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Health Insights

Victoria Health Services: Are you prepared for the Statutory Duty of Candour?

On 30 November 2022, the *Health Legislation Amendment (Quality and Safety) Act 2022* (Vic) will come into effect. This legislation amends the *Health Services Act 1988* (Vic)[1] (**Act**) to impose new legal obligations on relevant Victorian Health services, requiring them to provide a Statutory Duty of Candour to any patient who has suffered a serious adverse patient safety event (SAPSE). Under the duty, health services are obliged to apologise, explain what went wrong, and describe what actions will be taken to prevent re-occurrence of the event. There are consequences for non-compliance, and it is essential that relevant health services take proactive steps to prepare for the introduction of the SDC to prevent falling foul of the new law.

Why an SDC?

The SDC arose out of 'Targeting Zero', a report of the Review of Hospital Safety and Quality Assurance, which found there was a widespread lack of compliance within Victorian Health services with the principles of open disclosure. The SDC builds on the principles of open disclosure as set out by the Australian Open Disclosure Framework, currently used by health services for cases of harm and near miss. The reforms aim to ensure that the patient's right to open disclosure is respected and just culture is encouraged within health service entities to reduce blame and improve investigative processes for the purpose of promoting better patient outcomes.

Who does the SDC apply to?

The SDC will apply to relevant 'health service entities', which is defined under the Act as:[2]

(a) a public health service

(b) a public hospital

(c) a multi-purpose service

(d) a denominational hospital

(e) a private hospital

(f) a day procedure centre

(g) ambulance services

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[1] As well as the *Public Health and Wellbeing Act 2008* (Vic), *Ambulance Services Act 1986* (Vic), *Mental Health Act 2014* (Vic) and *Health Complaints Act 2016* (Vic).

[2] *Health Services Act 1988* (Vic) s 4.

(h) non-emergency patient transport services

(i) the Victorian Institute of Forensic Mental Health

Relevantly, the obligation lies with the health service as a whole and not individual employees. It does not apply to private medical practices.

SDC Process and Requirements

A SAPSE is a serious adverse patient safety event that occurred while the patient was 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 moderate or severe harm, or prolonged psychological harm being suffered by the patient.[3] It is the equivalent of an ISR 1 or 2 event within public health services (Victorian Health Incident Management System Scale).

Severe Harm means harm that causes a permanent lessening in the functioning of an individual that is unrelated to the natural course of a person's illness or underlying condition including harm that can lead to a person experiencing a permanent impairment of disability, or death.

Moderate Harm means harm that requires a moderate increase in treatment to a patient, such as an unplanned or unexpected return to surgery, but does not includes harm that causes permanent damage or injury to an individual.

Prolonged psychological harm means psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days.

When a patient has suffered a SAPSE in the course of receiving health services, the health service will be obligated to provide the patient, and/or their next-of-kin/carer, with the following:[4]

a) a written account of the facts regarding the SAPSE; and

b) an apology for the harm suffered by the patient; and

c) a description of the health service entity's response to the event; and

d) the steps that the health service entity has taken to prevent re-occurrence of the event.

They will also have to comply with any steps set out in the Victorian Duty of Candour Guidelines (**Guidelines**).

The Guidelines create a strict timeline of events which must be followed by a health service when a SAPSE has been identified. These steps are as follows:

1. **Within 24 hours** - the health service must provide a genuine apology for the harm suffered by the patient. Importantly, apologies offered to patients will not constitute admissions of guilt or liability, nor will they be admissible in civil proceedings.[5] This is relevant whether the apology is made orally or in

[3] SAPSE is currently defined in the draft form of the Victorian Duty of Candour Guidelines. The final definition will be included in regulations to be made under the *Health Services Act 1988* and may change slightly from the current definition.

[4] *Health Services Act 1988* (Vic) s 128ZC.

[5] Ibid s128ZD.

writing or is made before or after the civil proceeding was in contemplation or commenced. However, statements regarding a fact in issue, or tending to establish a fact in issue, are not protected under the Act.

2. **Within three business days** – the health service must take steps to organise an SDC meeting. At a minimum, the health service must confirm with the patient when and where the SDC meeting will be held, who will be at the meeting, details of the meeting, and details of key contacts.
3. **Within 10 business days** – The SDC meeting must be held. At a minimum, there must be in attendance one member from the health service who is experienced in the SDC process and one senior member of the clinical team that was involved. The health service must ensure that it provides the following in the SDC meeting:
    - An honest factual explanation of what occurred, in a language that is understandable to the patient
    - An 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.
4. **Within 10 days of the SDC meeting** – a copy of the meeting report must be provided to the patient. This report must include a detailed account of what was discussed in the meeting.
5. **Within 50 business days** – a report must be created which reviews the SAPSE and outlines any areas for improvement and offered to the patient. This deadline can be extended to 75 days if the SAPSE involves more than one health service entity.
6. **When the SDC is completed** - the health service must ensure that there is a record of the SDC being completed, including clear dates of when the SAPSE occurred and when each stage of the SDC was completed. The health service must ensure it has an appropriate reporting system to monitor compliance with the SDC as mandatory documentation and reporting requirements will demonstrate compliance with the SDC process. The health service must report its compliance with the SDC as legally required.

Importantly, if during the SDC process it is identified that an individual health practitioner has acted in a way that constitutes notifiable conduct under the *Health Practitioner Regulation National Law Act* 2009, a staff member of the health entity must submit a concern to the *Australian Health Practitioner Regulation Agency* (AHPRA). We recommend health entities inform the staff member before a notification to AHPRA is made.

Do patients have to agree to participate in the SDC process?

Patients may opt out from participating in the SDC process. If a patient confirms they wish to opt out of the process, the health service must ask them to sign a statement to this effect, store the statement securely, and

provide a point of contact for the patient at the health service if they wish to re-initiate the SDC in future.[6] If the patient opts out, the health service does not need to comply with the legislated SDC requirements. However, it is strongly recommended that a review is completed in any event, in case the patient later decides to engage in the process.

Reporting

The reporting requirements have not yet been finalised and will not come into effect until 1 July 2023. According to Safer Care Victoria, data that is to be collected is likely to include: the number of SAPSE, instances where SDC was commenced, instances where SDC was completed, and instances where patients opted out. Health services will need to ensure that they have appropriate systems in place to capture the data once the reporting requirements are prescribed.

Consequences for non-compliance

The Minister may publish a statement setting out the name of a relevant health service entity if, in the Minister's opinion, the relevant health service has failed to comply with the duty of candour on two or more occasions, and the failure to comply is of a serious nature.[7] If the Minister decides to publish a statement, it must be published on the internet site of the Department. However, before publishing a statement, , the Minister must give the health service a reasonable opportunity to make oral or written submissions on the proposed publication of the statement.

What can be done now to prepare?

The SDC comes into effect on 30 November 2022. While the purpose of the SDC is not to create a greater workload for health services beyond current open disclosure processes, it is clear that there will be significant planning and preparation required to ensure the legislative requirements are being met. Key considerations include:

- Who within the health service will ensure compliance with the SDC?
- Are staff within the health service appropriately trained in the SDC?
- Does the health service have adequate resources to comply with the SDC (staff, reporting software, storage etc)?
- What policies and procedures are currently in place around open disclosure and reporting of adverse events? Do these procedures require updating?

Further information about the SDC can be found at the Safer Care Victoria Website.[8] This website contains helpful resources for health services, including checklists, templates, fact sheets and webinars.

[6] Ibid s 128ZC.

[7] Ibid s 128ZH.

[8] https://www.safercare.vic.gov.au/news/preparing-for-statutory-duty-of-candour-in-victoria

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This insight was written by Principal Kellie Dell'Oro with the assistance of Solicitor Anna McBean. For further information about the implications and your legal obligations resulting from the introduction of the *Health Legislation Amendment (Quality and Safety) Act 2022* (Vic), please contact Kellie.

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