NSW DEPARTMENT OF HEALTH

REVIEW OF STATUTORY PRIVILEGE IN RELATION TO ROOT CAUSE ANALYSIS AND QUALITY ASSURANCE COMMITTEES UNDER THE HEALTH ADMINISTRATION ACT 1982

REPORT

August 2009

TABLE OF CONTENTS

REVIEW OF STATUTORY PRIVILEGE IN RELATION TO ROOT CAUSE ANALYSIS AND QUALITY ASSURANCE COMMITTEES UNDER THE HEALTH ADMINISTRATION ACT 1982

REPORT

Recommendations

Recommendation 1

1.1 The statutory privilege for review of SAC 1 clinical incidents by RCA teams should continue to enjoy the statutory privilege under Part 2 Division 6C of the *Health Administration Act*, subject to the recommended amendments discussed below.

1.2 That a current NSW Health review of policy and guidelines around Open Disclosure and related issues includes seeking to ensure that RCA processes and outcomes are not used inappropriately in the context of open disclosure

Recommendation 2

2.1 The definition of "reportable incident" in the Act should remain unchanged.

2.2 The Act should be amended to permit chief executives to appoint RCA teams for clinical incidents other than reportable incidents where it is considered the incident may give rise to potential systemic issues, such decisions to be guided by NSW Health policy.

2.3 NSW Health policy should be amended to require area health services (**AHSs**) to implement processes to allow local quality assurance committees and mortality & morbidity committees to recommend to the chief executive that an RCA team be appointed to review incidents or issues (only if recommendation 2.2 is adopted).

2.4 The Act should be amended to clarify that an RCA team may refrain from making any recommendations in its final report where it considers the reportable incident does not give rise to any system wide issues or concerns.

Recommendation 3

3.1 That section 20Q of the Act be amended to prohibit the disclosure by any person of any communication (whether written or verbal) made for the dominant purpose of an RCA team review.

3.2 If recommendation 3.1 is adopted, that NSW Health develop a role instruction letter for clinicians and experts with whom RCA teams communicate for the purpose of the RCA review to explain their legal rights and responsibilities.

3.3 That the Act be amended to permit the CEC or other appropriate body to carry out on an annual basis a review or audit of a sample of RCA investigations and reports.

Recommendation 4

4.1 Part 2, Division 6C of the Act be amended to include definitions of "professional misconduct", "unprofessional conduct", "impairment" and

"unsatisfactory professional performance" that reflect whatever definitions of these terms NSW adopts under the National Registration and Accreditation Scheme.

4.2 The Act be amended to permit RCA teams to report concerns held by the team arising from its review relating to system wide issues that give rise to a risk of serious and imminent harm to patients.

4.3 NSW Health policy be amended to clarify that where RCA teams have doubts as to whether a clinician's performance may involve unsatisfactory professional performance for the purposes of section 20O(2) of the Act, the RCA team should err on the side of caution and notify the concerns to the chief executive.

4.4 The Act be amended to require an RCA team, at the time of a s20O(1) or (2) notification, to:

(a) disclose the identity of the clinician in respect of whom the concern is held; and

(b) indicate whether the concern relates to professional misconduct, unsatisfactory professional performance, unsatisfactory professional conduct or impairment.

Recommendation 5

5.1 Section 20N(3) of the Act be amended to replace the requirement that RCA teams are to "*have regard to the rules of natural justice*" with a requirement that they are to act in a "*fair and reasonable manner*".

5.2 NSW Health policy be amended to include the following requirements regarding RCA teams:

(a) RCA team members should not have a personal (ie non-professional) connection with clinicians involved in the incident

(b) The RCA team must consult with all relevant clinicians involved in the incident

(c) Where the RCA team makes a notification under section 20O(1) or (2) in respect of a clinician, the chief executive must advise the clinician in writing of the notification and the basis for the notification (that is, whether the concern giving rise to the notification relating to professional misconduct, unsatisfactory professional conduct, impairment or unsatisfactory professional performance).

5.3 The NSW Health standard form letter to clinicians involved in incidents the subject of RCA review be amended to:

(a) advise that any communications between the clinician with the RCA team (written and verbal) made for the dominant purpose of the RCA review are privileged (only if recommendation 3.1 above is adopted);

(b) include a plain English guide to RCA processes that is based on upon the guide for patients and families that it is recommended be developed for patients and families in recommendation 8 below.

5.4 The proposed audit function of the CEC or other appropriate body is to include ensuring the integrity of RCA processes and that RCA teams comply with the requirements of the Act and NSW Health policy (only if recommendation 3.3 above is adopted).

Recommendation 6

6.1 A regulation should be made under section 20P(d) of the Act permitting the RCA team to communicate with the AHS in respect of its proposed findings and recommendations.

6.2 Amend NSW Health policy to require all communications between the RCA team and the AHS in respect of the proposed findings and recommendations of the RCA team to be in writing.

6.3 Amend NSW Health policy to clarify the role of individual human error, behaviour or conduct in the systems review carried out by RCA teams.

6.4 Amend NSW Health policy to clarify that the RCA team may decide it is unnecessary to make recommendations in respect of each causal factor identified in the causation statement, or to make any recommendations at all.

6.5 Amend 20R section of the Act to provide that a notification or RCA report:

(a) is not admissible as evidence in any proceedings,
(b) cannot be tendered in any proceedings, and
(c) cannot be used to cross-examine any witness in any proceedings,

except in proceedings in respect of any act or omission by a RCA team or by a member of a RCA team as a member.

Recommendation 7

7.1 NSW Health policy should be amended to clarify that as part of the Open Disclosure process patients and families may receive a copy of the RCA report (the report to be provided where possible in conjunction with the current process which involves a meeting with the patient/family to explain the RCA findings and steps to be taken to implement its recommendations, as well as to answer any questions).

7.2 NSW Health develop processes for the systemic feedback of RCA outcomes to clinicians involved in incidents giving rise to RCA reviews.

7.3 Amend the Act to clarify that the privilege does not restrict the persons to whom an RCA report may be disclosed, or (subject only to section 20R) the use to which it may be put.

Recommendation 8

NSW Health develop a guide for patients and families, in plain English, about what RCA processes involve, and what can and cannot be achieved from the RCA process.

Recommendation 9

NSW Health policy be amended to require the chief executive, when appointing an RCA team, to include at least one member who is external to the AHS, where it is practicable to do so.

Recommendation 10

The privileging of approved quality assurance committees be retained pending a more considered review of these committees and their activities.

A. BACKGROUND TO ROOT CAUSE ANALYSIS AND QUALITY ASSURANCE COMMITTEES

In 2004, the Walker Inquiry into Camden and Campbelltown Hospitals recommended the introduction of statutory privilege for root cause analysis (**RCA**) review of serious adverse incidents. The statutory amendments to the *Health Administration Act* 1982 (**the Act**) containing these protections commenced on 1 August 2005. The statutory provisions introduced a statutory privilege similar to that applying to approved quality assurance committees, providing certain protections for RCA processes and members of RCA teams. At the time the Walker Inquiry recommended the introduction of the privilege, it also recommended that the new provisions be reviewed after a period of 3 years from commencement of the provisions. Section 20U of the Act requires a review of the RCA provisions after a period of three years:

> *"to determine whether the policy objectives of the Division remain valid and whether the terms of the Division remain appropriate for securing those objectives".*

Shortly after the Parliament passed the legislation providing statutory protection to RCA processes, the General Purpose Standing Committee No 2 of the Legislative Council, NSW Parliament conducted a review of complaints handling within NSW Health (**the Parliamentary Inquiry into Complaints Handling**). The report of the Inquiry, *Review of Inquiry into Complaints Handling in NSW Health* (Nov 2006), recommended review of the confidentiality protections applied to RCA and other adverse events investigations, in the following terms:

> *"That the NSW Minister for Health instigate an urgent review of the nature and extent of privilege relevant to incident investigations. The proposed review should examine:*
> - *the possible extension of privilege in relation to incident investigations, including root cause analysis*
> - *the methods used to ensure root cause analysis investigations are conducted with procedural fairness."*

The NSW Health Department has conducted a review as required by section 20U of the Act. The review also addressed the recommendations of the Parliamentary Inquiry into Complaints Handling.

The RCA provisions were modelled on the provisions establishing approved quality assurance committees (**QACs**) under Part 2, Division 6B of the Act. Given these provisions have not previously been subject to a formal review, and are similar to the RCA provisions, the Department decided to broaden the review to include reconsideration of the QAC provisions in the Act.

Finally, it is also of relevance to note by way of background to this review that the Australian Commission on Quality and Safety in Health Care (**ACSQHC**) is currently undertaking a major project to seek to achieve a consistent national approach to qualified privilege and other legislative protection in the

context of quality assurance activities and open disclosure. The ACSQHC has advised that an issues paper on legal aspects of this project is due in September 2009.

B. CONSULTATION

The Department issued a Discussion Paper on 4 June 2009. Submissions were requested by 19 July 2009. The Discussion Paper was available on the Department's website, and copies of the Discussion Paper were also provided directly by the Department to a number of key stakeholders (see the list of recipients of the Discussion Paper in Appendix A).

The issues raised in this report also overlap to some extent with the CEC's recent review and report on RCA processes.[1] The CEC review deals with a number of important issues relating to RCA processes and methodologies which, whilst strictly outside the purview of this report, are nonetheless of great significance to the effectiveness of RCAs in achieving their intended goal of improving the quality and safety of clinical services.

Finally, whilst this report is concerned primarily with legislative review, many significant aspects of RCA team process are governed by NSW Health policy. Many of the submissions received by the Department as part of this review related to both legislative and policy issues. Accordingly, this report has also made a number of recommendations for changes to NSW Health policy where this has been considered appropriate.

C. CONSIDERATION OF ISSUES RAISED BY THE DISCUSSION PAPER

1. Should RCA privilege be retained?

1.1 The policy basis for the privilege

The first issue that arises for consideration is whether the statutory privilege for RCA review under Part 2 Division 6C of the Act should be retained. The Discussion Paper suggested three policy principles against which any proposal to protect certain processes or material with a statutory privilege should be measured:

(1) Can the privilege be justified as in the public interest, based on clear, demonstrable evidence?
(2) Is the privilege and the process it covers effective (from an operational perspective) in addressing the public interest and achieving its stated ends?
(3) Does the privilege allow an appropriate degree of transparency and

[1] *Position Paper – Agreed way forward. Review of Serious Clinical Incident Investigation Processes (RCA) in NSW*, July 2009.

accountability to the process, and properly address competing issues such as open disclosure and individual accountability?

The Discussion Paper sought submissions in relation to these questions, including any evidence that privileging of RCA processes encourages clinicians to participate in RCA investigations to a greater extent, and in a more full and frank manner, than would be the case in the absence of the privilege. It also sought submissions in respect of whether the confidential nature of RCA processes has resulted in inappropriate failure to notify individual clinician conduct, impairment or performance issues, and also whether the tort law reforms in NSW introduced in 2002 have reduced the need for the privilege.

1.2 Submissions

The retention of the privilege was strongly supported by all of the medical defence organisations (**MDOs**), as well as the AMA, the NSW Nurses' Association, the HSU, SICorp and the Medical Services Committee.

Three AHSs, as well as the ASNSW, also submitted that the privilege should be retained. On the other hand, another two AHSs expressed some ambivalence as the value of the privilege, submitting that feedback from staff indicated that the existence of the privilege does not encourage frank participation in RCAs. However both of these AHSs accepted that at least some clinicians, particularly some experienced senior medical practitioners, may be less likely to be engaged in RCAs in the absence of the privilege.

The only stakeholder that opposed the retention of the privilege was the HCCC, which submitted that the RCA privilege was fundamentally incompatible with the process of open disclosure.

In its Discussion Paper, NSW Health sought "*clear, demonstrable*" evidence to justify the existence of the privilege. Whilst no statistical or quantitative evidence was made available, those submissions that supported the retention of the privilege generally pointed to a clear pattern of feedback from clinicians that they remain concerned that information disclosed to RCA teams may be used against them in subsequent litigation, disciplinary action or elsewhere such as coronial inquiries, and that they are more willing to participate in RCA processes in the knowledge that their participation is protected by statutory privilege. Indeed, this was acknowledged in the HCCC's submission in the following terms: "*At this stage, there appears to be anecdotal evidence of strongly held views on the part of some clinicians that they would be reluctant to engage in RCA investigations in the absence of the statutory privilege*".

A number of separate issues arose in the submissions on the question of whether the privilege should be retained:

(a) Compatibility of the privilege with open disclosure

The Discussion Paper questioned whether the statutory privilege was

compatible with the principles of open disclosure. Different views were expressed by submissions on this issue. The HCCC submitted that as a result of the privilege "*none of the information obtained through an RCA investigation can be used for the purpose of explaining in detail the reasons for the adverse event to a patient or their family*". As a result, the HCCC considered the process "*fundamentally incompatible with the process of open disclosure.*"

A number of other stakeholders, including an AHS, MDOs and the AMA submitted however that root cause analysis and open disclosure serve different purposes and are not incompatible with each other. For example, Avant submitted that: "*The two pathways are fundamentally and philosophically quite distinct*". These submissions argued that issues have arisen where the two processes have become confused, or where RCA processes have inappropriately substituted for other processes. In the words of Avant: "*It is incumbent on the facility to explain the differing processes and to manage the separate reporting to both the area health service and patients and/or their families*". To the same effect, the AMA submitted that "*it is often the perception of patients and families that an RCA process will address individual accountability issues, and that patients and families need to be better informed by Area Health Services of the purpose of RCA processes*".

(b) Use of RCA reports in health system improvement

An important policy justification of the privilege is that RCA reports and recommendations result in improved clinical outcomes in health system overall. In this regard, the ACSQHC submitted that: "*If RCA recommendations are not consistently used to improve care, it becomes difficult to be certain that the public interest lies in continued privileging of RCAs.*" The ACSQHC linked this to the need for a process to review and monitor the implementation of RCA recommendations.

(c) Lack of feedback of RCA outcomes to clinicians

Submissions from the AMA and MDA National argued that there was limited clinician trust and confidence in RCA processes as a result of poor feedback to clinicians regarding RCA outcomes, or of the clinical improvements resulting from RCA processes. It was argued that this lack of trust and confidence was an important reason for the ongoing need for the statutory privilege.

(d) Notification of individual conduct or performance concerns

The Discussion Paper questioned whether there is any evidence the confidential nature of RCA processes has resulted in inappropriate failure to identify or refer individual clinician conduct or performance issues to relevant health services, professional registration or health complaints bodies. Generally, submissions were to the effect that there was no evidence of any inappropriate failure to notify clinician conduct or performance issues by RCA teams in accordance with the current requirements of the Act. The

submission from NSCCAHS noted that there had been a number of instances of RCA teams from that AHS making notifications to the chief executive. The only exception was the HCCC, which advised that it "*had only received one referral about the conduct of an individual health practitioner arising from an RCA team investigation. The Commission suspects that RCA teams do not appropriately identify and refer issues of individual responsibility*".

(e) Relevance of tort law reform

A final issue raised by the Discussion Paper was whether the tort law reforms introduced by the *Civil Liability Act* 2002 have reduced the nature and extent of civil claims against clinicians, as well as clinicians' concerns about litigation, and consequently increased clinicians' willingness to participate in RCA processes in the absence of the statutory privilege.

A number of stakeholders referred the Department to recent reports by the Medical Indemnity Industry Association of Australia (**MIIAA**)[2] and the Australian Competition and Consumer Commission (**ACCC**)[3] in support of the submission that in recent years the number of medical indemnity claims has either increased, or at least has returned to similar levels as those prior to the introduction of the *Civil Liability Act*. Both of these reports include information on the frequency of medical indemnity claims in Australia, however neither report provides a breakdown of claims by jurisdiction, so there is no NSW specific data. According to the MIIAA report, the frequency of claims per 1,000 doctors spiked in 2001-02, following which it gradually decreased thereafter, although there was a slight increase between 2005-06 and 2006-07 (the last year covered by the report).[4] The ACCC report similarly shows a claims spike in 2000-01 and 2001-02, following which there has been a slight decline, although the number of claims still remains at roughly the same as 1999-2000 levels.[5] According to the ACCC report, the ultimate claims costs by year of notification fell slightly in the years 2003-04 and 2004-05, but since that time has been gradually rising.

Additionally, a number of stakeholders submitted that clinicians' anxiety related to matters other than civil litigation, most importantly coronial, disciplinary, and employment, and that the *Civil Liability Act* does not address these concerns. In this regard, the SSWAHS and MDA National submissions both refer to recent HCCC data indicating there has been an increase in the number of complaints reported against practitioners.

1.3 Discussion

(a) Compatibility of the privilege with open disclosure

As indicated above, the HCCC was the only stakeholder that opposed the

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[2] Medical Indemnity Report – An analysis of premium and claim trends for medical indemnity insurance in Australia from 1996 to 2007, 31 July 2007 (**the MIIAA report**).
[3] Medical Indemnity Insurance, Sixth Monitoring Report, April 2009 (**the ACCC report**).
[4] MIIAA report, page 2.
[5] ACCC report, page 20.

retention of the privilege.[6] The basis upon which the HCCC opposed the retention of the privilege was that "*if the RCA privilege is retained, RCAs will be largely useless for the purpose of facilitating open disclosure.*"

It should be made clear that the HCCC concern that that "*none*" of the information obtained through RCA processes can be used as part of open disclosure is incorrect. The Act makes it clear that the privilege does not apply to the underlying medical records or other primary documentation relating to the incident under investigation. It only applies to material specifically created for the purpose of the RCA. Further, information that is included in the RCA team's final report may be provided to the patient or family. To that extent, the Department considers it is inaccurate to describe the RCA process as "*useless*" for the purposes of open disclosure.

Rather than RCA processes being "*incompatible*" with open disclosure as suggested by the HCCC, the Department considers the position is better reflected by those stakeholders that argued that open disclosure and RCA are carried out for largely different purposes which need to be carefully managed and explained by AHSs, both to patients and their families as well as clinicians. Current NSW Health policy relating both to open disclosure and incident management makes it clear that the RCA process and report is *one* of the sources of information that may be used in providing feedback on clinical SAC 1 events. Problems are likely to arise when there is an excessive or inappropriate reliance on RCA reports for purposes the RCA process is not designed to meet.

The other reason provided by the HCCC for opposing the continuation of the privilege relates to the lack of objective (in the sense of quantitative or statistical) evidence that clinicians are more likely to participate in RCA processes where the privilege is available. As discussed above, however, the HCCC also acknowledges there is strong anecdotal or informal evidence of clinician anxiety or concern that they may be at risk participating in RCA processes in the absence of the privilege. Evidence from other submissions indicates that this anxiety or concern is not limited to civil litigation, but extends to and indeed is primarily driven by anxiety about potential coronial inquests, disciplinary, employment and other matters. Irrespective of the objective basis for these perceptions, there would appear to be strong evidence that they are held by clinicians of different professional backgrounds (including medical, nursing and other staff), and that removing the privilege may substantially reduce the effectiveness of RCA processes for serious clinical incidents.

(b) Use of RCA reports in health system improvement

There are well established processes within NSW Health for the analysis and consideration of RCA reports to determine whether the issues and recommendations identified give rise to the need for any measures to be

[6] As noted above, whilst two AHSs were ambivalent as to whether the privilege encourages greater clinician involvement in RCAs, they did not oppose the continuation of the privilege.

implemented across the NSW public health system. All RCA reports are provided by the Department to the NSW Reportable Incident Review Committee (**the RIRC**), a specially privileged state wide committee established under the *Health Administration Act* which is responsible monitoring and analysing serious clinical incidents and ensuring that appropriate action is taken. The RCA reports are considered and reviewed by a subcommittee of the RIRC called the RCA Review Committee.[7] The RCA Review Committee provides monthly reports to the RIRC identifying trends or issues arising in RCA reports that have state wide implications. Having regard to the advice and analysis of the RCA Review Committee, the RIRC may recommend that state wide measures be introduced, such as policies or guidelines. Where particular themes or patterns have been identified out of review of RCA reports and other IIMS data, the CEC and NSW Health have recently developed clinical focus reports on particular clinical topics or issues.[8]

(c) Lack of feedback of RCA outcomes to clinicians

The importance of the availability of RCA reports to clinicians working within NSW Health is reinforced by the Special Commission of Inquiry into Acute Care Services in NSW Public Hospitals (**the Garling Inquiry**), which recommended that: "*Within 12 months the Clinical Excellence Commission to establish searchable intranet accessible to all NSW Health staff which contains all RCAs*" (recommendation 74). This recommendation has been supported by NSW Health. This issue of better feedback of RCA outcomes to clinicians involved in incidents is further discussed in section 7 of the report below.

(d) Notification of individual conduct or performance concerns

There does not appear to be any evidence that RCA teams are failing to comply with their obligation to notify AHSs of conduct, impairment or performance concerns of clinicians. The fact that the HCCC is aware of only one referral emanating from an RCA team does not necessarily mean that only one notification under the Act has occurred. The Act requires notification to the chief executive of the AHS that established the RCA, and not directly to the HCCC. Following receipt of a notification by an RCA team, chief executives are required under NSW Health policy to investigate the matter, which may result in it being resolved at a local level without the need to refer to the HCCC. Further, under the *Health Services Act* a chief executive is required to report to the relevant registration authority any matter the chief executive "*suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct*" (sections 99A and 117A).

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[7] Mental health and maternity incidents are considered by separate RCA review sub-committees.

[8] The clinical focus reports provide specific feedback to NSW Health clinicians and health services about issues related to clinical care. To date such reports have been produced in relation to such issues as airway management, acute coronary syndrome, patient falls, management of tracheostomy and tracheostomy emergency, and transfer of the unstable patient.

(e) Relevance of tort law reform

Regarding the effect of the *Civil Liability Act*, it is noted the MIIAA and ACCC reports referred to by stakeholders provide Australia-wide data only, although there appears to be no reason to believe the claims patterns in NSW are materially different from those Australia-wide. To the extent the data in the report reflects developments in NSW, overall they appear to support the submissions that the numbers of claims has not decreased significantly in the years immediately following the commencement of the *Civil Liability Act*, and may even have increased slightly in recent years.

Perhaps of more relevance is the submission by a number of stakeholders that fear of medical indemnity claims comprises only one part of clinicians' concerns about participating in RCA processes without the protection of the privilege. Also of relevance are concerns about potential coronial, disciplinary, or employment matters.

Analysis of policy issues identified in the Discussion Paper

(1) Can the privilege be justified as in the public interest, based on clear, demonstrable evidence?

Overall, the submissions indicates a clear and consistent message that the privilege addresses strong concerns held by clinicians that information they provide to RCAs may be required to be produced in various contexts (including coronial, litigation, disciplinary and other processes), that the existence of the privilege considerably allays those concerns, and that without the privilege clinician engagement and involvement is likely to be compromised. It is also clear that NSW Health agencies and other stakeholders view RCA processes as contributing to improved public health systems and clinical outcomes. As discussed above, there are well established NSW Health systems and processes in place for the consideration and, where appropriate, implementation of RCA findings and recommendations.

(2) Is the privilege and the process it covers effective (from an operational perspective) in addressing the public interest and achieving its stated ends?

This question relates to the operational aspects of the privilege, and is addressed in the balance of this report. Without discounting the concerns raised by the HCCC, it is clear that the statutory provisions as currently formulated have some limitations, and in the discussion that follows a number of amendments are recommended to seek to ensure the privilege operates to achieve its stated policy goals of system improvement, in particular by improving the transparency of the system to improve information flow to patients as part of open disclosure.

(3) Does the privilege allow an appropriate degree of transparency and accountability to the process, and properly address competing issues such as open disclosure and individual accountability?

Overall, the submissions indicate that there is no inherent inconsistency between the existence of the privilege for RCA processes and open disclosure. The main issues appear to have arisen in the AHS's implementation of these policies, as well as clinician and public understanding of the nature of RCA processes. It needs to be accepted that there have been practical difficulties in managing both processes in the early days, but the key to making them both work well is to ensure a proper understanding of their respective roles to avoid confusion between them, and not to seek a "short cut" with open disclosure by just using RCA outcomes. In this regard it is noted that the Department of Health is currently conducting a review of the NSW Health Open Disclosure Policy and Guidelines following a recent NSW Ombudsman investigation.

Finally, there is no persuasive evidence that there has been any failure of the safeguard built into RCA processes requiring notification of individual conduct, impairment and performance issues in order to ensure individual accountability.

Recommendation 1

1.1 The statutory privilege for review of SAC 1 clinical incidents by RCA teams should continue to enjoy the statutory privilege under Part 2 Division 6C of the *Health Administration Act*, subject to the recommended amendments discussed below.

1.2 That a current NSW Health review of policy and guidelines around Open Disclosure and related issues includes seeking to ensure that RCA processes and outcomes are not used inappropriately in the context of open disclosure.

2. The types of incidents covered by the privilege

2.1 Current position

The privilege applies only to "reportable incidents" (section 20L of the Act), which is defined as a clinical SAC 1 incident.[9] This includes, as would be expected, "*The death of a patient unrelated to the natural course of the illness*

[9] A "reportable incident" is defined to mean all clinical SAC (Severity Assessment Code) 1 incidents – see *Health Administration Act* 1982, section 20L; Health Administration Regulation 2005, cl 13, and NSW Health Policy Directive *PD2005_634 Reportable Incident Definition under section 20L of the Health Administration Act.*

and differing from the immediate expected outcome of the patient management". However, reportable incidents also include sentinel events reportable to the ACSQHC, irrespective of the probability of the recurrence of the incident. The current list of sentinel events includes incidents of the following kind:

- Procedures involving the wrong patient or body part
- Suspected suicide of a person (including a patient or community patient) who has received care or treatment for a mental illness from the relevant health services organisation where the death occurs within 7 days of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- Suspected homicide committed by a person who has received care or treatment for mental illness from the relevant health services organisation within six months of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation;
- Retained instruments
- Unintended material requiring surgical removal;

Under the current provisions of the Act, a privileged RCA must be undertaken for every clinical SAC 1 incident. There is, however, no discretion to conduct a privileged RCA for other, less serious incidents.

The Discussion Paper noted that there appeared to be conflicting views as to whether the definition of reportable incident should be amended to broaden or narrow the range of matters that are currently the subject of the privilege. A further approach would be to give AHSs greater discretion or flexibility as to when incidents are subject to RCA review.

2.2 Submissions

There were a range of varying submissions on this issue.

The Medical Services Committee, the NSW Nurses' Association and the HSU all submitted the current definition of reportable incident should be retained, although the HSU also referred to feedback from its members that the definition of reportable incident should be set out in the Act rather than requiring reference to a policy document.

A number of AHSs and the ASNSW submitted that the definition of reportable incident should not be amended (that is, RCA teams must continue to be appointed in respect of all clinical SAC 1 incidents), but that there should be a discretion should be given to AHSs to conduct privileged RCA review of less serious clinical incidents where the circumstances are considered to be appropriate for RCA review. SSWAHS also reported previous unusual clinical incidents that did not fall within the definition of SAC 1, but which were considered appropriate for RCA review. Generally these submissions

suggested that guidance should be given to AHSs by the way of State wide policy as to the circumstances in which such incidents could be the subject of RCA review.

In a similar vein, the HCCC submitted that SAC 1 incidents should remain subject to RCA processes, but supported a discretion to widen the application of the privileged RCA process to other relevant incidents.

SESIAHS submitted that sentinel events should be excluded from the SAC 1 criteria, but that AHSs have discretion to conduct privileged RCA review of such matters where it is considered appropriate. GSAHS submitted that it is questionable as to whether all clinical SAC1 incidents require an RCA (examples given include incorrect x-ray site, retained drill bit, or inpatient fall). SSWAHS made a similar submission in respect of suicide/suspected suicide by patients who have received mental health services. Given the time and financial resources required for RCA review, it was suggested that AHSs should have flexibility not to appoint an RCA team in respect of some SAC 1 incidents.

The AMA submitted that the current definition of reportable incident should be expanded so that it includes clinical SAC 2 incidents as well as SAC 1 incidents. The AMA also submitted that RCA teams should have a discretion not to proceed with RCA review of SAC 1 incidents where, following preliminary investigation, the RCA team identifies that no systemic issues arise out of the event. The AMA emphasised that this discretion should rest with the RCA team and not with the AHS.

MDOs adopted different positions on this issue. The ICA submitted that the definition of reportable incident should remain unchanged, and that no discretion should be given to AHSs in respect of which incidents to review on the basis that it would be inappropriate to leave decisions on matters relating to "*whether or not to review incidents of potential systemic significance to entities with a direct stake in the outcome of the investigation.*"

On the other hand, Avant submitted that review of a broader category of incidents should be permitted, including review of incidents referred by quality assurance committees. Similarly, MDA National submitted that the definition of reportable incident should be extended, but that if AHSs are given discretion as to the matters to be subject to RCA review then there must be transparent processes and reasons provided for this. MIGA also submitted that it seems sensible for some discretion to be vested in AHSs to refer a broader range of matters for RCA review as "*the health services are in the best position to determine whether the incident may be the consequence of a deficiency in the system or may demonstrate an area for systems improvement*".

2.3 Discussion

In seeking to draw the various views put in the submissions into a series of recommendations, the Department has been mindful of the fact that there

remains debate about applying the privilege at all. Given this, any extension would need to be justified on clear clinical improvement grounds.

Overall, the submissions supported the retention of the current definition of reportable incident. Further, there was considerable support for a discretion to be given to AHSs to refer less serious incidents, normally clinical SAC 2 incidents, for RCA review where it is considered the incident gives rise to potential systemic issues. Most submissions recommended the exercise of any such discretion should be guided by State wide policy.

The AMA submitted that the definition of reportable incident should be extended to include SAC 2 incidents, meaning that AHSs would be required to appoint an RCA team to review all such incidents irrespective of the systemic significance of any individual incident. According to CEC data, there are approximately four times the number of clinical SAC 2 incidents as there are clinical SAC 1 incidents in NSW public hospitals.[10] A requirement that all clinical SAC 2 incidents must be the subject of review by an RCA team is likely to impose a considerable extra burden on the system, in circumstances where the benefit in doing so is not clear. The AMA does not provide any persuasive explanation or evidence for the need to broaden the definition of reportable incident to include SAC 2 incidents for all such incidents.

Avant, ICA and MIPS considered that quality assurance committees should be permitted to refer or recommend RCA review of incidents or issues. If AHSs were to be given discretion to appoint RCA teams for less serious clinical incidents than SAC 1 incidents, then internal AHS administrative processes could be established pursuant to which quality assurance committees or mortality & morbidity committees can refer or recommend RCA review of particular incidents or issues.

The ACSQHC agreed that some SAC 2 incidents may be appropriate for RCA review, but submitted that his could be achieved through policy and local practice without the need to change the definition of reportable incident. While there is some merit in this approach, unless an incident falls within the definition of reportable incident, or is otherwise permitted by the statute, then it will not attract the statutory privilege.

Three AHSs raised concerns about the requirement to appoint an RCA team to review all SAC 1 incidents, with particular reference to sentinel events, and submitted there should be some discretion to exclude such incidents from privileged RCA review. The difficulty is that it may not be possible to determine in advance whether or not a sentinel event may involve potential systemic issues. An alternative approach proposed by the AMA is that RCA teams should continue to be appointed for all SAC 1 incidents, but that RCA teams are given a discretion not to proceed with the review if, following preliminary investigation, the RCA team identifies that no systemic issues arise out of the event. The Department's view is that the Act already permits

[10] In the period January –June 2008, there were 281 SAC 1 clinical incidents, compared with 1,148 clinical SAC 2 incidents: *Incident Management in the NSW Public Health System, January to June 2008*, page 10.

an RCA team to refrain from making any recommendations where it considers the incident does not give rise to any system wide issues or concerns, although there does not appear to be widespread understanding of this. Accordingly, it is recommended that the Act be amended to clarify that an RCA team may decide not to make any recommendations following an RCA review.

Finally, it is relevant to note that the concerns as to breadth of sentinel events for the purposes of the definition of reportable incident may be resolved to some extent as part of a forthcoming review by the ACSQHC of its definition of sentinel events. Any changes to the definition of sentinel events following this review can be expected to be adopted by NSW Health policy, and thereby incorporated into the definition of reportable incident.

Recommendation 2

2.1 The definition of "reportable incident" in the Act should remain unchanged.

2.2 The Act should be amended to permit chief executives to appoint RCA teams for clinical incidents other than reportable incidents where it is considered the incident may give rise to potential systemic issues, such decisions to be guided by NSW Health policy.

2.3 NSW Health policy should be amended to require AHSs to implement processes to allow local quality assurance committees and mortality & morbidity committees to recommend to the chief executive that an RCA team be appointed to review incidents or issues (only if recommendation 2.2 is adopted).

2.4 The Act should be amended to clarify that an RCA team may refrain from making any recommendations in its final report where it considers the reportable incident does not give rise to any system wide issues or concerns.

3. The extent of the privilege, including protection of non-RCA team members and audit of RCA processes

3.1 Current position

The privilege is limited to a person who is or was a member of an RCA team and the health services organisation itself. It does not include persons who are not members of the RCA team (including clinicians involved in an incident or experts consulted or engaged by the RCA team), or copies of documents in the possession or control of such persons, even if they were prepared for the purpose of the RCA.

Currently, it is an offence under section 20P of the Act for an RCA team member to disclose any information acquired in his or her capacity as a team member, except:

(a) for the purpose of exercising the functions of a member
(b) for the purposes of any recommendation of the RCA team
(c) for the purposes of the RCA team's final report, or
(d) in accordance with the regulations.

At present no regulations have been made under this section, which means the circumstances in which an RCA team member may disclose information are very narrow. A further area of concern relates to the fact there is no capacity for external audit or review of RCA team processes, both generally and where issues may have arisen in any particular case.

3.2 Submissions

(a) Extent of the privilege

With some exceptions discussed below, submissions overwhelmingly argued the restriction of the protection granted by the Act to members of RCA teams was unsatisfactory. The submissions supported the proposal in the Discussion Paper that the privilege be amended to protect all communications made for the purpose of the RCA team's review. According to MDA National's submission, there have been instances where non-RCA team members have been cross-examined on what was said during an RCA process, which is clearly contrary to the intention of the provisions of the Act.

Two AHSs submitted that it was unnecessary to extend the privilege to non-RCA team members such as clinicians or experts because it could be dealt with by including such persons on the RCA team as needed. The NSW Nurses' Association submitted it was not necessary to extend the privilege to communications between the RCA team and non-team members, although it did consider the privilege should extend to documents in the possession or control of non-RCA team members that had been created for the purpose of assisting the RCA team with its investigation.

(b) External audit/review

Regarding external audit, the submissions that addressed this issue were supportive of the proposal for audit or review powers by an external and independent body. The HCCC, the HSU and the Medical Services Committee all supported the CEC being given this role. The AMA submitted that an external body of clinicians should be constituted to review the effectiveness of RCA processes generally, and audit or review the implementation of RCA processes, both within AHSs and across the State.

SICorp submitted that in addition to a power of audit or review by an external body, there also needs to be "*an internal auditing process carried out by each*

of the Clinical Governance Units against defined criteria to ensure consistency".

3.3 Discussion

(a) Extent of the privilege

Given the overwhelming support for a "purpose" test in respect of the privilege, an amendment to section 20Q of the Act to this effect is recommended.

The approach adopted by two AHSs of including expert clinicians on the RCA team is not a satisfactory solution. First, this method of avoiding the current limitations of the Act does not extend protection to clinicians who were involved in the incident, who would generally not be appropriate to be appointed to the RCA team. Second, any RCA team additional members would need to be formally appointed by the chief executive pursuant to the requirements of section 20M of the Act. This is administratively burdensome, and would require an expert to take on the obligations of being a member of the RCA team, including participating in the process of developing a causation statement and recommendations, in circumstances where the RCA team wishes only to obtain advice from the expert on a specific clinical issue.

If the recommendation to adopt a "purpose" test is adopted, a question arises as to whether the communication is to be made for the "sole" or "dominant" purpose of the RCA team review. The AMA submitted that the privilege should attach to communications made for the "primary" purpose of RCA review, which is similar to a "dominant" purpose test. The advantage of a "dominant" purpose approach is that it is consistent with the current common law and statutory provisions in respect of legal professional privilege, which are generally well understood.

One AHS made the important point that if the privilege is extended to clinicians and experts consulted by the RCA team, given that they will be subject to the prohibition on production of documents or disclosure of communications in evidence, it is important that they are properly informed of these requirements. The AHS therefore suggested that a role instruction letter for clinicians and experts be developed by NSW Health similar to the current RCA team instruction letter.

(b) External audit/review

The overwhelming majority of submissions supported an audit or review power be given to an external body. The Discussion Paper proposed that this role may be given to the CEC. Most submissions did not directly address this issue, although a number specifically endorsed the CEC. Only the AMA suggested an alternative option, being a body of external clinicians. However, this would largely appear to reflect the role of the existing CEC. One stakeholder, SICorp, also recommended internal review by AHS clinical governance units.

A question arises as to the nature of any audit or review power, and whether it should include a power to investigate individual RCA teams where an issue or concern has been raised. Some submissions referred to clinician concerns about potential RCA team bias against individual clinicians, or RCA teams improperly making conduct or performance notifications against clinicians in circumstances where there was no proper basis for this. However, there was no real evidence provided justifying these concerns. Further, any such improper conduct by an RCA team member would arguably amount to a failure to act in good faith resulting in the RCA team member losing the protection from personal liability under section 20S of the Act.

Accordingly, the Department considers there is merit in a general review or audit role being given to the CEC or other appropriate body, although there is presently no compelling need to extend this to include a power to investigate the conduct of individual RCA teams or team members. The proposed review or audit role would involve the CEC or other appropriate body in the periodic review of a sample of RCA investigations and reports for the purpose of reviewing:

(i) their compliance with the Act and NSW Health policy
(ii) the integrity of RCA processes, and
(iii) the quality and effectiveness of RCA reports.

Recommendation 3

3.1 That section 20Q of the Act be amended to prohibit the disclosure by any person of any communication (whether written or verbal) made for the dominant purpose of an RCA team review.

3.2 If recommendation 3.1 is adopted, that NSW Health develop a role instruction letter for clinicians and experts with whom RCA teams communicate for the purpose of the RCA review to explain their legal rights and responsibilities.

3.3 That the Act be amended to permit the CEC or other appropriate body to carry out on an annual basis a review or audit of a sample of RCA investigations and reports.

4. Notification of individual conduct and performance issues

4.1 Current position

Under section 20O of the Act, RCA teams have an obligation to notify concerns about conduct that may involve professional misconduct, unsatisfactory professional conduct or individual impairment (the RCA team "*is to*" notify the relevant health services organisation of such matters), and

are permitted to report concerns of unsatisfactory professional performance (the RCA team "*may*" notify the relevant health services organisation of such matters).

The Discussion Paper sought submissions in respect of a number of issues, including:

- whether the meaning of the terms used in the Act in respect of notification by RCA teams – "professional misconduct", "unsatisfactory professional conduct", "impairment" and "unsatisfactory professional performance" – are sufficiently clear to members of RCA teams;
- whether the Act should be amended to require (as opposed to permit) notification of unsatisfactory professional performance; and
- whether the Act should be amended to allow RCA teams making a notification under section 20O to identify, as part of the notification, the individual clinician/s about whom concerns are held by the RCA team.

4.2 Submissions

(a) Circumstances in which individual conduct or performance is to be notified by the RCA team

With the exception of the NSW Nurses' Association and HCCC – which submitted that the concepts of professional misconduct, unsatisfactory professional conduct, impairment and unsatisfactory professional performance should be reasonably understood by RCA teams – all other submissions favoured clarification of the meaning of these terms.

A number of submissions, including NSCCAHS, the AMA, Avant, the ICA, MIPS and the ACSQHC, submitted that the Act should be amended to define the circumstances in which individual conduct or performance is to be notified by an RCA team. The AMA submitted that definitions could be included in the Act, or alternatively cross-refer to health registration Acts. Avant submitted that: "*Doctors who have had to consider this particular section in the context of RCA are concerned they do not have sufficient expertise to form an opinion whether an incident may amount to 'professional misconduct' or 'unsatisfactory professional conduct'*".

The Medical Services Committee submitted that the definitions of the terms used in section 20O should be consistent with those used in the new uniform national legislation proposed under the National Registration and Accreditation Scheme for the health professions. In this respect the Medical Services Committee noted a concern that the terms defined in the proposed new national legislation may involve a "*lower level of reporting*" than required under current NSW legislation, and that NSW should press for the maintenance of NSW definitions in the new national legislation.

The AHSs and MIGA favoured clarifying any uncertainty about the circumstances in which notification is to occur by providing guidance in the

form of NSW Health policy, rather than amending the Act to define the relevant terms.

MDA National submitted that either the Act or NSW Health policy should include definitions and guidance regarding the terms used in ss20O(1) and (2) of the Act. Alternatively, MDA National submitted that the definition of "reportable misconduct" as defined in section 71A(2) of the *Medical Practice Act* would be appropriate.

The ASNSW was generally in favour of clarification of the definitions, although it noted that some health worker groups are not classified as "professional" (such as ambulance officers) for the purpose of health professional registration acts.

(b) Whether notification of unsatisfactory professional performance should be mandatory

The AMA, ICA, MIPS and NSCCAHS submissions opposed amending the Act to require the notification of unsatisfactory professional performance. Other submissions did not address this issue. The ACSQHC also opposed such a requirement, although it considered "*that RCA teams should be instructed, in guidelines or policy, that where there is doubt about a clinician's performance, the team should err on the side of protecting patients and report their concerns to the health service.*"

The ICA's submission, by way of justification for its opposition to mandatory reporting of unsatisfactory professional performance, argued that the "*ability rather than obligation is appropriate because the RCA team may not have the expertise to develop a view*", and that by contrast the requirement to notify professional misconduct, unsatisfactory professional conduct, or impairment is "*less dependent on specialist knowledge*". NSCCAHS made a submission in similar terms.

The only submission that expressly supported mandatory notification by RCA teams of unsatisfactory professional performance was the HCCC.

(c) Broader power of notification of any concern held

Generally stakeholders opposed the power to make a notification in respect of "*any*" concern held by an RCA team. However, the ICA and MIPS submissions pointed out that it would be appropriate for RCA teams to have a power to notify where there the RCA review gave rise to serious issues or concerns of a systems nature and which did not concern any individual conduct or performance.

(d) Whether individual clinicians should be identified in a notification

Most stakeholders opposed the identification of individuals in an RCA team notification. However, a number of stakeholders submitted that notifications

identifying clinicians should be either required or permitted subject to certain qualifications:

- The HCCC submitted that the RCA should be required to name the clinician the subject of concern as well as provide the AHS with "*an outline of the nature of the particular concerns held by the RCA team*".
- NSCCAHS submitted that where the concerns related to issues of clinician professional performance that "*posed a significant risk to patients*", the RCA team should be permitted to include the name of the individual clinician in the notification "*in the interest of the public good*".
- GSAHS submitted notifications should be required to include the name of clinicians about whom concerns are held so as to "*allow clarification about the type of concern and also allow a starting point for a secondary investigation.*"
- SSWAHS submitted that the clinician's name and the basis for the concern should be disclosed by the RCA team where requested by the AHS Clinical Governance Unit for the purpose of assisting with the direction of further investigation.
- The ICA submitted that provided there is clarification of the circumstances in which a notification is to be made, RCA teams should be permitted to disclose an individual's name so long as the requirements of natural justice are complied with. The ICA also submitted that along with the individual clinician's name it would be "*appropriate to also include supporting information such as what are the nature of the concerns, the basis for the view formed and that the principles of natural justice have been followed*".
- The Nurses' Association submitted that the RCA team should be able to disclose the name and basis of the notification after having afforded the individual an opportunity to respond as part of natural justice.

(e) What does natural justice require?

Submissions on this issue in the context of notification under section 20O largely overlapped with the following section in the Discussion Paper (Section 5 – "Requirement to provide natural justice"), and therefore this issue in considered in the context of following section of this report.

4.3 Discussion

(a) Circumstances in which individual conduct or performance is to be notified by the RCA team

There were strong views in many submissions that clarification is required of the circumstances in which RCA teams are to notify chief executives of conduct, performance or impairment concerns. Most submissions considered this should be done in the Act, with a minority arguing for clarification or guidance by way of NSW Health policy.

It is helpful to have regard to the policy behind the inclusion of the notification provisions in section 20O of the Act, being:

1) to ensure individual matters are not considered by RCA teams; and
2) to ensure matters requiring professional oversight are not inadvertently overlooked.

It is reasonable to expect clinicians involved in RCA teams to have an understanding of these issues.

Accordingly, it would appear that retaining the current approach of requiring notification of professional misconduct, unsatisfactory professional conduct, impairment and unsatisfactory professional performance is the preferred approach. The main question is how these terms should be defined so as to improve consistency and clarity in respect of the circumstances in which notification is required.

Where submissions addressed the issue of the meaning of professional misconduct, unsatisfactory professional conduct, impairment and unsatisfactory professional performance, generally they suggested that these terms should be defined by reference to the definitions in NSW health professional registration legislation.

One exception to this approach was the ICA's submission that the notification should occur where the concerns identified are "*reasonably considered to place the public at significant risk compared with that of the practitioner's peers*". The main difficulty with this suggested approach is that the key factor is risk of harm, which is much more relevant to performance than to conduct issues. For example, a practitioner may engage in conduct that that is clearly unethical or professionally inappropriate, but which does not necessarily give rise to a "significant" risk of harm.

Alternatively, MDA National submitted that the definition of "reportable misconduct" as defined in section 71A(2) of the *Medical Practice Act* would be appropriate. However, the Department considers that this concept is too narrow, being restricted only to two very serious categories of misconduct (sexual misconduct and practising medicine whilst intoxicated) and "flagrant" departures from accepted standards of professional practice.

The National Registration and Accreditation Scheme for the health professions will culminate in new uniform national legislation – the *Health Practitioner Regulation National Law* – which has a proposed commencement date of 1 July 2010. Whilst the draft legislation is still being developed, it is expected that NSW will adopt a single definition of professional misconduct, unprofessional conduct, impairment and unsatisfactory professional performance for all registered health professionals. The Department considers it would therefore be appropriate for the meaning of these terms in the *Health Administration Act* to reflect whatever definitions NSW adopts under the National Registration and Accreditation Scheme.

(b) Whether notification of unsatisfactory professional performance should be mandatory

As discussed in more detail below, at present "unsatisfactory professional performance" falls well below both "professional misconduct" and "unsatisfactory professional performance" in terms of reporting obligations of chief executives under the *Health Services Act*. Further, unsatisfactory professional performance is generally not a basis for disciplinary action under health profession registration legislation.

As noted above, some stakeholders opposed making reporting of performance issues compulsory because RCA teams could not be expected to have relevant expertise to make such a notification. There are some difficulties with the argument that an RCA team would not normally have relevant expertise to make an assessment of unsatisfactory professional performance. Generally it would be expected that an RCA team appointed to investigate an incident would include members with clinical expertise relevant to the incident that is being reviewed, or that the RCA team would consult with clinicians with relevant expertise. For example, if the incident relates to the performance of radiological services, it would normally be expected that the RCA team would include a radiologist or that the RCA team would seek advice or an opinion from a radiologist. Further, the mandatory reporting provision contained in section 71A of the *Medical Practice Act* requires all medical practitioners to report "flagrant" departures from accepted standards of medical practice by their medical colleagues. The existence of this provision makes it more difficult to argue that an obligation to report performance issues of clinical peers is inappropriate on the basis of lack of expertise.

A more persuasive basis for retaining the current distinction between conduct and performance issues relates to the different status of conduct and performance issues in NSW health profession registration legislation. The legislation that recognises performance assessment (such as the *Medical Practice Act* 1992 and the *Nurses and Midwives Act* 1991) establishes different requirements and processes to deal with such matters: professional misconduct and unsatisfactory professional conduct are normally investigated by the HCCC, whereas performance issues are subject to performance assessment processes by the relevant health registration authority. The different status of conduct and performance issues in the RCA provisions of the *Health Administration Act* need to be understood in the context of these statutory provisions.

Also of relevance are the provisions of the *Health Services Act* that require chief executives to report to registration authorities any conduct of a member of AHS staff or a visiting practitioner that the chief executive "*suspects on reasonable grounds may constitute professional misconduct or unsatisfactory professional conduct*" (sections 99A and 117A). However, there is no similar reporting requirement for unsatisfactory professional performance.

Nearly all of the submissions that addressed this issue were opposed to mandatory reporting by RCA teams of concerns about professional performance. In the light of the above considerations, it is recommended that no change be made to this provision of the Act, although the Department supports the submission of the ACSQHC that "*RCA teams should be instructed, in guidelines or policy, that where there is doubt about a clinician's performance, the team should err on the side of protecting patients and report their concerns to the health service.*" Accordingly, a recommendation is made to this effect.

(c) Broader power of notification of any concern held

There is currently no power given to RCA teams to notify of issues or concerns of a systems nature and which did not concern any individual conduct or performance. The Department considers that where, for example, an RCA team investigating a death under anaesthesia identifies a potential product defect that may have contributed to the death, and which the RCA team considers requires urgent system wide consideration prior to the formal completion of the RCA report, the RCA team should be allowed to notify the chief executive of the AHS of the concern immediately without the need for the team to go through the formality of completing its report. Accordingly, a recommendation is made that there should be an amendment to the Act to permit an RCA team to make a notification to the chief executive where the RCA team forms concerns arising from its review relating to system wide issues that give rise to a risk of serious and imminent harm to patients.

(d) Whether individual clinicians should be identified in a notification

The AMA's submission set out a detailed analysis in support of the AMA's position opposing the identification of individual clinicians. The AMA submitted that:

> "*The disciplinary investigation should commence from an entirely fresh perspective with no preconceptions, which it cannot do if the RCA team has already outlined the basis of their allegation that an individual's performance is below standard.*"

However, it is not proposed in the Discussion Paper that the RCA team be permitted to "*outline the basis of their allegation...*" At present, the standard notification form under NSW Health policy requires the RCA team to indicate whether the concerns relate to conduct, performance or impairment. It is proposed only that, in addition to this information, the RCA also be either permitted or required to provide the identity of the clinician about whom the specified concern is held. It is not proposed that the RCA notification may outline the nature or basis of the concerns. Nor is the AMA's characterisation of a section 200 notification as an "*allegation*" accurate or helpful. The language used in the Act is that an RCA team is to make a notification where it "*is of the opinion that the reportable incident that it is considering raises matters*" of the relevant kind, which does not in the view of the Department amount to an allegation.

The AMA further submits that members of its Hospital Practice Committee:

> "*... have advised that their confidence in participating in an RCA investigation (or indeed, carrying out the investigation) is based on the fact that no evidence will be used in the disciplinary context. If this were to change, doctors would reconsider their role in such RCA investigations.*"

The Department considers that the proposal to permit or require the identity of a clinician to be included by an RCA team in a notification in no way involves the use of "*evidence*" provided to the RCA team being used in the disciplinary context. As discussed above, following a notification the investigation of the matter by the AHS effectively must start *de novo*.

At the other end of the spectrum of submissions received on this issue, the ICA submitted that the RCA team should be permitted to disclose "*supporting information such as what are the nature of the concerns [and] the basis for the view formed*". This is not supported by the Department because it would involve an inappropriate transformation of the RCA process into what is effectively a disciplinary investigation. The same comment applies to the HCCC's submission that the RCA team be required to provide the AHS with "*an outline of the nature of the particular concerns held by the RCA team*".

There appears to be an erroneous assumption made in some submissions that providing RCA teams with the ability to name a clinician in a notification will have the effect of significantly reducing duplication of resources required to be committed to any subsequent investigation. In its submission, for example, one AHS says that: "*Currently it is very difficult to determine where to focus the secondary investigation and it may be necessary to repeat a number of interviews. This is a considerable waste of resources and time. It also causes unnecessary concern for staff who may have to be re-interviewed*". The assumption in this submission that permitting clinicians to be identified in s20O notifications will reduce the need for staff to be re-interviewed is perhaps questionable. Interviews conducted and information collected by RCA teams will not be available for any subsequent investigation of individual staff members by the AHS. The only benefit to be gained in terms of resources savings from permitting the identification of individual clinicians is, as the same AHS says elsewhere in its submission, that it will "*allow clarification about the type of concern and also allow a starting point for a secondary investigation.*"

In summary then, there are benefits to be gained from permitting clinicians to be identified in s20O notifications, although these benefits should not be overstated, because as explained above RCA review is unrelated and completely separate from processes for investigating individual conduct, performance or impairment issues. The only remaining issue is whether the Act should be required or permitted to identify the clinician. The submissions did not consider this issue in any detail. The Department's view is that if the RCA team considers that a notification should be made, it is not clear why

different approaches should be permitted to the identification of the clinician or clinicians about whom concerns are held. A failure by an RCA team to name a clinician where there is an legislative ability to do so may result in an inference that the RCA team holds concerns about any or all clinicians involved in an incident. The Department's view is that an amendment is likely to have maximum practical benefit, as well as be fairest to all clinicians involved, if the RCA team is required in all cases to include in the notification the identity of the clinician. The Department also supports, as part of the same amendment, incorporating in the Act a requirement that the notification indicate whether the concern relates to professional misconduct, unsatisfactory professional performance, unsatisfactory professional conduct or impairment, as is currently required by NSW Health policy.

(e) What does natural justice require?

This issue is addressed in the context of the discussion in section 8 below.

Recommendation 4

4.1 Part 2, Division 6C of the Act be amended to include definitions of "professional misconduct", "unprofessional conduct", "impairment" and "unsatisfactory professional performance" that reflect whatever definitions of these terms NSW adopts under the National Registration and Accreditation Scheme.

4.2 The Act be amended to permit RCA teams to report concerns held by the team arising from its review relating to system wide issues that give rise to a risk of serious and imminent harm to patients.

4.3 NSW Health policy be amended to clarify that where RCA teams have doubts as to whether a clinician's performance may involve unsatisfactory professional performance for the purposes of section 20O(2) of the Act, the RCA team should err on the side of caution and notify the concerns to the chief executive.

4.4 The Act be amended to require an RCA team, at the time of a s20O(1) or (2) notification, to:

(a) disclose the identity of the clinician in respect of whom the concern is held; and

(b) indicate whether the concern relates to professional misconduct, unsatisfactory professional performance, unsatisfactory professional conduct or impairment.

5. Requirement to provide natural justice

5.1 Current position

Section 20N(3) of the Act states: "*A RCA team is to have regard to the rules of natural justice in so far as they are relevant to the functions of a RCA team*". Concerns were raised by the AMA before the Parliamentary Inquiry into Complaints Handling that this provision does not provide sufficient guidance as to how the principles of natural justice are to be given practical effect in RCA investigations.[11] The Parliamentary Inquiry recommended that the review of the statutory privilege should include "*the methods used to ensure root cause analysis investigations are conducted with procedural fairness*".

The Discussion Paper queried how the concept of natural justice, or procedural fairness as it is now more commonly known – which protects individual rights, entitlements and expectations – is relevant to RCA review, given that RCA teams are not permitted to "*conduct an investigation relating to the competence of an individual in providing services*" (section 20N(1)), or in their final report to disclose the name or address of a provider of services (or enable the identification of such a person) without that person's consent (section 20N(1)).

5.2 Submissions

The majority of submissions supported the ongoing application of the requirement of natural justice to RCA review under the Act. Specific issues raised in these submissions were as follows:

- Two AHSs submitted that the legislation should be more specific in relation to the content of the natural justice that should be provided, however this was not supported by another AHS.
- The HSU submitted that guidelines on natural should be developed by the CEC.
- The ICA and MIPS submitted that the Act should be amended to contain the broad principles of natural justice outlined in the Discussion Paper.
- MDA National submitted that the requirement to afford natural justice under the Act means that where an RCA team is considering making a notification about an individual clinician the RCA team is required to "*advise them of this possibility, and to inform them of the meaning and limits of protection afforded by the privilege*".
- The AMA submitted that natural justice should apply because of the serious nature of the matters considered by RCA teams, and also because doctors are more comfortable participating in RCA processes in the knowledge that natural justice is required to be afforded. The AMA submitted that the legislation should be more specific in relation

[11] General Purpose Standing Committee No 2, *Review of Inquiry into Complaints Handling in NSW Health* (Nov 2006), pages 10, 12.

to the content of the natural justice to be provided (discussed further below). It also submitted that if notifications by RCA teams are to include the name of clinicians, this would require, at the least, the individual being notified at the same time.

Some stakeholders opposed the retention of the statutory requirement of natural justice. The HCCC submitted that:

> *"Natural justice is not applicable to the operations of an RCA team. Where an RCA team refers concerns about a particular person to another body for consideration and possible further inquiry and/or action, that does not in itself constitute an actual or potential 'detriment' to the rights of that person. Any subsequent investigation of the person's conduct is, of course, legally required to accord procedural fairness to the person".*

GSAHS submitted that since RCA teams are not able to investigate individual clinicians, they cannot easily apply the rules of natural justice, except that all parties to the incident should be interviewed and their information fed into the process.

5.3 Discussion

The overwhelming majority of stakeholders, including most AHSs, supported the retention of the requirement for natural justice. However, none of these submissions directly addressed the basic issue raised by the Discussion Paper that natural justice is not relevant to RCA processes, and sends the wrong message regarding the nature and function of RCA review.

The Department remains unpersuaded as to the relevance of the statutory requirement to accord natural justice to RCA team functions. Natural justice is an administrative law concept related to the protection of individual rights and entitlements. The Department considers that in fact this requirement is a contributing factor to ongoing misunderstanding of RCA processes. There is an inherent contradiction in the position of a number of submissions seeking to specify natural justice requirements in the Act. On the one hand, many submissions argue persuasively that RCA processes need to be seen as completely separate from processes designed to investigate individual conduct and performance, and examples were cited where the failure to completely separate these processes has resulted in confusion and misunderstanding of the proper role of RCA review. On the other hand, the same stakeholders submitted that procedurally RCA review should provide individual clinicians which all the rights associated with an investigation of an individual's conduct or performance. The Department considers that such an approach – which emphasises individual rights and procedural entitlements – will only perpetuate misconceptions as to the role of RCA review.

Whilst the Department considers a statutory requirement to accord natural justice is inappropriate to the functions of RCA teams, the submissions received by the Department identified clear stakeholder support for the

principle that RCA teams should conduct their function in a fair and reasonable manner. Further, whilst it is true that RCA teams cannot investigate individuals, they have the potential to trigger such an investigation as a result of a notification made by an RCA team during the course of its review. The Department therefore considers that whilst the reference to the need for RCA teams to "*have regard to the rules of natural justice*" should be removed, it is appropriate to replace this provision with a requirement that RCA teams must act in a "*fair and reasonable manner*" in the conduct of their functions. This proposal retains the general requirement for RCA teams to act fairly and reasonably, but without importing the specific administrative law requirement of compliance with the rules of natural justice. The Department further recommends that NSW Health policy should be amended to give AHSs guidance in respect of the content of the requirement for RCA teams to act in a "*fair and reasonable manner*".

In this regard, the submissions usefully raised a number of specific issues relating to the processes of RCA teams. Whilst a number of these issues are already addressed by NSW Health policy, there are some respects in which they could be improved or clarified. Issues raised in submissions that are already dealt with by NSW Health policy include the following:

(1) *That clinicians involved in the incident under review should be given written notice of the RCA review and provided with information as to as to the nature of the process and the outcomes that can arise as a result of the inquiry*

Under current NSW Health policy there is a standard form letter which must be provided to all clinicians involved in an incident that advises the clinician that the RCA team has been appointed and that it will be interviewing the clinician as part of its review.[12] The letter contains information about the process, the functions of the RCA team, and the restrictions on and responsibilities of the RCA team under the Act. A number of submissions did, however, emphasise that there remained poor clinician understanding of RCA processes. It is therefore proposed that NSW Health develop a guide to RCA proposes for clinicians (that would be based on the recommended guide for patients and families in section 8 below), and that would be provided to clinicians at the same time as the standard letter.

(2) *That clinicians interviewed by an RCA team should be entitled to a support person*

This is already recognised under current NSW Health policy.

Some submissions argued that the Act or NSW Health policy should acknowledge further, specific procedural rights. Currently NSW Health policy says only that the RCA team "*has a duty to act fairly and without bias, and not*

[12] *Incident Management Policy* PD2007_061, Appendix E.

to prejudge issues before them".[13] These submissions were generally on the basis that such rights were required by natural justice, and included the following:

(1) Right to seek legal advice, before, during and after the RCA process

The Department considers that the inclusion of a statutory right to seek legal advice is only likely to reinforce the apprehension on the part of those clinicians that their performance or conduct is somehow the subject of investigation or review. Further, it needs to be reinforced that the whole point of providing the statutory privilege is for candid and open participation by clinicians, which may involve the clinician making admissions. If the object of statutory recognition of a right of legal advice is to assist the practitioner in avoiding making any such admissions, then it becomes more difficult to justify the existence of the privilege.

(2) Right to reply or respond to any evidence on which the RCA team relies in making a notification

Again, the statutory recognition of such a right is likely to reinforce the incorrect apprehension that the evidence relied on by the RCA team relates to the individual clinician. A right of response is usually relevant where an individual's interests may be adversely affected by a process. Whilst a robust RCA process would normally involve ensuring that all relevant clinicians involved in an incident are interviewed or consulted, and that they have an opportunity to consider any relevant information or documents, it is more accurate to view this as part of sound RCA process rather than a requirement of natural justice.

Further, at present the Act prohibits an RCA team from disclosing information obtained as part of the review from one clinician (which may include, for example, a statement by the clinician) to another clinician. The Department considers that if there was legislative amendment permitting an RCA team to disclose information obtained from one clinician to another clinician involved in the same incident, it would be likely to have overall effect of making clinicians less inclined to be frank and forthright in respect of the information they share with the RCA team, which would bring into question the need for the privilege at all.

The Department accepts that if a notification is to occur that the affected clinician has a right at least to be informed of the notification, and whether to notification relates to a concern as to conduct, performance or impairment.

[13] *Incident Management Policy* PD2007_061, page 26.

(3) Unbiased tribunal – opportunity to respond if reasonable apprehension of bias

As noted above, NSW Health policy already states that RCA teams must act without bias. For the reasons provided above, statutory recognition of a requirement of absence of bias towards individual clinicians by members of the RCA team is only likely to foster incorrect understanding of the role of RCA teams. The Department agrees that as part of the proposed requirement to act in a "fair and reasonable" manner, generally RCA team members should not have a personal (ie non-professional) connection with clinicians involved in the incident, and should at all times act in good faith. Indeed, failure to act in good faith would be likely to mean the team member would lose the protection from personal liability under section 20S of the Act.

Accordingly, the Department recommends that NSW Health policy be amended to state that RCA team member should not have a personal connection with any clinicians under review, and reinforce the obligation of RCA team members to act in good faith. The Department understands that in some small or rural facilities, there may be circumstances in which an RCA team member has a personal connection with a clinician involved in the incident. In that event, the NSW Health conflict of interest policy will apply, and the personal connection should be declared. If the conflict of interest cannot be appropriately managed, the AHS may need to consider appointing an external person to participate in the RCA.

This issue is also relevant to the discussion of the constitution of RCA teams in section 9 below. The recommendation made in that section is that RCA teams should, as far as practicable, include a member who is external to the AHS. This mechanism should also reduce the risk of bias or abuse of power by an RCA team.

(4) That the RCA team must ensure that the evidence on which the notification is objective or meets objective standards

For the reasons provided above, the Department considers it is not helpful to use the language of natural justice, which requires that decisions are based on logically probative evidence. The reason for this is that RCA teams do not make decisions, they only notify issues of concern for consideration and investigation by others. The Department's view is that it is difficult to specify with any particularity the level of evidence or information required by an RCA before it can or should make a notification. The Department has proposed a requirement that RCA teams must act in a "fair and reasonable" manner, but otherwise considers that it is appropriate to retain the language currently used in the Act, which requires notification where the RCA team "*is of the opinion that the reportable incident that it is considering raises matters that may involve*" professional misconduct, unsatisfactory professional conduct, impairment or unsatisfactory

professional performance (subject to the recommendation above that statutory definitions of these terms be included in the Act).

Finally, a further way of ensuring the integrity of RCA processes is the recommended audit process by the CEC or other independent body. It is intended that the proposed audit power would include ensuring the integrity of RCA processes, and that RCA teams comply with the Act and NSW Health policy.

Recommendation 5

5.1 Section 20N(3) of the Act be amended to replace the requirement that RCA teams are to "*have regard to the rules of natural justice*" with a requirement that they are to act in a "*fair and reasonable manner*".

5.2 NSW Health policy be amended to include the following requirements regarding RCA teams:

(a) RCA team members should not have a personal (ie non-professional) connection with clinicians involved in the incident.
(b) The RCA team must consult with all relevant clinicians involved in the incident.
(c) Where the RCA team makes a notification to the chief executive under section 20O(1) or (2) in respect of a clinician, the chief executive must advise the clinician in writing of the notification and the basis for the notification (that is, whether the concern giving rise to the notification relating to professional misconduct, unsatisfactory professional conduct, impairment or unsatisfactory professional performance).

5.3 The NSW Health standard form letter to clinicians involved in incidents the subject of RCA review be amended to:

(a) advise that any communications between the clinician with the RCA team (written and verbal) made for the dominant purpose of the RCA review are privileged (only if recommendation 3.1 above is adopted);
(b) include a plain English guide to RCA processes that is based on upon the guide for patients and families that it is recommended be developed for patients and families in recommendation 8 below.

5.4 The proposed audit function of the CEC or other appropriate body is to include ensuring the integrity of RCA processes and that RCA teams comply with the requirements of the Act and NSW Health policy (only if recommendation 3.3 above is adopted).

6. RCA reports

6.1 Current position

The RCA team is required to produce a written report that contains:

(a) a description of the reportable incident
(b) a causation statement, being a statement that indicates reasons why the RCA team considers the reportable incident occurred, and
(c) any recommendations by the RCA team as to the need for changes or improvements in relation to a procedure or practice arising out of the incident (section 20O(3) of the Act).

Issues raised by the Discussion Paper included:

- Whether there should be any change to current prohibition on RCA teams communicating with AHS management as to proposed findings and recommendations prior to the delivery of the final report.
- Whether there should be any change to NSW Health policy regarding sign-off on RCA reports by chief executives prior to submission to the Department.
- The provisions of the Act relating to the findings that may be made by RCA teams, including the relevance of human errors or behaviour.

6.2 Submissions

(a) Consultation with AHS prior to delivery of final report

Generally, AHSs submitted that RCA teams should be able to discuss their proposed findings and recommendations with senior AHS management prior to delivery of the RCA report, and that any such communications remain privileged. The main reason provided by AHSs in support of this submission was that RCA teams will not necessarily be aware of how their recommendations will impact on AHS processes and resources, or of current or future AHS strategic plans. This view was supported by most other stakeholders (including the ACSQHC, the ICA, MIPS, and the HCCC).

One AHS took the view that RCA teams are already permitted to communicate with the AHS in respect of proposed recommendations under section 20P(a) of the Act. This section provides that an RCA team member may divulge information obtained in the course of the RCA review "*for the purpose of exercising the functions of a member*". The relevant AHS described its current process as follows:

> "*[T]he process for developing recommendations mirrors the process for describing the event – recommendations are discussed with people outside of the team including the relevant managers to ensure engagement, appropriate identification of the people who will be responsible for the implementation and then sign off by those people.*

This is managed by identifying the outcome of the investigation (as detailed in the Final Report) but not revealing the content of the discussions that lead to the recommendations".

There is some uncertainty as to whether disclosure in these circumstances is permitted, and no other AHS appears to have adopted this approach.

The AMA submitted that the RCA team should be permitted to communicate with the chief executive or other persons or bodies, but that such communications should be documented to avoid the possibility or perception of the independence of the RCA team being compromised, and that such communications should be privileged.

However, some stakeholders opposed communication between RCA teams and AHSs in respect of proposed recommendations prior to the delivery of the final report. Avant opposed it on the basis considered it may create the "*potential for a conflict of agendas to provide*". The Nurses' Association submitted that communication with the chief executive prior to the final report would be acceptable where RCA team members are independent, but that if they are employees of the AHS then "*there could be legitimate apprehension that the chief executive could have power to influence the outcome and recommendations*". On this basis the Nurses' Association suggested the CEC would be a more appropriate source of advice.

(b) Sign off on final report

GSAHS submitted the role of the chief executive should be maintained. The AMA, noting that the CEC was to advise on this, submitted it had no evidence to suggest tempering of recommendations by chief executives, and the documentary requirements under current NSW Health policy make this unlikely.

(c) RCA team findings as to individual human factors

Submissions on this issue varied. A number of stakeholders (including the AMA, the HSU, and Avant) expressed concern about any shift being permitted in the focus of RCA review from systems to individuals. Other stakeholders, such as the ACSQHC, the ASNSW, and the HCCC, submitted that RCA teams should be permitted to make findings on issues of human behaviour, error or oversight in respect of serious clinical incidents.

A number of stakeholders took the view that, upon proper consideration, there was no real inconsistency between a systems approach and consideration of individual error or behaviour. The AMA, for example, submitted that: "*There is nothing currently in the legislation or policy to preclude statements about human factors, human behaviour or oversights or errors occurring, however investigation focuses not on individual fault but how a better system may have prevented such errors.*" Similar points were made in submissions by the ICA.

(d) RCA team recommendations vs risk management

Most stakeholders submitted that the RCA team's role should be focussed on recommendations for system improvement. Whilst this would include some element of risk assessment, RCA teams were not necessarily equipped to advise on risk management, which was seen as being primarily a matter for consideration by AHSs following receipt of the recommendations.

The AMA did not oppose the inclusion of risk management as an area the RCA team may report on in its final report.

(e) Admissibility of causation statement in subsequent proceedings

SICorp, in its submission, referred to section 20R of the Act, which provides that:

> *"A notification or report of a RCA team under section 20O is not admissible as evidence in any proceedings that a procedure or practice is or was careless or inadequate."*

SICorp pointed out that this provision "*does not necessarily extend privilege to the Causation Statement so that the Causation Statement may be admissible in litigation and Coronial inquests flowing from an adverse incident*".

6.3 Discussion

(a) Consultation with AHS prior to delivery of final report

Overall the submissions were in favour of permitting the RCA team to consult with the AHS prior to delivery of the final report. Whilst one AHS has taken the view that this is permitted under the current provisions, it is not entirely clear and the Department considers it would be prudent to amend the Act to expressly permit this by way of regulation under section 20P(d). It is clear however there need to be processes in place to prevent any actual undue influence, or the appearance of such. The AMA's suggestion that a written record of all such communications be kept is one option to address in part the concerns raised by some stakeholders as to the possibility of undue influence being exerted by the AHS over the RCA team. This is a matter best dealt with by policy rather than legislation.

(b) Sign off on final report

There was no objection to this process, and therefore no change to it is recommended. It is however noted that one of the Garling Inquiry recommendations was that the CEC consider and advise the Director-General of the NSW Health Department whether the involvement by the chief executive in the approval of the RCA process requires amendment, and if so in what respects. The CEC has now provided advice to the Director-General in response to the recommendation. The CEC's advice is that the RCA approval process does not require amendment, and that indeed there is very

strong support for the maintenance of this involvement by staff at all levels of the AHS.

(c) RCA team findings as to individual human factors

The most helpful submissions on this point were those that took the position that, on proper consideration, there is no real inconsistency between a systems approach and consideration of individual error or behaviour. A useful description of the interaction of systems and individual human behaviour or conduct was provided by the MDA National submission: "*One of the principles underlying RCA investigations is the creation of a culture where human error is expected to occur and actions are taken to mitigate harm from adverse events*".

An example of this would be where an RCA review identifies that fatigue on the part of an individual clinician contributed to an incident. Clearly, this would involve the RCA team considering individual human behaviour or conduct as a contributing factor to the incident, but the focus of the RCA team's analysis would be on the larger system issue of eliminating or reducing to an acceptable level risks associated with clinician fatigue, rather than on the conduct of performance of the individual clinician.

Whilst a power exists under the Act for regulations to be made in respect of "*the functions of RCA teams*", no such regulations have been made to date. Current NSW Health policy recognises in broad terms that RCA teams investigate "*system*" issues.[14] However these is no discussion or consideration of the relevance of individual human conduct, errors or behaviour. It would seem that it is the source of some unnecessary confusion, and that it would be appropriate to clarify this matter in NSW Health policy.

(d) RCA team recommendations vs risk management

In the light of the submissions, the Department does not consider there is any need for changes to the Act in respect of the making of recommendations by RCA teams. If recommendation 6.1 below is adopted (that RCA teams be permitted to discuss draft findings and recommendations with AHSs) this would provide an opportunity for AHSs to consider the draft recommendations in the context of overall risk management issues and to provide any appropriate feedback to the RCA team prior to finalisation of the report.

One AHS submitted that consideration should be given to "*removing from the legislation the requirement for RCA teams to make recommendations in regard to each contributing factor found*". In fact there is no such requirement in the Act, which provides only that the RCA report must contain "*any recommendations*" the team considers appropriate as to the need for changes or improvements. In this respect, the current wording of the NSW Health policy dealing with RCAs may be slightly misleading. It states that the RCA

[14] *Incident Management Policy* PD2007_061.

final report "*must contain...recommendations for system changes to improve procedures or practices to minimise recurrence of the incident (usually 3-5 recommendations)*". This part of the policy could be interpreted as requiring an RCA team to provide recommendations, which as explained above is not the case under the Act.

(e) Admissibility of causation statement in subsequent proceedings

The Department is not aware of any instance in which a Court or other body has ever admitted the causation statement of an RCA report as evidence that an act or omission of a clinician or a health service caused injury or harm to a patient. Nonetheless, the Department agrees with SICorp's submission that a Court or other body could take the view that the restriction on admissibility of an RCA report for the purpose of establishing a procedure or practice was "*careless or inadequate*" does not extend to findings as to causation.

A more significant issue relates to section 20R's focus on the use of RCA reports in litigation where there is a claim that a health service or clinician was negligent. It does not necessarily protect against the use of RCA reports in other contexts for which they were not intended, such as coronial inquests, criminal or disciplinary matters.

The Department's view, which is discussed further in section 7 below, is that generally there should be no legal restriction on the persons to whom an RCA report may be disclosed. An important public policy justification for the privileging of RCA processes is that the report and recommendations should be generally available for the purpose of improving the health system. Having said that, it is reasonable that there should be limits on the use to which RCA reports can be put in the context of litigation and other proceedings. The current section 20R of the Act recognises that an RCA report cannot be relied upon as evidence of negligence in civil litigation. Whilst the restrictions in the Act on RCA team processes and reports make it inherently unlikely that an RCA report may be used in criminal or disciplinary matters, the Department is aware that RCA reports have been referred to in a number of coronial inquests. The Department's approach to coronial inquests is that it makes available any relevant RCA report (or alternatively the recommendations of the report) to assist the coroner, as well as interested parties to the inquest, in understanding the system issues that have been identified by the RCA team, the recommendations that have been made to address those issues, and any steps that have been taken to implement the recommendations by the AHS. The Department is aware that in this way findings and recommendations by RCA teams have been of considerable assistance in a number of coronial inquests.

However, the Department would be opposed to the tendering of RCA reports, or their use in cross-examination of witnesses, including for example clinicians involved in an incident, in coronial inquests or in any other proceedings such as criminal or disciplinary matters. From discussions with stakeholders, the Department is aware that there is ongoing clinician concern as to the risk of RCA reports being use in this manner, particularly in coronial inquests. The

Department's view is that use of RCA reports in this way is not consistent with the purpose for which RCA reports are prepared, and that the Act should be amended to clarify this. The Department does however emphasise that the practice of making RCA reports and recommendations available for the purposes of assisting coronial processes will continue as described above. Similarly, RCA reports would also continue to be available to the HCCC where relevant, particularly in respect of an investigation into an AHS.

Recommendation 6

6.1 A regulation should be made under section 20P(d) of the Act permitting the RCA team to communicate with the AHS in respect of its proposed findings and recommendations.

6.2 Amend NSW Health policy to require all communications between the RCA team and the AHS in respect of the proposed findings and recommendations of the RCA team to be in writing.

6.3 Amend NSW Health policy to clarify the role of individual human error, behaviour or conduct in the systems review carried out by RCA teams.

6.4 Amend NSW Health policy to clarify that the RCA team may decide it is unnecessary to make recommendations in respect of each causal factor identified in the causation statement, or to make any recommendations at all.

6.5 Amend section 20R of the Act to provide that a notification or RCA report:

(a) is not admissible as evidence in any proceedings,
(b) cannot be tendered in any proceedings, and
(c) cannot be used to cross-examine any witness in any proceedings,

except in proceedings in respect of any act or omission by a RCA team or by a member of a RCA team as a member.

7. Disclosure of RCA reports

7.1 Current position

The Act does not specifically authorise the disclosure of the RCA report to any person, stating only that the RCA team "*must prepare a report in writing*" (section 20(3)). Given that the RCA report must contain, inter alia, "*any recommendations by the RCA team as to the need for changes or improvements in relation to a procedure or practice arising out of the incident*", the Act makes it inherently likely that the report will be disclosed to the chief

executive of the health services organisation that appointed the RCA, and this is required by the NSW Health policy. Further, as discussed above, NSW Health policy requires the chief executive to review the recommendations for consideration and endorsement before submitting the report to the NSW Department of Health.[15] In addition, under the *Open Disclosure Guidelines* following an RCA investigation the health service is required to provide the patient and their support person with details of the RCA report and an explanation of the report in plain English, a summary of the factors contributing to the incident (as established in the RCA report), and information on measures to be implemented to prevent a similar incident from occurring.[16]

The Act authorises the Minister to make regulations:

- permitting or requiring RCA teams to make specified information available to the public (section 20T(d)); and
- permitting or requiring RCA teams to furnish reports concerning their activities to the Minister and to relevant health services organisations (section 20T(e)).

Accordingly, the Act currently includes certain powers permitting or authorising the disclosure of RCA reports or other specific information, although no regulations have yet been made pursuant to these powers.

7.2 Submissions

NSCCAHS submitted that RCA reports should be available only within the health service, and also to patients and families, but should not be distributed more widely. It suggested that publicly available summary reports could be published by the Department on an annual basis.

HNEAHS supported amendment of the Act to clarify that the report is to be provided to the chief executive, but considered further legislative change unnecessary.

GSAHS submitted that the final report should be available to the patient, to all clinicians working in the NSW Health system, other agencies such as the CEC, and the public (though in this respect it suggested a summary report would be more appropriate).

SSWAHS submitted that public access to RCA reports may result in community misinterpretation. It recommended a de-identified searchable database (similar to the kind recommended by the Garling Inquiry).

The AMA submitted that whilst patients and families are informed of the findings of RCA during the open disclosure process, including providing patients and families with a plain English summary document, a copy of the RCA report should not be provided to patients and their families. In this

[15] *Incident Management Policy* PD2007_061, pages 24 and 28.
[16] *Open Disclosure Guidelines* GL2007_007, page 9.

respect the AMA submitted: "*Providing a RCA report to patient/families which is confusing and can be upsetting (due to its clinical context and language) is not helpful to the process*". The AMA further submitted that members of the public should not be provided with RCA reports, and that regulations should be made specifying the following as person/entities provided with a copy of the RCA report:

- relevant staff in AHSs
- the CEC or other body with an oversight role for RCA processes
- clinicians involved in an incident

The ACSQHC supported current NSW Health policy, which requires AHS to provide patients and families with details of the RCA report, an explanation in plain English, and information on measures implemented to prevent a similar incident from occurring. However, it also supported a copy of the RCA report being provided to the patient/family in most circumstances.

Avant submitted that the RCA report should not be released to the public as its format is inappropriate for this, and that it should only be provided to patients and families in conjunction with an explanatory discussion. Avant supported providing the reports to the CEC, or alternatively in an annual consolidated report.

The ICA submitted that current NSW Health policy in respect of disclosure (including disclosure to the chief executive) should continue, and should be confirmed by regulations. The ICA opposed release of RCA reports to the general public.

MDA National proposed a collective public report of overall RCA findings, which would avoid the risk of identifying facilities or individuals.

SICorp submitted that RCA reports should be provided to patients and to clinicians involved in the incident, and that further consideration should be given to a consistent approach to distributing RCA reports to other clinicians at ward level.

The HCCC advised it had received legal advice from the Crown Solicitor's Office to the effect that there was "*considerable ambiguity*" in relation to the circumstances in which an RCA report may be disclosed and to whom, and also the use to which it may be put. The Department understands from further discussions with the HCCC that this is based on section 20Q of the Act. The HCCC submitted that these matters should be expressly addressed in the legislation. The HCCC submitted that the RCA report should be available to clinicians, patients and other relevant agencies involved in the administration of the public health system, such as the CEC. The HCCC further submitted that any proposal to make RCA reports publicly available would require quality control as well as consideration as to how the report could be made more easily understood.

The Medical Services Committee submitted that RCA reports should be circulated to those facilities, departments or individual clinicians that face circumstances similar to those in which the incident or incidents occurred. Generally, the Committee submitted, these should be in simple terms and readily understandable by those involved.

7.3 Discussion

There was general approval in stakeholders' submissions of the current NSW Health policy regarding feedback to patients of a discussion/meeting with patient to explain the outcome of the RCA, including the provision of a summary of the report. Regarding the question of whether a copy of RCA report should be provided to the patient/family, the Department is aware of some instances in which this has occurred, and agrees with the ACSQHC that it is likely to be appropriate to do so in most cases where patient/family wishes to have a copy of the report. It is recommended that NSW Health policy be amended to clarify that there is no restriction on a copy of the RCA report being provided to the patient/family as part of the Open Disclosure process where the patient/family requests this or where it is otherwise appropriate.

Regarding the wider availability of RCA reports, with the exception of the HCCC, other stakeholders appeared to proceed on the assumption that disclosure of the RCA report, whilst not expressly dealt with by the Act, was impliedly permitted.

Some confusion appears to have been created by section 20Q(1) of the Act, which provides:

> *A person who is or was a member of a RCA team and the relevant health services organisation for which the RCA team was appointed are neither competent nor compellable:*
>
> *(a) to produce before any court, tribunal, board or person any document in his, her or its possession or under his, her or its control that was created by, at the request of or solely for the purpose of the RCA team, or*
>
> *(b) to divulge or communicate to any court, tribunal, board or person any matter or thing that came to the notice of a member of the RCA team as such a member.*

On one interpretation of this section, the RCA report may be regarded as a "*document*" under paragraph (b) in the possession or control of an AHS or an RCA team, which therefore cannot be produced before any court, tribunal or "*person*". However, the provision is limited to the *production* of documents by an RCA team member or AHS to a person or body, which the Department considers is restricted to circumstances in which the RCA team member or AHS is required to do so pursuant to some statutory power or authority. Further, whilst the provision may be ambiguous, the Department considers the better view is that it is not intended to apply to RCA reports.

The Department's view is that, in the context of the RCA provisions of the Act overall, there is no restriction on the persons or bodies to whom a final report may be disclosed or on the use to which it may be put. On this basis, the Department's position has been that the unrestricted availability of the RCA report is part of the quid pro quo for the protections given to the RCA processes and team members.

Nonetheless, the Department accepts the matter is not entirely free from doubt and that some stakeholders appear to be confused about it. It is therefore recommended that the Act be amended to clarify that there is no restriction on the persons or bodies to whom an RCA report may be disclosed, or the use to which it may be put (subject only to section 20R of the Act, as amended in accordance with recommendation 6.5 above).

One point on which submissions were unanimous was that RCA reports should not be made automatically available to the public. The reason provided for this was that the format and technical information contained in RCA reports was inappropriate for the general public, and may result in misunderstanding or confusion.

The Department accepts there are strong arguments against RCA reports being made routinely available to the public. In addition to the arguments referred to above, RCA reports may also give rise to privacy issues by inadvertently disclosing personal information. Theoretically, privacy issues should not arise because section 20N(2) of the Act provides that an RCA report should not disclose:

> "*(a) the name or address of an individual who is a provider or recipient of services unless the individual has consented in writing to that disclosure, or*
> *(b) as far as is practicable, any other material that identifies, or may lead to the identification of, such an individual.*"

Notwithstanding this, a number of submissions suggested that disclosure of information that would enable clinicians or patients to be identified was a real risk, especially in smaller facilities or in respect of unusual or high profile incidents.

On the other hand, for the reasons set out above, the granting of protections to members of RCA teams and to RCA processes requires a strong degree of openness and accountability in respect of the outcome those processes. This is recognised in section 20T(d) of the Act, which permits regulations to be made "*permitting or requiring RCA teams to make specified information available to the public*".

A number of submissions indicated support for the idea of summary or consolidated information being made available to the public on a periodic basis by the Department or some other body. Whilst this idea was raised by some stakeholders, NSW Health received no submissions from the public,

consumer or other groups making any such proposal. It is not apparent that there is at present any significant interest in such information that would justify the resources involved in producing, for example, an annual consolidated report of RCA reports. Were such interest were to arise in the future, consideration could be given to facilitating this by way of regulation under section 20T(d) of the Act.

Regarding the dissemination of information about RCA outcomes within the NSW Health system, under existing policy a copy of the report is provided to the Department of Health. Submissions from stakeholders supported RCA reports being made available to clinicians involved in incidents, as well as the public health system more broadly.

Feedback of RCA results to clinicians involved in an incident is currently required to be provided by AHSs under NSW Health policy, which states: "*The findings of the Clinical SAC 1 RCA Report should be provided to the relevant clinical team and presented at relevant staff meetings.*"[17] However, submissions indicated that this process was not always occurring. In this regard, the Department notes that the CEC's report on RCA processes reported unanimous support for the following proposal:

> "*That NSW Health work with area health services to develop a more robust process to facilitate and record that all affected parties have received feedback about RCAs for incidents in which they, their clinical unit or loved one were involved.*

The Department supports this recommendation.

Regarding the availability of RCA reports and recommendations within the broader public health system, this issue has been subject to consideration by the recent Garling Inquiry. One of the Garling Inquiry's recommendations was that the CEC is to establish within 12 months a searchable intranet accessible to all NSW Health staff which contains all RCAs (recommendation 74). This recommendation has been accepted by the NSW Government, and the CEC is currently working to implement it.

Recommendation 7

7.1 NSW Health policy should be amended to clarify that as part of the Open Disclosure process patients and families may receive a copy of the RCA report (the report to be provided where possible in conjunction with the current process which involves a meeting with the patient/family to explain the RCA findings and steps to be taken to implement its recommendations, as well as to answer any questions).

[17] *Incident Management Policy* PD2007_061, page 12.

7.2 NSW Health develop more robust processes for the systemic feedback of RCA outcomes to clinicians involved in incidents giving rise to RCA reviews.

7.3 Amend the Act to clarify that the privilege does not restrict the persons to whom an RCA report may be disclosed, or (subject only to section 20R) the use to which it may be put.

8. Communicating with patients and their families

8.1 Current position

Whilst NSW Health Open Disclosure policy requires feedback to be provided to patients and families of RCA outcomes, there have been concerns raised as to public understanding of RCA processes and their limited role in respect of systems issues within the health system. The focus of RCA review on systems issues can sometimes lead to the patient and their family feeling that their concerns have not been properly addressed.

A further issue raised by the Garling Inquiry, although not subject to a recommendation, relates to whether RCA teams should be permitted or required to produce an "interim" report a short time (perhaps 24 hours) following an incident. The interim report could be provided to clinicians involved in the incident, as well as provide the basis for initial communications with the patient's family as part of the open disclosure process. Any such proposal would of course require legislative amendment.

8.2 Submissions

(a) Feedback to patients and families

Regarding public and clinician understanding of RCA processes, most submissions accepted this was a significant issue. Rather than any legislative amendment, most stakeholders submitted that better information should be provided to patients, families and clinicians. A number of stakeholders supported the production of a guide for patients and families, in plain English, about what RCA involves, its place in the open disclosure process, and what can and cannot be achieved from the RCA process. This would include the provision of information of mechanisms available for the resolution of grievances, such as complaints.

A number of stakeholders submitted that clinicians also often have a poor understanding of RCA, and that better information needs to be made available for clinicians

It is noted that the ACSQHC is currently undertaking a major project involving interviews with 100 Australian patients documenting their experience of adverse events and open disclosure. The ACSQHC advises that the results

of this project are likely to be available by mid-2010, and it is expected that this will provide significant assistance in developing any guide for patients advising of RCA and its role.

The HCCC submission included a more radical proposal to seek to provide all relevant information to patients and families:

> *"However, production of the RCA report is not enough. The patient and family will have more questions than the report can answer, and will require considerable more detail. Indeed, the Commission's experience is that, in serious matters, production of an RCA report, together with a failure to adequately respond to questions arising because of the application of the RCA privilege, can have a serious adverse effect on the effectiveness of open disclosure.*
>
> *If privilege over RCA investigations is to be maintained, this would logically require the extension of the privilege to the open disclosure process, so that the information gathered through the RCA process could be provided to patients and families through open disclosure, but could not be used for the purposes of disciplinary proceedings or civil litigation."*

(b) Proposed interim report

Regarding the proposed interim report, this was opposed by most stakeholders on the basis there was unlikely to be sufficient information available at such an early stage of the RCA process (which would most likely be prior to the conduct of interviews) to enable a meaningful report to be produced. The result would be a report that may be unhelpful, or at worst misleading. The ACSQHC added that interim reports would create a risk of patient distress if subsequent investigations reveal different or conflicting information. Significantly, all AHSs that made submissions opposed the "interim" report proposal.

There were however a couple of exceptions to this position. The AMA submitted that RCA teams should be permitted to issue an interim report where they consider it appropriate or desirable. The ICA and MIPS submitted that RCA teams should be permitted to issue an interim report if there was an early view formed of significant systemic risk. They further submitted that any such report would need to be provided to the Chief Executive, and enjoy privilege. A similar issue was raised by the Medical Services Committee, which submitted that if an RCA team identifies an issue that needs to be urgently addressed in the interests of public safety, it should be able to do so by way of interim report.

8.3 Discussion

(a) Feedback to patients and families

There was strong stakeholder support for NSW Health developing a guideline or brochure for patients and families that explains in plain English what RCA processes involve, what can and cannot be achieved from the RCA process, and what alternative processes are available for grievances, complaints and other issues. . The Department also agrees it would be useful a clinician version of this guide to be provided to clinicians involved in the RCA process, which could be included as an attachment to the letter that is sent to clinicians at the time the RCA team is established (see recommendation 5.3(b) to this effect).

Regarding the HCCC submission that patients be permitted to seek information from RCA teams as part of open disclosure, as set out in section 1 of this report it is important to understand the limited role of RCAs and that AHSs should not seek to rely on them to an excessive extent for the purpose of open disclosure. The Department is not convinced that if RCA reports are of a high quality that there will necessarily be unanswered questions arising from patients and family members. It is to be hoped that the recommended process in section 6 above by which the proposed findings and recommendations of RCA reports are provided to AHSs will provide an opportunity for the AHS to raise questions and seek elucidation as to the basis of the findings, thus improving the reasoning, quality and completeness of the final report.

To the extent that RCA reports reach conclusions that family members would wish, for example, to have explained in greater detail, then that should be part of the open disclosure process. The Department accepts that there may be circumstances in which patients or families have specific questions about a matter in an RCA report that only the RCA team can answer. At present this information cannot be provided.

If there is a capacity for the privilege to be "broken open" to allow information to be given to family members as proposed by the HCCC, this would clearly represent a major dilution of the effect of the privilege. Even if such information could not be used in disciplinary matters or civil litigation, based on the submissions referred to in section 1 of this Report the Department accepts that there is a real risk that clinician confidence and engagement in the process would be significantly reduced.

Accordingly, the Department does not support the submission of the HCCC.

(b) Proposed interim report

Regarding the "interim report" proposal raised in the Garling Inquiry, perhaps the most persuasive argument made in favour of an interim report was that raised by the ICA relating to where the RCA team formed the view that the incident gave rise to a major systemic risk which as a matter of urgency

should be brought to the attention of the AHS as a matter of urgency. In that event, the situation is perhaps better described as a notification that is analogous to the power of RCA teams to report concerns about individual conduct or performance, rather than an "interim report". Under the current provisions of the Act, a notification by an RCA team in these circumstances is not expressly permitted. This issue has been addressed by recommendation 4.2 above that the Act be amended to permit RCA teams to report concerns held by the team arising from its review relating to system wide issues that give rise to a risk of serious and imminent harm to patients

Recommendation 8

NSW Health develop a guide for patients and families, in plain English, about what RCA processes involve, and what can and cannot be achieved from the RCA process.

(It is also noted that recommendations 1.2 and 5.3 (b) above will, if adopted, provide greater support for clinicians in respect of their understanding of RCA process and its appropriate role in the context of open disclosure).

9. Membership of RCA teams

9.1 Current position

The Act authorises the making of regulations relating to, inter alia, "*the constitution and membership of RCA teams*" (section 20T(a) of the Act). At present, no such regulations have been made. The constitution and membership of RCA teams is a matter that is covered to a limited extent by NSW Health policy. For example, NSW Health policy requires that RCA team members "*should have fundamental knowledge about the care processes in the area where the incident occurred, and not have been directly involved in the incident*", and also specifies certain requirements in relation to incidents involving patient suicides and patient homicides. Apart from these limited requirements, however, it is left to health service management to determine, in each instance, the composition of RCA teams.

9.2 Submissions

All AHSs and the ASNSW made similar submissions on this issue – that the composition of RCA teams should not be legislatively prescribed, but rather and should be left to the discretion of local AHSs discretion in respect of the constitution of RCA teams. HNEAHS submitted that the role of the AHS Clinical Governance Unit was to ensure that RCA teams include members with appropriate expertise and independence.

Generally submissions, including from AHSs, were of the view that it would not be appropriate to include as members of an RCA team clinicians who

were involved in an incident. This is prohibited under current NSW Health policy.

A number of stakeholders submitted that there should be at least one external or independent clinician on an RCA team to promote the independence and objectivity of the exercise, although there was generally lack of specificity as to what this would require. Obviously, it should be someone independent from the hospital or facility involved, although it was unclear as to whether it would require a clinician from a different AHS. Some submissions suggested that an appropriate degree of independence would only be obtained by a clinician from a different AHS. HNEAHS noted there are practical resourcing difficulties with "*mandating*" the involvement of external clinicians, particularly for rural and regional AHSs.

Generally the inclusion of members of the community on RCA teams was not favoured by stakeholders. The technical and systems focus of RCA teams was not seen as being conducive to community involvement, and a number of stakeholders said that improved public understanding and acceptance of RCA processes would be more likely to come from the provision of more appropriate information about RCA processes. One exception to this was the NSW Nurses' Association, which submitted that community member inclusion would provide better "*balance*" to RCA teams.

9.3 Discussion

Overall, the submissions suggested there was no pressing need to change the current policy of providing chief executives discretion to appoint RCA teams appropriate to each matter under review in the light of the clinical and other matters arising. The submissions suggest there would be merit in amending current policy to require the chief executive to appoint at least one clinician external to the AHS where it is practicable to do so.

Recommendation 9

NSW Health policy be amended to require the chief executive, when appointing an RCA team, to include at least one member who is external to the AHS, where it is practicable to do so.

10. Quality assurance committees

10.1 Current position

The statutory privilege provisions for approved quality assurance committees (**QACs**) have been in place since the 1980s, and are therefore longstanding provisions. Although not subject to the requirement for legislative review, the Department considered it may be appropriate to include as part of this review consideration of the privilege of QACs given that statutory regimes for RCA

and QAC privilege are virtually identical, and also because both processes are concerned with systemic improvement of quality and safety of health services. In both cases the statutory privilege is intended to enhance the process by facilitating maximum clinician involvement and by providing protections to members of the body undertaking the review. To this end, the Discussion Paper sought submissions on whether the statutory privilege for QACs should continue and/or if any amendments should be made to the QAC provisions.

10.2 Submissions

In respect of whether the privilege should be maintained, most submissions adopted a similar position in respect of QACs as they did with RCAs, so that overall there was support of retaining the privilege on the basis that it encourages clinician involvement and co-operation. However, submissions raised a number of significant operational issues in respect of the QAC provisions, including:

- Coverage appeared to be patchy and inconsistent, with widely varying use of the privilege
- Approval was difficult to obtain and maintain (the reporting obligations of QACs under the Act were perceived in some cases to be onerous)
- Because the privilege only protects QAC members, it reduces the educational value of such committees for junior or trainee clinicians who are not permanent staff members and who are therefore not members of the QAC
- There were concerns about privacy issues, particularly in small or rural facilities. In this regard the Medical Services Committee suggested that consideration be given to the establishment of AHS-wide QACs, with sub-committees of the AHS QAC established in individual hospitals or facilities.
- The availability of two privileged processes (QAC and RCA) creates confusion and duplication
- Some submissions (for example, Avant) proposed that the coverage of the privilege should be expanded to all quality assurance committees and mortality & morbidity committees. On the other hand, the Medical Services Committee argued that most quality assurance committees do not seek the privilege because of the reporting obligations required by approval.

10.3 Discussion

The submissions provided mixed views as to the benefits and operational issues associated with privileging of QACs, however generally submissions provided limited information and analysis of these issues. The question of the ongoing privileging of QACs, and if so the form it should take, is clearly a complex one. A relevant issue for this exercise is obtaining better information as to the reasons committees seek the privilege and their activities.

The Department notes that recommendations in respect of QACs are not required as part of the statutory review of RCA provisions, and therefore proposes to defer making any recommendations on QACs at this stage pending a more considered review of these committees and their activities.

It is also relevant to note that the ACSQHC is conducting a major project at present to seek to develop a consistent national approach to privilege of quality assurance activities, and a report by Professor Studdert on legal issues as part of this project is due in September 2009. The Department proposes to await the outcome of the ACSQHC review so that any recommendations or proposal arising from this project can be considered as part of the further consideration of the privilege associated with QACs in NSW.

Recommendation 10

The privileging of approved quality assurance committees be retained pending a more considered review of these committees and their activities.

APPENDIX A: Recipients of Discussion Paper

Area health services (including affiliated health organisations within each area)

Greater Southern Area Health Service

Greater Western Area Health Service

Hunter New England Area Health Service

North Coast Area Health Service

Northern Sydney Central Coast Area Health Service

South Eastern Sydney Illawarra Area Health Service

Sydney South West Area Health Service

Sydney West Area Health Service

Other NSW Health entities

Clinical Excellence Commission

Ambulance Service of NSW

The Children's Hospital at Westmead

Justice Health

Other health entities

Health Care Complaints Commission

Australian Commission on Safety and Quality in Health Care

Medical Services Committee

Professional and employee associations

Australian Salaried Medical Officers Federation NSW

Australian Medical Association (NSW)

NSW Nurses' Association

Health Services Union of Australia

Rural Doctors Association (NSW)

Professional indemnity insurers

Avant Mutual Group Limited

Insurance Council of Australia

Medical Indemnity Protection Society Ltd

Medical Insurance Group Australia

MDA National Insurance Pty Ltd

QBE Insurance Limited

APPENDIX B: Submissions to the Review

Ambulance Service of NSW (**ASNSW**)

Australian Commission on Safety and Quality in Health Care (**ACSQHC**)

Australian Medical Association (NSW) (**AMA**)

Avant Mutual Group Limited (**Avant**)

Greater Southern Area Health Service (**GSAHS**)

Health Care Complaints Commission (**HCCC**)

Health Services Union of Australia (**HSU**)

Hunter New England Area Health Service (**HNEAHS**)

Insurance Council of Australia (**ICA**)

Dr Frederik Lips, Specialist VMO in Anaesthetics, Port Macquarie Base Hospital

MDA National Insurance Pty Ltd (**MDA National**)

Medical Indemnity Protection Society Ltd (**MIPS**)

Medical Insurance Group Australia (**MIGA**)

Medical Services Committee

NSW Nurses' Association

New South Wales Self Insurance Corporation, NSW Treasury (**SICorp**)

Northern Illawarra Hospitals Medical Staff Council

Northern Sydney Central Coast Area Health Service (**NSCCAHS**)

Dr Peter Rankin, Senior Staff Specialist Haematologist, Lismore Base Hospital

St John of God Health Care

South Eastern Sydney Illawarra Area Health Service (**SESIAHS**)

Sydney South West Area Health Service (**SSWAHS**)