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ANMF (Vic Branch) Submission

A Statutory Duty of Candour: Report to the Minister for Health

Expert Working group advice on legislative reforms arising from Targeting Zero

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Introduction

The Australian Nursing and Midwifery Federation (ANMF) was established in 1924 and is the largest industrial and professional organisation in Australia for nurses and midwives, with Branches in each state and territory of Australia.

The ANMF (Victorian Branch) represents more than 93,000 nurses, midwives, and personal care workers (the latter predominantly in the private residential aged care sector). Our members are employed in a wide range of enterprises in urban, rural, and community care locations, and the public and private health and aged care sectors.

The core business for the ANMF (Victorian Branch), is the representation of the professional and industrial interests of our members and the professions of nursing and midwifery. We have additional interests in the areas of workplace health and safety, and continuous professional development for Victorian nurses and midwives.

The ANMF (Victorian Branch) (ANMF) participates in the development of policy relating to nursing and midwifery practice, professionalism, regulation, education, training, workforce, and socio-economic welfare, health and aged care, community services, veterans' affairs, occupational health and safety, industrial relations, social justice, human rights, immigration, foreign affairs, and law reform.

The ANMF welcomes the opportunity to provide feedback to the Department of Health (DHS) public consultation related to the implementation of legislative reforms associated with the *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*[1], and to respond to the Expert Working Group report and recommendations to the Minister for Health: A statutory duty of candour[2].

[1] Department of Health and Human Services 2020 *A statutory duty of candour: Report to the Minister for Health*, Expert Working Group to advise on legislative reforms arising from *Targeting Zero* Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020.

[2] Engage Victoria/Department of Health *Reforms to foster an honest and open culture in health services* https://engage.vic.gov.au/reforms-foster-honest-and-open-culture-health-services Accessed 9/03/2021

The ANMF, representing 93,000 Victorian nursing and midwifery professionals, are key stakeholders in this consultation, and met with DHHS/SCV on 23 February 2021, to be further briefed and provide our initial thoughts on the initiatives. The nursing and midwifery workforce are the largest health workforce and are therefore potentially the clinicians most significantly impacted by this legislative reform. It will be critical that nurses and midwives are properly consulted throughout the process for implementation of the Statutory Duty of Candour,, particularly in relation to nurse/midwife inclusion on the Expert Working Group (EWG), which does not include sufficient nursing and midwifery representation[3].

The ANMF acknowledges and welcomes the aim of the legislation to further strengthen a culture of openness and honesty across Victorian health services through open disclosure and *'alongside moves towards greater transparency about health care performance … and fostering just cultures in hospitals and health services to encourage open and honest conversations about opportunities for improvement'.*[4]

ANMF Reservations: Overview

ANMF has carefully reviewed the EWG report, and have significant concerns about the clarity of the guidelines proposed and the regulation of the duty and potential impacts of the recommendations and implementation as outlined in the report.

ANMF understands the intent of the proposed reform is to oblige hospitals and other associated health services to provide a proper, fulsome and active disclosure and response where an adverse event/sentinel event results in harm to an individual. Our concern is the report and recommendations lack clarity on the practical implementation of the obligations under the duty of candour and how the proposed regime will require health services to undertake a transparent and comprehensive investigation into the incident, and develop and implement valid quality improvement measures to ensure a wholistic approach. Without clear measures to regulate obligations, the initiative risks legislation that is unenforceable and in a practical sense results in more of the same.'[5]

[3] Department of Health and Human Services 2020 *A statutory duty of candour: Report to the Minister for Health*, Expert Working Group to advise on legislative reforms arising from *Targeting Zero* Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020.

[4] Department of Health and Human Services 2020 *A statutory duty of candour: Report to the Minister for Health*, Expert Working Group to advise on legislative reforms arising from *Targeting Zero* Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020 p 3

[5] Engage Victoria/Department of Health *Reforms to foster an honest and open culture in health services* https://engage.vic.gov.au/reforms-foster-honest-and-open-culture-health-services Accessed 9/03/2021

The report, including the proposal for Guidelines and 27 related recommendations, raises multifactorial and complex concerns, and could have significant impacts for Victorian nurses and midwives in its implementation. Some of the recommendations are protective and some, depending on their implementation, and the relevant health services understanding, are potentially very damaging.

Importantly, it is to be noted that all 27 recommendations from the report, have been in principle, agreed to by the government. It will be in the detail of the associated actions that the impacts will be felt on clinicians.

The Statutory Duty

While ANMF supports the obligation of the statutory duty as proposed, the framing of the statutory duty in legislation should be clear so as to identify:

1. The content of the duty;
2. The circumstances that give rise to the duty;
3. Responsibility for complying with the duty; and
4. Consequences for a breach of the duty.

The desire for a high level, minimalist approach to prescribing the duty of candour combined with a weak compliance regime potentially risks a legislative scheme that fails to properly reflect the intent of the duty, and ensure its application in terms that facilitate enforcement.

ANMF's Four Areas of Concern

In essence the EWG Report raises four main issues that are cause for concern to the ANMF, these include:

1. Confusion in respect of the subject matter to be addressed by the different levels of regulation, guidance and policy, resulting in a potential risk the duty of candour is not properly realised in its original intent.
2. The resulting lack of clarity regarding employer and clinician obligations and the need to ensure the integrity of claimed observance of the duty of candour including apologies and statements of fact.
3. The failure to ensure clinicians are central to the proposed scheme of candour, apology and open disclosure.
4. The failure to provide clinicians with expressed access to natural justice, in particular through lack of clarity in relation to parameters for qualified privilege and its application beyond patients/clients exposed to harm.

Engagement questions

Are there any matters which should be included or removed from the proposed content of the guidelines?

The ANMF submits that the EWG report and recommendations are confused in respect of the different levels of regulation, guidance, and policy. In particular, the scope and function of the Guidelines is extremely confusing.

It is the scope of the proposed Guidelines that raises most concern. While the guidelines are proposed as a "*subordinate instrument*", it is not clear what in fact is proposed. The *Subordinate Legislation Act 1994* provides for the making of "statutory rules" (e.g. regulations) and "legislative instruments" (i.e. an instrument made under an act or statutory rule that is of a legislative character)[6]. Significant confusion exists as to the extent of obligation afforded though the Guidelines as a subordinate legislative instrument, and how much will be through legislation, regulations and policy. The Guidelines appear to include when and where the duty will apply. On the other hand, it is suggested they also address documentation and the organisational and clinical roles and responsibilities[7]. Then again policy is proposed to contain processes to ensure compliance (Recommendation 21), a matter also proposed for inclusion in the guidelines[8].

ANMF recommends that the content proposed for the Guidelines be clarified in respect of the subject matter to be addressed by the different levels of regulation, guidance and policy. That is, while the Guidelines indicate they will assist in addressing the processes for health services to implement obligations for open disclosure and duty of candour, it is very unclear as to how the health services obligations will be regulated effectively through the Guidelines.

Much of the material allocated to the proposed Guidelines would be better made the subject of legislation or regulation or policy. Material proposed for Guidelines would be better included in a stronger regulatory framework – particularly in relation to triggers for the statutory obligation, monitoring and clinician engagement. Where there is a need for policy to support the application of proposed statutory duty, the policy should operate at departmental and/or employer level. However, these would be in the case of matters of

[6] Subordinate Legislation Act 1994 No. 104 of 1994 Authorised Version incorporating amendments as at 6 April 2020 https://www.legislation.vic.gov.au/in-force/acts/subordinate-legislation-act-1994/042

[7] Department of Health and Human Services 2020 A statutory duty of candour: Report to the Minister for Health, Expert Working Group to advise on legislative reforms arising from Targeting Zero Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020 p. 42, 82-83

[8] Department of Health and Human Services 2020 A statutory duty of candour: Report to the Minister for Health, Expert Working Group to advise on legislative reforms arising from Targeting Zero Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020. P 82-83

policy rather than of regulation.

Should the guidelines address how qualified privilege impacts on open disclosure process?

As discussed above, ANMF recommends that much of the material allocated to the proposed Guidelines would be better allocated to and made subject of legislation or regulation or policy.

It is important that matters of qualified privilege be addressed, particularly in relation to clinicians' access to natural justice.

This question as framed is itself confusing. Qualified privilege can only be provided by means of legislation. Such legislation will need to clearly articulate the circumstances in which qualified privilege will apply. The role of Guidelines in that case would be for the purpose of explanation rather than regulation or policy. Again, the need for clarity about the function of the Guidelines proposed is illustrated by this question.

Are there other issues or unintended consequences that should be addressed or considered as part of the development of the guidelines? Please note a draft of the guidelines will be released with the exposure draft of the legislation (anticipated in 2021).

As is clear from the observations above, the ANMF submits that the premise of this question needs to be reconsidered because the scope of the Guidelines proposed needs to be reviewed.

There are several issues and unintended consequences associated with the implementation of a statutory duty of candour:

1. **Integrity of the scheme:** Associated with the concern identified above as to the sources and clarity of an enforceable statutory duty, is the absence in the EWG proposals of provisions to secure the integrity of the scheme and observance of the duty of candour as proposed. ANMF submits the scheme (whether elements are in legislation or regulation) requires regulation in several respects to ensure it is observed in practice. The following are examples that serve to illustrate the need to ensure the integrity of regulation:

    a. The lack of clarity related to the various levels of regulation, guidance and policy may lead to the duty being reduced to an under-regulated 'tick box' exercise that

perpetuates punitive, blame orientated outcomes, undermining the quality intent of the process. For example, it is proposed that all Victorian Health Incident Management (VHIMS) ISR1 and ISR2 rated events constitute the "trigger" for the application of the proposed statutory duty. However, a health service can (and routinely do) downgrade an incident to a lower classification. Were a hospital to do so, this "trigger" would be avoided. Regulation is required to avoid such an occurrence.

b. The practice of health services failing to recognise systemic errors in favour of clinician failure continues to be an issue and will arise in the present proposal. The paltry level of reporting of systemic errors to Safer Care Victoria (SCV) illustrates the need for integrity arrangements in this regard[9].

c. Health services reporting of incident data is at best incomplete. Relying on this data as part of a proposal for monitoring of compliance with duty of candour would be insufficient and threatens the integrity of monitoring health service compliance with duty of candour obligations[10]. Further to this point, the recommendations in relation to responding to breaches again lack clarity and do not refer to the specific sections of each Act that applies to addressing serious breaches.

d. The legislative scheme needs to directly address the relationship between an investigation directed to compliance with the statutory duty of candour and an investigation outcome relating to a disciplinary process and/or AHPRA report by health service. In the absence of an imminent and ongoing threat to public health (i.e., a compulsory report), voluntary notification relating to an event attracting the statutory duty should await the outcome of the statutory duty investigation. All too often health services 'jump the gun' on AHPRA notifications and workplace disciplinary procedures leading, inevitably, to termination and/or report, prior to the completion of necessary internal investigation.

e. Clinicians, including nurses and midwives, often suffer harm in serious incidents/sentinel events. The report and recommendations do not address protections for nurses and midwives in a serious incident or sentinel event. While it is encouraging to see that there is recognition of the potential for clinician harm, ANMF would recommend additional work is undertaken to ensure open disclosure is

[9] Safer Care Victoria. Sentinel events annual report 2019 – 20. https://www.bettersafercare.vic.gov.au/publications/sentinel-events-annual-report-2019-20 Accessed 08/04/2021

[10] Department of Health and Human Services 2020 A statutory duty of candour: Report to the Minister for Health, Expert Working Group to advise on legislative reforms arising from Targeting Zero Victorian Government, 1 Treasury Place, Melbourne Copyright State of Victoria, Department of Health and Human Services, August, 2020. Pp. 10 & 64

afforded to the nurses and midwives who are often most likely to be the last hands on when an event occurs. An event that generally occurs because of a system failure.

It is submitted that these integrity issues require regulation rather than the 'light touch' approach adopted by the EWG in respect of the framing of the duty and compliance generally.

2. Clinician engagement

a. The third of the ANMF's concerns with the EWG report is that it is 'top down' in its perspective and affords too little weight to the role of the clinicians involved in events. No doubt it will be said that policy and procedure can address this issue. ANMF submits that the success and integrity of the scheme relies upon the mandatory requirement for the involvement of clinicians concerned and to articulate their views in the investigation, development of the response/explanation and apology. For example, apologies are presently made by health service management/board representatives, without reference to the clinicians involved. The provision of the 'factual information' as to what happened in compliance with the statutory duty, requires that the clinicians involved in the event are consulted in respect to the investigation and the proposed apology. Otherwise, the integrity of the investigation and response will be compromised.

b. ANMF also contends that all clinicians involved in the incident/event should be afforded natural justice and, due to the lack of clarity in relation to who the qualified privilege extends to, this should be clarified for clinicians directly involved. Such natural justice is imperative in any parallel industrial and professional processes conducted at the workplace and reports to AHPRA.

3. Compliance

a. As indicated above, ANMF submits that the 'light touch' approach to regulation and compliance (with the focus on reporting alone), is misplaced. It is submitted that the legislation supported by regulation should establish an unambiguous and enforceable duty of candour. That duty should at least be enforceable by way of injunction in the event of contravention. To ensure best outcomes for all parties, compliance should be genuine and not a 'tick box/lip service' approach apology.

b. Further, ANMF contends that without adequate monitoring and data systems, compliance cannot be properly assessed, particularly in the setting of uncertain data reporting and routine and largely unjustified changes to reporting of Victorian Health Incident Management (VHIMS) ISR1 and ISR2 rated events.

It is understood that health services will be under the legislative obligation of statutory duty of candour, however, while the purpose and obligations associated with the Guidelines are ambiguous, there is a risk that the implementation of the process will become a 'tick box' management activity, thereby undermining the quality improvement intent of the legislation. Clarification is required to outline how the scheme plans to impose regulations to oblige health services to respond to achieve the intended open disclosure and quality improvement measures. Further, this lack of clarity regarding the development of implementation Guidance and policy development, risks leaving the process open to error, inaccurate monitoring, and punitive outcomes that focus on shifting blame to individuals. To assist health services to achieve a comprehensive approach, the ANMF recommends that appropriate funding and human resourcing be provided to ensure a centralised approach to effectively govern systems of implementation, including targeted mandatory education and policies/procedures.

Supporting guidance must also be consistent and include Department of Health and stakeholder developed and properly resourced policies and procedures, with the expectation of universal implementation across all health services. This could be a further extension of the clinical governance framework.

Protections for clinical incident reviews - proposed model

i. ***Those involved in the clinical incident review and the commissioning health service entity are under a confidentiality obligation in relation to the clinical incident review***
ii. ***The report and working papers from the clinical incident review are exempt from Freedom of Information requests and are not admissible in court***
iii. ***Those involved in the clinical incident review cannot be required to give evidence about review documents and deliberations (e.g. interviews, discussions)***
iv. ***Disclosure of the review report to specified third parties is allowed, including disclosure to a person whom the commissioning health service entity considers has a sufficient personal and professional interest***
v. ***Permitted disclosure does not make the report admissible in court or available under the Freedom of Information Act 1982***
vi. ***Providing information to a review in good faith would not breach any professional ethics nor give rise to personal liability***
vii. ***Health service entities are obligated to offer the clinical incident review report to consumers and to provide the report when consumers accept that offer. This***

aligns with duty of candour and mitigates against restrictions on consumer use of information.

Do you support the proposed model for clinical incident reviews?
ANMF supports the model in principal but would require more detail to fully understand the implications of the model. In addition, ANMF supports an amendment to section 39 of the *Wrongs Act 1958* and an approach along the lines of the New South Wales Civil Liability Act 2002 (or the Queensland Civil Liability Act 2003) in respect of the issue of apology protection.

The linkages between the conduct and outcome of a clinical incident review and the obligations arising from the statutory duty of candour need to be further examined. For example, the review report might form the basis of aspects of the proposed factual description of events required by the statutory duty. The process by which this occurs might give rise to documentation that also needs to be accorded appropriate protection.

Are there any unintended consequences or issues with the model that should be addressed or considered?
It is critical that, where a clinician is facing AHPRA or workplace disciplinary processes, that this does not preclude them from accessing any reports or documents that relate to the matter, and should their matter progress, that they have access to natural justice.

Should there be a mechanism to disseminate learnings and/or recommendations from incident review processes for quality and safety improvement purposes, including to those involved in the relevant case (although only relevant information may be provided to individual clinicians involved in the case)?

Please see above response

To mitigate any unintended impact on decisions by health service entities about how incidents are classified, should there be a mechanism for a decision about an incident that does not meet the threshold for a protected incident review process and if so, what?

Yes, there will most certainly be circumstances where the current system misses incidents that should meet the threshold. Where this occurs, and a clinician and/or the patient/client/ family etc, have reason to judge the incident caused harm, there will need to be a referral process for the statutory incident review team to assess the incident for its relevance to the statutory duty of candour process.

Consideration should be given to a procedure by which a clinician making a referral for statutory review is provided with feedback akin to that accorded to a patient report and, importantly, advice if a reported matter is not rendered subject to statutory review. In such a case a clinician should have an opportunity to have that decision reviewed independently of the health service and be accorded full protections in doing so.

In addition, to assist in preventing missed incidents, reporting mechanisms should merge Victorian Health Incident Management (VHIMS) reported events with obligations to report all adverse events and a process of audit against reported ISR1 and ISR2 rated events and commencement of the process for implementation of statutory duty of candour.

What authorisations for information will ensure that protections for incident reviews do not restrict oversight and regulation of quality and safety, service delivery and professional conduct?

The process will need to have consideration for clinical governance processes that oversee, and have responsibility for regulation of quality and safety, service delivery, and professional conduct. Perhaps a nominated staff member from the service could be charged with the responsibility of ensuring that the restrictions are not occurring?

How and when should a statutory incident review team notify certain parties if they consider the incident to involve professional misconduct, unsatisfactory professional conduct, unsatisfactory professional performance or an impairment, to ensure there is clarity for services and practitioners?

A statutory incident review team should ensure that they act in response to legislation and standards that regulate health professional conduct, and outline requirements for mandatory notifications in relation to impairments, breach of professional standards, and sexual misconduct.

Should incident review protections include personal protections for those conducting or participating in a statutory incident review process in good faith?

Yes, incident review protections should include personal protections for those conducting or participating in a statutory review process. Those protections should extend to protections in relation to workplace investigations/disciplinaries and AHPRA notifications, where public safety is not at risk, these parallel processes should not commence until the incident review is complete.

Summary of ANMF (Vic Branch) recommendations

It is the ANMF recommendation that:

1. The ANMF's proposal for framing the statutory duty and the four main areas of concern identified in this submission be addressed.
2. Nurses, midwives, and the ANMF, as key stakeholders and the largest group of clinicians, be invited as part of the Expert Working Group, and instrumental in the development of the regulatory instruments, guidance, policy, and explanatory materials to support the implementation of the legislation into practice.
3. The candour and open disclosure 'guidance' information and documentation be designed to be more regulatory. That is, that the proposed Guidance material be redirected to legislation, regulation or policy, which health services are obliged to implement.
4. Appropriate funding and human resourcing be provided for centralised/governed systems of the implementation process, including education and policies/procedures.
5. Any guidance must be statewide and include policies and procedures that are expected to be implemented by all health services. This could be a further extension of the clinical governance framework.
6. In settings where there are risks for the clinician inherent in the implications of parallel processes such as performance management/disciplinary action, and AHPRA reporting, where public safety is not at risk, these parallel processes should not commence until the incident review is complete. Further processes of such, as performance management/disciplinary action, AHPRA reporting should be in line with recommendations related to the clinical incident review and any associated recommendations. This is of particular importance in the setting of systemic causes, and not as a punitive response related to a desire to be seen to be acting.
7. Provisions must be made available to facilitate recognition of harm to the nurse, midwife, and clinicians who are often also harmed in serious incidents/sentinel events.
8. Reporting mechanisms should merge Victorian Health Incident Management (VHIMS) reported events with obligations to report all adverse events and a process of audit against reported ISR1 and ISR2 rated events, and commencement of the process for implementation of statutory duty of candour. In addition, all ISR1 incidents must be reviewed for compliance to the process of duty of candour.
9. Steps must be taken to ensure that all clinicians involved (including ANMF members) have access to all incident review reports as part of the process, for the purpose of ensuring the integrity of the material and natural justice.
10. There is a requirement for mandatory and regular training of relevant staff who perform the clinical reviews. Consideration should be given to a hub and spoke model for statutory

incident review team staff, inclusive of nurses and midwives, who become subject matter experts in clinical incident review, and are able to support smaller, less well-resourced health services.

11. The DHS provide a process for centralised documentation of the completion of training on nurses and midwives' employment records, to ensure tracking of a migratory workforce and their skillset of knowledge and participation in clinical incident review.
12. An education package should be developed, with input from ANMF, to support all nurses and midwives to understand the review and disclosure processes and obligations. The education program should be based on a centralised/standardised education program developed through the DHS and SCV with input from ANMF and other stakeholders.
13. A formal review of the evaluation process to ensure effectiveness of the program
14. Consideration should be given to patient/client/consumer support representatives who are assigned to assist the consumer in understanding their rights and the protections for health services and the reasons for this as they go through the process.