

Open Disclosure & Statutory Duty of Candour

Open Disclosure is the process of open communication with the patient, and or their family/support person, following an adverse or unexpected event that result in harm while receiving healthcare.

The elements of open disclosure are:

- An apology or expression of regret, which should include the words 'I am sorry' or 'we are sorry'.
- A factual explanation of what happened.
- An opportunity for the patient, their family and carers to relate their experience.
- A discussion of the potential consequences of the adverse event.
- An explanation of the steps being taken to manage the adverse event and prevent recurrence.

Statutory Duty of Candour (SDC) builds on the open disclosure framework currently utilised for all cases or harm or near misses and is a legal obligation for Victorian health service entities to ensure that patients and their families or carers are apologised to and communicated with openly and honesty when a serious adverse patient safety event (SAPSE) has occurred.

If a patient suffers a SAPSE while receiving health services at SCDS, SCDS owes a SDC to the patient and must do the following unless the patient has opted out:

1. Provide the patient with:
 - A written account of the facts regarding the SAPSE;
 - An apology for the harm suffered by the patient;
 - A description of the health service entity's response to the event;
 - The steps that the health service entity has taken to prevent re-occurrence of the event;
 - Any prescribed information; and
2. Comply with any steps set out in the *Victorian Duty of Candour Guidelines*.

The open disclosure process will commence after the **detection of a clinical incident** by:

- A member of staff at the time of the incident.
- When an unexpected outcome is first detected sometime after the incident.
- A patient, family or carer who expresses concern or dissatisfaction with their health care either at the time of the incident or sometime after the incident.
- Incident discovered at audit, such as clinical audit or medical records review.

The open disclosure process will commence after **detection of a data breach** when:

- A customer's personal information is lost or stolen.
- A database containing personal information is hacked.
- Personal information is mistakenly provided to the wrong person.

- Employees accessing or disclosing personal information outside the requirements or authorization of their employment.
- Paper records stolen from insecure recycling or garbage bins.

SDC requirements

The steps set out in the *Victorian Duty of Candour Guidelines* must be followed below.

Stage 1: Apologise and provide initial information.

- **Requirement 1** – SCDS must provide a genuine apology for the harm suffered by the patient and initial information, as early as practicable (and no longer than 24 hours) after the SAPSE has been identified by SCDS.
- **Requirement 2** – SCDS must take steps to organise an SDC meeting within 3 business days of the SAPSE being identified by SCDS.

Stage 2: Hold the SDC meeting.

- **Requirement 3** – The SDC meeting must be held within 10 business days of the SAPSE being identified by SCDS.
- **Requirement 4** – SCDS 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.
 - Any implications as a result of the SAPSE (if known) and any follow up for the patient.
- **Requirement 5** – SCDS must document the SDC meeting and provide a copy of the meeting report to the patient within 10 business days of the SDC meeting.

Stage 3: Complete a review of the SAPSE and produce a report.

- **Requirement 6** – SCDS must complete a review for the SAPSE and produce a report outlining what happened and any areas identified for improvement. If the SAPSE is classified as a sentinel event, the health service entity must also outline in the report clear recommendations from the review findings.
- **Requirement 7** – The report created from Requirement 6 must then be offered to the patient within 50 business days of the SAPSE being identified by SCDS. If the SAPSE involves more than one health service entity, this may be extended to 75 business days of the SAPSE being identified by the initial health service entity.

Documentation and reporting

- **Requirement 8** – SCDS 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.

- **Requirement 9** – SCDS must report its compliance with the SDC as legally required.

Where patients do not want to be involved in the SDC process

Patients may opt out from participating in the SDC process or from receiving information from SCDS. If a patient confirms that they wish to opt out of the SDC process, SCDS must:

- Ask them to sign a statement to this effect and store this in an appropriate location.
- Provide a point of contact, such as a consumer liaison officer, if the patient wishes to re-initiate the SDC process at any time.

When a patient has opted out, SCDS does not have to comply with the requirements in *Victorian Duty of Candour Guidelines* (the Guidelines), or the SDC process within the relevant Acts. However, it is recommended that SCDS conduct an adverse event review to ensure relevant information is recorded when relevant staff are available. This is recommended as the patient may later re-initiate their participation in the SDC process and elect to receive information required under the SDC. If this occurs, the commencement date must be clearly documented in an appropriate location, and the requirements within the Guidelines must then be followed.

Circumstances requiring a delay

There may be circumstances where the SDC process needs to be delayed, including:

- If the patient lacks or has lost their capacity (either temporarily or permanently) through the harm; or
- The patient is medically unable to participate (either temporarily or permanently through the progression of their medical condition).

If the above applies and has been assessed and documented by an appropriate medical professional, SCDS must undertake SDC with:

- The patient's immediate family, carer or NOK; or
- A person nominated by the patient.

This must occur, unless the relevant person is not available, or they have opted out.

When the patient recovers capacity, regardless of whether the SDC has occurred with a person outlined in the list above or not, SCDS must commence the SDC process again with the patient (unless the patient has opted out). The agreed commencement date must be clearly documented in the appropriate location, and the requirements within the Guidelines must then be followed.

If the patient requests a delay within the SDC process, or the patient is not yet ready to participate, SCDS must:

- Negotiate a preferred date for the health service entity to contact the patient; or
- Provide the details of a point of contact, such as a consumer liaison officer at the health service entity, if the patient prefers to re-initiate the next interaction.

Once the patient and the health service entity have an agreed commencement date for the SDC, it must be clearly documented in the appropriate location, and the requirements within these Guidelines must then be followed.

If there is a delay in conducting the SDC meeting, SCDS must continue with Requirements 6 to 9 regardless.

SDC process

When responding to a SAPSE, the immediate priority is the safety and care of the patients and staff involved, and then identifying if there is a risk to other patients, members of the public or other staff members.

The SDC process must commence as soon as SCDS becomes aware of the SAPSE, either through the clinical incident management system or when identified by a clinician, patient, NOK, family or carer.

Refer to WI – Statutory Duty of Candour process and reporting requirements for more details regarding the SDC process.