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| Protected Quality Assurance Activities under the Health Practitioners Competence Assurance Act 2003 | July 2014 |

An explanation for health practitioners on what a quality assurance activity is, what the benefits are of having a quality assurance activity protected, and how to obtain that protection.

Protected quality assurance activities: key points

* A Quality Assurance Activity (QAA) is undertaken to improve the practices and competence of health practitioners by assessing the health services provided by them (eg, clinical audits of the outcomes of treatment).
* The Minister of Health can declare a QAA to be protected under the Health Practitioners Competence Assurance Act 2003, if satisfied that it is in the public interest.
* A protected QAA protects the confidentiality of information that becomes known as a result of the declared QAA and gives immunity from civil liability to people who carry out activities in good faith as part of the declared QAA. A protected QAA does not cover systemic investigation.
* Organisations may apply to the Ministry of Health to have a QAA protected. The application must set out what their proposed activity will involve, why confidentiality is in the public interest, and who the responsible person for the QAA will be.
* Separate formal inquiries (eg, by the Health and Disability Commissioner, a coroner etc) cannot access information that has become known solely as a result of a QAA. However, health practitioners may be asked to provide information to an inquiry into something that is also the subject matter of a QAA. Information cannot be provided as part of a protected QAA simply for the purpose of avoiding responding to any such inquiry.
* There are important reporting requirements for all QAAs.

## What is a quality assurance activity?

The term quality assurance activity (QAA) describes the way health practitioners review, assess and monitor their work. Quality assurance is an integral part of many businesses, trades and professions. However, it plays a particularly important role in the delivery of health care services, and is a useful tool in helping to avoid adverse health outcomes by improving practice or quality of care.

All health practitioners aim to provide excellent service to patients and achieve optimal health outcomes. Most health practitioners ensure this happens by constantly reviewing, assessing and monitoring their work – through formal performance management processes, ongoing reviews, regular ‘de-brief’ meetings with colleagues and managers, or the modification of surgical procedures or patient care management.

Regardless of the approach taken, the underlying aim of any QAA is to identify ways in which health practitioners’ practices and competence can be improved and the quality of current services can be maintained and improved. Much of the QAA undertaken recognises that the circumstances or systems within which health care is delivered may affect the health services provided by individual health practitioners.

Quality assurance activities encompass a wide range of activities including clinical audits of the outcomes of treatment, academic studies of the incidence of adverse patient outcomes, peer review activities to learn from colleagues, and systems review.

## What is a ‘protected’ quality assurance activity?

Health practitioners whose work is subject to ongoing assessment as part of a QAA can apply to the Ministry of Health to have that activity protected under the Health Practitioners Competence Assurance Act 2003 (the HPCA Act). Under the HPCA Act the Minister of Health can declare a QAA to be ‘protected’ if the Minister is satisfied that to do so is in the public interest.

A similar mechanism was previously available under Part 6 of the Medical Practitioners Act 1995. Under that Act, however, the protections could only apply to activities undertaken by medical practitioners. The HPCA Act extends this concept to all health practitioners covered by the HPCA Act.

A QAA is defined in section 53 of the HPCA Act as an activity that is undertaken to improve the practices and competence of health practitioners by assessing the health services provided by them.

A ‘protected’ QAA protects the confidentiality of:

* information that becomes known solely as a result of such activities
* documents brought into existence solely for the purposes of such activities.

It also gives immunity from civil liability to persons who engage in such activities in good faith.

## Is systemic investigation protected?

Not directly. The HPCA Act confidentiality provisions are not specifically about systems; they focus on activities of individual practitioners. This continues the practitioner focus of QAA provisions under the now repealed Part VI of the Medical Practitioners Act 1995. However, all practitioner outcomes have a systemic context and consideration of this context has an important bearing on the assessment of individual practitioner outcomes.

There is currently no legislative allowance for inquiries where the focus is specifically systemic. The Health Quality and Safety Commission is strongly supportive of open disclosure in the context of adverse events, and encourages the sharing of lessons learned from the review of adverse events.

## Who can apply to have a QAA ‘protected’ and how is this done?

Any group of health practitioners registered under the Health Practitioners Competence Assurance Act 2003 can be covered by the protected QAA. Applications can be made on behalf of health practitioner colleges, primary health organisations, an educational institution, a research body, a District Health Board or any other organisation that employs or engages health practitioners.

The Ministry of Health has published in the New Zealand Gazette the requirements relating to the form, content and quality standards of an application to have a QAA protected.

An applicant must apply to the Ministry of Health providing information about what their proposed activity will involve and how the methodology of the activity meets the essential elements of a protected QAA. The applicant must also nominate a ‘responsible person’ who will give the service provider of the participating practitioners a six-monthly report, and the Minister of Health an annual report regarding various aspects of the QAA. The responsible person will be a point of contact between the Ministry of Health and the applicant.

The annual report to the Minister of Health differs from the six-monthly report to the service provider of the participating practitioners. The report to the Minister must follow the statutory prescribed format as set out in the Ministry's template, which is available from the Ministry's website. The report must not contain any information that may directly or indirectly identify any individual such as a health practitioner or a consumer. The report should contain summary information about improvements that have been made to health services as a result of the protected activities. The report is an accountability measure to the Minister in return for the privilege of having protection. There is public interest in hearing these good news stories. From December 2014, the QAA annual reports will be published on the Ministry's website each calendar year.

The application needs to explain why granting confidentiality to the described activity is in the public interest. The QAA provisions in the HPCA Act operate on the underlying principle that there are benefits to the public resulting from effective QAAs. Applicants must consider that issue when making an application and ensure that a QAA is a suitable mechanism and is consistent with the overall purposes and objectives of the HPCA Act.

The definition and function of QAAs provided for in the HPCA Act is intended to reflect and strike a fair balance between candour, openness and transparency on the one hand, and a more cautious and restrained approach to information-sharing on the other. It is considered that it is in the overall public interest if information disclosed as the result of a quality assurance activity is kept confidential. The purpose of providing such a protective framework is to encourage activities that will maintain and improve the quality of health care services provided to the public.

A protected QAA may cover registered health practitioners of more than one profession. In such cases, applicants need to provide evidence that the application is generally supported by the professions who might be expected to participate.

The Minister of Health formally signs each protected QAA. These notices are treated as regulations for the purposes of the Legislation Act 2012. The Notices are published as part of the Statutory Regulations series and can be downloaded from the New Zealand Legislation website (www.legislation.govt.nz under regulations).

## Is it compulsory to have a QAA ‘protected’?

No. In fact, many health practitioners already carry out quality assurance processes without applying to have them protected.

## How does the confidentiality provision work?

The purpose of providing confidentiality is to encourage health practitioners to carry out QAAs that are robust and effective.

The confidentiality provision is based on the premise that QAAs can only be effective if the health practitioners involved are able to participate in them fully and frankly, without fear of recrimination. By protecting the confidentiality of information gathered as part of a QAA and by providing participants with immunity from civil liability, the current protection is considered to provide medical practitioners with such an environment. However, a balance must be achieved between protecting information and protecting the public.

The Minister of Health can only declare an activity protected – and so provide confidentiality – when the Minister believes it is in the public interest to do so. Once ‘protected’, no information prepared for the purposes of that QAA can be disclosed, except in very limited circumstances.

## What are your obligations if you participate in a protected QAA?

You must comply with any procedural requirements set out in the Quality Assurance Notice covering your organisation’s QAA. You must also keep confidential all information disclosed for the purpose of the activity, and which you become aware of during the activity. You must not disclose this information to any other individual or agency except in the circumstances set out in section 60 of the HPCA Act.

Other obligations may be imposed from time to time on a QAA’s participant by the sponsoring organisation, DHB or college. These are separate from the confidentiality obligations under the HPCA Act.

## In what circumstances can the protection be removed?

The Minister of Health is able to revoke the confidentiality provisions and to authorise release of information where it relates to a criminal offence (even when that information has become public as a result of a disclosure as part of a QAA).

## What if a separate formal inquiry is initiated?

Protected QAAs are not affected by the instigation of a formal inquiry into an incident or complaint. Information provided as part of an ongoing protected QAA remains protected. Equally, even if an event is reviewed as part of a protected QAA, that does not prevent a separate investigation or inquiry from being undertaken and relevant information being disclosed in that context.

Parallel (or consequential) inquiries can be undertaken:

* under Section 95 of the Mental Health (Compulsory Assessment and Treatment) Act 1992
* by the Director-General of Health
* by a coroner or the police
* by the Health and Disability Commissioner.

While such inquiries and investigations cannot access information that has become known solely as a result of the QAA, or in documentation that has been created solely for the purposes of the QAA, health practitioners may be asked to provide information to an inquiry or investigation into something that is also the subject-matter of a QAA. Information cannot be provided as part of a protected quality assurance activity simply for the purpose of avoiding responding to any such investigation or inquiry.

## Can a protected QAA be revoked?

The Minister of Health may revoke a QAA – and its confidentiality – at any time by written notice, if the organisation or the responsible person fails to meet the criteria required in the application. For example, if the Minister ceases to be satisfied that the QAA is in the public interest or if the applicant fails to report on their activity, provides a report that does not comply with the requirements of the HPCA Act or fails to make satisfactory progress over any two-year period. The Minister may also revoke the appointment of the responsible person if they become unavailable or unsuitable.

## Where can I get further information on protected QAAs?

For more information please contact the Ministry of Health, PO Box 5013, Wellington 6145.

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