

Quality Care 2020 Program Rules

The following rules apply to pharmacies undergoing accreditation on or after **Monday 3 October 2022.**

If your accreditation occurs before this date, please refer to the previous QCPP Rules on the QCPP Website.

Accreditation

Rule 1

Accreditation can only be issued if the Program Rules, Terms and Conditions, QCPP Requirements, Policies and AS85000:2017 Quality Care Community Pharmacy Standard (AS85000:2017) (together the Program Materials) are accepted by the pharmacy owner. These materials can be reviewed and accepted at the QCPP website. Alternatively, if you require a paper or electronic copy of these materials please email help@qcpp.com. The pharmacy owner will be granted access to the QCPP customer portal to facilitate QCPP accreditation.

Rule 2

QCPP accreditation of a pharmacy will be conferred or renewed subject to:

- a) demonstration through the assessment process, whether delivered remotely or onsite, that the pharmacy satisfies and maintains compliance with AS85000:2017 and the QCPP Requirements in respect of the pharmacy business;
- b) payment of all fees payable to QCPP under these Program Rules by the due date;
- c) the self-declaration being completed prior to assessment if the assessment is to be delivered remotely;
- d) the pharmacy owner complying with the QCPP Terms and Conditions and these Program Rules and Policies.

Rule 3

The accreditation cycle is for two years commencing from the initial assessment date, unless revoked before the end of that period in accordance with these Program Rules. QCPP accreditation ends at 11:59:00pm Australian Eastern Standard Time (AEST) the day before the second anniversary of the accreditation date.

Rule 4

The accreditation date may be changed:

- a) by agreement between the pharmacy owner and QCPP;
- b) unilaterally by QCPP, giving the pharmacy owner reasonable notice.



The website at <u>www.qcpp.com</u> (Website) and the QCPP Customer Portal, accessible only with secure login details QCPP Customer Portal contain current versions of the Program Materials.

Assessment bookings

Rule 6

Pharmacies requesting to undertake an initial assessment (whether because the pharmacy business has not previously been QCPP accredited or because its QCPP accreditation has expired or been revoked) are required to pay their first Accreditation Invoice prior to booking an assessment. Once this invoice has been paid, the pharmacy will be granted access to the QCPP Customer Portal.

Rule 7

All re-accreditation assessments must occur within the period three calendar months preceding the second anniversary of the accreditation date, unless otherwise agreed between QCPP and the pharmacy owner. An assessment after the re-accreditation date must be requested in writing prior to the second anniversary date, illustrating exceptional circumstances that necessitate the request.

Rule 8

Applications for extension of time will be assessed on their merits and the decision to grant the extension is entirely at the discretion of the QCPP. If any extension of time is given, the QCPP may impose such conditions as it deems appropriate in the circumstances.

QCPP Assessor

Rule 9

The pharmacy will be allocated an approved and independent QCPP assessor by the QCPP assessment services provider, Ernst & Young. A change of assessor can be requested by the pharmacy if a real or perceived conflict of interest can be demonstrated. Any alternate assessor will be allocated through the same allocation process.

Rule 10

The pharmacy will be allocated an assessment date by the assessment services provider. While all reasonable efforts will be made to find a mutually agreeable assessment date, should the pharmacy be unable to accommodate the most cost-effective date proposed by the assessment scheduling team, any additional expenses incurred in assessing the pharmacy will be invoiced to the pharmacy as an 'Additional Assessment Expenses Invoice' expense after the assessment, unless exceptional circumstances can be demonstrated.



If an assessment is cancelled within ten (10) calendar days of the agreed assessment date or the video component of the assessment is cancelled within 2 business days of the video component of the assessment then the full cost of one (1) assessment plus any travel expenses incurred to that point in time, will be invoiced to the pharmacy and a reassessment, where deemed appropriate, may be arranged.

If the video component of the assessment is rescheduled by a pharmacy owner or authorised delegate with less than 2 business days' notice, to an agreed upon time within the assessment period, the pharmacy will be invoiced the applicable rescheduling and/or cancellation fees.

Accreditation assessments

Rule 12

The assessment will be conducted using a compliant/non-compliant methodology.

Rule 13

If a QCPP Requirement is deemed to not be applicable to a particular pharmacy's business operations, it will not be assessed against that pharmacy.

Rule 14

All aspects of the operations of a pharmacy business (including the pharmacy premises) are subject to assessment against AS85000:2017 and the QCPP Requirements. For the avoidance of doubt, a QCPP assessment may include but is not limited to:

- a) all services offered by the pharmacy business;
- b) all products (including product range) offered by the pharmacy business, including online; and
- c) all marketing and promotion activities undertaken by or on behalf of the pharmacy business, including social media and website material.

Rule 15

If a pharmacy declares that a separate business entity is trading in stock or services in an area that is adjoining the pharmacy, for the purposes of seeking and maintaining QCPP accreditation, the pharmacy must ensure:

- a) the separate business provides independent customer access from a common public area;
- b) there is a floor to ceiling wall for at least 50 percent of the common boundary between the pharmacy and the adjoining business;
- c) the remainder of the common boundary is capable of being closed and locked so no access from one business to the other is possible;
- d) the pharmacy and any adjoining entity operate separate point of sale systems;
- e) pharmacy staff are identifiable as being unrelated to any adjoining entity; and



f) stock from any adjoining entity cannot be purchased in any other adjoining entity.

Rule 16

Where all of the above requirements are not met, the space occupied by all adjoining entities will be considered as part of the pharmacy premises and be subjected to the QCPP assessment.

Rule 17

During an assessment an authorised attendee may accompany the assessor. The role of the authorised attendee is to observe and/or validate the assessment approach used by the assessor. Any costs associated with attendance of the authorised attendee will be borne by QCPP. The pharmacy will receive advance notice that there will be an additional attendee attending their pharmacy assessment.

Rule 18

The QCPP Requirements define the evidence required to be provided at the time of assessment. The assessor must be able to sight the specified evidence during the assessment.

Rule 19

In some circumstances, the assessor will require evidence which may contain commercial in confidence or personal information. Assessors are required to satisfy themselves that any evidence provided is a genuine document, however a detailed investigation of the data contained within it is not required. Pharmacies may choose to mask commercial in confidence and must redact personal information from evidence provided for review in an assessment in circumstances where that information is not relevant to the assessment.

Rule 20

Access to Program Materials is mandatory and they must be demonstrably accessible to all staff at each assessment.

Rule 21

The outcome of any previous assessment(s), sanction(s) or investigation(s) in respect of the pharmacy business (including any related materials such as reports and correspondence relating to the pharmacy business), may be provided to the QCPP endorsed assessor for verification or review for the purposes of any current or future QCPP assessment.

Additional assessments

Rule 22

Once accredited, the pharmacy business may be required to participate in additional mandatory assessments.



A non-accreditation QCPP assessment is referred to throughout this document as an 'Additional Assessment'. All Additional Assessments are conducted by an approved and independent QCPP endorsed assessor.

Rule 24

Additional Assessments may be triggered where:

- a) QCPP imposes a sanction in accordance with rule 44 that requires full or partial reassessment;
- b) QCPP reasonably considers that:
 - i) the pharmacy owner may be in breach of the QCPP Terms and Conditions or these Program Rules;
 - ii) the accredited pharmacy does not comply with AS85000:2017 or any one or more of the QCPP Requirements; or
- c) the pharmacy has changed ownership; or
- d) any other event or circumstances that in the QCPP's reasonable discretion triggers the requirement for an Additional Assessment.

Rule 25

Additional Assessments include the following:

- a) supplementary assessment may consist of either onsite or remote documentation assessment. A maximum of two random assessments may be conducted in any calendar year;
- b) unannounced assessment (without notice); and
- c) Expansion of Services assessment if QCPP is notified, or believes, that the pharmacy business has expanded their service offering which is relevant to their QCPP accreditation.

Rule 26

Expansion of Services Assessment: Where a pharmacy seeks to add additional services to their business model between accreditation assessments, they must apply for an Expansion of Services assessment using the form available on the QCPP Customer Portal. This is an assessment of relevant pharmacy policies and procedures associated with the additional service/s. An Expansion of Services assessment will incur a fee which must be paid prior to any evidence being reviewed. Any Expansion of Services assessment request will be terminated if the invoice is overdue (see rule 37 for payment terms).

Rule 27

Where an accredited pharmacy business is found to have been offering or advertising a service for which it is not QCPP accredited, a sanction may be issued (in accordance with Rule 44).



Corrective Actions

Rule 28

The pharmacy business has 60 days to remediate any Non-Conformances and 90 days from the interim report date to remediate any Remedial Action Required (RAR) (together referred to as Corrective Actions) identified during an assessment. Should additional time be required, an extension must be requested via the QCPP Customer Portal prior to the existing due date, illustrating exceptional circumstances that necessitate the request. These applications will be assessed on their merits and the decision to grant the extension is entirely at the discretion of the QCPP. If any extension of time is given, QCPP may impose such conditions as it deems appropriate in the circumstances.

Rule 29

If Corrective Actions are not completed and verified in the specified timeframe, the pharmacy business will be deemed to have:

- a) not met the requirements of accreditation in the case of an initiating pharmacy; or
- b) not met the requirements for reaccreditation in the case of a currently accredited pharmacy business and their accreditation will lapse.

The pharmacy business is liable for any costs associated with any additional assessment activity required to verify evidence required to address the Corrective Actions.

Rule 30

Evidence provided to address Corrective Actions must be in de-identified format. The authorised assessor will not consider evidence containing identifiable personal information and any evidence received containing personal information will be deleted immediately.

Rule 31

A RAR may be closed at the time of an onsite assessment but will be recorded as an identified Corrective Action in the assessment report, together with the evidence provided to remediate the issue.

Rule 32

A Non-Conformance cannot be closed while the assessor is on site at the assessment and will require the pharmacy business to provide via the QCPP Customer Portal:

- a) a root cause analysis of factors leading to the identified Non-Conformance;
- b) steps taken to ensure the Non-Conformance will not recur, together with any additional evidence identified as required to address the specific issue.

Rule 33

If the same Non-Conformance is identified at two consecutive assessments (whether this be an Accreditation Assessment or an Additional Assessment) this may result in a sanction being issued pending investigation by QCPP. Immediate remediation may also be required.



Revoking or suspending accreditation

Rule 34

The pharmacy owner's QCPP accreditation may be lapsed, revoked or suspended by QCPP if:

- a) The pharmacy owner fails to pay any accreditation fees or other moneys payable to QCPP as they fall due;
- b) The pharmacy owner otherwise fails to comply with any of the QCPP Terms and Conditions or these Program Rules;
- c) The accredited pharmacy does not comply with AS85000:2017 and the QCPP Requirements at any time during the accreditation period; and
- d) The pharmacy owner engages in conduct in connection with the carrying on of the business of a community pharmacy or the practice of pharmacy which in the reasonable opinion of QCPP is likely to bring accredited pharmacies or QCPP into disrepute.

Fees

Rule 35

Fees are payable at the following stages of accreditation and reaccreditation (as applicable to the pharmacy business):

Invoice description	When payable
Administration invoice	A fee to recover administrative costs of QCPP delivering services additional to the onsite assessment. [Rule 44]
Assessment Cancellation	Fee incurred if assessment is cancelled within 10 calendar days of assessment date or failure to complete video component of assessment [Rule 10 and 11]
Assessment Reschedule	Fee incurred if video component is rescheduled within 2 business days of commencement [Rule 11]
Accreditation Invoice	The annual invoice required for maintenance of accreditation. Initial or return to program pharmacies are required to pay this invoice once the QCPP assessment has taken place.
Additional Assessment Expenses Invoice	Will be issued where the pharmacy has not accepted the most cost-effective assessment date or has cancelled an assessment and non-refundable assessment costs had already been incurred. [Rule 10 and 11]
Expansion of Services Invoice	Where a pharmacy requests to have evidence of additional professional services to be assessed out of cycle in order to add those expanded services to their accredited service offering. [Referred to in Rule 26]
Verification of Corrective Action	When an onsite visit of an authorised assessor is required to verify that a Non-Conformance or RAR has been resolved [Referred to in Rule 29(c)]



QCPP invoices are issued on 28-day terms.

Rule 37

Where an invoice is not paid in full by the due date, QCPP may reasonably apply sanctions to lapse or deny the accreditation of a pharmacy.

Rule 38

QCPP is not obliged to provide any assessment services or access to Program Materials where an invoice is outstanding.

Feedback and complaints

Rule 39

QCPP welcomes feedback on any aspect of the pharmacy's experience with QCPP, including complaints, concerns, compliments or suggestions.

Rule 40

Should a pharmacy have concerns about an assessor and/or the assessment process as applied during a specific assessment, a formal complaint detailing the nature of the complaint and resolution sought should be lodged in writing via email to <u>help@qcpp.com</u>, or using the complaint form available on the QCPP Customer Portal. All complaints will be investigated by an appropriate independent party and a written response provided. The pharmacy must support the investigation and provide a timely response to any requests for further information that it receives to allow QCPP to assess the complaint appropriately.

Rule 41

Complaints lodged about an accredited pharmacy will be investigated, providing the details of the complainant are disclosed.

Rule 42

All complaints lodged in relation to a pharmacy meeting accreditation requirements will be investigated by an appropriate independent party and a written response provided. The pharmacy must support the investigation and provide a timely response to any requests for further information that it receives to allow QCPP to assess the complaint appropriately. The details of a complaint or resulting investigation by QCPP, may result in a sanction being issued and be referred to appropriate authorities.

Sanctions

Rule 43

QCPP will investigate breaches of the QCPP Terms and Conditions or these Program Rules, or any failure to meet AS85000:2017 or the QCPP Requirements and apply sanctions



as it deems appropriate in line with the Sanctions Management Policy available on the QCPP website. Sanctions may include:

- a) issuing a warning: The issue(s) will be re-examined at the next routine assessment;
- b) partial or full QCPP re-assessment (as outlined at Rule 25): A partial or full QCPP reassessment of the pharmacy business against AS85000:2017 and the QCPP Requirements and will occur at a nominated time and date within six months of the sanction issue date. The identification of any Corrective Actions at the re-assessment resulting from a sanction will result in the immediate revocation or withdrawal of QCPP accreditation.
- c) unannounced assessment: A partial or full QCPP re-assessment of the pharmacy business against AS85000:2017 and the QCPP Requirements. If any Non-Conformances are identified at an assessment without notice, QCPP may (at its discretion) provide the pharmacy with a period of time to address the Non-Conformance or immediately revoke accreditation. If the pharmacy is provided with time to address any Non-Conformance in these circumstances, no extension of time will be permitted.
- d) Immediate withdrawal of accreditation, with a defined exclusion period from the QCPP accreditation program as deemed appropriate by QCPP.

Rule 44

The pharmacy is liable for all of QCPP's costs and expenses incurred in connection with a sanction, including in respect of undertaking any investigations, reviews and assessments that QCPP deems necessary.

Rule 45

Failure to comply with a sanction within the designated time frame may result in a higher sanction being applied.

Natural justice

Rule 46

Pharmacy owners or other relevant authorised parties who dispute a decision of QCPP have a right to appeal the following decisions in accordance with the Natural Justice Policy:

- a) QCPP assessment outcomes, including Corrective Actions;
- b) revocation or suspension of accreditation; and
- c) outcomes of investigations or assessments, including sanctions.

Rule 47

Any request for a review or an appeal is to be made in writing via the QCPP Customer Portal or to <u>help@qcpp.com</u>.



All appeals will be considered by the relevant authority as outlined in the Appeals Matrix in the Natural Justice Policy. The decision of the QCPP Impartiality Committee is final and no further correspondence will be entered into.

Promoting accreditation

Rule 49

The pharmacy will comply with the requirements associated with the use of the QCPP Brand as detailed in the accompanying Terms and Conditions.

Rule 50

Marketing and/or banner groups may only use the QCPP logo on group branded collateral, both printed and electronic and including webpages, where 100 percent of the pharmacies within the banner group are QCPP accredited. Pharmacies joining the marketing group have a period of six months to become QCPP accredited without affecting the use of the QCPP logo by the banner group as a whole.

Data provision

Rule 51

By registering with QCPP, whether accredited or not, the pharmacy is providing permission for:

- a) information about their accreditation status and the services the accredited pharmacy provides to be provided by QCPP to relevant organisations and bodies for the provision of services and payments to the pharmacy; and
- b) De-identified data relating to assessment, accreditation and registration to be used for statistical analysis and/or advocacy purposes.

General

Rule 52

Headings are inserted for convenience only and do not affect the interpretation of these Program Rules.

Rule 53

Where the context permits, words or expressions that are defined in the Terms and Conditions have the same meaning when used in these Program Rules.



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