

REQUIREMENTS FOR PERSONNEL CERTIFICATION BODIES (PROVISIONAL APPROVAL)

Voluntary Certification Scheme for Traditional Community Healthcare Providers (VCSTCHP)

0. INTRODUCTION:

- 0.1 The Personnel Certification Bodies (PrCBs), in order to operate under the **Voluntary Certification Scheme for Traditional Community Healthcare Providers (VCSTHCPs)**, hereinafter referred to as the Scheme, shall need to primarily comply with the requirements specified in ISO 17024 and the additional requirements prescribed by QCI-FRLHT, as the Scheme owners.
- 0.2 The PrCBs would not get an applicant and would not be able to offer their process for witnessing as part of accreditation process to the accreditation body to get accreditation or to get the relevant scope added in their accreditation, if already accredited, unless they are approved under the Scheme.
- 0.3 Further, in order to launch the Scheme, it is necessary that some PrCBs are available at the beginning.
- 0.4 Therefore, it is necessary to establish a procedure for provisional approval of PrCBs under the Scheme till such time they can get the scope added in their accreditation or get formally accredited from the **National Accreditation Board for Certification Bodies (NABCB)** and approved by the Scheme owners.
- 0.5 This document sets out the requirements to be fulfilled by PrCBs desirous of operating under the Scheme pending formal accreditation and approval.

1. SCOPE

- 1.1 This document defines the process for Personnel Certification Bodies (PrCBs) to obtain provisional approval to operate under the Voluntary Certification Scheme for Traditional Community Healthcare Providers pending formal accreditation for the Scheme by NABCB as per the prescribed international standard(s).
- 1.2 This approval shall be valid for a period of three years within which the approved PrCBs would have to obtain formal NABCB accreditation.

2. CRITERIA FOR APPROVAL

The PrCBs desirous of Traditional Community Healthcare Providers Certification under this Scheme shall meet the criteria as prescribed in clauses 3 and 4 of this document.

3. ADMINISTRATIVE REQUIREMENTS

- 3.1 **Legal entity:** The PrCB shall be a legal entity in the economy in which it is located, or shall be a defined part of a legal entity, such that it can be held legally responsible for all its Certification activities. A governmental certification body is deemed to be a legal entity on the basis of its governmental status. A PrCB, that is part of an organization involved in functions other than certification, shall be separate and identifiable within that organization.
- 3.2 **Organizational structure:** The PrCB shall define and document the duties, responsibilities and reporting structure of its personnel and any committee and its place within the organization. When the certification body is a defined part of a legal entity, documentation of the organizational structure shall include the line of authority and the relationship to other parts within the same legal entity.

3.3 **Integrity:** The PrCB and its personnel shall maintain integrity at all times. The PrCB shall implement adequate measures to ensure integrity.

3.4 **IMPARTIALITY:**

3.4.1 The PrCB shall be impartial.

3.4.2 The PrCB shall be so structured and managed as to safeguard impartiality.

3.4.3 The PrCB and its staff shall not engage in any activities that may conflict with their impartiality.

3.4.4 The PrCB shall act impartially in relation to its applicants, candidates and certified TCHPs.

3.4.5 The orientation programs undertaken by PrCBs for the TCHPs need to focus to explain the processes that the TCHP is required to abide by as per the scheme requirements.

3.4.6 The PrCB shall have a process to identify, analyze, evaluate, monitor, and document the threats to impartiality arising from its activities including any conflicts arising from its relationships on an ongoing basis.

a) This shall include those threats that may arise from its activities, or from its relationships, or from the relationships of its personnel. Where there are any threats to impartiality, the PrCB shall document and demonstrate how it eliminates or minimizes such threats and document any residual risk. The demonstration shall cover all potential threats that are identified, whether they arise from within the PrCB or from the activities of other persons, bodies or organizations.

b) The PrCB shall not have any relationship with any other body that places the PrCB in a place that affects its impartiality.

c) Top management shall review any residual risk to determine if it is within the level of acceptable risk. When a relationship poses an unacceptable threat to impartiality, then certification shall not be provided.

d) The risk assessment process shall include identification of and consultation with appropriate interested parties to advice on matters affecting impartiality including openness and public perception.

Note 1: Sources of threats to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.

Note 2: One way of fulfilling the consultation with the interested parties is by the use of an impartiality committee.

3.4.7 The PrCB shall not impart education and/or training in traditional community health practices within the same legal entity.

3.4.8 The PrCB shall have a process to eliminate or minimize risk to impartiality if training/education of TCHPs is carried out in a related body which is linked to the PrCB by common ownership etc.

3.4.9 The PrCB shall have a process to ensure that the evaluators is free of any conflict of interest with the applicant(s) by means of being a teacher in the recent past. A separation of 2 years is considered acceptable for the purpose.

3.5 **Confidentiality:** The PrCB shall ensure confidentiality of information obtained in the course of its certification activities by having a suitable system. Information gathered would not be used for any commercial or other purposes other than that to support certification of candidates.

3.6 **Security:** The PrCB shall develop and document policies and procedures to ensure security throughout the certification process.

3.7 **Liability and financing**

3.7.1 The PrCB shall be able to demonstrate that it has evaluated the risks arising from its certification activities and that it has adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its operations in each of its fields of activities and the geographic areas in which it operates.

3.7.2 The PrCB shall evaluate its finances and sources of income and demonstrate that initially, and on an ongoing basis, commercial, financial or other pressures do not compromise its impartiality.

4. **TECHNICAL REQUIREMENTS**

4.1 **Personnel**

4.1.1 The PrCB shall have, as part of its own organization, personnel, either employed or on contract, having sufficient competence for managing process of certification of Traditional Community Healthcare Providers (TCHP).

4.1.2 The PrCB shall have defined processes for selecting, training, and formally authorizing evaluators and for selecting technical experts, if needed, used in this activity.

4.1.3 The PrCB needs to generate and retain such records to demonstrate compliance to 4.1.2.

4.1.4 Evaluators are free to go for certification should they wish to. They shall have to go through the same process as per the Scheme criteria. They can go to the same PrCB where they are empanelled as evaluators but shall not be evaluated by the same TCHPs whom they have evaluated during the earlier certifications.

4.1.5 The TCHP evaluator shall not be from the same district where evaluation is to be conducted.

4.2 **Competence**

4.2.1 The evaluators used by the PrCBs shall have the following qualifications and experience:

a) Experience: Assuming practice is started at 18 years, should have 20 years of experience and be atleast 38 years old, this would mean if someone starts practice later, could be older.

b) Shall be recognized within the community:

- c) Shall be a good communicator
- d) Shall have a good understanding of the Competency Profile.
- e) Shall have a good understanding of the various medicinal plants in that geography and its uses for preventive or curative purposes in humans
- f) Shall be able to apply Standard pre-defined evaluation principles by the Scheme Owners;
- g) Shall be able to apply evaluation accommodations for disability, language, and other special needs;
- h) Shall be able to apply the assessment methods and the type of evidence collected for the specific competency unit(s) assigned;
- i) Shall be able to recognize and distinguish Prior Learning and Current Competency processes;
- j) Shall be able to apply all scoring and reporting processes;
- k) Shall be able to apply the evidence of practice from the community where the TCHP practices and reporting as required;
- l) Shall be able to conduct the Oral Evaluation of candidates for competency as per MSC; and
- m) Shall be able to use active proctoring methods.

4.2.2 The PrCB shall have a process of qualifying the evaluators by a more senior Traditional Community Healthcare Provider. The PrCB shall also define the competence requirements of the senior Traditional Community Health Professional who will qualify the evaluators.

4.2.3 Alternately the PrCBs can draw the TCHP expert from the Peer Evaluation Committee approved by the Scheme owners.

4.2.4 **Personnel records**

The PrCBs shall maintain up-to-date personnel records, as per requirements of the Scheme document, of each of its personnel involved in its certification activities.

4.3 **Certification process**

4.3.1 The PrCB shall manage the process of certifying Traditional Community Healthcare Providers as per the documented 'Certification Process' prescribed under the Scheme.

4.3.2 The PrCB shall maintain records to demonstrate that the certification process is effectively implemented.

4.3.3 The PrCB shall ensure the requirements of the Scheme are met with at any point in time.

4.3.4 The PrCB shall certify Traditional Community Healthcare Providers only under the Scheme and shall use the logo of the Scheme in the certificates issued to the certified Traditional Community Healthcare Providers.

4.3.5 The PrCB shall have written agreement with the certified TCHPs on the use of the certificate issued to them.

4.3.6 The PrCB shall have a process to handle appeals by the candidates against any of its decisions.

4.3.7 The PrCB shall have a process to handle complaints from the TCHPs, the users of the services of the certified TCHPs or any other stake holder.

4.4 **Certification agreement**

The PrCBs shall have a legally enforceable agreement for the provision of certification activities to TCHPs. In addition, the PrCBs shall ensure its certification agreement requires that the TCHPs comply to the specific requirements as prescribed in the relevant scheme document.

4.5 **Responsibility for decision on certification**

4.5.1 The PrCBs shall be responsible for, shall retain authority for, and shall not delegate, its decisions relating to certification, including the granting, maintaining, recertifying, expanding and reducing the scope of the certification, and suspending or withdrawing the certification.

4.6 **Publicly available information**

4.6.1 The PrCB shall maintain a website for providing information about the Scheme and its certification activities under the Scheme.

4.6.2 The PrCB shall maintain and make publicly available information describing its certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and about the certification activities and geographical areas in which it operates.

4.6.3 The PrCB shall make publicly available information about applications registered and certifications granted, suspended or withdrawn.

4.6.4 The PrCB shall make publicly available its processes for handling appeals and complaints.

5. **APPROVAL PROCESS**

5.1 **Application**

5.1.1 Any organization interested in approval as a PrCB for the purpose of the Scheme may apply to QCI in the prescribed application format along with the prescribed application fee. The applicant shall also enclose the required information and documents as specified in the application form.

5.1.2 The filled in application form for approval shall be duly signed by the CEO/authorized representative/s of the organization seeking approval.

5.1.3 On receipt of the application form, it will be scrutinized by the secretariat at QCI and those found complete in all respects will be processed further.

5.2 **Assessment process**

5.2.1 On review of the application for completeness, an assessment team comprising a team leader and member(s)/technical expert(s) will be nominated by QCI for the purpose of assessment at applicant's office and other locations, if required. Under normal circumstances, the assessment at head office will be for a total of two man days.

- 5.2.2 The names of the members of the assessment team along with their CVs will be communicated to the applicant giving it adequate time to raise any objection against the appointment of any of the team members, which will be dealt with by QCI on merits. All assessors/experts nominated by QCI have signed undertakings regarding confidentiality and conflict of interest.
- 5.2.3 If necessary, QCI may decide based on the report of office assessment or otherwise, to undertake witness assessment(s) of actual evaluation or any part of the certification process by the applicant.
- 5.2.4 The assessment team leader shall provide an assessment plan to the applicant in advance of the assessment.
- 5.2.5 The date(s) of assessment shall be mutually agreed to between the applicant and QCI/assessment team.
- 5.2.6 The Office assessment will begin with an opening meeting for explaining the purpose and scope of assessment and the methodology of the assessment. The actual assessment process shall cover review of the documented system of the organization to assess its adequacy in line with the assessment criteria as specified. It will also involve verification of the implementation of the system including scrutiny of the records of evaluators' competence and other relevant records and demonstration of evaluators' competence through means like interviews, etc. In short, it will be an assessment for verifying technical competence of the applicant for operating under the Scheme.
- 5.2.7 At the end of the office assessment, through a formal closing meeting, all the non-conformities and concerns observed in the applicant's system as per the assessment criteria and the assessment team's recommendation to QCI, shall be conveyed to the applicant.
- 5.2.8 Based on the report of assessment, and the action taken by the applicant on the non-conformities/concerns, if any, QCI shall take a decision on granting provisional approval to the applicant as PrCB under the Scheme.

6. Validity of approval

- 6.1 The approval shall be valid for a period of three years.
- 6.2 The PrCB may obtain formal accreditation as per ISO 17024 from NABCB within three years of approval by QCI depending upon the market requirements.
- 6.3 The approval shall be subject to suspension/withdrawal with due notice of 15 days in the event of any non-compliance to the requirements of the Scheme.
- 6.4 The approved PrCB shall inform QCI without delay about any changes relevant to its approval, in any aspect of its status or operation relating to;
 - a) Its legal, commercial, ownership or organizational status,
 - b) The organization, top management and key personnel,
 - c) Main policies, resources, premises and scope of approval, and
 - d) Other such matters that may affect the ability of the PrCB to fulfill requirements for approval

QCI shall examine such information and decide on the issue on merits with or without an on-site verification.

- 6.5 The PrCB shall send data of the candidates certified/rejected immediately within one week after issue of the certificate/conclusion of evaluation to QCI. The data shall be submitted in the specified format for maintaining the registry of the TCHPs.
- 6.6 The PrCB shall undergo surveillance assessment twice in one cycle of their provisional approval.

7. Fee

7.1 The following fee structure shall apply:

The following fee structure is applicable for three years and is subject to revision through appropriate procedure.

- 7.1.1 Application fees: Rs. 20,000
- 7.1.2 Document Review: 2 MDs (@ Rs. 20,000)
- 7.1.3 Office Assessment Fees: 2MDs (@ Rs. 20,000)
- 7.1.4 Report Writing Fees: 1 MD (@Rs. 20,000)
- 7.1.5 Follow up audit: MDs commensurate to NCs recorded (@Rs. 20,000 per MD)
- 7.1.6 Witness Assessment: Commensurate to scope of assessment (@ Rs. 20000 per MD).
- 7.1.7 Certification fees to be charged by QCI at Rs. 500 per certified TCHP client.

- 7.2 QCI at its discretion may revise/ levy any other fee or revise the fees necessary with due notice to the PrCBs.