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| Health Services (Health Service Establishments) Regulations 2024 |
| Fact sheet for health service establishments |
| OFFICIAL |

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# Overview

The Health Services (Health Service Establishments) Regulations 2024 (the 2024 Regulations) will commence on 31 August 2024.

The 2024 Regulations largely maintain the regulatory controls of the Health Services (Health Service Establishments) Regulations 2013 (the 2013 Regulations) and include new requirements. Additionally, a number of amendments have been made for clarification or to modernise terminology. To download the current version of the Regulations, visit: [www.legislation.vic.gov.au](http://www.legislation.vic.gov.au) <https://www.legislation.vic.gov.au/>.

# What’s new in the 2024 Regulations?

The structure and content of the 2024 Regulations is largely consistent with the 2013 Regulations. However, targeted changes have been made to improve the operation of the Regulations and address issues that have been identified by stakeholders. The substantive changes suggested by stakeholders and other administrative changes adopted in the 2024 Regulations are summarised below and detailed in [Appendix 1](#_Appendix_1).

To allow time for further consultation and the development of supporting guidelines, several amendments will have a delayed commencement. See [Appendix 1](#_Appendix_1) for details.

Please note that Regulations relating to workforce, senior appointments, reporting of infection surveillance data, and scope of services that require registration as a health service establishment (HSE) are generally being remade unchanged. However, Regulations relating to these areas are currently under review in a second phase of reforms that will continue in 2025. Information about upcoming consultation will be available [on the department's website](https://www.health.vic.gov.au/private-health-service-establishments/legislation-updates-for-private-health-service-establishments) <https://www.health.vic.gov.au/private-health-service-establishments/legislation-updates-for-private-health-service-establishments>.

## Objectives

The primary objective of the Regulations is unchanged: to provide for the safety and quality of care of patients by prescribing certain requirements. As examples of such requirements, the objectives provision now also refers to requirements for reporting, and requirements for protocols for quality and safety. This reflects the importance of those matters in supporting quality and safety.

## Clinical Governance

* Existing requirements have been continued that each HSE must have quality and safety protocols dealing with matters such as credentialling, scope of practice and continuous assessment of quality and safety indicators, and must maintain and implement the protocols. These are the same as in the 2013 Regulations.
* The Regulations now list additional matters to be addressed in an HSE’s quality and safety protocols. These will be required from 31 August 2025 to allow time for protocols to be updated and include:
  + the description and allocation of quality and safety roles for the HSE
  + processes and procedures for:
    - availability of appropriate adjunct diagnostic services
    - review of adverse patient safety events, including participation of all relevant personnel (whether employees or not)
    - addressing the specific needs of Aboriginal persons
    - recognising and responding to deteriorations in the condition of patients.
* The Regulations now allow the Secretary to:
  + determine best practice guidelines in relation to quality and safety protocols
  + review HSEs’ quality and safety protocols, having regard to the best practice guidelines
  + following a review, issue a direction for an HSE to update its protocols, with which the HSE must comply.
* The new power for the Secretary to review protocols will commence on 28 February 2026 to allow time for best practice guidelines to be developed and communicated to HSEs and other stakeholders.
* Where the 2013 Regulations required HSEs to publish their quality and safety protocols on their website, the 2024 Regulations also allow the Secretary to determine an alternative means of making the protocols available to the general public. At this time, no determination has been made in relation to this.

## Reporting and review of sentinel events

* There is no change to the definition of sentinel event in the Regulations, and no change to the 11 categories of sentinel events under the [Statewide sentinel events program](https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events) <https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events>.
* The requirement to report sentinel events now specifies that events must be reported in the time and manner determined by the Secretary.
* The Secretary has issued a [determination](https://www.health.vic.gov.au/private-health-service-establishments/legislation-updates-for-private-health-service-establishments) <https://www.health.vic.gov.au/private-health-service-establishments/legislation-updates-for-private-health-service-establishments> that stipulates:
  + Manner of reporting: submit a notification[[1]](#footnote-2) through the Safer Care Victoria (SCV) [Sentinel Events Portal](https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/about-the-sentinel-events-portal) <https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/about-the-sentinel-events-portal>, or if the portal is not available, email [SCV](mailto:sentinel.events@safercare.vic.gov.au) <sentinel.events@safercare.vic.gov.au>.
  + Time for reporting: notify within three days of becoming aware of the sentinel event.
* The Regulations now include a new requirement to review sentinel events and report on those reviews in the time and manner determined by the Secretary.
* The Secretary has issued a determination that specifies review and reporting requirements, which align with the Statewide sentinel events program and with established practice for HSEs reporting sentinel events.
* Noting that these requirements will formalise what is generally current practice for facilities who report a sentinel event, there is not a formally deferred commencement date for these provisions in the Regulations. However, acknowledging that these are new requirements, and that there are known challenges for constituting review panels, SCV may grant a time extension on request. The initial focus of the department and SCV will be to provide education and support for HSEs to conduct reviews.

## Admissions information and assessment

The Regulations now require that:

* pre-admission clinical risk assessments must be completed by a registered health practitioner
* the matters considered and assessed in the pre-admission clinical risk assessment must be recorded in the patient’s clinical record (not just the results)
* for an HSE that provides prescribed services but does not admit patients (for example, a mobile anaesthetic service), a pre-presentation clinical risk assessment must be completed and recorded at least 24 hours prior.

## Requirements to record, review or provide information

The Regulations now include updated requirements so that HSEs must:

* provide patients with information about any likely third-party fees and out of pocket expenses (an update to the existing requirement to provide information about fees on admission)
* record and review information about transfers out for escalation of care (an addition to the existing requirement to record and review information about key quality and safety indicators)
* make quality and safety review data available to the Secretary, on request
* in each discharge summary, include a detailed list of ceased, varied or new medications for all patients, plus a summary or statement about any other regular medications for overnight patients (streamlining the requirements in the previous Regulations)
* prominently display their certificate of accreditation
* for mobile services, submit specified data to the Secretary periodically (formalising previous informal practice – details set out in a Secretary determination.

## Fees

The Regulations list the fees that must be paid when an application is made under the Act. These have not changed, but there is a now a fee for an application to use particular land or premises as a private hospital or day procedure centre (not previously prescribed as no such applications had been made under the Act).

## Infringements

* The Regulations now prescribe infringement offences and penalties for existing penalty offences in the Regulations. This allows authorised officers to issue fines if those offences are committed.
* Implementation of this new power will be coordinated with the roll-out of other proposed reforms, pending passage of a Bill that is currently before the Victorian Parliament that will establish consistent powers for issuing infringement notices across a number of schemes administered by the Health Regulator. More information on those reforms can be found on [the department's website](https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria) <https://www.health.vic.gov.au/legislation/reforms-to-health-regulation-in-victoria>.

## Gender identity

In the updated Regulations, the continuing requirement for treating patients with dignity and respect now specifically refers to gender identity. In addition, pronouns are now gender neutral.

## Changes to terminology and to remove duplication

* The term ‘reversible agents’ has been replaced with ‘reversal agents’ in line with current industry practice.
* The term ‘Operation Theatre Register’ has been replaced with ‘Surgical Procedure Register’ to reflect the continuing requirements in the Regulations for keeping a register of surgical services.
* A requirement relating to the prevention of scalding has been removed as it duplicates an Australian Standard.

# Achieving compliance with the 2024 Regulations

## What HSEs should do

* Continue to comply with all elements of the Regulations that have been remade in the same form (most provisions).
* Continue to report sentinel events and review them and report from those reviews, noting the formal requirements in the Regulations and Secretary determination.
* Continue reporting on your Statutory Duty of Candor compliance activities. If you need more information or support in relation to these requirements [email Safer Care Victoria](https://encoded-592c9deb-987b-4562-aa3c-9fa3d37d83e9.uri/mailto%3aDuty%2520Of%2520Candour%2520(SAFERCARE)%2520%253cdutyofcandour%40safercare.vic.gov.au%253e) at <dutyofcandour@safercare.vic.gov.au>.
* Continue to conduct pre-admission clinical assessments and keep relevant records, review, and if necessary update, your processes to reflect the new requirements in Regulations 25, 26 and 28.
* Review, and if necessary update, your discharge documentation for patients, to reflect the updated streamlined requirements.
* Review, and if necessary update, documentation provided to patients to ensure it includes information regarding likely out of pocket expenses, including from third parties.
* Display your certificate of accreditation in a prominent location.
* If you are a mobile service, ensure you continue reporting data, as now formally required in the Regulations and set out in the Secretary determination.
* Ensure that your processes for recording and reviewing information about key quality and safety indicators includes information about patients transferred out of your facility for escalation of care.
* Be aware that quality and safety information recorded and reviewed must be made available to the Secretary on request.
* Update your quality and safety protocols before 31 August 2025 to include the new matters required under Regulation 8(3).
* Be aware that from 28 February 2026 the Secretary may review your quality and safety protocols and issue a direction to update your protocols.

## What the Health Regulator and Safer Care Victoria will do

* The Health Regulator and Safer Care Victoria will continue to provide information to HSEs as needed about their obligations under the Regulations and how HSEs can comply.
* The Health Regulator will continue to monitor compliance with the Regulations and the Act, including through data reported by HSEs and other intelligence, and through risk-based and periodic inspections of HSEs. Where risk or non-compliance is identified, the Health Regulator seeks to respond in a timely and proportionate manner. A common first step is seeking further information or documentation from the HSE.

# Appendix 1

Table 1: Summary of changes from the 2013 Regulations

| Former reg no. New reg no. | Amendment | Rationale | Date commencing |
| --- | --- | --- | --- |
| 1(a) | **Objectives**  Addition of ‘reporting requirements’ and ‘requirements for health service establishment protocols for quality and safety’. | Acknowledges the range of reporting requirements for oversight of risk and safety performance at a facility and system level and reflects the foundational role of clinical governance in safety and quality at a health service. | 31 August 2024 |
| 7A(2)  **8(2)** | **Health service establishment protocols for quality and safety**  Added an alternative option to the status quo of publishing protocols on the health service establishment’s website. | To ensure continuing transparency for consumers, while allowing the Secretary to determine a form and manner for making information available that will align with the proposed guidelines for quality and safety protocols (under new reg 9). | 31 August 2024  Noting that consultation will occur before a determination is made |
| 7A(3)  **8(3)** | **Health service establishment protocols for quality and safety**  Expanding matters that the health service establishment protocols must address to include:   * description and allocation of safety and quality roles; * availability of appropriate adjunct diagnostic services; * review of adverse patient safety events; * addressing the specific needs of Aboriginal persons; and * recognising and responding to deteriorations in the condition of patients. | This ensures additional key elements of clinical governance are included so that the department can monitor and enforce compliance through the State-based registration scheme. | 31 August 2025 |
| **NEW**  **9 and 10** | **Determination of quality and safety guidelines**  Allowing the Secretary to:   * determine best practice guidelines in relation to quality and safety protocols * review HSEs’ quality and safety protocols, having regard to the best practice guidelines, and issue a direction to an HSE to update their quality and safety protocols following a review. | Identifying the best practice guidance in this way allows transparency about the rationale for any updates to the protocols that the Secretary directs.  This will improve oversight of HSEs’ systems for managing core safety issues, and to identify and address issues and associated risk, including non-compliance with the Act and Regulations. Allows for a flexible, transparent and nuanced approach, as reviews are on a facility-by-facility basis. | Following further consultation, guidelines will be determined and published before 28 February 2026, when the Secretary’s power to conduct reviews comes into effect. |
| 8(2)  **11(2)** | **Application for approval in principle**  Addition of a prescribed fee for an application for approval in principle to use particular land or premises as a private hospital or day procedure centre. | An administrative amendment to align with existing fees for AIP. | 31 August 2024 |
| 20  **24** | **Information about fees and services**  Amended the Regulation toclarify that HSEs must provide information about *likely* third party fees and out of pocket expenses. | Removes ambiguity and meets community expectations of transparency in fees and charges. | 31 August 2024 |
| 20A  **25** | **Pre-admission assessment**  Amending the pre-admission clinical risk assessment requirement to specify that it must be completed by a registered health practitioner.  Requiring the matters considered and assessed in the pre-admission clinical risk assessment to be recorded in the patient’s clinical record (not just the results). | Amends the requirements for clinical assessments for clarity and to ensure appropriately qualified health practitioners are conducting clinical assessments. This will ensure that those assessments can effectively inform planning and delivery of care. | 31 August 2024 |
| **NEW**  **26** | **Pre-presentation assessment**  Requiring that for an HSE that provides prescribed services but does not admit patients (for example, a mobile anaesthetic service), a pre-presentation clinical risk assessment must be completed and recorded at least 24 hours prior. | This is a new requirement for clinical assessments of patients before treatment and will formalise current practice for patients who are not admitted (for example, those receiving mobile anaesthetic services) and ensure appropriate assessment and management. | 31 August 2024 |
| 22(d)(vi)  **28(d)(vi)** | **Information to be included in clinical record**  Redrafted to make clear that this includes clinical risk assessments and pre-admission assessments conducted before a patient receives a health service. | Reflects changes to amended Regulations regarding clinical assessments and ensures fulsome clinical records are kept. | 31 August 2024 |
| 25(a)  **31(a)** | **Respect, dignity and privacy**  Addition of gender identity to other aspects that must be given due regard when treating a person with respect and dignity. | To promote inclusivity and aligning with the accreditation standards. | 31 August 2024 |
| 28A  **37** | **Reversal agents must be available**  Rewording, now refers to ‘reversal agents’ | In line with current industry accepted terminology. | 31 August 2024 |
| 34(3)(e)  **44(3)(e)(f) and 44(4)** | **Discharge information**  Streamlining the requirement for discharge summaries to require a detailed list of ceased, varied or new medications for all patients, plus a summary or statement about any other regular medications for overnight patients. | This allows services some flexibility and discretion when providing information to patients regarding medications on discharge. To align with accreditation requirements and lessen burden on the sector. | 31 August 2024 |
| 37  **47** | **Surgical Procedure Register**  Replacing the term ‘Operation Theatre Register’ with ‘Surgical Procedure Register’. | Administrative change to clarify and ensure a register is kept for all surgical and endoscopy services. | 31 August 2024 |
| 41 | **Prevention of scalding regulation**  Removed | Deletes a Regulation that is duplicative of existing building requirements. | 31 August 2024 |
| 45  **57** | **Information to be prominently displayed**  Amending the requirement for information to be prominently displayed to include the certificate of accreditation. | To promote transparency of safety and quality accreditation for consumers. | 31 August 2024 |
| **NEW**  **59** | **Infringement offences and infringement penalties**  Prescribing new infringement offences and penalties for 29 of the existing penalty offences in the Regulations. | To allow the Health Regulator to issue infringement notices (fines) as a proportionate and timely response to non-compliance without the need for court proceedings or tougher sanctions. | 31 August 2024  To be coordinated with broader reforms across the Health Regulator. |
| 46(3) and (4)  **60(5)&(6)** | **Returns and reports to be given to the Secretary**  Amending the requirements for returns and reports to be given to the Secretary to include mobile services. | Formalising the current practice of annual reporting by HSEs that provide mobile services. This will allow regulatory oversight of relevant performance and safety indicators. | 31 August 2024 |
| 48(1)(b)  **63(1)(b)& (2)** | **Review of quality and safety of health services provided**  Amending the requirements to record and review information to include transfers out of patients for escalation of care, and to make information recorded under this Regulation available to the Secretary on request. | This will supplement the existing requirement to record and review information about other key indicators such as morbidity and mortality and adverse events.  The provision of this information to the Secretary on request is intended to provide a streamlined and transparent mechanism for the Secretary to request any of the data collected under this Regulation to improve the department’s oversight. | 31 August 2024 |
| 46A  **66**  **NEW**  **67** | **Reporting of sentinel events**  Amending the requirement to report sentinel events to specify that it must be reported in the time and manner determined by the Secretary. The determination specifies SCV’s Sentinel Events Portal.  Adding a new requirement to review sentinel events and report on those reviews in the time and manner determined by the Secretary. The determination specifies the requirements, which align with SCV’s [Sentinel Events Guide](https://www.safercare.vic.gov.au/best-practice-improvement/publications/sentinel-events-guide) <https://www.safercare.vic.gov.au/best-practice-improvement/publications/sentinel-events-guide> and [Adverse Patient Safety Event Policy](https://www.safercare.vic.gov.au/best-practice-improvement/publications/policy-adverse-patient-safety-events) <https://www.safercare.vic.gov.au/best-practice-improvement/publications/policy-adverse-patient-safety-events>. | Formalising reporting requirements to ensure robust reviews. A coordinated approach to review and reporting supports Safer Care Victoria’s State-wide sentinel events program, which provides system-wide oversight and consolidation of improvement insights. | 31 August 2024 |

To receive this document in another format, [email the Department of Health’s Legislative and Regulatory Reform Team](mailto:legandregreform@health.vic.gov.au) at <legandregreform@health.vic.gov.au>.

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In this document, ‘Aboriginal’ refers to both Aboriginal and Torres Strait Islander people.

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Available the Department of Health website [Private Health Service Establishments](https://www.health.vic.gov.au/hospitals-and-health-services/private-health-service-establishments)  <https://www.health.vic.gov.au/hospitals-and-health-services/private-health-service-establishments>

1. For the purposes of this document, the term ‘notification’ refers to the initial report that a sentinel event has occurred. This terminology aligns with SVC’s Victorian Sentinel Events Guide and Adverse Patient Safety Event Policy. [↑](#footnote-ref-2)