



The PHARMACY GUILD of AUSTRALIA
NATIONAL SECRETARIAT

The Pharmacy Guild of Australia

Response to

The Commission on Safety and Quality in Health Care

Consultation Paper: An Alternative Model for Safety and Quality Accreditation of Health Care, July 2007

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Introduction

The Pharmacy Guild of Australia is pleased to submit these comments on the key elements of an alternative model for the Australian accreditation system as proposed in the ACSQHC Consultation Paper.

Context

The Pharmacy Guild of Australia (the Guild) is an employer's organisation registered under the federal Workplace Relations Act. It represents the interests of some 5,000 community pharmacies across Australia.

In 1996, the Guild saw a need to introduce a voluntary system of quality assurance into Australia's community pharmacies and, together with other industry players, developed a quality assurance system known as the Quality Care Pharmacy Program (the QCPP).

The QCPP was rolled out to community pharmacy in 1997. At that stage it consisted mainly of quality assurance standards relating to the supply of pharmacist only medicines, cold chain standards and standards relating to the business of community pharmacy.

The initial take-up of the QCPP by community pharmacies was slow and in 2000, by arrangement with the Commonwealth Government, a system of financial incentives was introduced to encourage community pharmacies to take up the QCPP and to gain accreditation. This system of financial incentives was very successful and resulted in some 90 per cent of pharmacies gaining accreditation by 2005.

The Guild manages the accreditation system and recruited and trained a team of assessors to conduct the assessment of pharmacies against the standards. The team of assessors is comprised of a mix of qualified pharmacists and non-pharmacists, and each assessor has completed an assessor training course prior to conducting assessments.

The assessors are not employed by the Guild, although they are required to be licensed by the Guild to conduct assessments.

The assessors are therefore independent of the Guild, although the Guild will provide advice and guidance on the assessment process as well as providing interpretations on the standards from time to time.

In 2005, the QCPP underwent a major review of all of its standards and systems. This review took account of the lessons learned during the first seven years of the QCPP, including the need for a restructure of existing standards, the deletion of some standards which were considered to be no longer required, and the inclusion of some new standards. The review led to the QCPP 2nd edition.

One of the major lessons the Guild has learned with respect to rolling out a voluntary quality assurance system to 5,000 independent pharmacy operators is that businesses need a period of stability in the quality assurance system. At one stage the Guild was conducting mini-reviews of the standards each year, but this system was met with widespread concern by community pharmacy operators, and as a result it was felt that major reviews every five years, to coincide with the five-year agreements between the Guild and the Commonwealth Government, would be the best way to ensure that the standards remained current but lead to the least disruption to business.

The next major review of the QCPP is therefore due to take place in 2010, with possible roll out of the QCPP 3rd edition in 2011.

The Guild mentions these points so that ACSQHC can have an understanding of the context in which the development of an alternative model of safety and quality accreditation of health care may impact on the QCPP and how the QCPP may need to be reconfigured to take account of these developments.

However, the Guild also believes that community pharmacy has made much progress with respect to acceptance of minimum safety standards and believes that, while the QCPP may stand to benefit from the incorporation of a national set of minimum safety standards as developed by a national entity, that national entity should also recognise that its first priority is to roll out the national minimum safety standards to those industry sectors which may not have advanced as far as community pharmacy has.

The Guild believes that the national entity may need to undertake a risk analysis of the various industry sectors and prioritise the roll out of national minimum safety standards in

those sectors that represent the highest risk. Sectors with highest risk such as hospital and day facilities offering acute care and elective surgical procedures appear to be the highest priority for standardisation of safety standards setting and assessment. The primary care settings such as general practice and pharmacy have lower level of risk. It appears that although some standards that apply to secondary and tertiary care settings may apply, for example infection control standards, there are few high level risks in the primary care setting.

Although the Alternative Model outlines an approach that could be taken it appears that in practice the approach may be “overkill” and therefore costly to implement and maintain for the primary care sector.

The following comments are provided with respect to the key elements of the alternative model.

1. Separation of Safety Assurance and Quality Improvement Assessment Processes

At the outset, we must admit to some confusion about what this key element actually involves. On first consideration, we believe that safety and quality improvement necessarily go hand in hand. That is to say, we believe that a necessary criterion integral to any safety standard would be a quality improvement mechanism.

We are also unsure whether this key element means that the assessment of safety standards is to be separated from the assessment of the quality improvement processes which may be tied to those safety standards.

It is also unclear whether quality improvement will be applied to elements which are not safety related. For example, quality improvement could be applied to patient satisfaction with respect to timeliness or responsiveness.

Until we have a better understanding of this key element, our comments are necessarily restricted. We therefore need to see further explanation of this key element and how it may impact on the QCPP. That said, we make the following comments.

In the QCPP 2nd edition, the Guild has taken the approach that rather than each standard having its own quality improvement criteria, there should be one single standard covering

quality improvement. The QCPP 2nd edition consists of 18 standards, and **Standard 7, Complying with and Improving our Quality Program**, is concerned solely with quality improvement. All of the actions required in giving effect to this standard are regarded as mandatory to gain accreditation.

On balance, the Guild is supportive of a separation of the setting of safety standards and the process to measure safe delivery of care from quality standards setting and assessment including quality improvement standards setting and assessment processes.

For the Guild, this will mean that whilst there will be a set of national minimum safety standards which in all likelihood will need to be incorporated into the QCPP at some future time, the Guild can continue to be responsible for developing and keeping current a quality improvement program that is consistent with an agreed national framework.

As an accrediting body, the Guild would expect to have its independent assessors assessing against the set of national minimum safety standards, and other standards within the QCPP, including a quality improvement standard.

In terms of timeframe and resource implications, the Guild considers that the next major review of the QCPP would be an appropriate time to consider incorporation of the set of national minimum safety standards into the QCPP.

Therefore, development of the set of national minimum safety standards would need to take place before 2010.

As to resource implications, if the changes can be incorporated at the time of the next major review there should be relatively few additional costs involved.

2. Separation between Safety Standards Development and Assessment of Health Services

As mentioned above, the Guild currently is the body responsible for developing and keeping current the QCPP standards, albeit with widespread industry consultation and input.

The Guild is also responsible for the accreditation system, although the assessors who assess the pharmacies against the QCPP standards operate as independent contractors.

The Guild recognises that ACSQHC, and ministers, are committed to a separation of the standards setting and assessment functions. How such a separation will impact on the QCPP and the Guild in terms of the established QCPP structure will need careful consideration. This is because the current system with respect to the QCPP has worked well to date, and the Guild would be reluctant to introduce major structural changes which may have a deleterious impact on the QCPP and its take up by community pharmacies.

As stated above, the Guild believes that the primary care setting represents the lowest risk to consumers and those primary care providers take their professional responsibilities with respect to safety and quality seriously. In 1992 adverse events from warfarin use in Australia were estimated to cost \$100 million in direct hospital costs alone¹. Patients discharged from hospital are at high risk of experiencing adverse effects. A safety standard related to warfarin appears necessary. In the absence of such a standard, self-regulatory efforts such as the QCPP demonstrate that the existing system is proactive with respect to safety. The Guild has commissioned a project to conduct post-discharge warfarin monitoring therapy as a means to ensure these consumers are not readmitted to hospital with warfarin related problems.

Whatever changes which may be necessary to conform to a new system will therefore need to be considered in quite some detail, and the Guild would expect any changes necessary to be considered as part of the 2010 review of the QCPP. We respectfully suggest that the changes proposed to achieve the alternative model are ambitious and that incremental initiatives to develop the existing accreditation arrangements in the acute and primary care setting should be the primary objective. There may not be a need for a “one size fits all” approach and the primary care sector system could achieve the Commission’s objectives by different strategies and with a different timeline than the acute care sector.

¹ 1. Rigby K, Clark RB, Runciman WB. Adverse events in health care: setting priorities based on economic evaluation. *J Qual Clin Pract* 1999;19(1):7-12.

3. Accreditation of all Settings of Health Care where Services are Provided by Registered Health Professionals

The Guild agrees that all registered health professionals in Australia should be required to comply with a set of national minimum safety standards.

As to the mechanisms for achieving this outcome, the Guild has no specific comments.

However, the Guild does have strong views on the appropriateness of including non-registered health professional within the umbrella of national safety standards.

There is a growing preponderance of health food shops, etc. which are engaging in the sale of products that have some sort of therapeutic effect and could very well have adverse impacts on consumers' health if they are supplied without appropriate professional knowledge and advice.

The Guild strongly believes that those responsible for the sale of these products should also be subject to the national minimum safety standards for the primary care sector and we suggest the ACQSHC widens its terms of reference to include these areas in its review.

4. National Minimum Safety Standards that Apply across all Settings of Care

The Guild agrees that national minimum safety standards should apply across all settings of care, including the settings mentioned in the previous paragraph. The Guild also believes that it would be within the capacity of the proposed national entity to develop the standards directly, subject to appropriate consultation and input by the various industry stakeholders.

As to the other issues on which the ACSQHC is seeking stakeholder input, the Guild believes that these are matters of detail upon which we cannot provide considered comments at this point in time.

The Guild would prefer to have some sort of “skeleton” set of national safety standards before considering these matters in more detail. It appears that the scope of the suggested standards may be already covered by legislation.

Currently, there are developments with respect to credentialing of practitioners and the Guild does not see any role in this initiative for the credentialing of health professionals other than to require that facilities ensure they employ appropriately credentialed staff. The determination of what is appropriate credentialing for pharmacists is a matter for Pharmacy Boards.

In addition, it may be that some of the issues on which the ACSQHC requires comment are best left to be considered on an industry-by-industry basis, depending on the circumstances of the particular industry/sector.

The Guild believes that the ACSQHC should hold another series of stakeholder forums to progress some of these issues, with the ACSQHC developing papers on its thinking to assist in deliberations.

In informing itself on these matters, the ACSQHC may benefit from detailed discussions with stakeholders on the detail of the various systems and structures that are already in place.

5. Assessment of Non-clinical and Technical Compliance

The Guild agrees that assessment of non-clinical and technical compliance would benefit from a system of mutual recognition.

Where such areas are included in the set of national minimum safety standards the Guild would want its assessors to be able to assess against those areas.

Areas of non-clinical and technical compliance which are left outside of the set of national minimum safety standards should continue to be assessed by separate bodies.

Any developments in this regard may involve additional training and qualification on the part of QCPP assessors, and the costs thereof will need to be considered and, if necessary, appropriate funds allocated.

6. Development of a National Framework for Quality Improvement

As stated above with reservations due to the lack of clarity about the scope of the quality improvement framework. The language used in the Alternative Model paper is confusing. Page 16 refers to quality improvement framework and quality improvement standards. The Guild understands that it is possible to develop quality standards relating to elements of a quality service (including safety) and believes that such a system should be developed using a quality improvement approach. For example, the goal of the pharmacy professions' continuous quality improvement process is to identify opportunities for improvement. The review of the process is evaluated and the findings used to develop service improvements.

The Guild broadly supports the development of a national framework for quality improvement. In developing this framework, the ACSQHC should request examples of quality improvement standards that already exist in stakeholder systems of quality assurance, and the Guild would be pleased to provide you with copies of its quality improvement standard and an explanation of the systems that sit behind it. It appears that it may be difficult to develop a meaningful set of quality improvement standards that could apply to all health care setting and a principles-based approach to quality improvement may be a pragmatic (and achievable) first step. That is all organisations should incorporate a cycle of:

- Measuring and comparison of performance against the standards;
- Identification of possible courses of action to promote improvement;
- Implementation of actions; and
- Re-assessment of performance.

Actions may also include: continuing education, staff training, procedure and policy development, and monitoring of consumer satisfaction

The Guild would also wish to be involved in the development of the framework and requests participation on any working groups that are established to develop the framework.

As to timeframe, the Guild sees the next major review of the QCPP in 2010 as the appropriate time to consider how such a framework may impact on the QCPP, and any changes to the QCPP quality improvement standard which may be necessary.

If developments are considered as part of the next major review, the Guild expects that there would be few resource implications to consider.

7. Establishment of a National Entity to Lead and Co-ordinate Changes

The Guild is generally supportive of the establishment of a national entity to lead and co-ordinate changes.

As to options for establishment, we can see no problems with ACSQHC performing this role, and we have no strong views at this stage on whether another vehicle might be more appropriate. Our reservation relates to the need for an entity which may prove to be more costly than an alternative model to achieve the same objectives. The Guild suggests that the Commission should trial the model within the area of greatest risk; the acute care sector. This would allow the ACSQHC to determine the areas of commonality and difference between the acute and primary care sectors before deciding on the appropriateness of a “one size fits all” approach.

The important issue from the Guild’s point of view is that all industry stakeholders should have an opportunity for representation and for input of views.

It will be vitally important that there is some degree of flexibility as to how individual industry sectors respond to national initiatives and the timeframes for industry adoption of those initiatives. This is to ensure that there is a smooth and pain free transition to national initiatives so as not to put at risk all of the progress that may have been made with respect to the introduction of quality assurance initiatives by individual industry sectors.

The Guild believes that there is no barrier to the immediate establishment of the new national entity.

8. Review of Surveyor Training

The Guild would be interested in the outcomes of a review into surveyor training and assessment across the range of existing accreditation programs so that we can benchmark the training and assessment responsibilities of QCPP assessors against what might be considered to be best practice.

The Guild would hope that this review could be completed in time for the Guild to consider its options at the time of the next comprehensive review in 2010.

9. Associated Reforms

The Guild generally supports the suggested additional reforms being progressed in concert with the development of the broader reforms.

In particular, the QCPP already uses unannounced surveys to test compliance with particular aspects of the QCPP, and would expect that the system we have in place may also extend to testing compliance with national minimum safety standards by the QCPP assessors.

The other initiatives suggested may also add to the quality of individual sector quality assurance programs if such initiatives could be recognised as a guide to best practise.

Again, the Guild would want to be involved in the progression of these initiatives to ensure that the QCPP is best placed to adopt any of the initiatives and that they are capable of being adopted by the QCPP.

However, it may be that progression of the additional initiatives could await more substantial progress in the broader reforms.