# Statutory Duty of Candour Data Collection

## Reporting Guidelines

OFFICIAL

# Introduction

Effective from 30 November 2022, the *Health Legislation Amendment (Quality and Safety) Act 2022* requires relevant health service entities to undertake Statutory Duty of Candour (SDC) processes within 50-75 working days of the occurrence identification of a ‘serious adverse patient safety event’ (SAPSE). The SDC has been outlined in the *Health Services Act 1988*, the *Mental Health Act 2014* and the *Ambulance Services Act 1986*. The [*Victorian Duty of Candour Guidelines*](https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Guidelines%20-%20FINAL.docx) (legislative instrument) provides information on the timelines and requirements.

The SDC builds on the mandatory obligations of the [Australian Open Disclosure Framework](https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework), ensuring patients, their families or carers receive an apology and open, honest communication when a SAPSE has occurred. The Australian Open Disclosure Framework must be followed for all other cases of harm that do not meet the SAPSE definition.

The SDC data collection will report key performance metrics to allow relevant health service entities to monitor compliance with their legal obligations. Safer Care Victoria will monitor the uptake of SDC practices using this data collection.

For SAPSE events identified on and from 1 January 2023, reporting of SDC processes is voluntary/optional but any reporting completed from this date must be consistent with these specifications. For SAPSEs identified on and from 1 July 2023, reporting of SDC aligned performance measures using the Agency Information Management System (AIMS) Statutory Duty of Candour reporting webform is mandatory for relevant health service entities.

# Scope

The scope of the SDC includes relevant health service entities:

* 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*
* the Victorian Institute of Forensic Mental Health established by section 328 of the *Mental Health Act 2014.*

Non-Emergency Patient Transport (NEPT) services within the meaning of the *Non-Emergency Patient Transport and First Aid Services Act 2003,* although required to comply with the SDC, will not be required to report their data via this AIMS form.

# Agency level for SDC reporting

Agency level for SDC reporting includes:

* at **campus level** for Victorian public hospitals and health services, including denominational and multi-purpose hospitals, and private hospitals and registered day procedure centres
* relevant health service entities that have any other service under its governance, including but not limited to residential aged care or community services. Those services must also report SDC data, reporting data separately for each campus, or each aged care or community service, whether co-located on the same site as the acute health service/hospital or separately located
* at **whole-of-entity level** for all other health service entities required to undertake SDC processes under the legislation, i.e. ambulance services and the Victorian Institute of Forensic Mental Health.

# Reporting due date, frequency and period

SDC data is to be reported:

* at quarterly intervals
* by the 14th day of the month after the end of each calendar quarter (e.g. by 14 July for SDCs occurring between 1 January and 30 June inclusive)
* for SAPSEs that are identified in one quarter and the SDCs conducted or opted out of in that quarter and the following quarter, arising from those SAPSEs.

Reporting will be voluntary/optional initially, with mandatory reporting to begin with SAPSEs identified from 1 July 2023:

* **voluntary/optional** reporting can commence for SAPSEs identified in January to March 2023 and related SDCs for those conducted or opted out of during January to June 2023 to be reported by 14 July 2023
* **voluntary/optional** reporting can also be submitted for SAPSEs identified in April to June 2023 and related SDCs for those conducted or opted out of during April to September 2023 to be reported by 14 October 2023
* **mandatory reporting** to commence for SAPSEs identified in July to September 2023 and related SDCs for those conducted or opted out of during July to December 2023 to be reported by 14 January 2024
* **mandatory reporting** to continue thereafter for all relevant agencies for SAPSEs identified within each calendar quarter, and for the related SDCs for SAPSEs conducted or opted out of in the six months beginning on the first day of the calendar quarter, to be reported by the 14th day of the month after the end of the 6-month SDC reporting period.

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| **Quarter SAPSE identified** | **6-month period of SDC process** | **Due date for submission** | **Reporting status** | **AIMS Selector: Year** | **AIMS Selector: Period** |
| Apr - Jun 2023 | Apr – Sep 2023 | 1 – 14 Oct 2023 | *Voluntary* | **2022-23** | **4th Quarter** |
| Jul – Sep 2023 | Jul – Dec 2023 | 1 – 14 Jan 2024 | **Mandatory** | **2023-24** | **1st Quarter** |
| Oct – Dec 2023 | Oct 2023 – Mar 2024 | 1 – 14 Apr 2024 | **Mandatory** | **2023-24** | **2nd Quarter** |
| Jan – Mar 2024 | Jan – Jun 2024 | 1 – 14 Jul 2024 | **Mandatory** | **2023-24** | **3rd Quarter** |

# Data to be reported

Data is to be reported for the following metrics (further defined under Data definitions):

* number of SAPSE identified within the quarter being reported
* for these SAPSE:
	+ instances where the SDC was commenced within the 6-month reporting period
	+ instances where the SDC report was provided by the health service entity within the 6-month reporting period
	+ instances where the patient/NOK/carer opted out of that SDC within the 6-month reporting period.

# Data definitions

* **Number of SAPSE identified**
	+ Total number of SAPSE identified by the health service entity within the quarter. The events to be reported within the quarter will depend on when the events are identified by the health service entity as being SAPSEs.
	+ A significant portion of SAPSE will be identified on the date on which they occur. Other events may be determined/confirmed to be a SAPSE after further review of the event.
* **Instances where the SDC was commenced**
	+ Of the total number of SAPSE that were identified in the quarter being reported, the total number for which the SDC had commenced with the patient or their next-of-kin/family/carer by the end of the quarter after the quarter in which the SAPSE was identified.
	+ An SDC commencement for the purposes of this reporting occurs when the health service entity provides the initial apology and acknowledgment to the patient or their next-of-kin/family/carer.
* **Instances where the SDC report was provided by the health service entity**
	+ Of the total number of SAPSE that were identified in the quarter being reported, the total number for which the patient or their next-of-kin/family/carer is first presented with the SDC report produced post the review of the SAPSE, by the end of the quarter after the quarter in which the SAPSE was identified.
	+ The patient or their next-of-kin/family/carer may seek further discussion of the report, but it is the timing of the first presentation of the SDC report that is to be reported.
	+ This is not the SDC meeting report, but the report provided following the review of the SAPSE.
* **Instances where the patient/NOK/carer opted out of the SDC**
	+ Of the total number of SAPSE that were identified in the quarter being reported, the total number for which the patient or their next-of-kin/family/carer opted out of the SDC process by signed statement, by the end of the quarter after the quarter in which the SAPSE was identified.
	+ Where the patient or their next-of-kin/family/carer verbally declines involvement but does not provide the health service entity with a signed statement to opt out, the SDC remains open and is not reported as an opt out, because the patient or their next-of-kin/family/carer may subsequently decide to engage in the SDC process: if they do so, that would be reported as a SDC commencement only if the decision is made within the six months for reporting SDC activity related to that SAPSE.
	+ Where the patient lacks capacity or has died, a decision to opt out of the SDC made by the patient’s immediate family, carer, next-of-kin, or a person nominated by the patient is reported here.

# Reporting guidelines

To be reported as a SAPSE, the event must meet the definition of a SAPSE within the *Health Services (Quality and Safety) Regulations 2020* (the Regulations) under the *Health Services Act 1988.* The Regulations include the following definition of a SAPSE under Regulation 3B:

**Serious adverse patient safety event**

(1) For the purposes of the definition of a *serious adverse patient safety event* in Section 3(1) of the *Health Services Act 1988*, a prescribed class or category is an event that -

1. occurred while the patient was receiving health services from a health service entity; and
2. in the reasonable opinion of a registered health practitioner, has resulted in, or is likely to result in, unintended or unexpected *harm* being suffered by the patient.

(2) To avoid doubt, an event in sub-regulation (1) includes an event that is identified following discharge from the health service entity.

* *Harm* includes *moderate harm*, *severe harm* and *prolonged psychological harm*;
* *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 include harm that causes permanent damage or injury to an individual;
* *Prolonged psychological harm* means psychological harm which a patient has experience, or is likely to experience, for a continuous period of at least 28 days;
* *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 or disability, or death.

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| SAPSE identification |
| A SAPSE is an adverse patient safety event with an Incident Severity Rating (ISR) of 1 or 2, severe or moderate harm, in the Victorian Health Incident Management System (VHIMS), whilst also meeting the SAPSE definition.  |
| The timing of the initial apology and acknowledgement is not influenced by public holidays and weekends. |
| Where more than one SAPSE is identified for a single patient, each individual SAPSE identified in the quarter must be counted and reported, and the SDC actions that occur in the 6-month reporting period associated with each individual SAPSE must also be counted and reported. |
| Upon identification of a SAPSE, the health service must make reasonable efforts to contact the patient/next-of-kin/family/carer, however where they cannot be contacted, including where this continues for some time, the health service should proceed to review the circumstances of the SAPSE, and document their efforts to make contact in the patient record. Where the health service entity cannot contact the patient/next-of-kin/family/carer during the 6-month SDC period for the SAPSE, the SAPSE identified by the health service entity is reported, but no data is reported for the three SDC items – SDC commenced, SDC report provided and SDC opted out.  |
| There may be instances where the SAPSE being identified and the SDC commencement is within the reporting period, however the date that the SDC report was provided to the family is not, and therefore is extended beyond the reporting period of six months. In this situation, the date the report is provided to the family is not captured in this reporting timeframe. Similarly, if the SDC commencement was outside of the six month reporting period due to a delay, this would not be captured. **In summary, no data relating to prior quarters’ SAPSE should be included in subsequent reporting periods.**  |

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| Apology and SDC meeting |
| The initial apology should be provided verbally and in person, where able, by a suitably qualified health professional. It is recommended that evidence of this apology is documented within the clinical incident management system, and/or the patient’s medical record, as well as to whom it was delivered. |
| The meeting with the patient/next-of-kin/family/carer to acknowledge and apologise for the SAPSE can be conducted in person, by telephone, or via a teleconference platform, with the preference of the patient/next-of-kin/family/carer to be considered in determining the medium used. The health service should document this preference, including instances where a face-to-face meeting is declined by the patient/next-of-kin/family/carer. |

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| Opting out or declining |
| Where the patient/next-of-kin/family/carer verbally declines to participate in the SDC process and/or declines to provide the health service entity with a signed statement to opt out, the health service may make e-forms available, but if the patient/next-of-kin/family/carer decline to sign, the SDC process remains open.  |
| If the patient/next-of-kin/family/carer declines a meeting with the health service entity but would like a copy of the report, this is not opting out of the SDC process, so is included in the counts of SDC processes commenced and SDCs where a report was provided. It is not included in the count of instances opted out of the SDC.  |
| Where the patient/next-of-kin/family/carer formally opts out of the SDC process by providing the health service entity with a signed statement to opt out, the health service entity is not required to offer them a copy of the report.  |

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| Multiple health service entities |
| If the SAPSE occurs across 2 or more health service entities (i.e. events at each entity likely contributed to the harm), it should be discussed how the SDC process would be conducted, but all entities must participate. However, it will be the responsibility of each entity to report their compliance with the SDC. This is to ensure that the requirement to complete the SDC sits with each health service entity.  |
| If the SAPSE occurs at one health service entity and the patient is admitted to or transferred to another health service entity for care, it is the responsibility of the health service entity where the event occurred to report the SAPSE and conduct and report on the SDC. See the [Victorian Duty of Candour Framework](https://www.safercare.vic.gov.au/sites/default/files/2022-10/Victorian%20Duty%20of%20Candour%20Framework%20-%20FINAL.docx) for further information, including regarding collaboration between health service entities in such circumstances. |

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| No SAPSEs or unsure |
| Where a health service entity has zero SAPSEs to report for that quarter (such as in the case of a mobile service or single operator), they must still complete each data item on the AIMS form and submit the data to ensure compliance with their reporting obligations under the relevant Act. |
| At times, the severity of the harm may not be clear when the event is entered into the clinical incident management system and requires an external review (including coronial review). In these cases, ‘time zero’ would be when this is identified by the health service entity as a SAPSE post the review. The SAPSE in such instances would be reported in the quarter in which it is identified as a SAPSE. |
| For harm events that seem unclear whether they meet SAPSE criteria, or for all other harm events, health service entities are encouraged to take a patient-centred approach to ensure that the appropriate steps and communication is being completed. In the case where a service has further questions, they can contact the Safer Care Victoria project team by email <dutyofcandour@health.vic.gov.au>. |

# Access to HealthCollect

The Statutory Duty of Candour Data Collection is available from **1 July 2023** at the [HealthCollect portal](https://www.healthcollect.vic.gov.au/) <www.healthcollect.vic.gov.au>.

To request a HealthCollect login for a new user, or to have this new data collection assigned to an existing HealthCollect user, the staff member must complete the [HealthCollect Portal User Request form](https://forms.office.com/Pages/ResponsePage.aspx?id=H2DgwKwPnESciKEExOufKIQCYRhq7MNNvvjya8xeYoZUNzE3UEZWTlpPNlc0WUhaMERaMEw1SjRDSS4u) <https://forms.office.com/Pages/ResponsePage.aspx?id=H2DgwKwPnESciKEExOufKIQCYRhq7MNNvvjya8xeYoZUNzE3UEZWTlpPNlc0WUhaMERaMEw1SjRDSS4u>.

When completing the HealthCollect User Request Form, at the question ‘Do you need access to AIMS forms?’, select ‘Yes’, and on the next screen, select ‘Statutory Duty of Candour data collection’.

To assign new campuses to your user log in, please enter the names of the campuses in the form under ‘Campuses you will submit data for (if applicable)’.

Information on how to access the HealthCollect portal to submit data, as well as information about the SDC AIMS form, is available in the AIMS Manual on the [Agency Information Management System (AIMS) webpage](https://www.health.vic.gov.au/data-reporting/agency-information-management-system-aims) <https://www.health.vic.gov.au/data-reporting/agency-information-management-system-aims>. This manual has been created to assist health service entities to obtain access to the secure data portal and complete SDC data reporting each quarter.

# Mandatory reporting obligations

Reporting of the SDC for publicly funded health service entities has been included in the [Policy and Funding Guidelines](https://www.health.vic.gov.au/policy-and-funding-guidelines-for-health-services) <https://www.health.vic.gov.au/policy-and-funding-guidelines-for-health-services>.

Reporting of the SDC has been made mandatory for health service establishments (private hospitals and day procedure centres) in the [*Health Services (Health Service Establishments) Regulations 2013*](https://www.legislation.vic.gov.au/in-force/statutory-rules/health-services-health-service-establishments-regulations-2013/005)<https://www.legislation.vic.gov.au/in-force/statutory-rules/health-services-health-service-establishments-regulations-2013/005>.

# Further information

Health service entities should refer to the relevant Act and the [*Health Services (Quality and Safety) Regulations 2020*](https://www.legislation.vic.gov.au/in-force/statutory-rules/health-services-quality-and-safety-regulations-2020/002) for more details on the SDC requirements, and the SAPSE definition.

To support health service entities in establishing SDC processes, Safer Care Victoria has compiled a range of [resources](https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour) <https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour>.

Questions regarding definitions or data to be reported to the SDC data collection can be directed to the Safer Care Victoria project team by email <dutyofcandour@health.vic.gov.au>.

Questions about accessing the HealthCollect portal can be emailed to the HDSS HelpDesk <hdss.helpdesk@health.vic.gov.au>.

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