Safer Care Victoria

September 2022

Health Legislation Amendment (Quality and Safety) Act 2022

Statutory Duty of Candour (SDC) + associated reforms

VICTORIA State Government

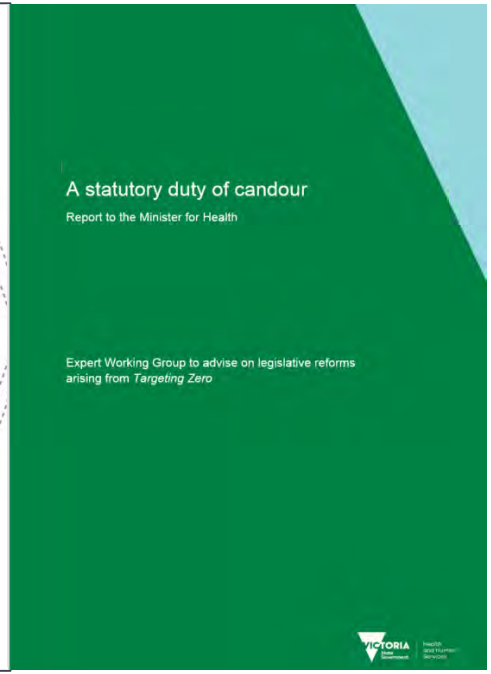
Why these reforms?

“Patients and consumers have a fundamental right to a full explanation and an apology when something goes wrong in their health care. This right is as important as the well-recognised right to be fully informed when giving consent to a medical procedure.

It is the hallmark of a great healthcare system that mistakes are acknowledged, that patients are informed of harm, that appropriate redress and remedies are provided and that lessons are learned to prevent repetition.”

Quote from: “Expert working group report on statutory duty of candour”

Background, Engagement and Consultation



Department of Health

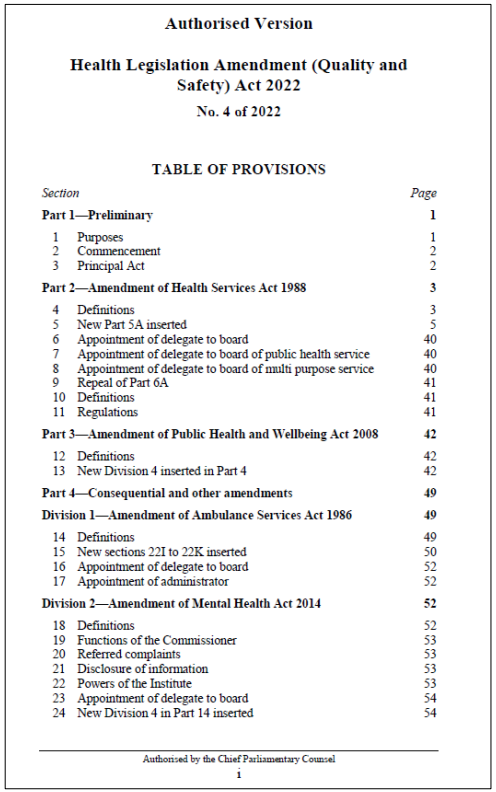
Reforms to foster an honest and open culture in health services

The Victorian Government is seeking your feedback on reforms aimed strengthening quality and safety in health care delivery.

What is the intent of these changes?

Elevate safety & quality across the health system as a whole	Increase the ability to identify quality & safety risks + address them	Strengthen an open and honest culture in health services
Elevate obligations: open disclosure + apologies	Promote a just culture where people can participate in reviews in good faith	Build trust between patients + health practitioners
Increase the benefits of reviews – protected space for learning	Contribute to a patient-centred approach	Improve patient experience + outcomes

Health Legislation Amendment (Q&S Act) 2022



Authorised Version

Health Legislation Amendment (Quality and Safety) Act 2022

No. 4 of 2022

TABLE OF PROVISIONS

Authorised by the Chief Parliamentary Counsel

1

2022

The Act:

1. establishes a Chief Quality & Safety Officer
2. provides for quality and safety reviews of health service entities
3. creates a new Statutory Duty of Candour (SDC)
4. extends protections for apologies under the SDC
5. introduces new protections for serious adverse patient safety event (SAPSE) reviews
6. amends the powers for Victorian Perioperative Consultative Council (VPCC)

Statutory Duty of Candour (SDC)

What is it and who does it apply to?

Open Disclosure vs. Statutory Duty of Candour (SDC)

SDC complements and elevates existing obligations of Open Disclosure.

Open Disclosure	Statutory Duty of Candour
• Clinical Governance standard • *Australian Open Disclosure Framework* • Should be followed in all cases of harm and near misses	• New Victorian legislation • *Victorian Duty of Candour Guidelines* • Applies to all serious adverse patient safety events (**SAPSE**)

Elements of Open Disclosure

The elements of Open Disclosure are:

- an apology or expression of regret
- 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.

Note: SDC has been built off the open disclosure principles already mandated in Victoria.

Statutory Duty of Candour (SDC)

If a patient suffers a **SAPSE**, health service entities will be obligated to provide the patient with:

1. a written account of the facts regarding the event
2. an apology for the harm suffered by the patient
3. a description of the health service response to the event
4. the steps that the health service 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*.

Note: Patients/next of kin may opt out.

The SDC will apply to relevant **health service entities**:

- public health services
- public hospitals
- multi-purpose services
- denominational hospitals
- private hospitals
- day procedure services
- ambulance services
- non-emergency patient transport service
- the Victorian Institute of Forensic Mental Health

Serious adverse patient safety event (SAPSE)

A SAPSE is an event that:

a) occurred while the patient was receiving health services from a health service entity; and

b) 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.

To avoid doubt, the above includes an event that is identified following discharge from the health service entity.*

A SAPSE is the equivalent of an **ISR 1 or 2 event** within public health services (Victorian Health Incident Management System scale).

*This definition may be subject to slight alteration as the regulations are in draft.

Statutory Duty of Candour (SDC)

Apologies made under the SDC are protected.

Saying sorry will not constitute an implied admission of fault or liability, or be relevant to civil or disciplinary proceedings

This refers to apologies made verbally or in writing, either before or after a civil proceeding may have commenced

Factual statements of what occurred however may not be protected, as the patients medical record is still available under the *Freedom of Information Act 1982* (Vic) and *Health Records Act 2001*

Victorian Duty of Candour Guidelines

Stage 1: Apologise and provide initial information

•Requirement 1

•The health service entity 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 the health service entity.

•Requirement 2

•The health service entity must take steps to organise an SDC meeting within **3 business days** of the SAPSE being identified by the health service entity.

Victorian Duty of Candour Guidelines

Stage 2: Hold the SDC meeting

•Requirement 3

•The SDC meeting must be held within **10 business days** of the SAPSE being identified by the health service entity.

•Requirement 4

•The health service entity must ensure that it provides the following in the SDC meeting:

1. an honest, factual explanation of what occurred in a language that is understandable to the patient;

2. an apology for the harm suffered by the patient;

3. an opportunity for the patient to relate their experience and ask questions;

4. an explanation of the steps that will be taken to review the SAPSE and outline any immediate improvements already made;

5. any implications as a result of the SAPSE (if known) and any follow up for the patient.

-Requirement 5

-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.

Victorian Duty of Candour Guidelines

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

•Requirement 6

•The health service entity 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 the health service entity. 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.

Victorian Duty of Candour Guidelines

Documentation and reporting

•Requirement 8

•The health service entity 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

•The health service entity must report its compliance with the SDC as legally required.

Victorian Duty of Candour Framework

A framework to complement the Act and will include considerations such as:

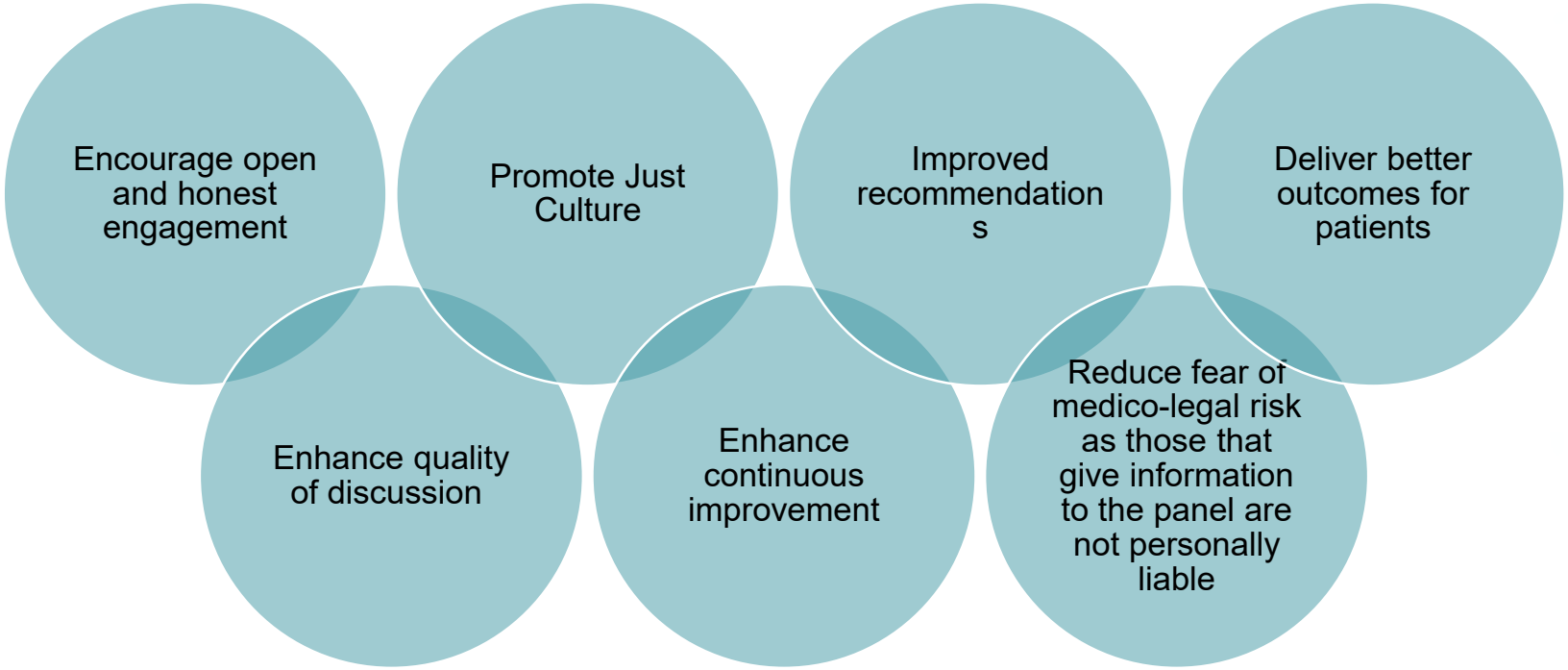
Linguistic	Vision and hearing impairments	Cognitive impairment
Mental Health Act 2014	Cultural incl. Aboriginal and Torres Straight Islander	SAPSE definition expanded
SAPSE across multiple health service entities	SAPSE that affects multiple patients	Escalation processes

Serious adverse patient safety event (SAPSE) reviews

SAPSE reviews are protected reviews conducted in accordance with Division 8 of Part 5A of the *Health Services Act 1988* (Act) and regulations.

A SAPSE review does not need to be completed for all SAPSE. It simply refers to a protected review process, and is optional.

Why may a health service want to protect a review?



Note: the protections do not restrict a patient rights to accessing their medical record.

SAPSE review

If a SAPSE has occurred, the CEO (however named) of a health service entity **may** appoint a **SAPSE review panel** to conduct a **SAPSE review**, and produce a **SAPSE review report**.

The SAPSE review report must contain 1 or more of the following:

- a description of the SAPSE
- analysis identifying why the event happened
- factors that contributed to the event
- any recommendations about changes or improvements in a policy, procedure or practice.

The SAPSE review report…

Must be offered to:

- a patient
- a person nominated by the patient;
- the immediate family, carer or next of kin of a patient, if the patient is deceased or lacks capacity.

Must be produced to:

- the Secretary if they request a copy of the report.

May be produced to:

- a coroner for the intent of an investigation or an inquest.

SAPSE review - Protections

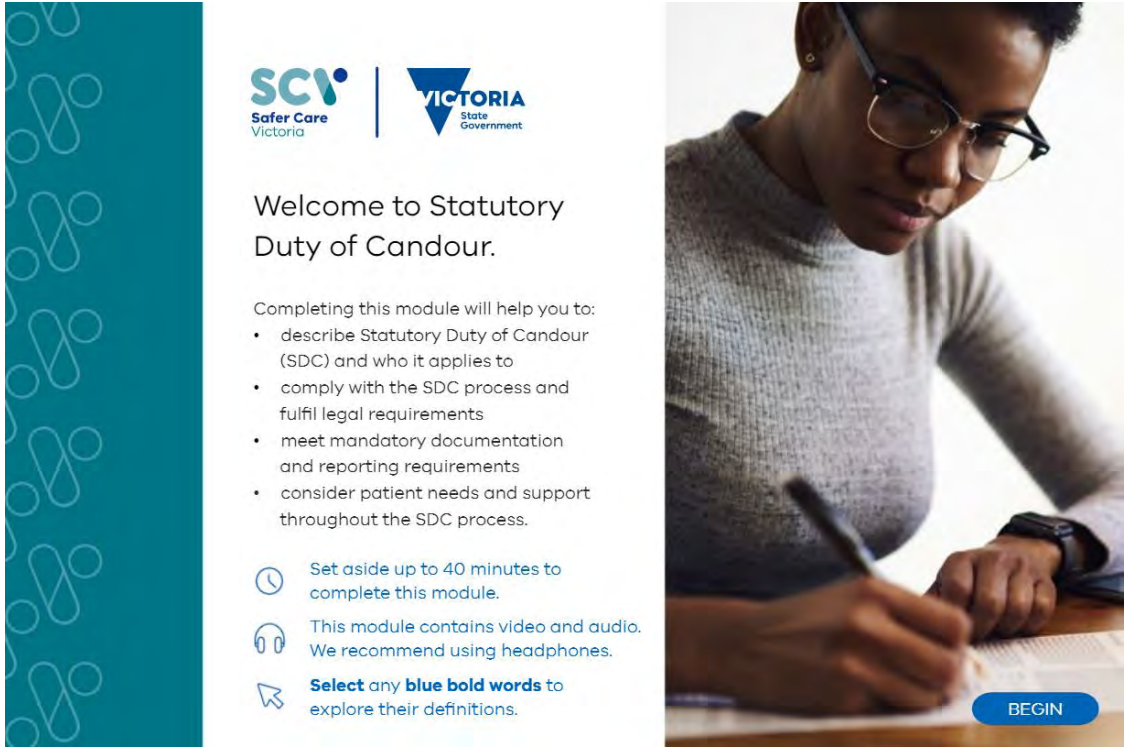
- Panel members and participants have certain liability protections
- Panel members and participants must not be required to produce a report/any document from a SAPSE review in a legal proceeding
- Panel members and participants must not be compelled to divulge information in a legal proceeding regarding the SAPSE review
- Documents relating to the review are not admissible in legal proceedings or subject to FOI requests / privacy legislation, i.e. working notes, interview records, draft / final SAPSE review reports

SCV have developed a resource called **Protections for serious adverse patient safety event (SAPSE) reviews** to assist health services understand the requirements of a SAPSE review.

Resources – Available / Upcoming

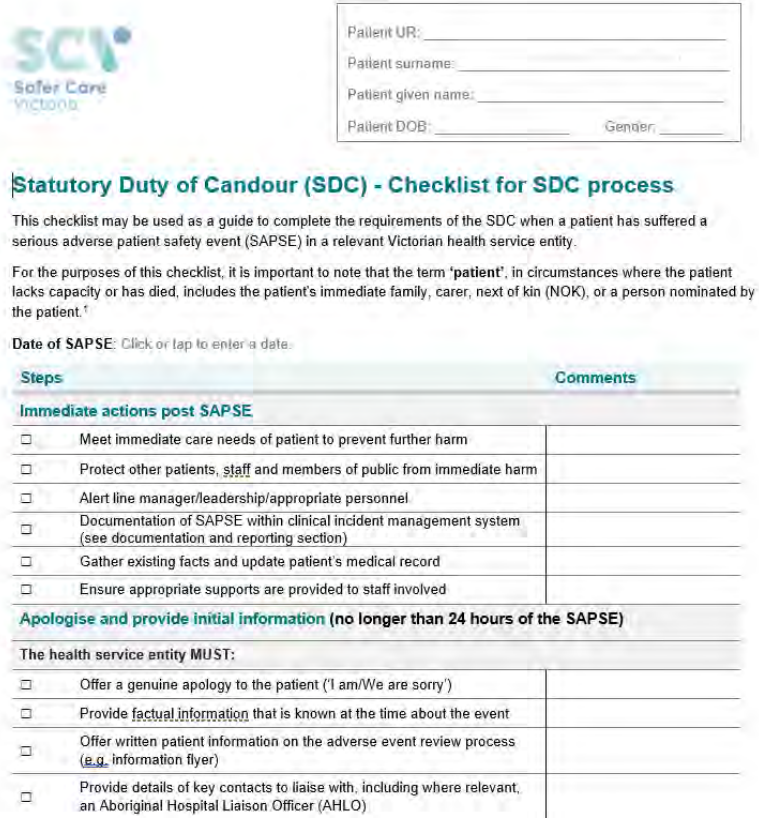
Resource Title	Date Available
Victorian Duty of Candour Guidelines	23 August 2022
Protections for serious adverse patient safety event (SAPSE) reviews	23 August 2022
Checklist for SDC process	23 August 2022
SDC - Initial meeting ‘note’ template	23 August 2022
SDC – Meeting report template	23 August 2022
SDC - FAQs	5 September 2022
SAPSE reviews - FAQs	5 September 2022
PowerPoint presentation for staff	5 September 2022
3 eLearning modules	WB 19 September 2022
Victorian Duty of Candour Framework	October 2022

eLearning modules



1. Statutory Duty of Candour
2. Protections for SAPSE reviews
3. Introduction to open disclosure

Checklists / Templates



Safer Care Victoria

Patient UR: _____

Patient surname: _____

Patient given name: _____

Patient DOB: _____ Gender: _____

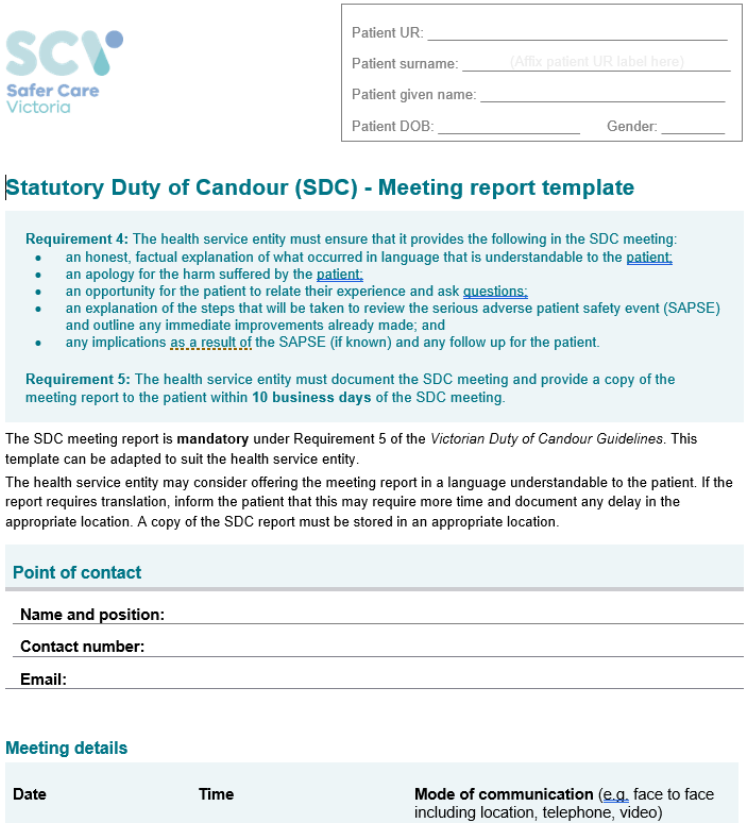
Statutory Duty of Candour (SDC) - Checklist for SDC process

This checklist may be used as a guide to complete the requirements of the SDC when a patient has suffered a serious adverse patient safety event (SAPSE) in a relevant Victorian health service entity.

For the purposes of this checklist, it is important to note that the term **'patient'**, in circumstances where the patient lacks capacity or has died, includes the patient's immediate family, carer, next of kin (NOK), or a person nominated by the patient.[1]

Date of SAPSE: Click or tap to enter a date.

Steps		Comments
Immediate actions post SAPSE		
☐	Meet immediate care needs of patient to prevent further harm	
☐	Protect other patients, staff and members of public from immediate harm	
☐	Alert line manager/leadership/appropriate personnel	
☐	Documentation of SAPSE within clinical incident management system (see documentation and reporting section)	
☐	Gather existing facts and update patient's medical record	
☐	Ensure appropriate supports are provided to staff involved	
Apologise and provide initial information (no longer than 24 hours of the SAPSE)		
The health service entity MUST:		
☐	Offer a genuine apology to the patient ('I am/We are sorry')	
☐	Provide factual information that is known at the time about the event	
☐	Offer written patient information on the adverse event review process (e.g. information flyer)	
☐	Provide details of key contacts to liaise with, including where relevant, an Aboriginal Hospital Liaison Officer (AHLO)	



Safer Care Victoria

Patient UR: _____

Patient surname: _____ (Affix patient UR label here)

Patient given name: _____

Patient DOB: _____ Gender: _____

Statutory Duty of Candour (SDC) - Meeting report template

Requirement 4: The health service entity must ensure that it provides the following in the SDC meeting:

- an honest, factual explanation of what occurred in 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 serious adverse patient safety event (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.

Requirement 5: 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.

The SDC meeting report is **mandatory** under Requirement 5 of the *Victorian Duty of Candour Guidelines*. This template can be adapted to suit the health service entity.

The health service entity may consider offering the meeting report in a language understandable to the patient. If the report requires translation, inform the patient that this may require more time and document any delay in the appropriate location. A copy of the SDC report must be stored in an appropriate location.

Point of contact

Name and position:

Contact number:

Email:

Meeting details

Date	**Time**	**Mode of communication** (e.g. face to face including location, telephone, video)

SCV launch - Quality and Safety Act 2022

1. Recording of the SCV launch

Statutory Duty of Candour launch

2. PowerPoint slides

Launch presentation slides

Dr Charlotte Hopkins video on duty of candour

Consultant, Barts Health, NHS Trust

Consumer resources

SCV will partner with the Health Issues Centre (HIC) to **co-design** consumer resources which **may** include:

- consumer-friendly version of the *Victorian Duty of Candour Guidelines*
- explanatory video on SDC
- pamphlet on the SDC timelines and requirements
- pamphlet on protections for SAPSE reviews.

We aim to bring together a diverse consumer group, including those with lived experience of adverse events to assist with the development of resources.

Closing notes

- If a **SAPSE occurs**, Statutory Duty of Candour **(SDC) must be completed,** unless the patient opts out
- Health service entities **must comply with the *Victorian Duty of Candour Guidelines*** which includes completing an internal review of the SAPSE (such as a root cause analysis or in-depth case review)
- If a health service entity **wants to protect the review**, they must also **follow the requirements in accordance with the Act and regulations**
- These reviews will then be called a '**SAPSE review**' and relevant protections will apply
- **A SAPSE review <u>is not mandatory</u>**

Why?

Helpful resources

The Act: Health Legislation Amendment (Quality and Safety) Act 2022

SCV Website: Statutory Duty of Candour and protections for SAPSE reviews | Safer Care Victoria

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