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| Response Template |
| Proposed Health Services (Health Service Establishments) Regulations 2024 |
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**Responding to the proposed Regulations**

A Regulatory Impact Statement (RIS) has been prepared with respect to the proposed *Health Services (Health Service Establishments) Regulations 2024*. The RIS should be read in conjunction with the proposed Regulations when responding to the questions below. The questions are also available on page 21 of the RIS.

Copies of the RIS and the proposed Regulations may be obtained from the Department of Health [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>>

Interested parties are encouraged to provide feedback on the proposed Regulations. In providing feedback, you may wish to respond to the questions below or provide a comment against the proposed regulatory changes. You may use this template to submit your response or provide your feedback in another written format. You do not need to comment on each proposed change or address all the questions.

For further assistance about the public comment process, please contact the Legislative and Regulatory Reform Team, Regulatory Reform Branch, Regulatory, Risk, Integrity and Legal Division at Department of Health at [legandregreform@health.vic.gov.au](mailto:legandregreform@health.vic.gov.au)

## Making a submission

Thank you for making a submission to the Department of Health (**Department**) in response to theRegulatory Impact Statement and proposed *Health Services (Health Service Establishments) Regulations 2024.*

Please read the collection notice below before completing a submission.

Once you have completed your response, please email it to [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au)  <legandregreform@health.vic.gov.au>.

**Submissions are due by** **11:59pm 29 May 2024.**

## Collection Notice

The Department is committed to protecting your privacy. Any personal information you provide is collected and handled in accordance with the *Privacy and Data Protection Act 2014.*

The information in your submission is collected by the Department to administer the public consultation process associated with the Regulatory Impact Statement and proposed *Health Services (Health Service Establishments) Regulations* 2024.

You have the option of providing your name and contact details when making your submission. If you provide your name and contact details, these will be used by the Department to contact you regarding your submission. Your name and contact details will not be published or disclosed to third parties.

You are not asked to provide personal information in your submission responses. Please do not include any personal information relating to any other individual. Any personal information inadvertently included in submission responses will be removed upon review of the submissions.

The Department may provide copies of your submissions to the Scrutiny of Acts and Regulations Committee of Parliament (SARC) as part of their role in overseeing compliance with the requirements of the *Subordinate Legislation Act 1994*. The Department may also share your submission with third parties as required for the purposes of the Review. Your name and contact details will be removed before sharing your submission with other entities.

## Publication of submissions

All submissions are considered public documents.

Your submission may be referred to in further consultation material developed by the Department, including being included in summary form in the Response to Public Comment that will be published on the Department’s website. If you do not wish your submission to be included in summary form in the in the Response to Public Comment published on the Department website, please email [Legislation and Regulation Reform](https://encoded-592c9deb-987b-4562-aa3c-9fa3d37d83e9.uri/mailto%3aLegislation%2520and%2520Regulation%2520Reform%2520(HEALTH)%2520%253clegandregreform%40health.vic.gov.au%253e) <legandregreform@health.vic.gov.au> before 31 May 2024.

Before publishing your submission in any form, the Department will remove your name and contact details and will take all reasonable steps to remove any personal information included in your submission responses. The Department reserves the right not to publish submissions for any reason including if they include material that is offensive, potentially defamatory or out of scope for the consultation.

By publishing your submission, in full, part or summary form, the Department does not imply any acceptance of, or agreement with, the views expressed in the submission. Copyright in submissions received by the Department rests with the author(s), not with the Department. If you are not the copyright owner of material in your submission, you should reference or provide a link to this material in your submission.

For more information on the Department’s privacy collection practices, please refer to the Department’s [Privacy policy](https://www.health.vic.gov.au/department-of-health-privacy-policy) <https://www.health.vic.gov.au/department-of-health-privacy-policy>.

You may contact the Legislative and Regulatory Reform team supervising the consultation by emailing [Legislation and Regulation Reform](mailto:Legislation%20and%20Regulation%20Reform%20(HEALTH)%20%3clegandregreform@health.vic.gov.au%3e) <legandregreform@health.vic.gov.au>.

You may contact the Department’s Privacy team by emailing [Privacy team](mailto:privacy@health.vic.gov.au) <privacy@health.vic.gov.au>.

You/your organisation can request access and changes to information that you provide to the Department using the email contacts above.

**By providing your submission, you acknowledge that you have read and understood all the information detailed in this collection notice and agreed to provide your submission.**

## Contact details

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| --- | --- |
| Question | Your response |
| Name and title (optional) |  |
| Email address (optional) |  |
| Organisation / association / peak body / regulator / government agency (if relevant) |  |
| Are you authorised to provide this response on behalf of your organisation? | Yes  No  N/A |
| Would your organisation like to remain anonymous if material in your submission is published? | Yes  No  N/A |

**Questions for public comment**

See below questions to guide your response. A template is provided if you wish to address these with respect to specific proposed amendments.

* Is there further information you wish to provide about potential impact of the proposed changes?
* Is there information or feedback you wish to provide to inform implementation of the changes? For example, should there be time allowed after the Regulations are remade and before some changes come into effect, to allow time for preparation for implementation? If so, how long should be allowed?

**TABLE: Summary of key proposed amendments for comment**

Note: Current regulation numbers and text are in black, with strikethrough indicating text to be deleted. Proposed new regulation numbers and text are in red. **Amendments to the Regulations that are administrative in nature or to streamline or modernise wording, rather than changing the substantive effect, are not included in the table.**

| **Reg no.**  **(current and new)** | **Excerpt of regulations**  **(showing changes from current to proposed text)** | **Change proposed and rationale** | **Stakeholder comment** |
| --- | --- | --- | --- |
| 1(a) | **Objectives**  The objectives of these Regulations are—   * 1. to provide for the safety and quality of care of patients receiving health services in or from health service establishments by prescribing—      1. requirements for staffing; and      2. procedures for the handling of complaints; and      3. records to be kept; and      4. reporting requirements; and      5. other requirements to ensure the welfare of patients; and | Adds reporting requirements into the objectives of the Regulations. This reflects the range of reporting requirements in the Regulations (including those being added and amended in this reform process), which allow oversight of risk and safety performance at the facility and system level, including to support continuous improvement. |  |
| 3 | **Commencement**  ~~These Regulations come into operation on 8 September 2013.~~  These Regulations come into operation on 31 August 2024. | Specifies when the Regulations come into effect. 31 August 2024 is the commencement date to ensure there is no gap when the current Regulations expire on 1 September 2024. It is expected some provisions will come into effect some time after to allow stakeholders and the Department time to prepare for implementation. Feedback is sought on timeframes required for such preparation.  For the purposes of consultation, as indicative timeframes the draft Regulations allow 6 months lead time for implementation of updated requirements for contents of clinical governance protocols and 12 months for implementation of new mechanisms for review of those protocols by the Secretary (see below). |  |
| 7A(3)  8(3) | **Health service establishment protocols for quality and safety**   1. The health service establishment protocols must include the following—    1. processes for assessing every 3 years the credentials of each health professional practising at the health service establishment;    2. processes for setting the scope of practice for each health professional practising at the health service establishment;    3. processes for continually assessing the competence and performance of each health professional practising at the health service establishment;    4. processes for continually assessing and reviewing health services provided by each health professional at the health service establishment;    5. processes for continually assessing the capacity of the health service establishment to provide safe, patient centred and appropriate health services to patients at each of its premises;    6. setting the frequency of, and procedures for, meetings of any committees of the health service establishment with responsibility for the quality and safety of health services provided at, or from, the health service establishment;   **Note** Relevant committees may include, but are not limited to, a medical advisory committee, a quality and safety committee and the board of the health service establishment.   * 1. processes for ensuring that appropriate arrangements have been made for evaluating, monitoring and improving the quality and safety of health services provided at each premises of the health service establishment;   2. on and from 28 February 2025, the description and allocation of safety and quality roles in relation to the health service establishment;   3. on and from 28 February 2025, having regard to the kind or kinds of health services being provided at, or from, the health service establishment, processes and procedures for—      1. the availability of appropriate adjunct diagnostic services;      2. review of adverse patient safety events, including participation of all relevant personnel in the review (whether employees or not);      3. addressing the specific needs of Aboriginal persons;      4. recognising and responding to deteriorations in the condition of patients. | Adds several matters into the list of things that must be addressed in a facility’s clinical governance protocols.  This ensures those additional key elements of clinical governance are included as required elements under the Regulations so that the Department can monitor and enforce compliance through the State-based registration scheme. As set out in the RIS, clinical governance is a vital foundation of safety and quality and there is evidence that greater oversight by regulatory and other oversight bodies is required to drive improvements so that all facilities meet expectations. |  |
| NEW  9 | **Determination of quality and safety guidelines**   1. The Secretary may determine approved quality and safety guidelines in relation to the health service establishment protocols for quality and safety set out in regulation 8. 2. The Secretary must cause a notice of a determination under subregulation (1) to be published—    1. in the Government Gazette; and    2. on the Department’s Internet site. 3. A notice of a determination of an approved quality and safety guideline must state—    1. where a copy of the approved quality and safety guideline may be obtained; and    2. the date on which the approved quality and safety guideline takes effect. | New power for the Secretary to identify best practice guidelines (guidance) that can be taken into account when a review of a facility’s clinical governance protocols is conducted. [See below for new power for Secretary to review protocols and direct a facility to update them]  Identifying the best practice guidance in this way allows transparency about the rationale for any updates to the protocols that the Secretary directs.  It is intended that there be further consultation and communication with stakeholders about the guidelines the Secretary would approve for this purpose. |  |
| NEW  10 | **Review of health service establishment protocols for quality and safety**   1. On and from 31 August 2025, the Secretary may determine to conduct a review of the health service establishment protocols for quality and safety prepared by a health service establishment under regulation 8(1). 2. The Secretary may, after conducting a review of a health service establishment’s protocols for quality and safety, determine to issue a written direction to the proprietor of that health service establishment to update the protocols for quality and safety in the manner directed by the Secretary. 3. The Secretary may determine to issue a written direction to the proprietor of a health service establishment if the Secretary considers that the protocols for quality and safety of that health service establishment—    1. are inconsistent with the Act or these Regulations; or    2. are otherwise inadequate for ensuring the quality and safety of health services provided at, or from, the health service establishment. 4. In conducting a review of health service establishment protocols for quality and safety, the Secretary may have regard to an approved quality and safety guideline referred to in regulation 9(1). 5. The proprietor of a health service establishment must ensure that a written direction of the Secretary to update the health service establishment’s protocols for quality and safety is complied with. | Creates new power for the Secretary to review health service establishments’ protocols and to issue directions for updates to the protocols, including by reference to best practice guidelines approved by the Secretary for this purpose [see above].  Proposed to improve oversight of facilities’ systems for managing core safety issues, and to identify and address inadequate arrangements and associated risk, including any non-compliance with the Act and Regulations. Allows a flexible, transparent and nuanced approach, as reviews are on a facility-by-facility basis. |  |
| 8(2)  11(2) | **Application for approval in principle**   1. For the purposes of section 70(2)(b) of the Act, the following fees are prescribed—    1. for an application for approval in principle to use particular land or premises as a private hospital or day procedure centre—325 fee units;    2. for an application for approval in principle to construct premises for use as a private hospital—325 fee units;    3. for an application for approval in principle to make alterations or extensions to a premises used or proposed to be used as a private hospital—290 fee units;    4. for an application for approval in principle to construct premises for use as a day procedure centre—285 fee units;    5. for an application for approval in principle to make alterations or extensions to a premises used or proposed to be used as a day procedure centre—276 fee units;    6. for an application for approval in principle to use particular land or premises as a health service establishment from which health services are to be provided at premises other than the first-mentioned premises—91 fee units; | Creates a new fee for an application for approval in principle (AIP) to use particular land or premises as a private hospital or day procedure centre, as permitted under section 70(2)(b) of the Act. AIP has historically been sought for constructing or altering premises, so no fee was prescribed for ‘use of land or premises’. As the Health Regulator now receives this type of application, it is proposed to prescribe a fee of 325 fee units. This amount is the same as the fee for AIP to construct premises for use as a private hospital, reflecting similar administrative costs for the Health Regulator to process and assess these applications. |  |
| 20  24 | **Information about fees and services**   1. The proprietor of a health service establishment must ensure that on or before admission each patient of the hospital or centre is given—    1. a statement containing information in relation to the health ~~care~~ services provided at the health service establishment that complies with subregulation (2); and    2. information about fees ~~to be charged and any~~ and likely out of pocket expenses to be charged by the health service establishment or a third party in relation to the health services to be provided to the patient at the health service establishment ~~and any likely out of pocket expenses which may be incurred by the patient~~; and    3. a clear explanation of the treatment and other health services to be provided to the patient at the health service establishment. | Amends the requirement for provision of information in relation to costs to clarify and remove ambiguity, to ensure patients are informed of potential fees, including charges from third parties. |  |
| 20A  25 | **Pre-admission assessment**  ~~For the purpose of ensuring the quality and safety of health services provided at a health service establishment, t~~ The proprietor of ~~the~~ a health service establishment must ensure that for a non-emergency patient admitted to the health service establishment ~~that~~—   * 1. a pre-admission clinical risk assessment is carried out by a registered health practitioner for ~~each~~ that patient before admission; and   2. the ~~results~~ following matters ~~of the pre-admission clinical risk assessment~~ are recorded in writing, not less than 24 hours before admission~~; and~~—      1. the matters considered and assessed by the registered health practitioner as part of the pre-admission clinical risk assessment; and      2. the results of the pre-admission clinical risk assessment;      3. the name and signature of the registered health practitioner carrying out the pre-admission clinical risk assessment; and   3. the ~~procedure~~ health service for which the patient is admitted is assessed in relation to the scope of practice of the ~~relevant~~ registered health practitioner who will provide ~~providing~~  the health service~~s~~ to that patient ~~at the health service establishment~~. | Amends the requirements for clinical assessments to clarify and remove ambiguity and ensure appropriately qualified health practitioners are conducting clinical assessments. This is to ensure that those important assessments effectively inform planning and delivery of care. |  |
| NEW  26 | **Pre-presentation assessment**  The proprietor of a health service establishment must ensure that for each non-emergency patient that is provided with a health service by the health service establishment but is not admitted to the health service establishment—   * 1. a pre-presentation clinical risk assessment is carried out by a registered health practitioner; and   2. the following matters are recorded in writing, not less than 24 hours before the health service is provided—      1. the matters considered and assessed by the registered health practitioner as part of the pre-presentation clinical risk assessment; and      2. the results of the pre-presentation clinical risk assessment;      3. the name and signature of the registered health practitioner carrying out the pre-presentation clinical risk assessment.   3. the health service for which the patient presents is assessed in relation to the scope of practice of the registered health practitioner who will provide the health service to that patient. | Inserts new requirement for clinical assessments of patients before treatment, regardless of admission status. To formalise current practice for patients who are not formally admitted (for example, those receiving mobile services) and ensure appropriate assessment and management. |  |
| 22(d)(vi)  28(d)(vi) | **Information to be included in clinical record**  The proprietor of a health service establishment must take reasonable steps to ensure that each clinical record contains the following information—   * 1. relevant clinical details of the patient including the following—      1. ~~pre-procedure assessment;~~ clinical risk assessments conducted before a patient receives a health service, including a pre-admission assessment conducted in accordance with regulation 25. | Amends current requirement for contents of clinical record for each patient to reflect the required clinical assessments under the amended Regulations [see above] and ensure those are kept on the clinical record. |  |
| 25(a)  31(a) | **Respect, dignity and privacy**  The proprietor of a health service establishment must ensure that a patient—   * 1. is treated with dignity and respect, and with due regard to ~~his or her~~ their gender identity, religious beliefs and ethnic and cultural practices; | Amends this existing provision to also require that due regard is had to gender identity, to promote inclusivity and aligning with the accreditation standards. |  |
| 28A  37 | **~~Reversible~~ Reversal agents must be available**  If health services are provided at a health service establishment involving the use of anaesthesia or other sedation for which there are ~~reversible~~ reversal agents, the proprietor of the health service establishment must ensure that these ~~reversible~~ reversal agents are available for immediate access at the premises of the health service establishment. | Minor amendment to the language used for medications that must be on hand, to reflect industry accepted terminology. |  |
| 34(3)(e)  44(3)(e)(f) and 44(4) | **Discharge information ~~to be given to patients~~**   1. A patient's discharge summary must include the following information—    1. in the case of a patient of a private hospital who was admitted overnight, a ~~list~~ summary of all medications currently prescribed for the patient, irrespective of whether the medication is in relation to the heath service received at the health service establishment, including cessations, variations or additions to the regular prescribed medication of the patient;    2. in the case of a patient of a private hospital who was admitted and discharged within one day, or a patient of a day procedure centre—       1. a list of medications prescribed for the patient at the time of discharge in relation to the health service provided to the patient by the health service establishment; and       2. a list of any changes made to the regular prescribed medication of the patient, including cessations, variations or additions to the regular prescribed medication of the patient. 2. The proprietor of the health service establishment must have regard to the clinical profile of a patient in deciding the nature and detail of information to be included in a medication summary prepared in accordance with subregulation (3)(e). | Amends the existing requirement for provision of information about medication on discharge, to allow some flexibility, aligning with accreditation requirements and lessen regulatory burden on the sector. |  |
| 37  47 | **~~Operation Theatre~~ Surgical Procedure Register**   1. The proprietor of a health service establishment at which surgical health services or speciality health services for the provision of endoscopy may be ~~carried on~~ provided must ensure that a~~n~~ ~~Operation Theatre~~ Surgical Procedure Register that complies with subregulation (2) is kept at the health service establishment. 2. For the purposes of subregulation (1), a~~n~~ ~~Operation Theatre~~ Surgical Procedure Register must be in writing and contain the following ~~information~~ records with respect to each procedure performed at the health service establishment—    1. the date and time of the procedure;    2. the unit record number of the patient;    3. the full name of the patient, ~~his or her~~ their sex and date of birth;    4. the nature of the procedure;    5. the name of the registered health practitioner undertaking the procedure and assistant (if any);    6. the name of the anaesthetist and assistant (if any);    7. the names of attending ~~theatre~~ clinical staff;    8. any remarks concerning the outcome of the procedure;    9. any anaesthetic or procedural complications encountered. | Makes a minor amendment to the existing requirement to keep a register of certain procedures to clarify or remove ambiguity - ensure the required register is kept for all surgical services and endoscopy specialist services regardless of where in the facility they are performed. |  |
| 41 | **~~Prevention of scalding~~**  ~~The proprietor of a health service establishment must ensure that every bath, shower and hand basin used by patients is installed with a system or mechanism to avoid the risk of scalding by controlling the outlet temperature of hot water.~~ | Deletes this provision as it is duplicative of other existing legal standards with which facilities are required to comply |  |
| 45  57 | **Information to be prominently displayed**  The proprietor of a health service establishment must display in a prominent position at the entrance foyer or reception area of the health service establishment the following information—   * 1. the certificate of registration of the premises as a health service establishment or a full size copy of the certificate;   2. the certificate of accreditation for any accreditation scheme applicable to the health service establishment and approved by the Secretary under section 107(1) of the Act;   3. the name of the Director of Nursing (if required to be appointed) and the name of any appointed ~~if a~~ Chief Executive Officer or Medical Director (however titled) ~~has been appointed, the name of the Chief Executive Officer or Medical Director~~;   4. the name and contact telephone number of the person nominated under regulation ~~29~~ 38 to receive and deal with complaints. | Inserts new requirement to display the facility’s certificate of accreditation in a prominent place, to promote transparency of safety and quality accreditation. |  |
| NEW  59 | **Infringement offences and infringement penalties**   1. For the purposes of section 155(1) of the Act, an offence specified in Column 1 of the Table in Schedule 9 is prescribed as an infringement offence. 2. For the purposes of section 155(1) of the Act, the prescribed infringement penalty for an infringement offence referred to in subregulation (1) is the penalty specified in Column 2 of the Table in Schedule 9 in respect of that infringement offence. | Inserts new provision to prescribe offences in the Regulations so that infringement notices (fines) can be issued for non-compliance. This is to allow proportionate and timely compliance tools available to the regulator. |  |
| 46(3) and (4)  60(5) and (6) | **Returns and reports to be given to the Secretary**   1. The Secretary may determine to direct the proprietor of a health service establishment that provides health services solely at premises other than the premises for which it is registered to prepare a return in the manner and form directed by the Secretary. 2. The proprietor of a health service establishment must ensure that a return prepared under subregulation (5) is given to the Secretary within the time directed by the Secretary. | Inserts new reporting requirement to formalise reporting already done by mobile service providers who do not admit patients, to allow regulatory oversight of relevant performance and safety indicators. |  |
| 48(1)(b)  63(1)(b) and (2) | **Review of quality and safety of health services provided**   1. The proprietor of a health service establishment must ensure the following information is recorded in writing and reviewed at least every 3 months—    1. information in relation to the decisions and actions taken for the purposes of improving the quality and safety of health services provided;    2. if applicable, information in relation to—       1. all adverse events occurring at the health service establishment; and       2. all sentinel events occurring at the health service establishment; and       3. mortality and morbidity occurring at the health service establishment; and       4. all transfers of patients from the health service establishment to another health service establishment or health care agency for the escalation of patient care; and       5. compliance with the health service establishment's protocols; and       6. results from surveys about patient experience and about staff safety culture. 2. The proprietor of a health service establishment must make information recorded under this regulation available to the Secretary on request. | Inserts a new requirement for HSEs to record and regularly review transfers out due to escalation of care, as a key quality and safety indicator, supplementing existing requirement to record and review information about other key indicators such as morbidity and mortality and adverse events.  Includes new requirement to provide information recorded under this regulation to the Secretary on request. This 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, including when there are concerns about an HSE operating outside its capability or about its quality and safety performance. |  |
| 46A  66 | **Reporting of sentinel events**  The proprietor of a health service establishment must report in writing ~~a~~ each sentinel event that ~~occurred~~ occurs at the health service establishment to the Secretary— ~~within the time determined by the Secretary.~~   * 1. within the time determined by the Secretary; and   2. in the form and manner determined by the Secretary. | Process amendment to the existing requirement to report (notify) the Secretary of each sentinel event, to ensure clarity and consistency in the data reported, to improve sector/system-wide monitoring, and to allow the Secretary to determine the timeframes and mechanisms for reporting (e.g. through a central portal). Does not change the definition of sentinel event. |  |
| NEW  67 | **Review of sentinel events**   1. For the purpose of ensuring the quality and safety of health services provided by a health service establishment, the proprietor of a health service establishment must ensure that a review is conducted of each sentinel event that occurs at the health service establishment. 2. A review conducted under subregulation (1) must be conducted in the manner and within the time determined by the Secretary. 3. The proprietor of a health service establishment must record the outcome of a review conducted under subregulation (1) in writing and submit it to the Secretary within the time and in the form determined by the Secretary. | New requirements to formalise review requirements for sentinel events and requirements for reporting to the Secretary about those reviews. Intended to ensure that reviews are robust so they identify causes of sentinel events and mitigations and improvements, to provide Safer Care Victoria with oversight of review processes and outcomes at a facility level (as a key safety indicator), and to inform Safer Care Victoria’s State-wide sentinel event program, which provides system-wide oversight and consolidation of improvement insights. | . |

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