

Regulation of Physician Assistants under the *Regulated Health Professions Act (RHPA), 1991*

Application Guide

Health Professions Regulatory Advisory Council
(HPRAC)



Ontario

Health Professions Regulatory
Advisory Council

Conseil consultatif de
réglementation des professions
de la santé

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1. About the Health Professions Regulatory Advisory Council (HPRAC)

The Health Professions Regulatory Advisory Council (HPRAC) is established under *the Regulated Health Professions Act, 1991 (RHPA)*, with a statutory duty to advise the Minister on health professions regulatory matters in Ontario. This includes providing advice to the Minister on:

- Whether unregulated health professions should be regulated;
- Whether regulated health professions should no longer be regulated;
- Amendments to the *Regulated Health Professions Act (RHPA)*;
- Amendments to a health profession's Act or a regulation under any of those Acts;
- Matters concerning the quality assurance programs and patient relations programs undertaken by health colleges; and,
- Any matter the Minister refers to HPRAC relating to the regulation of the health professions.

The Minister of Health and Long-Term Care relies on recommendations from HPRAC as an independent source of evidence-informed advice in the formulation of policy in relation to health professional regulation in Ontario. In providing its advice and preparing its recommendations, HPRAC is independent of the Minister of Health and Long-Term Care, the Ministry of Health and Long-Term Care, the regulated health colleges, regulated health professional and provider associations, and stakeholders who have an interest in issues on which it provides advice. This ensures that HPRAC is free from constraining alliances and conflict of interest, and is able to carry out its activities in a fair and unbiased manner.

When considering health professions regulatory matters, HPRAC ascribes to the following overriding principles:¹

- Meeting public expectations for improved access to high quality and safe care;
- Supporting inter-professional care and optimizing the contribution of all health professionals;
- Applying standards for the regulation of health professionals;
- Ensuring a shared accountability agenda that encourages and values collaboration and trust;
- Using resources efficiently;
- Sustaining the health care system; and,
- Maintaining self-regulation.

HPRAC presents its recommendations in a report to the Minister of Health and Long-Term Care for consideration. This report is confidential until released by the Minister. As per the *RHPA*, HPRAC recommendations are advisory only. The minister is not bound to accept HPRAC's advice. The release of an HPRAC report and any follow-up action are at the discretion of the Minister. Should the minister choose to accept HPRAC's advice, the Ministry of Health and Long-Term Care is responsible for implementation based on the direction of the government.

Please visit www.hprac.org for more information about the HPRAC's mandate and role.

¹ Health Professions Regulatory Advisory Council. (2008). *Critical links: transforming and supporting patient care*. Toronto: Author. pp. 2-3.

2. Purpose of the Guide

HPRAC will assess applications from unregulated health professions to determine whether to recommend them for regulation under the *RHPA* only if the Minister of Health and Long-Term Care directs the Advisory Council do so. HPRAC also wishes to remind interested parties that the purpose of regulation under the *RHPA* is to protect the public. The purpose of this document is to provide guidance for interested parties on the criteria that HPRAC will apply in deciding whether to recommend to the Minister of Health and Long-Term Care that a currently unregulated health profession should be regulated under the *RHPA*. This document sets out the requirements that the Advisory Council makes of applicant professions seeking regulation under the *RHPA*, and in doing so, gives an indication of the issues with which the Advisory Council is concerned.

3. The Application of the Criteria

The following guidelines are intended to assist a profession in compiling its application. A new profession requesting regulation under the *RHPA* will be assessed according to the following methodology. HPRAC will use a two part assessment as the means by which it will decide whether to recommend a health profession for regulation. In the first part of the assessment (primary criterion), HPRAC will determine whether the applicant meets the 'risk of harm threshold' to be considered for regulation under the *RHPA*. This part is designed to ensure that the assessment retains a focus on 'risk of harm'. In the second part (secondary criteria), HPRAC will determine whether it should recommend regulating a profession that it has determined to be posing a risk of harm to the public. The secondary criteria also aim to assist in determining whether an application meets the overriding principles outlined in p. 1.

All proposals for regulating new professions under the *RHPA* will be assessed against the following criteria. Please note that, as per the *RHPA*, HPRAC will assess a profession's suitability for regulation only on the request of the Minister of Health and Long-Term Care. In determining whether the primary and secondary criteria have been met, HPRAC relies on relevant, verifiable evidence from applicants.² As such, it is incumbent upon the applicant to present such evidence related to both the primary and secondary criteria outlined below. The HPRAC criteria for regulating a new profession will be continuously updated to keep pace with the evolving health professions regulatory and health system landscape in Ontario.

Primary Criterion:

The primary criterion assesses whether the health profession seeking regulation under the *RHPA* poses a risk of harm to the health and safety of the public, and it is otherwise in the public interest that the particular profession be regulated under the *RHPA*. The applicant must demonstrate with evidence that there is a risk of harm to the public. As such, applicants from new professions seeking regulation under the *RHPA* must meet the risk of harm threshold. In order to meet the risk of harm threshold, the applicants must meet *all* three conditions below and demonstrate with relevant, verifiable evidence that:

² Please see Appendix A for a description of evidence. 'Relevant evidence' in this context means information that is able to make the existence of any fact that is of consequence to the determination of decision or outcome more probable or less probable than it would be without the evidence.

- the profession is involved in duties, procedures, interventions and/or activities with the significant potential for physical or mental harm to patients/clients, including instances where the profession delivers services under direct or indirect supervision by another regulated or unregulated health professional;
- the profession is engaged in making decisions or judgment that can have a significant impact on patients'/clients' physical or mental health, including instances where the profession delivers services under direct or indirect supervision by another regulated or unregulated health professional; and,
- there is a significant potential of risk of harm occurring within the professional duties and activities.

Applicants that meet the primary criterion with relevant, verifiable evidence will then be assessed on the extent to which they meet the secondary criteria.

Secondary Criteria:

Once the primary criteria are met with relevant, verifiable evidence, HPRAC will apply the secondary criteria to measure the appropriateness of regulation under the *RHPA*. The secondary criteria:

- have equal weight;
- focus on the profession specific factors and assess whether regulation under the *RHPA* is, in fact, the most appropriate and effective means to protect the public.;
- provide applicants with an understanding of where the requirements for statutory regulation lie, and in doing so, give an indication of the issues with which HPRAC is concerned;
- are intended to identify other salient factors that need to be addressed to ascertain whether regulation under the *RHPA* is in the public interest; and,
- are not intended to provide a barrier for a profession that meets the primary criteria to prevent regulation under the *RHPA*.

HPRAC may not necessarily decide to recommend against regulation of a profession if its application does not satisfy all the secondary criteria. However, HPRAC strongly recommends that applicants make every effort to provide all relevant evidence to support their applications to allow the Advisory Council to make evidence-informed decisions.

4. The Criteria for Regulating a New Profession under the *RHPA*

To determine whether a health profession should be regulated under the *RHPA*, HPRAC will apply the primary and secondary criteria outlined below. The primary criterion must be met in order to be considered for regulation under the *RHPA*. If the applicant meets the primary criteria, it will then be assessed on the extent to which it meets the secondary criteria. The secondary criteria will each have equal weight. The secondary criteria have been organized by the following themes: professional autonomy; competency and scope of practice; mechanisms of regulation and economic impact; and health system impact.

The applicable questions for each criterion can be found in the accompanying application.

Primary Criterion

Risk of Harm

The fundamental principle with respect to health professional regulation under the *RHPA* is the protection of the public from harm in the delivery of health care, premised on the fact that it is in the public interest to do so. As such, it is vital to demonstrate that the health profession seeking regulation under the *RHPA* poses a risk of harm to the health and safety of the public. The term risk of harm refers to actions where a substantial risk of physical or mental harm may result from the practice of the profession.³ This criterion is intended to provide a clear articulation of the degree of harm posed by the profession to the health and safety of the public. In addressing the risk of harm in this context, the applicant is asked to identify the risks associated with the practice of the profession concerned, as distinct from risks inherent in the area of health care within which the profession operates.

³ The harm clause in the *RHPA* prohibits an individual from treating or advising someone about his/her health in circumstances in which it is reasonable to assume that serious bodily harm may cause. The purpose is to capture dangerous actions that may not be specifically prohibited by the controlled acts, particularly to capture unforeseeable risky activities. Referring to the 2006 HPRAC report entitled "Regulation of Health Professions in Ontario: New Directions" at pp. 55-56, citing *R. v. McCraw*, [1990] 3S.C.R. 72, Steinecke notes that the word "bodily" replaces the word "physical" in order to capture mental harm," see Steinecke, R. (2010). *A complete guide to the RHPA*. Aurora: Canada Law Book, 11:20.30

Secondary Criteria

Criterion: Professional Autonomy

The central element of professional autonomy is the assurance that individual professionals have the freedom to exercise their professional judgment in the care and treatment of their patients. This criterion is intended to assess the degree to which the profession is able to exercise professional judgement autonomously in the delivery of care.

Criterion: Educational Requirements for Entry to Practice

The applicant is asked to demonstrate whether the profession has defined the educational routes to the profession. The route can begin with completion of studies at an independently accredited educational institution or a post-secondary program offered by a recognized educational institution. These institutions will prepare candidates to meet externally validated entry qualifications. This criterion is intended to assess whether the profession possesses skills and competencies necessary to deliver safe and competent care on entry.

Criterion: Body of Knowledge and Scope of Practice

This criterion assumes an intersection between body of knowledge and scope of practice. The body of knowledge refers to the extent to which practitioners must call upon a distinct set of concepts, terms and activities in the practice of the profession (i.e., what the profession does and how the profession practices). The scope of practice refers to the rules, regulations, and boundaries within which a qualified health professional with appropriate training, knowledge, and experience may practice in an area of health care. This criterion is intended to assess whether there is a body of knowledge that can offer the basis for the profession's scope of practice.

Criterion: Economic Impact of Regulation

The applicant must demonstrate an understanding and appreciation of the cost of regulation on the profession, the public and the health care system. The costs and benefits of the preferred regulatory mechanism must be outlined. The applicant is required to show that the practitioners of the profession are able to support the full costs and responsibilities of regulation. This criterion intends to assess the sustainability and viability of regulating the profession concerned under the *RHPA*.

Criterion: Regulatory Mechanisms

The applicant is asked to demonstrate that regulation under the *RHPA* is the most appropriate means to regulate the profession. The applicant is asked to explore potential statutory and non-statutory regulatory regimes which could be appropriate and merit consideration. In other words, the applicant is required to demonstrate why it prefers a particular type of regulatory mechanism over others. This criterion is intended to provide information to ascertain the most appropriate way to regulate the health profession concerned.

Criterion: Leadership's Ability to Favour the Public Interest and Membership Support and Willingness of the Profession to be regulated

The applicant must demonstrate that the profession's leadership has shown it will distinguish between the public interest and the profession's self-interest. Regulatory colleges are mandated to privilege the former over the latter. In addition, the applicant must also demonstrate that the members of the profession support regulation with sufficient numbers and commitment, such that widespread compliance with regulation is likely. Members of a profession requesting regulation must also recognize that regulation will cost them money, time and effort. The applicant is asked to show that the practitioners of the profession are sufficiently numerous to support and fund, on an ongoing basis, the requisite number of competent personnel to enable the regulatory body to continue to discharge its functions effectively. This criterion intends to assess whether the leaders and members are able and committed to support the public interest mandate of regulation.

Criterion: Health System Impact

The applicant is asked to demonstrate the extent to which the regulation of the profession concerned would produce positive health system impacts in relation to inter-professional collaboration, labor mobility, access to care, health outcomes, and productivity. This criterion is intended to assess the overall impact of regulating the profession to the broader health care system in Ontario.

a. Inter-professional Collaboration: Inter-professional collaboration in health care is now considered a high priority, as concerns about patient safety, health and human resources shortages, and effective and efficient care have reached significance. The applicant is asked to demonstrate the profession's willingness and capacity to effectively collaborate with other professions in a client-centered model of care. This criterion attempts to assess to what degree the regulation of the profession concerned would support and sustain the collaborative delivery of health care.

b. Labour Mobility: The effect of national labour mobility legislation on regulated health professions includes freer movement of care providers between Canadian jurisdictions. Given possible implications for mobility stemming from regulation, the applicant is asked to demonstrate an appreciation for the risks and benefits of increased labour mobility, and provide evidence of strategies to handle any challenges and opportunities. This criterion attempts to assess the impact of regulation on the Labour mobility in the health sector and supply and demand of practitioners concerned.

c. Access to Care: Given the importance of access to care in eliminating health disparities as well as facilitating the prevention of disease and the promotion of health, the applicant is asked to demonstrate how regulation will increase access to safe, high quality and efficient health care in Ontario. This criterion attempts to assess how the regulation of the profession concerned would impact existing health care needs of Ontarians.

d. Health Human Resource Productivity:⁴ The profession is asked to demonstrate how regulation will improve health outcomes (health status protection or improvement for individuals or populations) relative to required health human resource inputs (time, effort, skills and knowledge). This criterion aims to assess whether the regulation of the profession concerned would have an influence on the issues of productivity and health human resources.

⁴ Productivity is defined as the output per unit of input; it is a function of how quickly and how well we do things. Most experts talk about productivity in terms of labour productivity – the quantity of output per unit of time. This is a particularly relevant metric in health care since approximately 70 percent of the cost of health care is attributable to labour or health human resources, Centre for Productivity and Health Human Resources (2009), Retrieved from: http://www.cprn.org/documents/51766_EN.pdf.

e. Health Outcomes: This term refers to the impact healthcare activities of the profession concerned have on people. Health outcomes normally fall within one of three domains: clinical, psychosocial and quality of life. The profession is asked to demonstrate how regulation will improve health outcomes. This criterion aims to assess health outcomes which may be attributable to interventions of the profession concerned.

5. The Recommendation-Making Process

1. The Minister may request that HPRAC undertake a review of a health profession seeking regulation and/or other health professions regulatory matters, and make recommendations. As per the *RHPA*, HPRAC undertakes reviews only on the Minister's request.
2. Following receipt of the Minister's referral, the Advisory Council may arrange a meeting with the applicant(s) to discuss the timeframe and other process management issues.
3. If similar or related professions are involved in consideration of a referral, responses to the proposal may be considered jointly by the Advisory Council. Applicants will be informed, to the extent possible, should HPRAC intend to combine projects where there is an overlap in issues to be considered.
4. HPRAC will provide the applicant(s) with: (1) a package that includes questions and guidelines to aid the development of proposal; (2) research conducted by the Advisory Council (e.g., literature, jurisdictional and jurisprudence reviews); (3) timelines; and, (4) other relevant material.
5. These materials will also be posted on the Advisory Council's website at www.hprac.org.
6. Upon receipt of the proposal from the applicant, HPRAC will notify stakeholders (e.g., the public, health professionals, health professional associations, health professions regulatory colleges, etc.) that the applicant's response to the questionnaire has been posted on the HPRAC website for stakeholder feedback.
7. Following notice, stakeholders interested in the review may participate in the feedback process. Notice of opportunities for stakeholder participation in the Advisory Council's review of a matter will be communicated via the Advisory Council's website at www.hprac.org and other media. Stakeholders are encouraged to visit the HPRAC website for regular updates concerning the specific referral, or follow HPRAC on Twitter at <http://Twitter.com/HPRACOntario> to obtain updates and notifications.
8. The purpose of the feedback process is to obtain comments on the proposal for regulating a profession and/or other regulatory matters referred to HPRAC by the Minister. HPRAC will provide questions, guidelines and timelines to aid the feedback process. Stakeholder responses may contain information, with citations and evidence where applicable, that they consider relevant to the question(s) under consideration.
9. The stakeholder feedback can be provided via the HPRAC on-line consultation platform, e-mail, fax or mail. To ensure transparency and encourage open dialogue, the feedback HPRAC receives will be posted on the HPRAC website (please see the section on access to information for guidelines).

10. If required, HPRAC may consult with experts as well as hold focus groups or meetings to obtain information it deems necessary to complete the review of the Minister's referral. Persons or organizations with identified expertise may be invited, at the discretion of the Advisory Council, to make presentations, reports or submissions to the Council. Summaries of these sessions may be posted on HPRAC website (please see the section on access to information for guidelines).
11. HPRAC will conduct all its consultations in both official languages. In some cases, advance notice of the need for French language services may be required.
12. At the conclusion of the recommendation-making process, HPRAC will submit a report containing its recommendations to the Minister for consideration. This report is confidential until released by the Minister. As per the *RHPA*, HPRAC recommendations are advisory only. The Minister is not bound to accept HPRAC's advice. The release of an HPRAC report and any follow-up action are at the discretion of the Minister. Should the minister choose to accept HPRAC's advice, the Ministry of Health and Long-Term Care is responsible for implementation based on the direction of the government.

6. Access to Information

Comments submitted will be considered by the Health Professional Regulatory Advisory Council (Advisory Council) and will help it to determine appropriate recommendations to make to the Minister. To ensure transparency and encourage open dialogue, the feedback received by the Advisory Council may be posted on our website in accordance with our Privacy Statement, available at www.hprac.org/en/privacy.asp.

Please note that unless requested and otherwise agreed to by the Advisory Council, any information or comments received from organizations will be considered public information and may be used and disclosed by the Advisory Council. The Advisory Council may disclose materials or comments, or summaries of them, to other interested parties (during and after the consultation period). An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization.

The Advisory Council will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent unless required to do so by law. However, the Advisory Council may use and disclose the content of the individual's submission to assist it in fulfilling its statutory mandate.

The Advisory Council reserves the right to refuse to post a submission, in whole or in part, that, in its sole discretion: is unrelated to the issue under consultation, or, is abusive, obscene, harassing, threatening or includes defamatory comments. If you have any questions about the collection of this information, you can contact the Advisory Council at 416-326-1550.

Appendix A: What is Evidence?

“Evidence concerns facts (actual or asserted) intended for use in support of a conclusion”⁵

Types of evidence that inform the policy process can be grouped as research, knowledge/information and economics (see Table 1). Evidence is usually sought to show effectiveness, the need for policy action, guide effective implementation and/or show cost effectiveness (feasibility).⁶ The table below is designed to act as a guide for the proponent, as to what constitutes appropriate evidence for their proposal for regulation. The type of evidence required will differ based on which criteria the proposal is addressing.

Table 1: Types of Evidence⁷

Types of Evidence	Examples*
Research	Empirical evidence from randomized control trials (1) and other trials
	Analytic studies such as cohort (2) or case control studies (3)
	Time series analyses (4)
	Anecdotal (5)
	Qualitative studies (6)
	Before and after studies (7)
	Surveys (8)
Knowledge and information	Results of consultation processes with networks/groups
	Expert knowledge (9)
	Grey Literature (10)
Economics	Financial Sustainability (11)

* See notes for definitions and further details.

Notes:

(1) Randomised control trials:⁸ Randomised controlled trials are the most rigorous way of determining whether a cause-effect relation exists between treatment and outcome and for assessing the cost effectiveness of a treatment.

They have several important features:

- Random allocation to intervention groups
- Patients and trialists should remain unaware of which treatment was given until the study is completed- although such double blind studies are not always feasible or appropriate

⁵ Oxman, A.D., Lavis, J.N., Lewin, S. and Fretheim (2009). A SUPPORT Tools for evidence-informed health policymaking (STP) 1: What is evidence-informed policymaking? *Health Research Policy and Systems* 7(Suppl 1):S1. Retrieved from: <http://www.health-policy-systems.com/content/pdf/1478-4505-7-S1-s1.pdf>

⁶ Bowen S, Zwi AB (2005) Pathways to “evidence-informed” policy and practice: A framework for action. *PLoS Med* 2(7): e166. Retrieved from: <http://www.who.int/rpc/evipnet/Pathways%20to%20Evidence-Informed%20Policy%20and%20Practice%20a%20framework%20for%20action.pdf>

⁷ Ibid.

⁸ Sibbald, B., Roland. M. Understanding controlled trials: Why are randomized controlled trials important? *British Medical Journal (BMJ)*, 316 : 201. Retrieved from: <http://www.bmj.com/content/316/7126/201.full>

- All intervention groups are treated identically except for the experimental treatment
- Patients are normally analyzed within the group to which they were allocated, irrespective of whether they experienced the intended intervention (intention to treat analysis)
- The analysis is focused on estimating the size of the difference in predefined outcomes between intervention groups.

(2) Cohort Study:⁹ This study identifies a group of people and follows them over a period of time to see how their exposures affect their outcomes. This type of study is normally used to look at the effect of suspected risk factors that cannot be controlled experimentally, for example the effect of smoking on lung cancer.

(3) Case Control Study:¹⁰ A case-control study is an epidemiological study (epidemiology is the study of factors that affect the health and illness of populations) that is often used to identify risk factors for a medical condition. This type of study compares a group of patients who have that condition with a group of patients that do not have it, and looks back in time to see how the characteristics of the two groups differ.

(4) Time Series Analysis:¹¹ A time series is a collection of observations of well-defined data items obtained through repeated measurements over time. For example, measuring the value of retail sales each month of the year would comprise a time series. Data collected irregularly or only once are not time series. An observed time series can be decomposed into three components: the trend (long term direction), the seasonal (systematic, calendar related movements) and the irregular (unsystematic, short term fluctuations).

(5) Anecdotal: This may include observations, experiences etc, which are non-scientific in nature.

(6) Qualitative Studies:¹² Qualitative research uses individual in-depth interviews, focus groups or questionnaires to collect, analyse and interpret data on what people do and say. It reports on the meanings, concepts, definitions, characteristics, metaphors, symbols and descriptions of things. It is more subjective than quantitative research and is often exploratory and open-ended.

(7) Before and After Study:¹³ A before and after study measures particular characteristics of a population or group of individuals at the end of an event or intervention and compares them with those characteristics before the event or intervention. The study gauges the effects of the event or intervention.

(8). Surveys:¹⁴ Survey research is one of the most important areas of measurement in applied social research. The broad area of survey research encompasses any measurement procedures that involve asking questions of respondents. A survey can be anything from a short paper-and-pencil feedback form to an intensive one-on-one in-depth interview.

(9) Expert Knowledge: Expert knowledge will be acquired through key informant interviews.

(10) Grey literature¹⁵ is defined as: "Information produced on all levels of government, academia, business and industry in electronic and print formats not controlled by commercial publishing i.e. *where publishing is not the primary activity of the producing body.*" (ICGL Luxembourg definition, 1997 - Expanded in New York, 2004).

⁹ National Health Service (NHS), Retrieved from: <http://www.nhs.uk/news/Pages/Newsglossary.aspx>

¹⁰ Ibid

¹¹ Australian Bureau of Statistics (2008) Retrieved from:

<http://www.abs.gov.au/websitedbs/d3310114.nsf/4a256353001af3ed4b2562bb00121564/b81ecff00cd36415ca256ce10017de2f!OpenDocument>

¹² Supra, see note 5

¹³ Supra, see note 5

¹⁴ Colorado State University, Retrieved from: <http://writing.colostate.edu/guides/research/survey/>

¹⁵ University of British Columbia Library (2011). Retrieved from: <http://toby.library.ubc.ca/subjects/subjpage2.cfm?id=878>

Grey literature (also known as gray literature or greylit) is not published commercially or indexed by major databases. While some greylit may be of questionable quality, it can nonetheless have an impact on research, teaching and learning. Greylit may sometimes be the only source for specific research questions. Although some grey literature research is published eventually, in many cases it is not. Since greylit is often not subject to peer review, it must therefore be scrutinized accordingly. Some examples of grey literature include:

- Theses and dissertations
- Conference proceedings and abstracts
- Newsletters
- Research reports (completed and uncompleted)
- Published *documents/reports* (including policy evaluations and statistical analyses)
- Technical specifications, standards, and annual reports

(11) Financial Sustainability: In order to demonstrate financial sustainability, a business plan is required. A business plan allows a business to look ahead, allocate resources and prepare for problems and opportunities. A vital part of the business plan is a projected budget template. A budget template should include projected profit and loss, costs (salaries, legal costs, rent, etc), cash flow etc.



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