific health equity and cultural safety lead and continue the journey for improvement of health equity and cultural safety (embedded within a refresh of regulatory tools).	6 months (up to 31 May 2022) and ongoing

Functions under section 118 HPCA Act 2003 and their related core performance standards

Purpose and requirements

Responsible Authorities are designated under the Health Practitioners Competence Assurance Act 2003 (the Act) to fulfil certain functions. An amendment in 2019 to the Act adding section 122A, required a performance review of all Responsible Authorities be conducted within three years of enactment. The Ministry of Health (the Ministry) is responsible for the facilitation of these reviews.

Performance reviews provide assurance to the Crown and the public that responsible authorities are performing their functions efficiently and effectively. This includes the assurance that: the responsible authorities are carrying out their required functions in the interests of public safety, their activities focus on protecting the public without being compromised by professional self-interest, and their overall performance supports high public confidence in the regulatory system.

This initial performance review will assess a responsible authority's performance against the full set of Core Performance Standards. These standards are aligned with the functions under section 118 of the HCPA Act.

Risk management

Identify the degree of risk to patient safety and/or public confidence that is associated with the level of attainment the responsible authority achieves for each criterion. Review the 'risk' in relation to its possible impact, based on the consequence and likelihood of harm occurring if the responsible authority does not fully attain the criterion. Use the risk management matrix when the audit result for any criterion is partially attained or unattained.

To use the risk management matrix, you need to:

1. consider what consequences for consumer safety might follow from the responsible authority achieving partially attained or unattained for a criterion, within a range from extreme/actual harm to negligible risk of harm occurring
2. consider how likely it is that this adverse event will occur due to the provider achieving partially attained or unattained for a criterion, within a range from being almost certain to occur to rare
3. plot the findings on the risk assessment matrix to identify the level of risk, and prioritise risks in relation to severity
4. approve the appropriate action the provider must take to eliminate or minimise risk within the timeframe. Note that timeframes are set based on full resolution of the requirement, which may include a systems change or staff training programme. Anything requiring urgent attention is identified in the report, along with any longer timeframe needed to make sustainable change.

The Risk management matrix uses a probability versus impact quadrant with the following risk categories: low, low-med, medium and high.

Function 1: Section 118a) To prescribe the qualifications required for scopes of practice within the profession, and, for that purpose, to accredit and monitor educational institutions and degrees, courses of studies, or programmes

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
1.1	the RA has defined clear and coherent competencies for each scope of practice	<p>The Council has three scopes of practice fully described on their website that include:</p> <ul style="list-style-type: none"> • Intern Pharmacist • Pharmacist • Pharmacist Prescriber <p>Competencies for the Pharmacist scope of practice are described in Competence Standards for the Pharmacy Profession 2015 which is published on the Council website.</p> <ul style="list-style-type: none"> • <i>Intern Pharmacist</i>: must be assessed as competent in all elements of the Competence Standards (through completion of the EVOLVE Intern Training Programme and passing the Pharmacy Council Intern Assessment Centre). • <i>Pharmacist Prescriber</i>: also meet the Pharmacist Prescriber Prescribing Competency Framework and Standards. <p>Scopes of Practice are identified in the New Zealand Gazette Notice: <i>Pharmacy Council Scopes of Practice and Prescribed Qualifications Amendment Notice 2014</i>.</p>	FA			

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1.2	the RA has prescribed qualifications aligned to those competencies for each scope of practice	<p>Information about qualifications is published on the Council website. Qualifications are specific to registration pathways and align to the three scopes of practice. Courses and assessments leading to registration must be aligned to the Aotearoa NZ competence standards.</p> <p>Accreditation is the process by which Bachelor programmes, the intern training programme and the postgraduate prescriber programme demonstrate that programmes of learning align to the competencies. Accreditation standards for each programme reference the relevant competence standards, specifically a requirement that the programme be mapped to the competencies and demonstrate achievement thereof.</p> <p>Qualifications have arisen from and retain alignments with qualifications for pharmacist registration (or licensing) in international jurisdictions where the practice of pharmacy is similar to Aotearoa NZ, most especially Australia, the UK and Ireland. The Pharmacy Council monitors international qualifications and proactively considers the fitness for purpose of qualifications for the New Zealand pharmacy practice context. Significant changes to qualifications that have occurred after external review to improve</p>	FA			

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		<p>effectiveness, defensibility and proportionality of regulation have included:</p> <ul style="list-style-type: none"> • Introduction of a 10-station OSCE assessment of intern pharmacists. • Removal of the intern written examination. • Psychometric testing to provide Council, the profession, and the public with assurance regarding the Assessment Centre including validity evidence, reliability, defensibility, and fairness for is stated purpose. 				
1.3	the RA has timely, proportionate, and transparent accreditation and monitoring mechanisms to assure itself that the education providers and programmes it accredits deliver graduates who are competent to practise the relevant profession	<p>Accreditation occurs against accreditation standards that are specific to the type of programme. List of accredited programmes is published on the Council's website.</p> <p><u>Intern training programme</u></p> <ul style="list-style-type: none"> • Provider: Pharmaceutical Society of New Zealand • Programme: EVOLVE <p><u>Bachelor of Pharmacy</u></p> <ul style="list-style-type: none"> • Education providers: University of Otago and University of Auckland • Programme — Bachelor of Pharmacy 	PA	L	To continue to complete (currently part way through) setting up its own accreditation standards, structures, processes and policies. This work will include cultural safety and an ongoing monitoring framework for annual reporting.	9 months (up to 31 August 2022)

		<p><u>Pharmacist Prescriber</u></p> <p>One programme jointly developed by both universities. Delivered in 2021 by University of Auckland.</p> <ul style="list-style-type: none"> • Education providers: University of Auckland and University of Otago • Programme: Postgraduate Certificate in Pharmacist Prescribing <p>Accreditation cycles are ongoing for established pharmacy education programmes, currently six years for BPharm and pharmacist prescriber programmes and three years for the intern training programme.</p> <p>Where concerns are identified through the accreditation process, the Council applies conditions and/or monitoring requirements until issues are resolved to the Council's satisfaction. A record is kept of all accreditation recommendations made to Council and Council decisions are recorded in meeting minutes and are conveyed in writing to the education provider.</p> <p>Until 31 August 2021, the Pharmacy Council contracted the Australian Pharmacy Council to undertake evaluation and recommendation of Aotearoa NZ pharmacy education programmes using standards and processes that were the same or highly similar for all programmes in Australia and Aotearoa NZ. In December 2020, Council made the decision to end its contract with APC and bring the accreditation process in-house.</p> <p>The arrangement with the Australian Pharmacy Council had been in place since</p>				
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		<p>the Council's inception and has largely functioned well as a proportionate, timely and defensible system; however, over the past five years the Council increasingly wanted more transparency to have comfort with the decisions it was making, based on the recommendations made to it. This was especially the case for accreditation decisions relating to delivery of cultural competency components of programmes because the Council was placing more emphasis on cultural competence of registrants through this time.</p> <p>A project has been initiated to set up the standards, structures and processes for delivery of NZ based accreditation from mid-2022. It has been recognised by the Council that it is necessary to include expertise in teaching, learning and evaluation of cultural competence in the evaluative elements of accreditation of an education programme. The current intention to include cultural safety in competence standards will require extension of this expertise to accreditation systems in both the content of the standards and its approach to its development – ensuring authentic protection, partnership and participation from a Treaty perspective but moving forward to an articles, Te Tiriti approach. The in-house accreditation system that is currently being developed will ensure</p>				

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		cultural expertise appropriate to Aotearoa is involved in the accreditation evaluation of each programme. All pharmacy programmes are currently fully accredited. The in-house process is intended to be in place before accreditation considerations are required in 2023.				
1.4	the RA takes appropriate actions where concerns are identified	<p>All accreditation programmes are currently accredited without conditions. The accreditation reports show that monitoring requirements and conditions can occur at the time of accreditation with timeframes for completion and reporting.</p> <p>Also, actions the Council has taken to address some concerns specific to qualifications include:</p> <ul style="list-style-type: none"> • change recert framework (effective, proportionate) • remove written exam (proportionate) • change accreditation system (transparency, responsive, effective) 	FA			

Function 2: Section 118b) To authorise the registration of health practitioners under this Act, and to maintain registers.

Section 118c) To consider applications for annual practicing certificates

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2.1	The RA maintains and publishes an accessible, accurate register of registrants (including, where permitted, any conditions on their practice)	<p>Every practitioner registered with the Pharmacy Council (whether current; inactive; or suspended) is searchable on their website.</p> <p>This information is always available. Each entry contains real-time data including:</p> <ul style="list-style-type: none"> • legal name of practitioner • registration number • base pharmacy qualification • date of initial registration in the Pharmacist scope of practice • work address (if consent granted to display) • practising status (registered, current; registered, inactive; or suspended) • if registered, current, Interim or Annual Practising Certificate • conditions on scope of practice • scope(s) of practice • region • HPI (Health Provider Index) <p>As at 20 September 2021 there are a total of 4,344 practitioners who hold a current APC. The breakdown by scope of practice is:</p> <ul style="list-style-type: none"> • Intern Pharmacists = 259 • Pharmacists (only) = 4,048 • Pharmacists and Pharmacist Prescribers= 37 <p>There are 1,079 registered practitioners who do not hold a current APC.</p>	FA			

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		<p>Note that approximately 2% of pharmacists identify as Māori.</p> <p>Data is held in a secure Pharmacy Council database in a single source of truth-type model. The database can be updated manually via team members, automated steps with application processes, or scheduled actions (e.g., changing practising status from registered, current to registered, inactive on 1 April if no application is received). These changes are made according to the policy or Standard Operating Procedures (SOPs) relevant to the process. Data from the central database is then used to populate the online public register and the MARCO user interface that is used internally by staff.</p> <p>The Council advise that they have not received notifications of register inaccuracies from either the public or practitioners. This provides Council with a high level of assurance that the data maintained and displayed in the register is accurate. Further, there is a secondary degree of cross checking via the provision of data to Medicines Control where they reconcile pharmacy license holder data to registered pharmacist data.</p>				
2.2	<p>The RA has clear, transparent, and timely mechanisms to consider applications and to:</p> <ul style="list-style-type: none"> Register applicants who meet all statutory 	<p>The vast majority of applications for practising certificates are made via online processes and each registered practitioner has a secure online access.</p> <p>Council's recertification year runs from 1 April to 31 March each year and pharmacists are asked to</p>	FA			

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	<p>requirements for registration</p> <ul style="list-style-type: none"> • Issue practicing certificates to applicants in a timely manner • Manage any requests for reviews of decisions made under delegation 	<p>recertify each March. Any practitioners that have not submitted application for re-certification by 31 March (either active or inactive status) will have their practising status set to registered, inactive in the early hours of 1 April and will not be eligible to practise.</p> <p>A register revision process as per s144 is typically commenced in May and concluded in the following November/December.</p> <p>Online applications are built from the WordPress platform. The forms:</p> <ul style="list-style-type: none"> • Provide applicants access to a secure account • Allow applicants access to relevant applications • Allow applicants to input and submit relevant application information • Manage and record payment of application fees • Route applications for manual review to appropriate staff members according to policy and process • Identify outstanding applications to ensure timely and appropriate action • Issue communications to applicants and where appropriate PDF copies of practising certificates/receipts • Update the internal database and online register • Maintain a timestamped audit trail of application actions <p>Applications are not received at a uniform rate during the year with a peak of applications in March. These applications are for reissue of practising certificates</p>				

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		<p>or renewal of non-practising status (i.e., annual re-certification).</p> <p>In March/April 2021, of the approximately 4,000 applications for reissue of an annual practising certificate received, about 5% of applications met criteria that required review by a team member with 95% of applications processed within one hour of submission.</p> <p>Council communicates the requirements and process to recertify in advance to ensure that applicants are clear in the process and provide appropriate responses.</p> <p>Other than March and April, the other period of high registration workload is early December through to late January. During this period two types of application are received: pharmacy degree graduates seeking registration in the Intern Pharmacist scope of practice and Intern Pharmacists seeking registration in the Pharmacist scope of practice. Approximately 220 to 250 applications of each type will be received in this period.</p> <p>Graduates do not require registration until February and registrations officers ensure that all applications are completed by this deadline. Applications for registration as a pharmacist are generally completed within five working days of submission.</p> <p>Throughout the year, the other main type of application received are return to practice applications. Council would expect to receive approximately 90 return to practice applications</p>				

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		<p>annually. Applicants from differing jurisdictions need to be managed differently given the need to ensure qualifications are equivalent to those required for NZ pharmacist registration. These applications are classified depending on the origin of the qualification and fall into three broad categories – someone with qualifications from Australia (as Trans-Tasman Mutual Recognition Agreement (TTMRA)), those from jurisdictions which we say the qualifications is equivalent (REQR), and those from non-recognised qualification equivalency (Non-REQR). Typically, Council would receive less than 15 of each type of application per year.</p> <p>Pharmacy Council has a Reconsideration of Decisions Policy for reconsideration of decisions, including decisions that do not have clear reconsideration mechanisms under the Act (e.g., Accreditation decisions, examination attempts).</p> <p>Council advises it will investigate whether a user experience survey will provide additional information to monitor our performance.</p> <p>Council has identified SOPs for registrations processes must be reviewed, updated, and improved so that an inexperienced registrations officer could use the document to execute the process successfully. A rolling annual review schedule has been formulated to facilitate and perpetuate this quality review and improvement. Reviewed SOPs should adhere to a standard format. SOPs do not currently exist for requests for reviews of decisions</p>				

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		made under delegation and these are in the process of being formulated and implemented..				

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Section 118e) To recognise, accredit, and set programmes to ensure the ongoing competence of health practitioners.

Section 118k) To promote education and training in the profession

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3.1	<p>The RA has proportionate, appropriate, transparent and standards-based mechanisms to:</p> <ul style="list-style-type: none"> Assure itself that applicants seeking registration or the issuing of a practicing certificate meet, and are actively maintaining, the required standard Review a health practitioner's competence and practice against the required standard of competence Improve and remediate the competence of practitioners found to be below the required standard Promote the competence of health practitioners 	<p><u>Programmes to ensure ongoing competence</u> Beyond initial registration in a scope of practice, the Pharmacy Council sets a programme of annual activities to promote individual competence for role and provide assurance that pharmacists take appropriate action to continue to be competent for their practice role. The annual programme of actions is referred to as recertification requirements because its completion is a requirement of annual recertification. Compliance of the profession with recertification requirements gives the Council assurance that the public can continue to place trust in pharmacy professionals.</p> <p>The Pharmacy Council monitors recertification (re-licensing) thinking and practice amongst health profession regulators and academics in Aotearoa NZ and overseas. It also continually monitors feedback on its own recertification programme and in recent years has sought to be a more proportionate and effective regulator. As a result of these activities the Council introduced a new recertification programme in April 2021 that increases assurance about competence (effectiveness) and reduces the cost and</p>	FA			

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		<p>burden of compliance to individual pharmacists (proportionate).</p> <p>The framework was developed in collaboration with practising pharmacists to ensure it is relevant and achievable for pharmacists in a range of settings and roles.</p> <p>New recertification framework and requirements are published on the Council website.</p> <p>The 2021 recertification programme is being implemented through 2021 and 2022 after which comprehensive feedback and analysis will inform an ongoing quality improvement programme which will be developed during 2022.</p> <p>The Council now delivers and communicates all aspects of its recertification programme which contrasts with previous recertification programmes being delivered by a professional membership organisation on behalf of the Council.</p> <p><u>Review (i.e. identifying pharmacists where competence may be an issue)</u> Under delegations the Registrar receives and makes enquiries into notifications and concerns raised about a pharmacist's</p>				

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		<p>competence. In practice, most formal concerns are discussed by the Compliance team on a weekly basis to set tasks according to the risk-based priority given to a case. For each case, the team assess the concern, determines what information is necessary, identifies possible solutions and decides on the best course of action. Pharmacists who are the subject of a formal concern are given a fair opportunity to make a written submission. Many HDC complaints raise questions about the pharmacist's performance against competence standards, and in addition to the information provided to HDC, we expect some reflection on the relevance of the competence standards to the actions/inactions which contributed to the adverse event.</p> <p>Further to considering a written submission, and subject to the level of perceived risk, further enquiries may be made with the pharmacist's consent. This could include a practice visit by an experienced pharmacist, or a semi-structured interview. For most cases, where the evidence does indicate a risk of harm, or does not indicate significant gaps in the pharmacist's competence, various non-statutory options can be employed (mostly educative) to mitigate the likelihood</p>				

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		<p>of further related incidences. This approach is common for complaints referred by HDC associated with a dispensing error, provided the pharmacist shows evidence of corrective actions and reflection.</p> <p>If the information indicates that the pharmacist's competence may pose a possible risk of harm, this is referred to the Council's Competence and Fitness to Practise Committee (CFPC).</p> <p><u>Remediate (i.e. improving competence where at risk)</u></p> <p>The CFPC has delegation to order a competence review, notify under section 35, make interim orders under section 39 (risk of serious harm pending review or assessment), and sets the terms of reference of the competence review.</p> <p>A competence review is mostly carried out at the pharmacist's place of work and utilises tools that observe aspects of practice, seeks feedback from colleagues and health practitioner peers, and Professional Conversation, a tool enabling the pharmacist to present evidence of competence. The review is completed by two trained and experienced pharmacists with similar practice experience to the pharmacist under review. The reviewers</p>				

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		<p>report their findings against specific competence standards, indicate whether evidence has been provided demonstrating competence for these standards, and advise whether they consider the pharmacist practises below the expected standard of competence. Where the standard falls below expectation, the reviewers will recommend activities that could be included in a competence programme. The pharmacist is given the opportunity to comment or challenge the facts of the review, and prior to consideration by the CFPC can make submissions (written and in person) on the review report.</p> <p>The CFPC after considering the report and submissions has the authority to order a competence programme, place conditions, order examination, assessment or counselling.</p> <p><u>Promote</u> Council actively monitors competence within the wider profession via:</p> <ul style="list-style-type: none"> engagement with professional bodies (e.g., Pharmacy Guild of New Zealand, Pharmaceutical Society of New Zealand, Pharmacy Defence Association) and the Ministry of Health 				

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		<p>(including Medsafe and Medicines Control)</p> <ul style="list-style-type: none"> analysis of complaints and notifications for indicators of areas of risk <p>Council also has three currently practising pharmacists on staff to provide feedback on contemporary practice.</p> <p>If Council identifies a competence deficiency that is pervasive throughout the profession it will communicate the issue to the profession. These communications will be delivered to all registered practitioners via the email address held on the register. The nature of the communication will depend on the nature of the concern.</p> <ul style="list-style-type: none"> Safety Alerts will be delivered on an ad-hoc basis if a series of dispensing errors indicate a lack of knowledge around the dispensing of a specific pharmaceutical. Historical safety alerts are viewable on the website. When Council determines that substandard practice is occurring with respect to a particular aspect of practice, it may release a statement or guideline. The aim of these documents is to clarify, contextualise, and support 				

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Section 118k) To promote education and training in the profession

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		<p>expectations already expressed in the Code of Ethics and/or competence standards for specific practice situations. A statement would be developed and published on our website and also published in the next available Pharmacy Council newsletter.</p> <ul style="list-style-type: none"> • Council sends a newsletter approximately every 2 to 3 months (following each Council meeting). This is sent to all registered practitioners via their registered email address. Articles within this newsletter can be used as a less formal method of raising issues with practitioners. Historical newsletters remain available on the website. <p>For all concerns about individual pharmacists that raise questions about maintenance of competence standards, but not requiring statutory action, the Council reviews the pharmacist's reflection and remedial action and provide written feedback on the expect standard. This might be supported by a professional discussion or agreed follow-up action, such as professional development activity.</p>				

Function 4: Section 118f) To receive information from any person about the practice, conduct, or competence of health practitioners and, if it is appropriate to do so, act on that information.

Section 118g) To notify employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner that the practice of a health practitioner may pose a risk of harm to the public.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
4.1	<p>The RA has appropriate, timely, transparent, fair, and proportionate mechanisms for:</p> <p>Providing clear, easily accessible public information about how to raise concerns or make a notification about a health practitioner</p>	<p>Complainants and notifiers can bring concerns to Council's attention using a range of options, including an online notification form (Notify online). The Council website provides an overview of the options (including the role of HDC). Similarly, a pharmacist who is the subject of a complaint or notification can access general information on how Council manages concerns, with more detailed information provided in individual letters.</p> <p>In the year to 30 June 2021, 48 formal concerns were lodged, 19 of which were referred by the HDC. Despite efforts to direct health consumer concerns to HDC, the Council receives a high proportion of informal concerns (121, 71.6% of total concerns). This includes telephone calls, complainants either requesting withholding of identity or indicating that the concern is not formal or is an enquiry of service expectations. Included are concerns not within Council's mandate (e.g. employment, service charges, civil disputes) in this category. A few of these informal concerns, after further enquiry and with the notifier's consent escalated to a formal concern.</p>	FA			

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4.2	<ul style="list-style-type: none"> • Identifying and responding in a timely way to any complaint or notification about a health practitioner • Considering information related to a health practitioner's conduct or the safety of the practitioner's practice • Ensuring all parties to a complaint are supported to fully inform the authority's consideration process 	<p>A risk-based prioritisation approach is applied for managing complaints and notification. The risk to the public is assessed and reviewed every time new information is received.</p> <p>The recently implemented Case Management System (CMS) is gradually replacing a process that was reliant on spreadsheets and document folders. The first iteration (a minimal viable product, MVP) links complaints and notifications received via the online notification form, or email to case data, which records case summary data, comments, risk assessments, complaints taxonomies, task management, holds documents and supports formal correspondence, (data incorporated into letter templates).</p> <p>Incremental improvements are planned to the MVP and further functions will allow external committees (PCC and CFPC) to access relevant case information. PCCs will be supported with task management tools.</p> <p>Complaints referred by HDC or concerns about conduct may be referred to a PCC. The PCC is supported by a secretariat</p>	FA			

Function 4: Section 118f) To receive information from any person about the practice, conduct, or competence of health practitioners and, if it is appropriate to do so, act on that information.

Section 118g) To notify employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner that the practice of a health practitioner may pose a risk of harm to the public.

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		<p>service, training and comprehensive guidelines to set its procedures.</p> <p>Typically, there may be between three and eight concurrent PCC and HPDT investigations. There are 24 Council-approved members (including 5 lay members) in the PCC members' pool.</p> <p>Whilst the numbers of formal competence reviews are low (2 in the last 2 years), Council advised they are more active in considering this option, including considering for other practice concerns (conduct or health) where practice may pose a risk of harm. Whilst conditions and suspensions are shown on the public register, situations arise that require greater awareness of orders made by Council. The Naming Policy sets out Council's position for naming individual pharmacists subject to a Council order.</p> <p>The CFPC's secondary function is to support the Registrar for certain decisions, whether required through the Chair (interim health actions and ordering health assessments, notices of conviction) or to advise the Registrar on the exercise of delegation for complex cases.</p>				

Function 4: Section 118f) To receive information from any person about the practice, conduct, or competence of health practitioners and, if it is appropriate to do so, act on that information.

Section 118g) To notify employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner that the practice of a health practitioner may pose a risk of harm to the public.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>A new Complaints and Notifications Policy is under development (in draft) which sets out a more explicit risk-based approach to the management of concerns raised about individual pharmacists. It will be a further opportunity, guided by Council's Principal Advisor (Māori), to explicitly recognise and incorporate tikanga Māori, and embed culturally safe policy and procedures.</p> <p>The Compliance team is updating standard operating procedures to include further details relating to the CMS which is scheduled to be fully functional by 30 June 2022 and work on the procedures will be finalised before the end of 2022.</p> <p>Work is underway developing Business Intelligence initiatives which use the data to support regulation. Better access to notification data and analysis of trends may enable earlier detection of risks associated with competence concerns and support proactive regulatory action for the profession.</p>				
4.3	Enabling action, such as informing appropriate parties (including those specified in section 118(g)) that a	By prioritising based on risk assessment, the compliance team addresses concerns in a timely manner, using statutory and non-statutory regulatory options (e.g.	FA			

Function 4: Section 118f) To receive information from any person about the practice, conduct, or competence of health practitioners and, if it is appropriate to do so, act on that information.

Section 118g) To notify employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner that the practice of a health practitioner may pose a risk of harm to the public.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
	practitioner may pose a risk of harm to the public	<p>educative, cautions or voluntary arrangements) as is necessary to mitigate the risk.</p> <p>All parties are kept informed and this includes where identified employers, the Accident Compensation Corporation, the Director-General of Health, and the Health and Disability Commissioner.</p>				

Function 5: Section 118h) To consider the cases of health practitioners who may be unable to perform the functions required for the practice of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
5.1	<p>The RA has clear and transparent mechanisms to:</p> <ul style="list-style-type: none"> • Receive, review, and make decisions regarding notifications about health practitioners who may be unable to perform the functions required for the practice of the profession • Take appropriate, timely, and proportionate action to minimise risk 	<p>Notifications can be received for health, conduct or competence. Health disclosures occur at registration, APC renewal or could occur in between APC renewals.</p> <p>The approach is covered by delegation documents, terms of reference and procedures. This includes the registrar, CFPC and referrals to PCC.</p> <p>Since the start of 2014, Council or its delegate has ordered ten health assessments, 1.25 per year on average. In the last two years the Pharmacy Council has managed concerns about pharmacists with health conditions that may impact their practice without having to use the statutory mechanisms. The last interim condition and health assessment orders were made in June 2019. This is more a reflection on the nature of the concerns in this period and the professionalism of the pharmacists concerned, rather than an intention to limit the use of statutory orders. Most of the current concerns managed were self-referred through the APC disclosure process. Regardless, the Council through its delegation to the Registrar (in consultation with the Chair of CFPC), enables prompt statutory action to mitigate significant risk of harm where necessary.</p>	FA			

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
6.1	<p>The RA sets standards of clinical and cultural competence and ethical conduct that are:</p> <ul style="list-style-type: none"> Informed by relevant evidence Clearly articulated and accessible 	<p>Pharmacy Council's key standards are:</p> <ul style="list-style-type: none"> Code of Ethics. The latest revision was published in 2018. The Code aims to "articulate the professional and ethical values to which all pharmacists should conform and can expect of their colleagues". The Code is structured into seven principles. Each of these principles is further described by several clauses. The Competence Standards for the Pharmacy Profession 2015 sets of the cultural, clinical, and professional expectations Council expects of practising pharmacists and the standards that intern pharmacists should work towards to demonstrate required competency to register as a pharmacist. The standards are divided into two mandatory (applicable to all pharmacists) and four optional (applicable to certain types of practice) domains. The domains are divided into competencies, which are further divided into behaviours. The Pharmacist Prescriber: Prescribing Competency framework & standards are the competence standards that apply to pharmacist 	PA	L	To continue to evolve the clinical and cultural standards via the projects for Clinical Governance (CG) & Quality Improvement (QI), Cultural Safety and health equity and the Prescriber Standards.	6 – 9 months (up to 31 August 2022)

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>prescribers in addition to the pharmacist competence standards.</p> <p>Competency standards are reviewed on a periodic basis to ensure they are informed by relevant evidence, clearly articulated and accessible, developed in consultation with the profession and other stakeholders, and support practitioners to interact effectively and respectfully with Māori.</p> <p><u>Standards are informed by relevant evidence</u></p> <p>In regard to the current competency standards for the Pharmacist scope published in 2015, the Pharmacy Council leverages standards set by international peer regulators with similar health system environments such as Australia, Canada, Ireland and the United Kingdom (UK) – which are generally and globally regarded as “good practice” for pharmacy practice. International standards provide a platform by which critical reflection (e.g. gap analysis) and customisation is undertaken specific for Aotearoa NZ settings. For example, conscious and deliberate effort was undertaken to ensure competency standards weaved and supported cultural competencies and the fulfilment of Te Tiriti – facets missed or only superficially covered in international competency standards.</p>				

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>More recently from 2019, review processes to determine whether existing standards still reflect contemporary and relevant evidence and practice and inform areas for further improvement has been undertaken. The process used included a comparison between existing competency standards for the Pharmacist scope against comparable peer pharmacist regulators (e.g. UK, Australian) and non-pharmacist peer regulators (e.g. Nursing, Occupational Therapy, Dental). To determine if competency standards are responsive to relevant evidence of emergent public safety risks and issues and contemporary regulatory practice, a synthesis of literature has been undertaken.</p> <p>Further, contemporary and relevant evidence on cultural safety, health equity and Te Tiriti in relation to its application to competency standards have been canvassed as part of assessment against existing competency standards.</p> <p>Regarding the pharmacist prescriber competence standards, they were developed in collaboration with the UK National Prescribing Centre (NPS) and strongly influenced by NPS's "Maintaining Competency in Prescribing –An outline framework to help pharmacist prescribers" generally recognised as leaders of good practice. The current qualifications</p>				

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		<p>required to be a pharmacist prescriber, international evidence of the safety of pharmacist prescribers (i.e. 0.3% of prescribing (c.f. 7% medical prescribers) alongside no complaints and notifications received by the Pharmacy Council provides a level of assurance that the current standards are fit for purpose.</p> <p>More recently from 2020, the pharmacist prescriber competence standards are currently undergoing review and a drafted document has been produced. This document was adapted from "A Competency Framework for all Prescribers" produced by the Royal Pharmaceutical Society and not significantly dissimilar to those set by the NPS MedicinesWise in Australia. The Pharmacy Council are currently undertaking mapping work with the six other RAs (Medical Council, Dental Council, Dietitians Board, Midwifery Council, Nursing Council, Optometrists and Dispensing Opticians Board) that regulate prescribing health professionals to i) assess how comprehensive our drafted standards are, and ii) work towards a set of competence standards that may be adopted across all of the prescribing health professions.</p> <p><u>Clearly articulated and accessible</u></p>				

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>Standards are written in plain English and are structured in a logical fashion. The standards are intended to be broad enough to be adapted to a wide range of practice, including non-patient facing roles, while still providing a high level of guidance to ensure that expectations are clear. All statements, standards, and the Code are publicly available on the Council website.</p> <p>Council has identified some aspects in need of further improvement are:</p> <ul style="list-style-type: none"> • Greater consistency in how standards were written (e.g., active voice rather than passive, shifting to a more outcome-based competency standards style) • Being more explicit as to when an optional standard is or is not applicable • Making the document more concise overall <p>To refresh existing competency standards and further strengthen competency standards, the Council recognise the key areas for improvement are health equity, cultural safety and Te Tiriti and clinical governance and quality improvement competencies.</p>				

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Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>Building on existing work and changes to the health system landscape and policies such as the Health & Disability Systems Review (HDSR), WAI2575, Whakamaua: Māori Health Action Plan 2020-2025 and other legislative and policy changes the Council has projects in place and these re-enforce the strategic direction.</p> <p>Project plans with timelines, key deliverables and budget was developed and approved by the Pharmacy Council Board at their June meeting. A project status update report current to September 2021 provides an overview of the progress for achieving key deliverables.</p> <p>Broadly, these include strategic initiatives to be implemented over the FY21/22 period on:</p> <ul style="list-style-type: none"> • Clinical Governance (CG) & Quality Improvement (QI) • Cultural Safety and health equity • Prescriber Standards 				
6.2	Developed in consultation with the profession and other stakeholders	In regard to the current 2015 competency standards for the Pharmacist scope of practice, submissions were sought, incorporated and received from individual practitioners, professional associations and organisations, academic/teaching organisations and other responsible authorities (RAs) from both Aotearoa NZ	FA			

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>and Australia (e.g. Pharmaceutical Society of Australia and Australian Pharmacy Council).</p> <p>More recently from 2019, Council engaged a representative sample of 79 pharmacists, stakeholder group and contracted expertise to assess the relevancy of competency standards for the pharmacist scope of practice with a view to refresh and further refine them. Efforts to further increase engagement and co-design with stakeholders (both profession and other RAs) has also been recently undertaken alongside the implementation of "Special Interest Networks" (SIN) via electronic means (i.e. Microsoft Teams) by which engagement with the profession can be undertaken in a more dynamic manner to augment more traditional formal consultation approaches. An informal and organic special interest group & network for HPCA regulators to share knowledge and help each other with a view to better foster and support collaboration across HPCA regulators has also been operationalised using Microsoft Teams as a platform with advisors from Nursing and Dental joining as part of pilot testing.</p> <p>The Council's recruitment of a Māori principal advisor is to improve capability to engage with whānau, hapu and iwi.</p>				

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>The pharmacist prescriber competency standards are also within a review process currently. Council is working with six other RAs to potentially determine a common set of competency standards for prescribing. The approach so far has been to:</p> <ol style="list-style-type: none"> 1. Map the UK standards against our current standards. 2. Early engagement with schools of pharmacy as education providers was initiated. 3. Adapt the standards to reflect the Aotearoa NZ context. 4. A public consultation was held 5. Further amendments were made based on submissions <p>Development of this draft was undertaken as part of Council's scheduled review of the standards; however, the draft document has been shared with other RAs that regulate prescribing health professionals. It is recognised that the current version may require extensive review before it is fit to be adopted across seven health professions.</p>				
6.3	Inclusive of one or more competencies that enable practitioners to interact effectively and respectfully with Māori	The expectations that pharmacists will interact effectively and respectfully with Māori is consistently and deliberately "weaved" within the documents. For example:	FA			

Function 6: Section 118i) To set standards of clinical competence, cultural competence (including competencies that will enable effective and respectful interaction with Māori), and ethical conduct to be observed by health practitioners of the profession.

Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<ul style="list-style-type: none"> Principle 3 of the Code aims to support “the pharmacist’s role in providing equitable and safe access to resources, recognition of Te Tiriti o Waitangi, avoidance of discrimination, and participation in public health initiatives”, and “Must recognise the status of Māori and Te Tiriti o Waitangi in the New Zealand health sector and take appropriate steps to recognise and respond appropriately to the health needs of Māori including inequities in health and access to healthcare services.” Clause A is at a broader level: “Supports the right of all people, to access culturally safe and responsive, high quality professional services.” Mandatory competency standard M1.5 requires that pharmacists understand the relevance of Te Tiriti o Waitangi and Māori perspectives of health, and that they actively practise to interact with those of Māori ethnicity respectfully and to reduce disparities in health outcomes. 				

Function 7: Section 118j) To liaise with other authorities appointed under this Act about matters of common interest						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
7.1	The RA understands the environment in which it works and has effective and collaborative relationships with other authorities.	<p>The Council works with the other responsible authorities in recognising changes to the environmental landscape for HPCA regulators and the desire by the Director General of Health and Minister for increased collaboration between RAs. For example, the Pharmacy Council is currently leading the facilitation and development of a unified prescriber competency standards across RAs where prescribing is part of the scope of practice.</p> <p>The use of technology such as Microsoft Teams has been piloted in conjunction with peer regulators such as Dental and Nursing Council to establish a more agile RA network to share lessons learned and resources and support greater standardisation and consistency. Council has also recently worked with Dental, Medical and Nursing on a joint statement and/or aligned statement on health practitioner response to vaccinating against COVID-19.</p>	FA			

Function 8: Section 118ja) To promote and facilitate inter-disciplinary collaboration and cooperation in the delivery of health services.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
8.1	The RA uses mechanisms within the HPCA Act such as competence standards, accreditation standards, and communications to promote and facilitate inter-disciplinary collaboration and cooperation in the delivery of health services.	<p>The Pharmacy Council is a responsible authority established under the HPCA Act 2003. It is responsive to events such as COVID-19 and changes to the health system landscape and policies such as the Health & Disability Systems Review (HDSR), WAI2575, Whakamaua: Māori Health Action Plan 2020-2025, Therapeutic Products Bill and other key legislative and policy changes.</p> <p>Examples where the Pharmacy Council has effectively collaborated with other authorities:</p> <ul style="list-style-type: none"> Effectively partnering with Ministry to administer the COVID-19 Pharmacy Team Relief Funds and the issuing of emergency practitioner certificates as part of supporting Aotearoa NZ's pandemic response, recovery and vaccine roll-out efforts. Effectively partnering with Medsafe with the development of a joint Pharmacy Regulatory Quality Improvement Project to further improve the quality of pharmacist/pharmacy practice for better health outcomes. Whakawhanaungatanga and partnering with other central agencies (e.g. PHARMAC, ACC, HQSC, HDC, DHBs, Medsafe, professional associations and organisations) on 	FA			

Function 8: Section 118ja) To promote and facilitate inter-disciplinary collaboration and cooperation in the delivery of health services.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>pan-health system areas of improvement such as clinical governance and quality improvement and health equity and cultural safety.</p> <ul style="list-style-type: none"> Active participant in most pharmacy profession sector groups: for example, DHB forums on the pharmacy national agreement and less recent, the Pharmacy Sector Strategy Group (formerly known as the HOSPOP – Heads of Schools of Pharmacy and Other Pharmacy Organisations). <p>While some relationships (e.g. Medsafe, Ministry, HDC, RAs) are relatively more mature, others (e.g. PHARMAC, ACC, HQSC, DHBs) can be further improved. The Pharmacy Council is already beginning to develop more effective mechanisms for collaboration and engagement. This includes to implement regular meeting times and developing publicly available project overviews to enable shared understanding with authorities so there is better awareness of Council activities with a view for greater collaboration.</p>				

Function 9: Section 118I) To promote public awareness of the responsibilities of the authority.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
9.1	<p>The RA:</p> <ul style="list-style-type: none"> Demonstrates its understanding of that the principal purpose of the HPCA Act is to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practice their professions 	<p>The Council has a very good understanding of its role protecting public health and safety and carries out its statutory purpose and functions as a responsible authority (RA) in regulating just over 4,000 practitioners registered under the Intern Pharmacist, Pharmacist, or Pharmacist Prescriber scopes of practice.</p> <p>Policies and processes consistently recognise the Council's principal purpose to protect public safety.</p> <p>The discussions with the Council representatives (chair and lay member), Chief Executive, Registrar, Chief Strategic Advisor, Māori Principal Advisor and other key staff demonstrated their understanding of the importance to protect public safety.</p> <p>The <i>Strategic Plan 2019 and Beyond</i> outlines the strategic intent and objectives for the Pharmacy Council. This includes its two core objectives, to minimise harm to the public, and to maximise competency of pharmacists.</p>	FA			
9.2	<ul style="list-style-type: none"> Provides clear, accurate, and publicly accessible information about its purpose, functions and core regulatory processes 	<p>The Council provides public information as follows:</p> <ul style="list-style-type: none"> comprehensive website – recently redeveloped and structured around three audiences: public, potential pharmacists and registered pharmacists. 	FA			

Function 9: Section 118I) To promote public awareness of the responsibilities of the authority.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<ul style="list-style-type: none"> Newsletters – 5 times a year, directly following Board meetings, mostly for Pharmacists but also sent to relevant media, relevant Ministry of Health staff and relevant member organisations Other information with respect to the professions such as; MyRecert email reminders, Emailed alerts, Webinars, and Consultation material. Professional Organisations conferences – presenting and participating in a number. <p>Based on some contracted work with a specialist engagement and communications company (i.e. Henley Hutchings), there appears variable understanding of the Council's role. The Pharmacy Council is conscious that while its purpose is to serve the public, relatively little effort has been undertaken to engage the public. Overall, feedback suggests the need for Council to reconsider what and how it can more effectively engage and communicate with the public and stakeholders – especially in regard to enabling work which is more co-design and mahi tahi in nature.</p> <p>Specialist advice on engagement, communication, Tikanga and Kaupapa Māori approaches from Henley Hutchings and Maru Consulting has been sought. Work is underway to develop an effective</p>				

Function 9: Section 118I) To promote public awareness of the responsibilities of the authority.						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		<p>engagement plan for implementation and operationalisation.</p> <p>Also, with respect to registrations processes, Council has identified two areas where improved communication would be beneficial.</p> <ul style="list-style-type: none"> • There appears a lack of knowledge around the Council's public register, so Council is making additional efforts to ensure that practitioners, employers, and the public are fully aware that the online register is i) available ii) the definitive source of registration information (as opposed to physical or electronic copies of a practising certificate). • Despite requirements being posted on the website, Council team members regularly field enquiries around return to practice requirements. This suggests that practitioners are not always aware of the requirements or the implications when changing practising status. <p>The Council is undertaking a process to review its communication strategy to ensure that this information is more well known amongst practitioners and/or the public.</p>				

Function 10: Section 118m) To exercise and perform any other functions, powers, and duties that are conferred or imposed on it by or under this Act or any other enactment						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
10.1	<p>The RA:</p> <ul style="list-style-type: none"> Ensures that the principles of equity and of te Tiriti o Waitangi/ the Treaty of Waitangi (as articulated in Whakamaua: Māori Health Action Plan 2020-2025) are followed in the implementation of all its functions 	<p>The Council's weaving of core principles of equity and Te Tiriti across regulatory tools, strategy, governance, organisational values and culture and operations has occurred over a number of years.</p> <p>While the Council has made good progress, it is aware of the need to do more.</p> <p>To this end, the improvement of health equity and cultural safety (embedded within a refresh of regulatory tools) has been prioritised for improvement for 2021/2022 alongside the recruitment of a specific health equity and cultural safety lead to bolster the Council's capability and capacity.</p>	PA	L	To complete the recruitment of a specific health equity and cultural safety lead and continue the journey for improvement of health equity and cultural safety (embedded within a refresh of regulatory tools).	6 months (up to 31 May 2022) and ongoing
10.2	<ul style="list-style-type: none"> Ensure the principles of Right-touch regulation are followed in the implementation of all its functions 	<p>The six principles of right-touch regulation are proportionate, consistent, targeted, transparent, accountable, and agile.</p> <p>The Council demonstrates these principles through its policies, processes, systems, consultations, plans, strategic direction and how it works with the profession and stakeholders.</p> <p>The <i>Strategic Plan 2019 and Beyond</i> is not limited to a period of 5 years. The strategies essentially require: to understand what is happening from a risk of harm and competency perspective;</p>	FA			

Function 10: Section 118m) To exercise and perform any other functions, powers, and duties that are conferred or imposed on it by or under this Act or any other enactment						
Ref #	Related core performance standards	Reviewer's comments	Rating (FA/PA/UA)	Risk Level if PA /UA (L, L-M, M, H)	Recommendation	Timeframe (months / date)
		develop and maintain proactive regulatory tools; develop and maintain the reactive regulatory tools; and to sustain capacity and capability to be a successful regulator. It is used to guide the Council's annual work programme and key projects.				
10.3	<ul style="list-style-type: none"> Identifies and addresses emerging areas of risk and prioritises any areas of public safety concern 	<p>There is a risk management map dated Sept 2021 that is reviewed quarterly by Council governance. It includes a heat map, risk status, controls and evaluation matrix.</p> <p>The Pharmacy Council has several mechanisms by which emerging areas of risk and harm are identified, analysed and synthesised, which includes but is not limited to:</p> <ul style="list-style-type: none"> Complaints and notifications received External reports by other agencies (e.g. ACC Treatment injuries, HQSC, HDC) In-house and commissioned environmental reports Regular engagement with various key stakeholders <p>A synthesis of findings from the sources above are used to identify and monitoring emerging areas of risks. Once identified, appropriate and responsive actions are taken. For example, Medsafe's Pharmacy</p>	FA			

Function 10: Section 118m) To exercise and perform any other functions, powers, and duties that are conferred or imposed on it by or under this Act or any other enactment						
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		Quality Audit results suggest areas of risk. Another example is variations of care and likelihood of systemic racism leading to health inequities. This was subsequently identified and prioritised for improvement as part of the FY21/22 work plan programme under clinical governance and quality improvement and health equity and cultural safety programmes of work.				
10.4	<ul style="list-style-type: none"> Consults and works effectively with all relevant stakeholders across all its functions to identify and manage risk to the public in respect of its practitioners 	<p>The Council consults with the profession on key changes such as the relevancy of competency standards for the pharmacist scope of practice.</p> <p>Established relationships with Medsafe, Ministry, HDC, other RAs and is strengthening ties with PHARMAC, ACC, HQSC, and DHBs.</p> <p>The Council works closely with Medicines Control, the regulator of pharmacies, and a Memorandum of Understanding for sharing information supports the management of risks associated with pharmacies and pharmacists.</p> <p>The key aim is to protect the public.</p>	FA			
10.5	<ul style="list-style-type: none"> Consistently fulfils all other duties that are imposed on it under the HPCA Act or any other enactment 	<p>The Council has governance meetings five times a year which are held over two days. There is a Finance Assurance and Risk Management Committee (FARMC) that is</p>	FA			

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		<p>moving to meeting four times a year from meeting five times a year.</p> <p>The annual report is published on the web-site each year. It provides information about the strategic plan / priorities, functions, scope and standards, assurance of qualifications / competence, Registration, complaints, and discipline and financial performance.</p> <p>New Council members complete an induction and receive a comprehensive orientation based on the Handbook for Pharmacy Council (Governance) Members.</p> <p>Other duties also include:</p> <ul style="list-style-type: none"> • Publication of a demographic report for the benefit of profession development. • Administration of COVID-19 Pharmacy Teams Relief Fund and issuing emergency practising certificates to support Aotearoa NZ's pandemic response, recovery and vaccine roll-out efforts. <p>The Council identifies that it fulfils its obligations as an employer and as a public, administrative and regulatory body.</p> <p>Opportunity for Improvement</p> <p>This performance review identified a need to update references to privacy legislation in identified polices to refer to the Privacy</p>				

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		Act 2020 and continue to implement an ongoing and timely policy and SOP review process.				