Australian
Health Law
Bulletin

# Statutory Duty of Candour

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## Summary

A new statutory duty of candour for Victoria will come into effect on 30 November 2022, imposing a legal obligation on many health services to provide open disclosure to patients in response to a serious adverse event.

## Introduction

Health services in Australia have been required to provide open disclosure and even apologies to patients for adverse events and patient harm for some years as part of their accreditation obligations. In the UK this concept has been legislated in recent times as a "statutory duty of candour".

The Victorian Government has recently introduced a statutory duty of candour as part of several changes to state health legislation. The statutory duty of candour comes into effect on 30 November 2022 and is intended to build on the existing open disclosure framework. The changes have been introduced in response to recommendations contained in the statutory duty of candour report published by an Expert Working Group to advise on legislative reforms arising from *Targeting Zero*, led by Chair Michael Gorton AM (Principal, Russell Kennedy).[1] The duty imposes a legal obligation on specified health services to provide information to patients following a serious adverse event. Health services affected by the statutory duty will be required to take several steps to comply with their statutory duty, including providing the affected patient with an apology and conveying the steps that will be taken to prevent a re-occurrence of the event.

## A statutory duty of candour and the open disclosure framework

The Health Legislation Amendment (Quality and Safety) Act 2022 (Vic) (the Act) amends the Health Services Act 1988 (Vic) and the Public Health and Wellbeing Act 2008 (Vic) and enshrines a statutory duty of candour (SDC) into legislation.[2] The Act also makes consequential and miscellaneous amendments to the Ambulances Services Act 1986 (Vic), the Mental Health Act 2014 (Vic) and the Health Complaints Act 2016 (Vic).[3] The Act permits the Minister for Health to make guidelines which set out the steps a health service entity must take to comply with the SDC.[4] On 4 August 2022, the Minister endorsed the Victorian Duty of Candour Guidelines (Guidelines) to be released in draft form, which will officially take effect on 30 November 2022.[5]

The SDC is intended to build on, and not replace, the open disclosure framework. In their response to the Expert Working Group's Report on a proposed SDC, the Victorian Government summarised the purpose of the SDC as a "complementary legal obligation to support improved compliance within a defined set of circumstances".[6] The Government's response also states that it is not expected that the requirements for health services will be substantially different in terms of burden from the existing and ongoing obligations of the open disclosure framework.[7]

## Requirements of SDC

A serious adverse patient safety event (SAPSE) is an event that occurs while a patient is receiving health services from a health service entity and, in the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in, unintended or unexpected harm or prolonged psychological harm.[8] If a patient suffers a SAPSE in the course of receiving care, the health service responsible owes an SDC to the patient pursuant to Division 9 of the Act. The SDC applies to health services, ambulance services and mental health service providers. Health services include public health services, public hospitals, multi-purpose hospitals, denominational hospitals and private hospitals.[9] The steps required for compliance with the SDC are as follows:

1 Apologise and provide initial information
2 Hold an SDC meeting
3 Conduct a SAPSE review

Each step is set out in more detail below. Further information is provided in the Guidelines and Safer Care Victoria has published a Checklist[10] for the SDC process which covers each step as outlined below.

### *Step 1: Apologise and provide initial information*

The health service entity must provide a genuine apology for the harm suffered by the patient and initial information as early as practicable (but no longer than

24 hours) after the SAPSE has been identified by the health service.[11] If the apology cannot be provided to the patient where the patient lacks capacity or has died, the apology must be provided to the patient's immediate family, carer, next of kin or a person nominated by the patient. The Guidelines recommend that the responsible health service entity considers the following when issuing the apology:

- express compassion, regret or sympathy;
- say the words "I am/We are sorry"; and
- avoid jargon or legalistic wording.[12]

An apology will not be taken to be an admission of liability by the health service entity.[13]

Initial information provided with the apology must include:

- factual information that is known at the time about the event;
- written patient information on the SAPSE review process (e.g. information flyer); and
- details of key contacts the patient can liaise with, including where relevant, an Aboriginal Hospital Liaison Officer (AHLO).[14]

The health service entity can also consider providing/obtaining further information such as:

- confirming the patient knows how to access their health records if necessary;
- confirming any specific needs of the patient;
- confirming the patient's preferred form of communication;
- answering/recording any questions the patient may have;
- outlining how the patient can raise concerns outside the SDC process, such as complaints through the Health Complaints Commissioner or Mental Health Commissioner.[15]

### *Step 2: Hold SDC meeting*

The health service entity must take steps to organise an SDC meeting within 3 business days of the SAPSE being identified.[16] The health service must then hold the SDC meeting within 10 business days of the SAPSE being identified and the health service entity must ensure that it provides the following to the affected persons in the SDC meeting:[17]

- an honest, factual explanation of what occurred in a language that is understandable to the patient;
- another apology for the harm suffered by the patient;
- an opportunity for the patient to relate their experience and ask questions;
- an explanation of the steps that will be taken to review the SAPSE and outline any immediate improvements already made; and
- any implications as a result of the SAPSE (if known) and any follow up for the patient.

At a minimum, one member from the health service entity who is experienced and suitably qualified in open disclosure or the SDC process and a senior member of the clinical team that was involved (e.g. doctor or nurse) must be in attendance at the meeting.[18] The health service entity must document the SDC meeting and provide a copy of the meeting report to the patient within 10 business days of the SDC meeting[19] and the meeting report must include a detailed account of all the different elements of SDC that were discussed.[20]

### *Step 3: SAPSE review*

A SAPSE review must then be undertaken by an independent panel appointed by the responsible health service.[21] The review will establish the facts of the event, identify the factors that may have led or contributed to the SAPSE, and highlight remedial or preventative measures.[22] The review panel must prepare and produce a report for the health service entities which appointed it as soon as practicable.[23] The health service entities must then offer a copy of the report to the patient or any associated person within 50 business days of the SAPSE being identified by the health service entity.[24] This may be extended to 75 business days if the SAPSE involves more than one health service.[25]

### *Documentation and reporting*

The health service must ensure that there is a record of the SDC being completed, which includes clear dates of when the SAPSE occurred and when each stage of the SDC was completed.[26] The health service entity must ensure that it has an appropriate reporting system to monitor compliance with the SDC, such as a clinical incident management system, and report compliance with the SDC process to relevant bodies as legally required (eg notification to the Australian Health Practitioner Regulation Agency if a health professional has acted in a way that constitutes notifiable conduct under the Health Practitioner Regulation National Law Act 2009).[27]

### *Opting out of SDC process*

A patient may choose not to receive information in accordance with the SDC by providing the responsible health service with a signed statement.[28] Under these circumstances, it is recommended that the health service entity conducts a SAPSE review to ensure relevant information is recorded, which may be required if the

patient later elects to participate in the SDC process (which they are entitled to do).[29]

### *Circumstances requiring a delay*

Circumstances in which the SDC process may need to be delayed include:

- where the patient lacks or has lost their capacity (either temporarily or permanently) as a result of the harm; or
- where the patient is medically unable to participate through the progression of their medical condition.[30]

If one of the above circumstances applies, it should be documented by an appropriate health professional and the responsible health service entity must undertake the SDC with either the patient's immediate family, carer or next of kin or another person nominated by the patient.[31] If and when the patient recovers, the health service must commence the SDC process again with the patient (unless the patient has opted out).[32]

## Non-compliance with SDC

The Minister or the Secretary may take into account the failure of a health service entity to comply with the duty of candour when assessing whether the entity provides safe, patient-centred and appropriate health services and the quality and safety of health services provided by the entity.[33] The Minister may also publish a statement on the Department's website stating the name of the relevant health service entity if:

- the entity has failed to comply with the SDC on 2 or more occasions; and
- the failure to comply is of a serious nature.[34]

The Minister must also take into account the compliance history of a health service when considering whether to appoint a delegate to the board.[35]

## Legal protections for health service entities

An apology by a health service entity provided in accordance with the SDC requirements does not constitute an express or implied admission of liability under the Act for the purposes of any civil proceedings where the death or injury of a person is in issue.[36] An apology cannot be used as evidence and will not be relevant to the determination of fault or liability in connection with any such proceedings.[37] These protections apply whether the apology was made orally or in writing, and either before or after a civil proceeding.[38]

## Conclusion

Whilst the obligations of health service entities under the SDC do not differ materially from those under the existing open disclosure framework, the SDC enshrines these obligations in law and thus strengthens the accountability of health services in the event of a SAPSE. It is important that specified health services are aware of the requirements under the SDC framework and the possible consequences of non-compliance, which could include significant reputational, commercial and even legal implications.

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## Footnotes

1. Department of Health and Human Services (Victoria) — Expert Working Group to advise on legislative reforms arising from *Targeting Zero*, *A statutory duty of candour* (2020).
2. Health Legislation Amendment (Quality and Safety) Act 2022 s 1. See also T Cockburn *Statutory duty of candour to mandate open disclosure proposed for Victoria* (2021) 29(5&6) HLB 97 for a further discussion on the then proposals and the UK position.
3. Health Legislation Amendment (Quality and Safety) Act 2022 s 1.
4. Above, n 3, ss 128ZC, 22I, 345B.
5. Safer Care Victoria, *Victorian Duty of Candour Guidelines (Draft)* at [1.1].
6. Department of Health and Human Services (Victoria), *Victorian Government response to the Expert Working Group's report — A statutory duty of candour* at 8; online at www.health.vic.gov.au/sites/default/files/migrated/files/collections/policies-and-guidelines/e/expert-working-group-report-on-statutory-duty-of-candour.docx.
7. Above n 6, at 9.
8. Above n 5, at [2].
9. Above n 3, s 128ZG.
10. See www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour.
11. Above n 3, at [3.2].
12. Above n 5, at [4.1].
13. Above n 3, s 128ZD.
14. Above n 3, s 128ZD.
15. Above n 5, at [4.1.2].

16. Above n 5, at [3.2].
17. Above n 5, at [3.2].
18. Above n 5, at at [4.2.1].
19. Above n 5, at [4.2.1].
20. Above n 5, at [4.2.1].
21. Above n 3, s 128P, Q.
22. Above n 3, s 128O.
23. Above n 3, s 128T.
24. Above n 5, at [3.2].
25. Above n 5, at [3.2].
26. Above n 5, at [3.2].
27. Above n 5, at [5].
28. Above n 3, s 128ZC(2).
29. Above n 3, s 128ZC(3).
30. Above n 5, at [3.4].
31. Above n 5, at [3.4].
32. Above n 5, at [3.4].
33. Above n 3, s 128ZE.
34. Above n 3, s 128ZH.
35. Above n 3, s 128ZH.
36. Above n 3, s 128ZD.
37. Above n 3, s 128ZD.
38. Above n 3, s 128ZD.