**Statutory Duty of Candour (SDC)** – Frequently asked question (FAQ) sheet

**Please note, this FAQ sheet is to be released in draft form until relevant regulations under the *Health Services Act 1988* have been made.**

#### When does the SDC legislation come into effect?

The SDC legislation takes effect from 30 November 2022 and is legislated under section 128ZC of the *Health Services Act 1988,* section 22I of the *Ambulance Services Act 1986,* and section 345B of the *Mental Health Act 2014*.

1. **Why do we need the SDC legislation?**

The SDC builds on the Australian Open Disclosure Framework and has similar principles and requirements. Although the Australian Open Disclosure Framework is not legislated across the State, it is however mandated in Standard 1 of the National Safety and Quality Health Service (NSQHS) Standards, which provide a nationally consistent statement of the level of care consumers can expect from health service entities.

The SDC process will be legislated for all SAPSEs and in the case that an event is not a SAPSE, open disclosure will still be required. Open disclosure (and the SDC) is a patient right, is anchored in professional ethics, considered good clinical practice, and is part of the care continuum.

#### Who must comply with the SDC?

A health service entity for the purposes of the *Health Services Act 1988* (Vic)(Act) includes:

* a public health service
* a public hospital
* a multi-purpose service
* a denominational hospital
* a private hospital
* a day procedure centre
* an ambulance service within the meaning of the *Ambulance Services Act 1986*
* a non-emergency patient transport service within the meaning of the *Non-Emergency Patient Transport and First Aid Services Act 2003* that is licensed under that Act, and
* the Victorian Institute of Forensic Mental Health established by section 328 of the *Mental Health Act 2014*.

#### I am the manager of an aged care facility attached to a (public or private) hospital. Do I need to comply with the SDC?

Only defined health service entities are required to comply with SDC. If the corporate entity that is registered as the (public or private) hospital is different from the corporate entity that is registered as an approved provider under the *Aged Care Act 1997* (Commonwealth), the approved provider of aged care does not have to comply with the SDC as it is not listed as a relevant health service entity. However, your health service entity will need to do its own assessment and determine which of your corporate entities are a ‘health service entity’ and therefore must comply with the SDC.

#### I work at a community health service. Do I need to comply with the SDC?

At this stage, the obligation to comply with the SDC only applies to certain health service entities and does not apply to community health services and publicly funded mental health community support services.

There may be future amendments to add to the list required to comply with the SDC, although this would be post consultation and communication.

#### What is a SAPSE?

A serious adverse patient safety event (SAPSE) is an 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 sustained by the patient.

For the avoidance of doubt, an event may be identified following discharge from the health service entity.

A SAPSE is likely to be the equivalent of an ISR 1 or 2 event within services that utilise the Victorian Health Incident Management System scale. However, it has been noted that some health service entities use their incident management system to capture data that may not otherwise be an adverse event. It will be important for the relevant team (e.g. quality team) within a health service entity to discuss whether an event meets the above criteria, and therefore be a SAPSE.

**If a patient suffers a SAPSE in the course of receiving health services, the health service entity responsible for providing those services owes a SDC to the patient.**

#### Who is a registered health practitioner?

Examples of registered health practitioners, as listed on Ahpra, include:

* Aboriginal and Torres Strait Islander Health practitioner
* Medical practitioner (doctors/surgeons)
* Medical radiation practitioner
* Nurse
* Midwife
* Occupational therapist
* Paramedic
* Pharmacist
* Physiotherapist
* Podiatrist
* Psychologist

#### What do I need to give the patient as part of the review of the SAPSE (requirement 6 and 7)?

The report created as a result of the review must include the matters required by section 128ZC of the *Health Services Act 1988*, being:

* 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, and
* the steps that the health service entity has taken to prevent re-occurrence of the event.

As part of the SDC process, the review report must then be offered to the following, unless the patient has opted out:

* the patient, or
* if the patient is deceased or lacks capacity, a person nominated by the patient, the immediate family, carer or NOK of a patient.

Dependent on what type of review methodology is used, Safer Care Victoria (SCV) recommend providing the patient with this full report once completed in line with open and honest communication. It is also recommended that any learnings are then disseminated throughout the unit where the harm occurred, to improve future practices.

#### The requirement to obtain a signed statement from a patient/family/next-of-kin to opt out of the SDC process may be difficult in some situations. Are they able to decline verbally?

Unfortunately, as outlined in section 128ZC of the *Health Services Act 1988*, section 22I of the *Ambulance Services Act 1986* and section 345B of the *Mental Health Act 2014*, it clearly states that:

* a patient may choose not to receive information in accordance with this Division by providing the health service entity with a signed statement.

This therefore would be a breach of the Act if this was not obtained, verbally obtained, or signed by a clinician on their behalf and then SDC was not completed. It can also be disputed by the patient, leaving the health service entity in a vulnerable position. A health service entity may consider creating an electronic form for the patient/NOK to obtain signed declaration.

#### What if a patient signs a declaration to opt out?

If a patient has signed a declaration to opt out, the health service entity does not have to comply with the Requirements in the Act or the *Victorian Duty of Candour Guidelines* (Guidelines). It is recommended, although not required, that the health service entity should continue Requirements 6-9 within the Guidelines*.*

If the patient decides at a later date to be involved by withdrawing their declaration to opt out, the health service entity must comply with the request.

#### What if a patient indicated they want to opt out, but do not sign a declaration to this effect?

The Requirements within the Act and the Guidelines will continue to apply, and the health service entity must continue to attempt to engage with the patient/family, until a declaration has been signed.

#### What if a patient has decreased capacity (and may never recover capacity), and also doesn’t have a NOK/carer/any family?

The Act and the Guidelines include provisions to involve the family, carers, next of kin or nominated persons of the patient in the event of decreased capacity of the patient. If none of these people are available for a particular patient in these circumstances, the health service may determine who is appropriate to involve in SDC, such as an appointed medical treatment decision maker.

#### What are the legal implications for the health service entity?

The relevant health service entity must comply with the legal requirements of the SDC if it is listed as a ‘health service entity’ within the Act, meaning it must comply with the Act and the Guidelines, including timelines and reporting requirements.

If your health service entity fails to comply with the SDC, the Secretary or Minister may take this into account when assessing:

* whether the entity provides safe, patient-centred and appropriate services
* the quality and safety of health services provided by the entity.

The Minister may also then publish a statement on the internet site of the Department of Health (DH) setting out the name of a certain health service entity if, in the Minister's opinion:

* the relevant health service entity has failed to comply with the duty of candour on 2 or more occasions; and
* the failure to comply is of a serious nature.

#### What are the legal implications for me as a clinician?

If you offer the patient, next-of-kin, or carer an apology if the patient has suffered a SAPSE, you can be assured that this apology does not constitute an admission of fault or liability. However, it is important to note how to offer this apology. SCV recommend completing the Open Disclosure and Statutory Duty of Candour eLearning modules developed to understand more.

There are current reporting obligations for the health service entity if a clinician has acted in a way that constitutes a ‘prohibited act’ or is notifiable under the Health Practitioner Regulation National Law. In these cases, the Australian Health Practitioner Regulation Agency (Ahpra) will be contacted as per usual procedure, and the apology protections do not prohibit this from occurring or from any disciplinary proceedings that follow in regards to the actual event.

For those involved in conducting the review and providing the review report to the patient or their family, the timelines of the Guidelines must be followed.

#### What if I am a Visiting Medical Officer (VMO), do I have to comply with the SDC?

In respect of a SAPSE that occurs to a patient “in the course of receiving health services”, the obligation to comply with the SDC is on the health service entity responsible for providing those services. The Act regulates health service entities not individual health practitioners, and the regulation of individual registered health practitioners is the responsibility of the Health Practitioner Regulation National Law. It may be an option to include the SDC into contractual agreements, similar to ensuring compliance with open disclosure with VMOs.

#### What are the apology protections?

In a civil proceeding where the death or injury of a person is in issue or is relevant to an issue of fact or law, an apology:

* does not constitute an express or implied admission of liability for the death or injury; and
* is not relevant to the determination of fault or liability in connection with that proceeding.

The above applies whether the apology was made orally or in writing, and either before or after a civil proceeding.

Evidence of an apology made by or on behalf of a person or a health service entity in connection with any matter alleged to have been caused by the person or health service entity is not admissible in any civil or disciplinary proceedings as evidence of the fault or liability of the person or health service entity in connection with that matter.

#### Who decides if an event is a SAPSE?

With reference to the definition of SAPSE and the “reasonable opinion of a registered health practitioner”, it will depend on the assessment of a registered health practitioner as to whether an event is a SAPSE. However, your health service entity’s policy may also specify who decides whether an event is a SAPSE if there is any disagreement on whether it is reasonable to hold the opinion that the event was a SAPSE. This could be a committee of the health service entity, or in the case of a small service it could be the Chief Executive Officer (CEO). Each health service entity must make its own assessment as to how it will ensure that the health service entity complies with the legislation.

Each health service entity will have to develop its own processes to ensure that every adverse event that could potentially fulfil the definition of SAPSE is assessed by one or more registered health practitioners, and a judgement made as to whether it is a SAPSE or not.

It is possible that a policy could reflect the reasonable opinion of a registered health practitioner – that is, one or more registered health practitioners could make a policy that events that fall within the ISR 1 and ISR 2 criteria, also satisfy the definition of a SAPSE. However, arrangement would need to exist within the policy for an assessment to be made of incidents that are borderline ISR 2’s (or equivalent).

#### What happens if there is a difference of opinion between the health service entity and patient as to whether an event is a SAPSE?

If a health service entity decides an event is not a SAPSE, an appropriate record of that decision should be made in their quality and safety systems. However, a patient is entitled to complain about that assessment in the same way that they are entitled to complain about any other aspect of the services that they have received from the health service entity. The health service entity may reconsider and change their decision as to whether an event is a SAPSE after considering a complaint.

All health service entities should have processes in place for dealing with complaints, which may first involve raising a complaint with the health service entity. In addition, a patient may then complain to the Health Complaints Commissioner (HCC) or Mental Health Complaints Commissioner (MHCC) as appropriate. New paragraph 5(1)(da) of the *Health Complaints Act 2016* provides that a person may complain to a health service provider about a failure to comply with the SDC. This will involve an examination of the health service entity’s decision that a particular event was not a SAPSE. Similarly new sections 6(1)(da) and 7(1)(da) permit complaints to be made to the HCC about a failure to comply with the SDC.

#### What happens if a breach of SDC is found?

Breaches to the SDC may be found through a variety of ways:

* internally through an audit
* internally through a complaint to a clinician or a consumer liaison officer
* externally from a complaint to the HCC, MHCC, Secretary or Minister’s office, DH or SCV
* as an outcome from an accreditation report

Both the HCC or MHCC may report to the Secretary if they find that a health service entity has not complied with the SDC (see new sections 228(ja) and 233(1)(ea) of the *Mental Health Act 2014* and amended section 118(1)(l) of the *Health Complaints Act 2016*).

#### What if the SAPSE occurred across multiple health services? Who is liable?

In the case of a SAPSE that involves two or more health service entities (i.e. event at each service likely contributed to the harm), the health service entities should discuss how to conduct the SDC process, but all entities must participate. If the harm includes a health service entity within another state, the Victorian service must still meet SDC requirements.

In the event that two or more health service entities involved in an event disagree as to whether the event constitutes a SAPSE (which then triggers the SDC), or there is a disagreement about how to conduct the SDC process, these matters should be escalated to the Secretary. It may be that the Secretary could defer these concerns to the Chief Quality and Safety Officer (CQSO).

#### Will an individual employee, officer or director of a hospital ever be personally liable for a failure to comply with the SDC obligations?

No. Any liability resulting from an act or omission that would attach to the person instead attaches to the health service entity.

#### What if a patient states they have suffered a SAPSE, but the health service entity disagrees?

If a patient self-reports a harm that is disputed by a registered health practitioner, the health service entity should provide the patient with a means of escalation to mediate the disagreement. This point of escalation may be:

* the internal consumer liaison officer (or equivalent) if it is disputed by a registered health practitioner
* the Health Complaints Commissioner (HCC), or
* the Mental health Complaints Commissioner (MHCC).
1. **What are the reporting requirements under the legislation?**

The reporting requirements are to be finalised although may include the following data collection points:

* number of SAPSE
* instances where SDC was commenced
* instances where SDC was completed
* instances where patient/NOK opted out.

This data will likely be collected via an Agency Information Management System (AIMS) form via the Victorian Agency for Health Information (VAHI). It is likely it will be required to be submitted to VAHI on a quarterly basis and will be monitored by SCV/DH.

#### In the circumstance that a health service entity may only have become aware of a SAPSE following commencement of legal proceedings, is it expected that the SDC process would still proceed with the applicable timeframes?

Yes, SDC should commence from the time a health service entity becomes aware that an event is a SAPSE. The patient may have a nominated person that the health service entity must communicate with in these circumstances.