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| A statutory duty of candour  Victorian Government response to the  Expert Working Group’s report |
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# Ministerial foreword

In September 2017, then Minister for Health, the Hon Jill Hennessy appointed the Expert Working Group to provide advice on legislative reforms arising from *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*, the report of the Review of Hospital Safety and Quality Assurance in Victoria led by Dr Stephen Duckett (*Targeting Zero)*.

Its task was to consider the implementation of a statutory duty of candour in Victoria.

The Expert Working Group undertook a thorough review of the relevant issues, drawing on the wealth of expertise and experience of its members, and taking into consideration the matters raised by stakeholders, relevant literature and comparable models operating elsewhere in Australia and internationally.

Its report is compelling and thoughtful. At no point does the Expert Working Group shy away from the complexities that must be engaged with in designing a workable and effective statutory duty of candour that will contribute to the meaningful change envisaged by *Targeting Zero*.

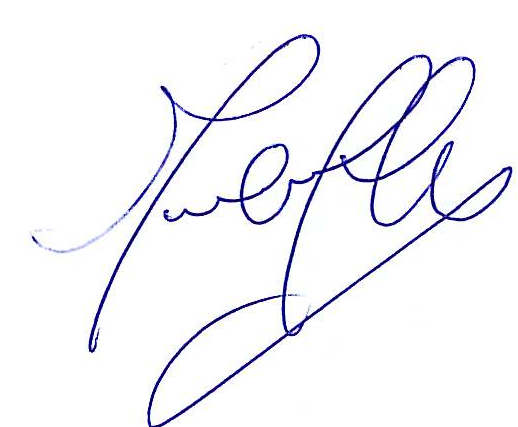
Despite this challenge, the report presents a framework for how Victoria can introduce a statutory duty of candour.

I have considered the report and agree in principle to all its 27 recommendations. It is the government’s intention to develop legislative reforms that reflect the report’s recommendations.

I express my sincere gratitude to each member of the Expert Working Group for its clear and comprehensive report. A statutory duty of candour is an important reform that will consolidate Victoria’s position as a leader in improving the quality and safety of hospital care.

I acknowledge the support that my colleague The Hon. Gabrielle Williams, then Parliamentary Secretary for Health and Parliamentary Secretary for Carers and Volunteers (now Minister for Prevention of Family Violence, Women and Youth), has provided to the Expert Working Group in this endeavour and The Hon. Jill Hennessy for commissioning the review. I would also like to acknowledge the work of the previous Minister for Health, The Hon. Jenny Mikakos, for her work in overseeing this process.

I also thank all the members of our community and health sector who have taken the time to contribute their ideas and wisdom toward the development of these important reforms. That more than 60 submissions were received by the Expert Working Group is testament to their significance for Victoria. I encourage and welcome further involvement from you as we work to refine the design of these reforms.



Martin Foley MP

Minister for Health

# Introduction

## *Targeting Zero*

In September 2017, the then Minster for Health appointed an Expert Working Group to provide advice on legislative reforms arising from *Targeting Zero: Supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care*, the report of the Review of Hospital Safety and Quality Assurance in Victoria led by Dr Stephen Duckett (*Targeting Zero)*. The review was commissioned by the then Minister in 2015.

*Targeting Zero* provided a detailed and extensive analysis of quality and safety supports and oversight across the Victorian hospital system. It made 179 recommendations aimed at delivering better protections and improved outcomes for patients. *Targeting Zero* called for changes at government, board and management level to encourage and establish a culture of inquiry and open disclosure, and to introduce systems to monitor and improve the safety and quality of health care. A significant finding of the review was that the events that prompted the review occurred in the context of catastrophic failures in clinical governance at all organisational levels. Importantly, the review found that the conditions that led to these failings were not unique to any hospital, and that there was a need to elevate safety and quality across the hospital system as a whole.

The Minister chose implementation of a statutory duty of candour in Victoria as the topic for the Expert Working Group’s consideration. The Minister asked the Expert Working Group to consider this in response to Recommendation 5.3 made in *Targeting Zero* (p. 201):

*That a statutory duty of candour be introduced that requires all hospitals to ensure that any person harmed while receiving care is informed of this fact and apologised to by an appropriately trained professional in a manner consistent with the national Open Disclosure Framework.*

This was one of a suite of recommendations aimed at improving the flow of information in the health system to ensure deficiencies in care are identified and focus attention on opportunities for improvement. It recognised that the faith of the community in the hospital system must be built up through strengthened accountability to patients and greater transparency about hospital safety and quality. This recommendation was also made in the context of strong observations about the influence of organisational culture and the need to establish a ‘just’ culture within the healthcare environment.

## Expert Working Group

The Expert Working Group’s term ceased in 2018. The Expert Working Group comprised representatives of health service providers, health service consumers and clinical experts. Its members were:

* Mr Michael Gorton (AM) (Chair), Partner, Russell Kennedy; Chair, Board of Alfred Health; Member, Board of Ambulance Victoria; Chair, Australian Health Practitioner Regulation Agency
* Ms Sophy Athan, Chair, Board of Health Issues Centre; Member, Victorian Clinical Council
* Dr Michael Walsh, Chief Executive Officer, Cabrini Health
* Ms Jan Child, Chief Executive Officer, Bass Coast Health Service
* Dr John Ballard, Administrator, Djerriwarrh Health Services; Associate Vice-Chancellor (Victoria), Australian Catholic University
* Dr Victoria Atkinson, Group General Manager Clinical Governance/Chief Medical Officer, St Vincent’s Hospital; Deputy Chair, Board of Better Care Victoria; Member, Board of Alfred Health
* Dr Joanna Flynn, Chair, Medical Board of Australia; Chair, Board of Eastern Health; Member, Board of Ambulance Victoria
  + Ms Karen Cusack, Health Complaints Commissioner.

## Public consultation

In late 2017, the Expert Working Group conducted a public consultation process. Its consultation paper was released on 2 November 2017 and distributed to a broad range of health sector and consumer stakeholders. It posed the following questions:

* *The scope of the duty* – which healthcare providers should be subject to the statutory duty?
* *When the duty applies* – what should be the trigger for the statutory duty to apply?
* *Requirements of the duty* – what elements of the process should be legislated?
* *Barriers and enablers* – what is required to ensure that the statutory duty is effective?
* *Legal protections* – are changes to apology laws or other protections required?
  + *Monitoring and compliance* – how should breaches of the duty be identified and responded to?

Despite the short timeframe available for submissions to be made, there was significant interest in the topic, with a total of 61 written submissions received from 18 individuals and 43 organisations including health service providers, regulators, unions and professional associations, insurers, legal firms, ombudsmen/commissioners and peak bodies representing providers and consumers.

## Report on statutory duty of candour

The Expert Working Group submitted a comprehensive report to the Minister. The report presents consultation and research findings and makes recommendations about an appropriate statutory model for the introduction of a duty of candour. Its advice covers:

* the scope of the duty and thresholds to apply
* the processes, compliance measures and protections to accompany such an obligation
  + the non-legislative supports required to implement the statutory change.

The Victorian Government has progressed several other legislative reforms related to *Targeting Zero* since 2017 and is now in a position to respond to the report. This document sets out the Victorian Government’s response to the Expert Working Group’s report.

# Response to the Expert Working Group’s report

## Supporting the reforms in principle

The fundamental purpose of a statutory duty of candour – and open disclosure in general – is to engender a culture of honesty and openness in our hospitals and to improve the quality of health care, with a focus on safety and person-centeredness.

We agree with the Expert Working Group that Victorians should have confidence in the safety and quality of our health system and – in the unfortunate event that harm does occur – have a right to an apology, an explanation of what happened and why, and to be informed of lessons learnt and efforts made to ensure it never happens again.

The Expert Working Group’s consultation process has yielded some valuable insights. The reforms it proposes represent an important step in improving the quality and safety of services across Victoria’s hospital system and reducing avoidable harm to consumers. They would implement the *Targeting Zero* recommendation for an Australian-first statutory duty of candour.

The Expert Working Group makes 27 recommendations in total. While most are squarely about legislative reform, several recommendations recognise that legislative change must be accompanied by non-legislative enablers and supports, in order to successfully achieve its objectives.

The government has considered the Expert Working Group’s report and supports in principle all 27 recommendations. There will be further consultation sought before introducing the legislative reforms that reflect the report’s recommendations into Parliament. This consultation, however, will not be duplicative of the Expert Working Group’s work.

The anticipated benefits of the recommendations made by the Expert Working Group are clear and compelling:

* *improved consumer experience and outcomes in relation to their health care, through provision of timely and accurate information to consumers in an effective and constructive way* – open and honest communication with consumers and their families following healthcare incidents is designed to contribute to a more patient-centred approach to healthcare provision and thereby improve patient experience, patient outcomes and quality of service provision.
* *potential improvements to the quality and safety of care provided by the entity, as a result of increased reporting and learning practices resulting from serious incidents (which is more likely in a ‘just culture’ environment)* – in an open and transparent culture, staff will be more likely to spend time learning from incidents rather than trying to hide or defend themselves.

## Further consultation to design the reforms

While the report provides a valuable framework for the reforms, further work is required to ensure we get the balance right in their design. The government considers it prudent to rigorously test the proposed reforms with the public and relevant stakeholders in the course of finalising the detail. We will consult and engage further with sector and consumer stakeholders regarding issues and concerns related to the legislative reforms. This will help to ensure that the detailed design of the reforms reflects and achieves the government’s policy intention.

Consultation will occur in two stages:

* to inform the development of *Victorian candour and open disclosure guidelines* and proposed protections for clinical incident reviews (in 2020)
* to provide feedback on the exposure draft of legislation and the associated guidelines (anticipated to occur in 2021).

## Statutory duty of candour

The government intends to create a new statutory duty of candour, which would require specified health service entities, in the course of open disclosure, to provide consumers impacted by a serious adverse healthcare incident with:

* the facts about what occurred
* an apology
  + a description of the health service entity’s response and the improvements being put in place following the incident.

The statutory duty of candour will not replace current obligations to practice open disclosure under the existing Australian Open Disclosure Framework. Rather, the duty will be a complementary legal obligation to support improved compliance within a defined set of circumstances.

As recommended by the Expert Working Group, the *Victorian candour and open disclosure guidelines* will be developed as a subordinate legislative instrument that will be referenced in the legislative provisions introducing the statutory duty of candour. Guidelines will set out the minimum requirements for compliance with the statutory duty of candour and open disclosure obligations, as well as guidance and information to support best practice. The detail to be included in the guidelines will be the subject of consultation in 2020. Draft guidelines will be released along with an exposure draft of the legislation for further public comment (anticipated to occur in 2021).

As recommended by the Expert Working Group:

* factual statements about what has occurred will not be restricted from use in legal proceedings
* saying sorry will not constitute an admission of fault or be relevant to court determinations
  + information provided about any changes or improvements made subsequent to an incident will not be taken as an admission of fault or liability but will be admissible in legal proceedings.

The government intends to legislate protections for apologies provided by a health service entity in connection with the provision of a health service. In the health service context, an apology – being an expression of sympathy, regret or compassion, even if it may admit or imply an admission of fault –will not constitute an admission of fault or liability and will not be relevant to any determination of fault or liability any civil or disciplinary proceedings. Factual explanations of what has occurred, which will be required to be provided under the duty, will not be protected and can be used as evidence in any legal proceedings. We note that consumers also have access to information about what occurred during the course of their treatment in a number of other ways, and changes to apology protections will not restrict the use of this information in any medico-legal claim.

These protections for apologies are consistent with recommendations made in 2016 and 2017 for strengthened apology protections under the *Wrongs Act 1958*.

## Protections for clinical incident reviews

In addition to establishing the statutory duty of candour, we intend to introduce legislative reforms to establish protections for conduct of serious incident review processes by specified health service entities.

These reforms would support and encourage an organisational and system-wide culture where errors and harm are effectively identified, discussed and reviewed and consumers are kept informed. In turn, such a culture would improve consumer experience and allow for timely risk identification and mitigation, to optimise the ongoing safe delivery of quality healthcare in Victorian hospitals.

We are committed to introducing these reforms at the earliest opportunity. However, these additional statutory reforms recommended by the Expert Working Group raise complex policy issues. In the course of preparing the legislation, it has become evident that the legislative design must strike a complex balance. The reforms include elements aimed at increasing transparency and consumer access to information. They also establish restrictions on access to certain information, to support robust investigation and analysis of errors or adverse events and quality and safety risks.

The government anticipates that some stakeholders may have concerns about aspects of the reforms. For example, service providers and clinicians (and their legal representatives and insurers), may have concerns about increased exposure to medico-legal risk as a result of new transparency measures. Conversely, consumers and their representatives and advocates may be concerned about potential restrictions on their access to information as a result of protections introduced for reviews.

We are not alone in grappling with the complexities posed by these reforms. Recent work in the United Kingdom underlines the need for careful consultation and design for such reforms. In September 2017 the UK government released an exposure draft of legislation that would establish arrangements for protected investigations of adverse incidents. This followed the 2013 report from the review of the Mid Staffordshire NHS Foundation Trust. Feedback on the draft legislation led to the establishment of a Joint Parliamentary Committee to undertake further review and consultation. The report of that Committee was released in August 2018. The Committee considered how protections for investigations should be balanced with the existing UK duty of candour. Ultimately, a Health Service Safety Investigations Bill went to second reading in the House of Lords in October 2019. If passed, the Bill will create a ‘safe space’ for health service safety investigations prohibiting the disclosure of information except in very limited circumstances.

While this development in the UK is directly relevant to the reforms recommended by the Expert Working Group – and in some instances the Expert Working Group referred to relevant approaches taken in other jurisdictions – what operates elsewhere will not necessarily be a perfect fit for Victoria. In designing the best model for Victoria, we are paying careful attention to the Expert Working Group’s advice but are not bound by the specific wording or parameters of its recommendations.

These are complex issues. Transparency and accountability are clear objectives. We also recognise the value of an environment where errors and systemic issues are discussed and analysed robustly, so that effective improvements can be made.

We do not expect that the requirements for health service entities will be substantially different, in terms of burden, than existing and ongoing obligations for open disclosure and incident review. Rather, the reforms are designed to support and encourage improvements to maximise the quality and safety. The benefits identified are anticipated to flow from improvements in practice, for example open disclosure conducted with greater openness and compassion, and incident reviews conducted with increased frankness and rigour.

We intend to engage and consult further as we finalise the detail of the proposals, and the involvement of health sector and consumer stakeholders in that work will be invaluable.

# Areas for further consultation

Consultation in 2020 will cover the following areas:

* *Victorian candour and open disclosure guidelines*
  + proposed model for clinical incident review protections.

## *Victorian candour and open disclosure guidelines*

As recommended by the Expert Working Group, the proposed statutory duty will apply to incidents of a high severity rating (1–2) and will complement existing obligations under the Australian Open Disclosure Framework. The legislation will be high level. The *Victorian candour and open disclosure* guidelines will offer detailed instructions to health service entities on apologies, explanations, and details of preventative action. As recommended by the Expert Working Group, the guidelines will set out the minimum requirements for compliance with the statutory duty of candour and open disclosure obligations, as well as guidance and information to support best practice, including:

* the **underpinning principles** and the anticipated benefits of candour and open disclosure
* a simple description of the **service settings in scope** for the statutory duty and the scope of broader open disclosure obligations
* an accessible and easily understood description of **when the statutory duty will apply** and when open disclosure should be undertaken (for incidents that may not reach the thresholds established for the statutory duty, but which otherwise warrant an open disclosure process)
* mandatory requirements for discharging the statutory duty
* **documentation and reporting requirements** to demonstrate compliance with the statutory duty
* **roles and responsibilities** in relation to the statutory duty
  + **organisational requirements**.

The Expert Working Group included draft content for the *Victorian candour and open disclosure guidelines* in their report (Appendix D, pages 82–83). Once the guidelines have been developed, they will also be released with the exposure draft of the legislation.

The Expert Working Group also identified significant confusion amongst both individual health practitioners and healthcare organisations as to when the qualified privilege afforded to ‘quality assurance committees’ declared under section 139 of th*e Health Services Act 1988* does and does not apply. In particular, it was not clear to stakeholders how Victoria’s current regime of qualified privilege impacts on existing open disclosure obligations.

We consider that the elements of the duty proposed by the Expert Working Group are no more onerous than those set out in the Australian Open Disclosure Framework.[[1]](#footnote-2) We do not expect the requirement for an apology and factual explanation of what occurred to place a significant additional burden on health service entities given the existing requirements of open disclosure. The likely extent of increased investment in open disclosure to meet the intended standard of practice under the duty of candour will be further explored in consultation with stakeholders.

Potential costs to health service entities include:

* costs of conducting the required disclosure process, including preparing for and conducting meetings and preparing documentation to provide to consumers
* costs to strengthen both internal and external publicity about its existing policy on candour – likely to be mainly transitional costs
* costs to support and encourage staff to behave candidly and conduct effective open disclosure processes
* costs for record keeping of compliance with the duty
  + costs of reporting about compliance.

The effects of creating a statutory duty of candour on litigation costs is uncertain. On the one hand, to the extent litigation is a result of ongoing dissatisfaction on the part of the consumer, creating a statutory duty of candour that improves consumer experience may lead to decreased litigation costs. On the other hand, there may be a perceived risk of an increase in medico-legal proceedings upon introduction of a duty of candour, due to the increased level of information available to consumers. Although evidence suggests that the introduction of a duty of candour may lead to a temporary increase in medico-legal proceedings, evidence from the United States suggests that the disclosure of error has the potential to reduce legal costs. There has not been any obvious change to the number of claims or complaints being made since the introduction of a similar obligation in the United Kingdom.

### Consultation questions – *Victorian candour and open disclosure guidelines*

#### Q1 Do you support the proposed content and format of the *Victorian candour and open disclosure guidelines* (noting they are a detailed legislative instrument underpinning high level primary legislation)?

#### Q2 Are there any matters which should be included or removed from the proposed content of the guidelines?

#### Q3 Should the guidelines address how qualified privilege impacts on open disclosure process?

#### Q4 For health service entities and practitioners:

#### Will the introduction of a duty of candour lead to a significant alteration of practices given overlap with open disclosure? If so, please provide more information on compliance with open disclosure obligations.

#### Is it likely that the additional requirements of candour, though largely similar to those for open disclosure, will lead to an increase in costs for compliance? If so, please provide more information and, if possible, an estimate of costs.

#### Is it likely that you will need to alter internal governance and reporting practices on open disclosure following introduction of a statutory duty (for example more regular or detailed reporting to the board or other high-level governance bodies)? If so, please provide more information.

#### Q5 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).

Department of Health

## Proposed model of protections for clinical incident reviews

Clinical incident review processes are valuable quality and safety improvement processes conducted or commissioned by health service entities in relation to serious incidents, including where systemic issues are identified or suspected. Such processes involve sometimes speculative discussion about factors that may have contributed to the incident and/or related harm. It has been argued that the nature of that discussion is such that if details of the discussion were relied upon as evidence in civil legal proceedings, inappropriate or perverse outcomes may result.

The proposed model will ensure protections for reviews of specified serious incidents. Health service entities will be able to take advantage of the protections if they choose to conduct a review under the proposed provisions. The conduct of a review under the proposed provisions will only be mandated when an entity is directed by the Secretary of the Department of Health and Human Services to appoint a review team.

Consultation will occur on the following proposed model for clinical incident review protections:

* 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
* The report and working papers from the clinical incident review are exempt from Freedom of Information requests and are not admissible in court
* Those involved in the clinical incident review cannot be required to give evidence about review documents and deliberations (e.g. interviews, discussions)
* 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
* Permitted disclosure does not make the report admissible in court or available under the *Freedom of Information Act 1982*
  + Providing information to a review in good faith would not breach any professional ethics nor give rise to personal liability
  + 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.

Reports will not be admissible in court. The protections do not apply to primary source documents such as medical records and other corporate records of the health service entity. These are matters of fact and should be available to consumers and others, to the extent that they currently are.

### Consultation questions – protections for clinical incident reviews

#### Q6 Do you support the proposed model for clinical incident reviews? If not, is there an alternative model that would better meet the policy objective of fostering open and honest culture in health services?

#### Q7 Are there any unintended consequences or issues with the model that should be addressed or considered?

#### Q8 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)?

#### Q9 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?

#### Q10 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?

#### Q11 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?

#### Q12 Should incident review protections include personal protections for those conducting or participating in a statutory incident review process in good faith?

1. Compliance with the Australian Open Disclosure Framework is required by the Australian Commission on Safety and Quality in Health Care in order for health service entities to receive accreditation. In Victoria, the Department of Health and Human Services’ funding and policy guidelines require compliance with the framework for public entities. Since 1 July 2018, regulations made under the *Health Legislation Amendment (Quality and Safety) Act 2017* require private sector entities to also comply with the framework. Accreditation is also required by private health insurers as a precondition for the subsidisation of treatments provided to privately insured patients. [↑](#footnote-ref-2)