

Review of the Health Services (Health Service Establishments) Regulations 2013

Discussion paper – August 2023

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Acronyms and abbreviations

Acronym / abbreviation	Meaning
ACSQHC / the Commission	Australian Commission on Safety and Quality in Health Care
Act	<i>Health Services Act 1988</i>
Ahpra	Australian Health Practitioner Regulation Agency
APSE	Adverse Patient Safety Event
AHSSQA Scheme	Australian Health Service Safety and Quality Accreditation Scheme
AusHFG	Australasian Health Facility Design Guidelines
CCRN	Critical Care Registered Nurse
CQSO	Chief Quality and Safety Officer (appointed under the Health Services Act 1988. Currently Chief Executive Officer of Safer Care Victoria).
Department	Victorian Department of Health
DMS	Director of Medical Services
DON	Director of Nursing
DPC	Day procedure centre
HCC	Health Complaints Commissioner
HDU	High Dependency Unit
ICU	Intensive Care Unit
MAC	Medical Advisory Committee
MBA / the Board	Medical Board of Australia
NSQHS Standards / the Standards	National Safety and Quality Health Service Standards
Regulations	Health Services (Health Service Establishments) Regulations 2013
RIS	Regulatory Impact Statement
SAPSE	Serious Adverse Patient Safety Event
SCV	Safer Care Victoria
SDC	Statutory Duty of Candour
VAHI	Victorian Agency for Health Information
VMO	Visiting Medical Officer

Executive summary

This discussion paper seeks your views on potential reforms to the Health Services (Health Service Establishments) Regulations 2013 (the Regulations) made under the *Health Services Act 1988* (the Act).¹

The Act (primarily Parts 4 and 5A) and Regulations establish the minimum requirements for the safety and quality of patient care in Victoria's private hospitals and day procedure centres (including mobile health services).² Under the Act and Regulations, the Secretary to the Department of Health (the department) is the regulator of health service establishments. A private hospital or day procedure centre cannot commence operation (or continue operation), nor admit patients unless the premises are registered under the Act.

In accordance with the *Subordinate Legislation Act 1994*, the current Regulations will expire (or 'sunset') on 1 September 2024. The department considers that the Regulations should be re-made in whole, part, or a modified form, to ensure the Act and Regulations can continue to operate as intended and provide for minimum requirements for the safety and quality of patient care.

This review will include stakeholder consultation about whether the Regulations are fit for purpose and meet the objectives of the regulatory scheme. The department will consider all submissions, then conduct further public consultation with the likely release of a Regulatory Impact Statement (RIS) and draft new Regulations.

This paper explores whether the key elements remain fit for purpose and achieve the outcome of safe, quality patient care, including:

- the definition and scope of prescribed health services including those relating to cosmetic surgery
 - staffing requirements including staff-to-patient ratios and senior appointments
- clinical governance requirements including reporting, patient admission and discharge, credentialling, external labour hire accountability, and fatigue management.

Not every issue or concern canvassed in this paper or raised by stakeholders will need a regulatory reform solution – in some cases, an administrative solution may be preferable, or it may be determined that no action is required. The department acknowledges that some proposed changes, if enacted, may require a transition period for compliance. This will be addressed in more detail at the next round of consultation.

Please contribute to the review of the Regulations by commenting on specific proposals in this discussion paper or by making any other suggestions to improve regulation of private hospitals and day procedure centres across Victoria and ensure safe, quality patient care.

Your views are important and welcome.

¹ The Regulations and Act are available on the [Victorian Legislation website](https://www.legislation.vic.gov.au/) at <<https://www.legislation.vic.gov.au/>>.

² The Act and Regulations collectively refer to these services as 'health service establishments'.

About the consultation process

Who to contact

For general enquiries about this discussion paper and the broader consultation process, please email [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au>.

How to make a submission

We invite written submissions that address (but are not limited to) the issues and questions in this paper. You are not obliged to respond to every question.

Submissions are due by midnight 24 September 2023.

Please number your responses to match the questions in the paper or use the response template at Appendix B – Response template.

Submissions may be sent by email to [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au>.

You may choose to share personal or professional experience or knowledge, as well as qualitative and quantitative data. We ask you not to provide any identifying, or potentially identifying, information about patients, health practitioners or facilities. The department welcomes lived experience and consumer perspectives and will arrange dedicated consultation fora to seek that input into the review. It is not intended that a formal submission to this paper will be the primary mechanism for sharing personal stories that include identifying details. If you wish to participate and share your personal experience with identifying details, please email [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au> and you will be advised how to proceed.

If you have concerns about treatment received from a particular medical practitioner, or about a medical practitioner's conduct, you should report these directly to the [Australian Health Practitioner Regulation Agency](https://www.ahpra.gov.au/about-ahpra/contact-us.aspx) <https://www.ahpra.gov.au/about-ahpra/contact-us.aspx> or on 1300 419 495. You can also raise complaints about services received at a facility with the [Health Complaints Commissioner](https://www.hcc.vic.gov.au/) <https://www.hcc.vic.gov.au/> or on 1300 582 113.

Publication of submissions

All submissions will be considered public documents unless marked 'private and confidential'. They may be referred to in further consultation material developed by the department, including being included in full or in summary in the Regulatory Impact Statement (RIS) that will be published on the department's website.

Clearly mark your submission 'private and confidential' if you are disclosing personal or other information that you prefer not to publish.

Alternatively, you can submit material marked 'private and confidential' in a separate attachment to non-confidential material that can be published.

You may withdraw consent for the department to publish all or part of your submission by emailing [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au> before 8 October 2023.

Before publishing, the department will remove your contact details and may remove other personally identifying information from your submission.

The department reserves the right to not publish submissions for any reason including material that is offensive, potentially defamatory or out of scope for the consultation. The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the department.

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.

Please read the Privacy Collection Notice in Appendix B – Response template before completing a submission.

Introduction

Background

Regulation is not static. It must respond to changes in:

- practices
- methods of service delivery
- technology
- community expectations
- workforce
- the broader regulatory environment.

Under the *Subordinate Legislation Act 1994*, regulations in Victoria have a fixed maximum life of 10 years (unless extended for up to 12 months as in the case of the Regulations). Reviewing and rewriting regulations forces a comprehensive review. These reviews are referred to as a ‘sunset’ review. This is the type of review currently required for the Regulations.

Regulations set the minimum standard of what is required. There are many reasons why a hospital or day procedure centre may choose to exceed the minimum regulatory standards. Regulations are an important safeguard, setting foundational requirements and empowering a regulator to monitor compliance and take action where services do not meet the minimum required standards.

The Act and the Regulations for private hospitals and day procedure centres were last significantly reviewed and amended in 2018. This was in response to *Targeting Zero – supporting the Victorian hospital system to eliminate avoidable harm and strengthen quality of care: Report of the Review of Hospital Safety and Quality Assurance in Victoria* (Targeting Zero Report)³, which recommended a range of improvements to the hospital sector overall. The 2018 amendments were designed to reduce the risk of patient harm.

The department would like Victorians to experience safe and high-quality healthcare, whether this is provided in public or private hospitals. The department recognises the different models of care

³ Available at the [Department of Health website](https://www.health.vic.gov.au/publications/targeting-zero-the-review-of-hospital-safety-and-quality-assurance-in-victoria) at <<https://www.health.vic.gov.au/publications/targeting-zero-the-review-of-hospital-safety-and-quality-assurance-in-victoria>>.

between private and public hospitals and seeks to ensure that mechanisms to achieve this, including regulation, are appropriate to the sector.

What are private hospitals and day procedure centres?

In Australia, hospital services are provided by both public and private hospitals. The state and territory governments largely own and manage public hospitals, with funding also provided by the Australian Government. Private hospitals are owned and managed by private organisations – either by for-profit companies or not-for-profit non-government organisations. Hospitals are very diverse and differ in location, size, services provided, and patient acuity.

Some private health facilities provide health services on a day-only basis (i.e. patients are not expected to stay overnight and are admitted and discharged on the same day). Where they are providing the types of services prescribed in the Regulations, these are referred to in the Act and Regulations as 'day procedure centres'. Some prescribed speciality services, such as anaesthesia and IV sedation, can be delivered by mobile service providers in unregistered settings – for example, dental or radiology offices. These mobile health service providers are registered with the department as day procedure centres.

Private hospitals and day procedure centres play a significant role in the delivery of health services in Victoria. In 2021-22, 1.083 million – more than 37% of all hospital admissions in Victoria – occurred in private hospitals, and private hospitals currently perform well over half of all elective surgical procedures carried out in Victoria.⁴

Private hospitals and day procedure centres primarily provide elective surgery to patients who are treated by a doctor of their choice. Some private hospitals also provide accident and emergency services. Patients are charged fees for accommodation and services provided by private hospitals and day procedure centres and relevant medical and allied health practitioners. These costs to individuals are often subsidised through a combination of government and private health insurance payments.⁵ Overall, private hospitals (relative to public hospitals) treat lower acuity patients and have fewer unplanned admissions. Private hospitals exist in response to patients' willingness to pay for a choice of doctor, private ward facilities, and relatively faster access to hospital services.

Private hospitals and day procedure centres operate under fee-for-service funding models that reward additional activity. Therefore, private hospitals and day procedure centres may generally have an incentive to maximise the number of people they treat.

The department commissions private hospitals to provide public services, often to reduce waiting lists.

How are private hospitals and day procedure centres regulated?

Victoria has 77 registered private hospitals, 104 registered day procedure centres and 24 mobile services (as at 11 July 2023).⁶

⁴ Australian Institute of Health and Welfare, 2023, [Admitted patients data 2022](https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients), Australian Government, viewed 21 July 2023, <<https://www.aihw.gov.au/reports-data/myhospitals/sectors/admitted-patients>>.

⁵ Australian Institute of Health and Welfare, 2022, [Australia's hospitals at a glance](https://www.aihw.gov.au/reports/hospitals/australias-hospitals-at-a-glance/contents/summary), Australian Government, viewed 21 July 2023, <<https://www.aihw.gov.au/reports/hospitals/australias-hospitals-at-a-glance/contents/summary>>.

⁶ A list of all registered private hospitals and day procedure centres in Victoria is available on the [Department of Health's website](https://www.health.vic.gov.au/private-health-service-establishments/private-hospitals) at <<https://www.health.vic.gov.au/private-health-service-establishments/private-hospitals>>.

The department is responsible for regulating these private hospitals and day procedure centres under the Act and the Regulations (or regulatory scheme). This regulatory scheme sets out the legal powers of the department to monitor and enforce minimum patient safety and quality of care requirements.

Under the scheme, the department:

- manages the lifecycle of approvals in principle (AIP), registrations and registration renewals
- monitors compliance and conducts regulatory inspections of facilities
- provides advice and information to support service providers to comply
- conducts investigations where serious issues or risks are identified
- uses enforcement tools to address non-compliance (for example, action plans, registration conditions)
- applies sanctions where necessary to protect the public from harm (for example, registration suspensions or revocations and court proceedings).

Other government bodies

The department's role as regulator of health service establishments is complemented by the functions of other government agencies concerned with promoting safety and quality in health service delivery across Victoria, in both the public and private sectors. These bodies work together and share information to give government a system-wide understanding of the healthcare landscape, support health service providers to continuously improve, and provide transparency to healthcare consumers and the public.

Safer Care Victoria

Safer Care Victoria (SCV) is responsible for monitoring and improving the quality and safety of care delivered across the health system. In 2022, the *Health Legislation Amendment (Quality and Safety Act) 2022* established the role of Chief Quality and Safety Officer (CQSO), whose remit covers public health services, private hospitals and day procedure centres (collectively referred to as 'health service entities'). In November 2022, SCV's Chief Executive Officer was appointed as the inaugural CQSO. Under this legislation, the functions of the CQSO involve:

- conducting quality and safety (Q&S) reviews of services provided in or by health service entities (with or without notice)
- providing information to the Secretary concerning Q&S reviews
- working co-operatively with other bodies involved in the oversight or regulation of quality and safety in health service entities
- issuing guidelines to health service entities concerning the provision of services.

Victorian Agency for Health Information

The Victorian Agency for Health Information (VAHI) is a division of the department responsible for data collection, management, insights and reporting. It analyses and shares information across Victoria's healthcare system to build an accurate picture of hospital and health service performance. VAHI ensures that data and information on the quality, safety and performance of Victoria's

healthcare system is readily available to health services, government departments and agencies, researchers and the Victorian community.

Health Complaints Commissioner

The Health Complaints Commissioner (HCC) receives and manages complaints about healthcare and the handling of health information in Victoria. The HCC acts independently and impartially to investigate matters and review complaints data to help health service providers improve the quality of their service.

Mental health service oversight

Under the *Mental Health Act 2014*, a 'mental health service provider' (as defined) is subject to oversight, including by the Mental Health Complaints Commissioner and Chief Psychiatrist. This oversight does not apply to any health service establishments. From 1 September 2023, that legislation will be replaced by the *Mental Health and Wellbeing Act 2022*. Under that legislation the Mental Health and Wellbeing Commission (the Commission) will have oversight roles in relation to 'mental health and wellbeing service providers' as defined. While this will generally not apply to health service establishments, the complaints-handling and other oversight functions of the Commission may apply to some health service establishments that receive State funding to deliver mental health services. Further information will be released in relation to application of that legislation in preparation for its commencement.

Health service establishments providing mental health services as prescribed in the Regulations are subject to all relevant obligations in the Act and Regulations and it is intended that continue when the new Regulations are made.

Scope of the review and consultation

The review aims to consider whether the Regulations remain fit for purpose, or whether reforms are needed to ensure they effectively achieve the regulatory objectives of safe, quality patient care. The department welcomes feedback on all aspects of the Regulations, including what needs to be regulated and what may be better managed through other means, and the impact of the Regulations or proposed changes.

This paper canvasses issues and concerns that have been raised by interested parties with the department previously. It outlines some areas for possible reform and presents options for consideration. However, stakeholders are encouraged to provide feedback on any issues related to the Regulations.

The scope of this review is limited to issues and amendments related to the Regulations. Any reforms that would require amendments to the Act are out of scope but may be noted by the department for future consideration.

While the review may consider alignment between requirements and arrangements for public and private sector hospitals, reforms affecting the public sector are beyond the scope of the review.

This discussion paper does not replace or intend to interpret the Act and Regulations (or other relevant acts and regulations). It is recommended that health service establishment operators obtain legal advice for interpretation of specific provisions, as required.

How changes are made to the Regulations

Under section 158 of the Act, the Governor in Council may make regulations related to private hospitals and day procedure centres. The making of any regulations must comply with the requirements of the Subordinate Legislation Act. The Governor in Council makes regulations under the Act based on the recommendation of the Minister for Health.

Anticipated timelines

The Regulations will expire on 1 September 2024.

Public consultation on discussion paper	August – September 2023
Stakeholder engagement on discussion paper feedback and preparation of Regulatory Impact Statement and draft Regulations	October 2023 – March 2024
Public consultation on Regulatory Impact Statement and draft Regulations	April 2024 – May 2024
Development and making of proposed Regulations	June 2024 – August 2024
Making of new Regulations	By September 2024

1. Health service definitions and scope

1.1. Current health service definitions

The Regulations prescribe health services for the purposes of the definition of ‘day procedure centre’ (r.6) and ‘private hospital’ (r.7). The effect of prescribing a health service (for example endoscopy, oocyte retrieval, anaesthesia) is that the health service can only be provided in a registered private hospital or day procedure centre (not in consulting rooms, for example).

Prescribing health services under the Regulations ensures they are performed in registered facilities that meet minimum safety and quality standards and are regulated by the department to protect patients from risks of harm associated with those health services. Patient protection must be balanced against the impacts of requiring health services to be performed in registered private hospitals or day procedure centres. Impacts could include reduced access to health services (especially in regional and rural areas) and increased costs of health services.

The Regulator draws on the list of prescribed health services in the Regulations to specify in a health service establishment’s certificate of registration the specific services that a premises is registered to provide.

Some health services are defined in the Regulations (r.5), including medical health service, surgical health service, speciality health service, anaesthesia (a type of speciality health service), emergency medicine (a type of speciality health service), and renal dialysis (a type of speciality health service). **Table 1** includes a list of defined health services and their definitions.

Other speciality health services are mentioned in the Act or Regulations but are not defined (see **Table 2**). Terms not defined in the Act or Regulations (or *Interpretation of Legislation Act 1984*) are taken to mean their firmly established ‘legal or technical meaning’ if there is one (such as a meaning established through case law or a meaning that is well established by a health profession college) or ordinary meaning (its meaning in the Macquarie Dictionary).

Table 1: Health services currently defined in the Regulations (r.5)

Health service	Definition
Medical health service	Means a health service (other than emergency stabilisation treatment) that – (a) is provided to a patient by a registered medical practitioner; and (b) involves diagnosis and treatment that requires – (i) nursing supervision and care; or (ii) the use of anaesthesia.
Surgical health service	Means a health service (other than emergency stabilisation treatment) that – (a) is ordinarily provided by a registered medical practitioner, registered dental practitioner, registered medical radiation practitioner or a registered podiatrist; and (b) involves the use of surgical instruments and an operating theatre, procedure room, or treatment room; and (c) uses or requires one or more of the following – (i) anaesthesia; or

Health service	Definition
	(ii) the attendance of at least one other registered health practitioner; or (iii) post-operative observation of the patient by nursing staff.
Speciality health service	Means a health service (other than emergency stabilisation treatment) that – (a) is ordinarily undertaken by, or under the supervision of, a registered medical practitioner, a registered dental practitioner, a registered medical radiation practitioner or a registered podiatrist; and (b) requires one or both of the following – (i) specialist equipment; (ii) an area that is specifically fitted out for the kind of service provided.
Anaesthesia (a type of speciality health service)	(a) means any of the following – (i) general anaesthesia; (ii) a major regional anaesthetic block; (iii) intravenous sedation; (iv) a high dose of local anaesthetic that has the potential to cause systemic toxicity; and (b) does not include a dental nerve block.
Emergency medicine (a type of speciality health service)	Means the medical or surgical treatment of patients as a matter of urgency for the purpose of – (a) saving life; or (b) preventing further serious damage to health; or (c) preventing suffering or the continuation of suffering of significant pain or distress.
Renal dialysis (a type of speciality health service)	Means (haemodialysis) treatment that uses a dialyzer machine to remove waste and excess water from the blood.

1.2. New health service definitions

The department is seeking feedback on whether current definitions of ‘speciality health services’ in the Regulations are workable, effective and remain fit for purpose. Noting that the new Regulations will last for 10 years, the department will consider whether new definitions are needed to accommodate future developments in health service delivery.

In general, definitions in regulations are only needed to remove ambiguity or as a shortening device.⁷ This may include a definition clarifying what is out of scope for the purposes of a set of

⁷ Office of the Chief Parliamentary Counsel Victoria, May 2017, [Notes for guidance on the preparation of statutory rules](https://www.vic.gov.au/developing-legislation-chief-parliamentary-counsel), State Government of Victoria, viewed 21 July 2023, <<https://www.vic.gov.au/developing-legislation-chief-parliamentary-counsel>>.

regulations. For example, the Regulations do this for the definition of anaesthesia, which states that for the purposes of the Regulations anaesthesia does not include dental nerve block.

Defining a term can have benefits. It can improve clarity for stakeholders including regulated entities, the regulator, and the community. This can improve the workability, effectiveness, and enforceability of a regulatory scheme if the meaning of a term might otherwise be so ambiguous that the relevant expectations or requirements might not be consistently understood.

Defining a term can also have risks. The definition may unintentionally narrow or broaden the scope of the relevant term or may not remain current. Health services and practices evolve and can do so rapidly in response, for example, to technological and clinical innovations. This may make defining some speciality health services in the Regulations impractical.

Prescribed speciality health services for private hospitals and day procedure centres that are *not* currently defined in the Act or Regulations are summarised in **Table 2**.

Table 2: Health services *not* currently defined in the Regulations

Undefined prescribed speciality health services for private hospitals and day procedure centres
<ul style="list-style-type: none"> • bariatric procedures • cataract surgery • endoscopy • liposuction (removing in total at least 200ml of lipoaspirate) • mental health services⁸ • oncology (chemotherapy) • oncology (radiation therapy) • oocyte retrieval • paediatric services (provided to patients aged at least 28 days and under 18 years when admitted) • specialist rehabilitation services
Undefined prescribed speciality health services for private hospitals only
<ul style="list-style-type: none"> • alcohol or drug detoxification (detoxification – acute phase) • cardiac surgery • cardiac catheterisation • intensive care • neurosurgery • neonatal services (provided to patients aged 28 days and under when admitted) • obstetrics

⁸ As noted below, the department is considering how this term will be understood in new regulations, in the context of recent changes to specific mental health legislation, being the introduction of the *Mental Health and Wellbeing Act 2022*, which will come into operation on 1 September 2023.

The department is interested in hearing from stakeholders about the health services currently prescribed in the Regulations and whether there are any issues with their definition or scope. For example, is there any ambiguity about whether:

- specific procedures are included in the existing (defined or undefined) speciality health service categories
- health services not currently listed in the Regulations are within scope and must therefore be performed in registered facilities
- certain speciality services can be performed in day procedure centres or only in private hospitals.

The department is aware that some parts of the health sector may have experienced uncertainty about the scope of acute alcohol and other drug (AOD) detoxification services that must be provided in a registered premises (described in Regulations currently as ‘alcohol or drug detoxification (detoxification – acute phase)’). The department welcomes suggestions from both registered and unregistered AOD service providers on how the Regulations could address any ambiguities, noting that the department does not intend to expand the Regulations to cover sub-acute or rehabilitation AOD services.

The department is aware that the term ‘mental health services’ may require clarification, including in light of the new legislative framework for mental health and wellbeing services (the *Mental Health and Wellbeing Act 2022*, coming into operation on 1 September 2023, and associated regulations). The department will be considering this issue and would welcome any relevant feedback from stakeholders.

1.2.1 Cosmetic surgery

In response to recent concerns expressed about safety and quality in the cosmetic surgery sector, a significant national reform program is underway. National bodies like the Australian Commission on Safety and Quality in Health Care (the Commission), the Australian Health Practitioner Regulation Agency (Ahpra) and the Medical Board of Australia (Medical Board) are leading different elements of the reforms.

The department is taking the opportunity to consider adding ‘cosmetic surgery’ as a speciality health service in the Regulations so that Victoria’s legislation supports the national reforms. The background for this proposed amendment is summarised below.

1.2.1.1 National cosmetic surgery licensing framework and standards

In 2022, federal, state and territory health ministers tasked the Commission with leading a review of licensing arrangements for private hospitals, day procedure centres and clinics where cosmetic procedures are performed, and developing national standards for the safe delivery of high-quality cosmetic procedures.⁹

⁹ Department of Health and Aged Care, [Health Ministers' Meeting - Statement on cosmetic surgery 2 September 2022](https://www.health.gov.au/resources/publications/health-ministers-meeting-statement-on-cosmetic-surgery-2-september-2022), Australian Government, viewed 21 July 2023, <<https://www.health.gov.au/resources/publications/health-ministers-meeting-statement-on-cosmetic-surgery-2-september-2022>>.

The Commission conducted consultation to inform its review of current licensing schemes and development of options to achieve greater national consistency.¹⁰ Stakeholders from the Victorian private hospitals sector have also participated in the Commission's consultation process.

The health ministers are due to consider the Commission's proposals later in 2023.

1.2.1.2 National requirements for cosmetic surgery practitioners

Recommendations from the independent review of cosmetic surgery regulation¹¹ commissioned by the Ahpra and the Medical Board are currently being implemented.¹² These include a range of measures, such as:

- new *Endorsement of registration of registered medical practitioners for the approved area of cosmetic surgery*¹³
- updated *Guidelines for registered medical practitioners who perform cosmetic surgery and procedures*¹⁴
- new *Guidelines for registered medical practitioners who advertise cosmetic surgery*.¹⁵

A reform to protect the title 'surgeon' is also underway, with the Health Practitioner Regulation National Law (Surgeons) Amendment Bill 2023 currently before the Queensland Parliament.¹⁶

1.2.1.3 Cosmetic surgery definitions

The department is considering whether adding cosmetic surgery as a defined category of health service in the Regulations may improve the regulation of cosmetic surgery and support consistency with these national reforms.

The Medical Board defines cosmetic surgery as follows:

Cosmetic surgery and procedures are operations and other procedures that revise or change the appearance, colour, texture, structure or position of normal bodily features with the dominant purpose of achieving what the patient perceives to be a more desirable appearance.

¹⁰ Further information is available on [Australian Commission on Safety and Quality in Health Care website](https://www.safetyandquality.gov.au/standards/cosmetic-surgery-project) at <<https://www.safetyandquality.gov.au/standards/cosmetic-surgery-project>>.

¹¹ Ahpra, 2023, [Independent review of the regulation of medical practitioners who perform cosmetic surgery 2022](https://www.ahpra.gov.au/resources/cosmetic-surgery-hub/cosmetic-surgery-review.aspx), viewed 21 July 2023, <<https://www.ahpra.gov.au/resources/cosmetic-surgery-hub/cosmetic-surgery-review.aspx>>.

¹² For more information, see [Making cosmetic surgery in Australia safer](https://www.ahpra.gov.au/Resources/Cosmetic-surgery-hub.aspx) <<https://www.ahpra.gov.au/Resources/Cosmetic-surgery-hub.aspx>>.

¹³ Medical Board of Australia, 2023, [Registration standard: endorsement of registration of registered medical practitioners for the approved area of cosmetic surgery](https://www.medicalboard.gov.au/Registration-Standards/Reg-Std-Endorsement-of-registration-cosmetic-surgery.aspx), viewed 21 July 2023, <<https://www.medicalboard.gov.au/Registration-Standards/Reg-Std-Endorsement-of-registration-cosmetic-surgery.aspx>>.

¹⁴ Medical Board of Australia, 2023, [Guidelines for registered medical practitioners who perform cosmetic surgery and procedures](https://www.medicalboard.gov.au/codes-guidelines-policies/cosmetic-medical-and-surgical-procedures-guidelines.aspx), viewed 21 July 2023, <<https://www.medicalboard.gov.au/codes-guidelines-policies/cosmetic-medical-and-surgical-procedures-guidelines.aspx>>.

¹⁵ Medical Board of Australia, 2023, [Guidelines for registered medical practitioners who advertise cosmetic surgery](https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Guidelines-for-registered-medical-practitioners-who-advertise-cosmetic-surgery.aspx), viewed 21 July 2023, <<https://www.medicalboard.gov.au/Codes-Guidelines-Policies/Guidelines-for-registered-medical-practitioners-who-advertise-cosmetic-surgery.aspx>>.

¹⁶ Office of the Queensland Parliamentary Counsel, [Health Practitioner Regulation National Law \(Surgeons\) Amendment Bill 2023](https://www.legislation.qld.gov.au/view/whole/html/bill.first/bill-2023-008), Queensland Government, viewed 21 July 2023, <<https://www.legislation.qld.gov.au/view/whole/html/bill.first/bill-2023-008>>.

Cosmetic surgery involves cutting beneath the skin. Examples include breast augmentation, abdominoplasty, rhinoplasty, blepharoplasty¹⁷, surgical face lifts, cosmetic genital surgery, and liposuction and fat transfer.¹⁸

Procedures that are not considered cosmetic surgery are also described. For example:

- non-surgical cosmetic procedures that do not involve cutting beneath the skin but may involve piercing the skin, such as cosmetic injectables, thread lifts, fat dissolving injections, cryolipolysis (fat freezing), laser hair removal, dermabrasion, chemical peels and hair transplants
- mole removal for the purposes of appearance (even though it may involve cutting beneath the skin)
- reconstructive surgery
- gender affirmation surgery.

The procedures described above as cosmetic surgery (except low-volume liposuction¹⁹) must already be conducted in registered and accredited facilities under the Victorian Regulations. This is because they come under one of the existing r.5 definitions of medical service, surgical health service or speciality health service, or involve the use of anaesthesia as defined in r.5.

Although these procedures are captured under various existing definitions, there may be benefits to adding cosmetic surgery as a defined health service in the Regulations. The department favours a broad definition that will align with the Medical Board's definition and any definition developed by the Commission and agreed to by the health ministers. This will bring consistency and ensure the Regulations cover current cosmetic procedures and any future innovations in cosmetic surgery practices, procedures and technology.

Prescribing cosmetic surgery as type of health service may have several benefits, including:

- reducing complexity and misalignment in how cosmetic surgery is categorised across different jurisdictions
- removing any current ambiguity for health service providers about which procedures must be conducted in registered premises and are in scope of regulation by the department
- increasing visibility for the community about which health services provide cosmetic surgery – for example, facilities that perform these speciality services would have cosmetic surgery listed on their registration certificate issued by the department.
- complementing Ahpra's endorsement standard and guidelines and supporting medical practitioners to comply with their obligations to only perform cosmetic surgery in accredited facilities.

The department is aware that ongoing and future developments in the national reforms in relation to cosmetic surgery may raise issues for stakeholders and invites any comments or questions on that

¹⁷ With the exception of upper eyelid blepharoplasty without sedation and which does not breach the orbital septum.

¹⁸ Medical Board of Australia, 2023, [Guidelines for registered medical practitioners who perform cosmetic surgery and procedures](https://www.medicalboard.gov.au/codes-guidelines-policies/cosmetic-medical-and-surgical-procedures-guidelines.aspx), viewed 21 July 2023, <<https://www.medicalboard.gov.au/codes-guidelines-policies/cosmetic-medical-and-surgical-procedures-guidelines.aspx>>.

¹⁹ Currently, the Regulations do not require low-volume liposuction to be conducted in registered facilities. The speciality health services provided by day procedure centres (r.6(c)) and private hospitals (r.7(c)) include 'Liposuction (removing in total at least 200ml of lipoaspirate)'.

as part of the review of the Regulations, noting that some matters may be beyond the scope of the review and require separate consideration.

Questions for consultation

1. Are the definitions for medical health service, surgical health service, speciality health service, anaesthesia, renal dialysis, and emergency medicine clear, current, workable, and effective?
2. Are additional definitions of prescribed speciality health services needed in the Regulations to address ambiguity?
 - a. If not, why?
 - b. If so, can you provide details about what issues you experienced or expect due to ambiguity about the meaning of a prescribed speciality health service?
 - c. If additional definitions are needed to reduce ambiguity, which speciality health services should be defined and what authoritative source should the definition draw on?
 - d. Do you consider clarification is required in relation to the terms ‘alcohol or drug detoxification (detoxification – acute phase)’ or ‘mental health services’? If so, please provide details of the ambiguity or clarification needed.
3. Do you support amending the Regulations to define cosmetic surgery as a type of health service? If yes, why? If not, why not?
4. Do you have any other comments about the scope of prescribed speciality health services in the Regulations and any current or anticipated future impacts on quality, safety and access to health services?

2. Registration and accreditation

2.1 Registration

Victoria uses a registration-based regulatory scheme for private hospitals and day procedure centres. The registration stages include:

- approval in principle (for use of land or premises, construction of premises, alterations or extensions to premises)
- registration (to be the proprietor of a health service establishment)
- variation (for changes to the number of beds or types of prescribed services provided, transfer of proprietor of the establishment, changes to other registration conditions)
- renewal (every two years or another period specified by the Secretary).

The Act specifies the criteria that must be considered in any decision about whether to approve or refuse a registration. These include whether the proprietor of the health services establishment (an individual or body corporate):

- is 'fit and proper'
- has the financial capacity to carry on the business and secure tenure over the premises
- has met the approved guidelines for the design, construction, fittings and equipment of premises, or of parts of premises²⁰
- has suitable arrangements for management and staffing of the facility
- will provide safe, patient-centred and appropriate health services and foster continuous improvement in quality and safety
- has a record of complaints, non-compliances or convictions as proprietor of another health service establishment.

These criteria are established in the Act so are not in scope of the review of the Regulations. However, they are the basis for key safety assessments conducted under the regulatory scheme, supported by powers under the Act to obtain information for the purposes of those assessments – for example, s.70(4) (approval in principle), s.82(3) (registration), s.88(4) (renewal), s.92(4) (variation).

The department may apply additional safeguards by setting conditions on registration. These are listed on the registration certificate (s.85(c)). For example, conditions may restrict the types of health services a private hospital or day procedure centre can provide.

Registration criteria and conditions are complemented by additional quality and safety requirements under the Act and the Regulations – for example, the obligation to comply with an approved accreditation scheme (see below).

²⁰ The approved guidelines are the Australasian Health Facilities Guidelines (AusHFG), which are available on the [Australasian Health Facility Guidelines website](https://healthfacilityguidelines.com.au/) at <<https://healthfacilityguidelines.com.au/>>.

2.2 Accreditation and related standards

The Act requires private hospitals and day procedure centres to comply with an approved accreditation scheme. The approved scheme for the purposes of that requirement is the Australian Health Service Safety and Quality Accreditation Scheme (the Scheme)²¹, which is administered by the Australian Commission on Safety and Quality in Health Care (the Commission). The Scheme requires private hospitals and day procedure centres to be accredited against the National Safety and Quality Health Service Standards (NSQHS Standards).

Roles and responsibilities in relation to the Scheme include the following:

- The Commission is responsible for developing the NSQHS Standards and administering the Scheme.
- Qualified third parties approved by the Commission conduct the accreditation assessments and certifications. Accreditation assessments are carried out at short notice, typically within 48 hours of notification.
- Proprietors of private hospitals and day procedure centres must meet the accreditation requirements and take remedial actions to address identified issues. The Regulations require them to send the accreditation report to the department (r.46(6)), and the Act requires them to notify the department if they fail to obtain or maintain accreditation (s.107B) or if safety risks are identified during accreditation assessment (s.110D).
- The department monitors the accreditation status of private hospitals and day procedure centres and takes enforcement action where needed (see below).

The primary aim of the NSQHS Standards is to protect the public from harm, improve the quality of health service provision, and ensure national consistency.

The eight NSQHS Standards are:

- Clinical governance
- Partnering with consumers
- Preventing and controlling infections
- Medication safety
- Comprehensive care
- Communicating for safety
- Blood management
- Recognising and responding to acute deterioration

Many of the requirements under the NSQHS Standards are strengthened by specific requirements in the Regulations, as discussed throughout this paper.

²¹ [Gazette Notice G 34 23 August 2018, 1841](http://www.gazette.vic.gov.au/gazette/Gazettes2018/GG2018G034.pdf#page=31)

<<http://www.gazette.vic.gov.au/gazette/Gazettes2018/GG2018G034.pdf#page=31>> approves the Australian Health Service Safety and Quality Accreditation Scheme as an approved accreditation scheme for the purposes of s107(1) of the Act.

Following a number of quality and safety concerns in hospitals that were NSQHS accredited, SCV has contributed to cross-jurisdictional work with the Commission on improvements required to strengthen assessment against the standards.

The department considers the provisions in the Act and Regulations relating to accreditation to be appropriate and necessary but welcomes any reflections from stakeholders on how they function operationally, including in the context of the related requirements in the Regulations.

Accreditation against the NSQHS Standards is an important marker for patients and the public about a facility's compliance with foundational safety requirements. Reflecting this, the Commission publishes information about accreditation status and assessment on its public website.²² To enhance this transparency, a requirement could be included in the Regulations for the proprietor to display the accreditation certificate issued under the Scheme in a prominent position – similar to the requirement to display the certificate of registration issued under the Act (r.45).

The department is aware of other clinical or service standards that may be relevant to safe healthcare delivery – for example, the College of Emergency Medicine (ACEM) Quality Standards for Emergency Departments and Hospital-Based Emergency Care Services²³. The department seeks feedback on introducing additional standards and accreditation processes, noting that any benefits would need to be weighed against additional costs and administrative impacts for service providers.

2.3 Consequences for non-compliance with registration and accreditation requirements

The Act includes a range of penalties associated with registration and accreditation. For example, the proprietor of a health service establishment may receive a penalty for:

- s.107A – failing to comply with the requirements of an approved accreditation scheme
- s.107B – failing to notify the Secretary that accreditation has been refused or revoked
- s.108, s.108B, s.115 – various offences related to constructing, altering or extending a health service establishment and using these areas without the Secretary's approval
- s.110D – failing to inform the Secretary about a serious risk to patient health or safety, including where identified by an accreditation agency during an accreditation assessment
- s.111 – conducting a health service establishment from an unregistered premises or without a current certificate of registration or renewal
- s.112 – exceeding the registered number of beds
- s.113 – providing prescribed health services for which the health service establishment is not registered
- s.144 – contravening a condition of registration.

²² Information can be searched by service or facility at ACSQHC, [Public reporting on hospital performance: NSQHS Standards](https://www.safetyandquality.gov.au/consumers/public-reporting-hospital-performance-nsqhs-standards#find-your-hospital) <https://www.safetyandquality.gov.au/consumers/public-reporting-hospital-performance-nsqhs-standards#find-your-hospital>.

²³ Australasian College for Emergency Medicine, [Quality Standards for Emergency Departments and Hospital-based Emergency Care Services](https://acem.org.au/Quality-Standards) <https://acem.org.au/Quality-Standards>.

The Act also allows for health service establishments to be suspended or revoked under certain circumstances related to registration and accreditation. For example:

- s.100 and s.101 – the Secretary may suspend registration of specified health services or of a health service establishment if satisfied that the proprietor has failed to carry on the health service establishment in accordance with the Act, Regulations or registration conditions.
- s.102 – the Minister may revoke the registration of a health service establishment if satisfied that the proprietor has failed to carry on the health service establishment in accordance with the Act, Regulations or registration conditions or has not complied with the requirements of an approved accreditation scheme.

In addition to the sanctions under the Act, the Regulations include a requirement related to registration, and non-compliance can attract a penalty:

- r.45 – the proprietor of a health service establishment must display the certificate of registration in a prominent position at the entrance foyer or reception area.

Questions for consultation

5. Do you have any comments about the registration of private hospitals and day procedure centres (noting that amendments to registration criteria or other provisions in the Act are outside the scope of this review of the Regulations)?
6. Do you have any comments about the role accreditation to the NSQHS Standards plays in ensuring the safety and quality of health services provided by private hospitals and day procedure centres?
7. In relation to the accreditation process, are there opportunities to better communicate the respective roles of the Commission, accreditation assessment bodies and the department?
8. Do you support amending the Regulations to require health service establishments to display their accreditation certificate in a prominent place? If not, why not?
9. Do you see any role for additional accreditation schemes to supplement quality and safety requirements under the Act, Regulations and NSQHS Standards? If yes, which ones, and why? What would be the impact on private hospitals and day procedure centres (for example, in terms of additional costs, involvement of third-party accreditation agencies)?
10. Do you have any comments on the penalties and sanctions related to registration and accreditation (noting amendments to the Act are beyond scope of this review but feedback on this issue may inform decisions on any future reforms)?

3. Clinical governance

The first NSQHS Standard is the Clinical Governance Standard, which:

...aims to ensure that there are systems in place within health service organisations to maintain and improve the reliability, safety and quality of health care. This standard, together with the Partnering with Consumers Standard, set the overarching requirements for the effective implementation of all other standards. The Clinical Governance Standard recognises the importance of governance, leadership, culture, patient safety systems, clinical performance and the patient care environment in delivering high quality care.²⁴

The Act and Regulations also have provisions that require appropriate clinical governance processes and systems to support safe and quality patient care and continuous improvement. This includes the requirement to prepare health service protocols for quality and safety (r.7A) which are often referred to as 'by-laws' by private hospitals and day procedure centres. Matters that must be included in these protocols include (but are not limited to):

- processes for assessing every three years the credentials of each health professional practising at the health service
- processes for setting the scope of practice for each health professional practising at the health service
- processes for continually assessing the capacity of the health service to provide safe, patient-centred, and appropriate health services to patients
- setting the frequency and procedures for meetings of committees with responsibility for the quality and safety of health services.

In addition, regulation 48 requires that services record in writing information about key safety indicators, including compliance with its established protocols, and requires that the recorded information be reviewed at least every three months.

The department is considering whether amendments or additions to these requirements might be appropriate, to strengthen the foundational regulated standards for clinical governance, as a key factor in safety and quality of services. These possible changes to the Regulations are discussed below.

3.1 Mandating Safer Care Victoria Clinical governance framework

SCV has published the [Victorian Clinical Governance Framework](#)²⁵ and a range of [other materials](#)²⁶ to further support services to establish and maintain the robust clinical governance required to deliver safe care. This is designed to complement the governance requirements in the NSQHS Standards. Private hospitals are already encouraged to adopt the Victorian Clinical Governance

²⁴ ACSQHC, [NSQHS Standards - Clinical governance standard](#), ACSQHC, Sydney, viewed 21 July 2023, <<https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance/clinical-governance-standard>>.

²⁵ Safer Care Victoria, 2017, [Clinical Governance Framework](#), State Government of Victoria, viewed 21 July 2023, <<https://www.safercare.vic.gov.au/sites/default/files/2018-03/SCV%20Clinical%20Governance%20Framework.pdf>>.

²⁶ Safer Care Victoria, 2023, [Clinical governance](#), State Government of Victoria, viewed 21 July 2023, <<https://www.safercare.vic.gov.au/support-training/clinical-governance>>.

Framework and adapt it to align with their existing protocols and plans, to clearly establish and document how the organisation assures good governance.

SCV provides support to private and public health services to improve their clinical governance capability.

The department is considering including a requirement in the Regulations to effectively mandate adoption of the Victorian Clinical Governance Framework and seeks feedback on the benefits and implications of such a reform. It is noted that there may be elements of the Framework that may benefit from adaptation or clarification so that they effectively reflect and support best practice clinical governance in private hospitals and day procedure centres. For example, the Framework describes health service boards and their roles and responsibilities in relation to clinical governance in a manner that reflects public sector hospital entities established under the Act. Feedback is sought on any updates to the Framework that might ensure it would apply effectively if mandated in the Regulations.

Questions for consultation

11. Do you support private hospitals and day procedure centres being required to comply with the SCV Victorian Clinical Governance Framework? If yes, why? If not, why not?
12. Are there elements of the Victorian Clinical Governance Framework that might require clarification or adjustment in order to apply effectively to private hospitals and day procedure centres?
13. What impacts on private hospitals or day procedure centres do you anticipate this requirement would have?

3.2 Mandating Safer Care Victoria credentialling policy

The SCV [Credentialling and scope of clinical practice for senior medical practitioners policy](#)²⁷ details requirements for senior medical practitioner credentialling and scope of clinical practice. It provides 'what to do' and 'how to do it' guidance for senior Victorian medical practitioners and their employing health service or health services where they have, or wish to obtain, visiting rights. All public hospitals are required to comply with this policy. However, currently it is only a recommended policy for private hospitals and day procedure centres in Victoria.

The department is considering whether it should be mandatory for all private hospitals and day procedure centres to comply with this SCV policy for the credentialling of registered medical practitioners who work in the facility. This would provide the basis for a consistent approach to credentialling and defining the scope of clinical practice across both public and private facilities.

For example, the department is aware that not all private hospitals and day procedure centres require 100 points of identification or photo identification. The department considers this to be a patient safety risk due to the possibility of impersonation of medical practitioners. The SCV policy requires proof of identity based on a 100-point check of original documents.

²⁷ Safer Care Victoria, 2020, [Credentialling and scope of clinical practice for senior medical practitioners policy](#), State Government of Victoria, viewed 21 July 2023, <<https://www.safercare.vic.gov.au/publications/credentialling-and-scope-of-clinical-practice-for-senior-medical-practitioners-policy>>.

The department is aware that some services may credential a large number of medical practitioners and the department is specifically interested in the impacts that this proposal may have for these facilities to inform the impact analysis for this requirement.

Questions for consultation

14. Do you support private hospitals and day procedure centres being required to comply with SCV's *Credentialing and scope of clinical practice for senior medical practitioners policy*? If yes, why? If not, why not?
15. What impacts on private hospitals or day procedure centres do you anticipate this requirement would have?

3.3 Mandating the Guideline for providers of liposuction

In August 2022, the department published the [Guideline for providers of liposuction: best practice guideline for clinicians, and those involved in the provision of liposuction](#) (the Guideline).²⁸ The Guideline was developed to support clinicians and strengthen quality and safety in the practice of liposuction. It includes guidance on:

- Admission, discharge and follow-up care
- Patient assessment
- Informed consent and shared decision making
- Staffing and credentialling
- Facilities and equipment
- Procedures
- Reporting and audit
- Complaints and open disclosure

Following publication of the Guideline, the Secretary issued a direction under s.105 of the Act to the proprietors of health service establishments, requiring them to comply with the Guideline. The Secretary informed proprietors that failure to comply with the direction could result in a penalty or registration suspension or revocation.

The department is considering mandating the Guideline through the Regulations (as permitted under s.158(1) of the Act) rather than through a direction from the Secretary. As health service establishments that conduct cosmetic surgery are already required to comply with the Guideline, this administrative change should have no material impacts.

²⁸ Department of Health Victoria, 2022, [Guideline for providers of liposuction: best practice guideline for clinicians, and those involved in the provision of liposuction](#) (the Guideline), State Government of Victoria, viewed 21 July 2023, <<https://www.health.vic.gov.au/guideline-for-providers-of-liposuction>>.

Questions for consultation

16. Do you support mandating the *Guideline for providers of liposuction; best practice guideline for clinicians, and those involved in the provision of liposuction* through the Regulations instead of through a direction from the Secretary? If yes, why? If not, why not?

3.4 Key clinical governance roles

As the Commission has stated in the NSQHS Standards, clinical leadership roles are central to ensuring the safety and quality of services provided in a health service:

Strong leadership can drive safety and quality improvements, and make them a priority. Commitment from leaders is important, because their actions and attitudes influence the perceptions, attitudes and behaviours of the workforce.

The Commission goes on to say that clinical governance arrangements should:

...[d]efine the delegated safety and quality roles and responsibilities of clinical leaders. These may include implementing strategic direction, managing the operation of the clinical governance system, reporting on safety and quality, and implementing the organisation's safety culture.²⁹

The department is considering including a requirement in the Regulations that the clinical governance protocols of a service must set out the roles and responsibilities of key clinical leadership positions – for example the Director of Medical Services and Director of Nursing. This would be consistent with the NSQHS Standards and may already be reflected in established protocols, so the change to the Regulations may not impose significant additional burden.

Questions for consultation

17. Do you support a requirement in the Regulations that the clinical governance protocols of a health service must set out the roles and responsibilities of key clinical leadership positions? If not, why not? If so, which positions do you consider should be addressed in the protocols?

3.5 Accountability for non-employee personnel

The department is aware that some health services use external agencies to contract clinical staff to work in the facility including, for example, medical practitioners to work in their emergency departments. In addition, it is understood that visiting medical officer (VMO) arrangements are often used.

It is essential for quality and safety that health services have clear chains of command and responsibility and powers to direct clinical personnel, including those who are not directly employed by the health service, and ensure their compliance with the facility's clinical governance and other safety and quality protocols. For example, if an adverse event occurs, there must be certainty about the directions the health service can give to medical practitioners, nurses or other relevant

²⁹ ACSQHC, [NSQHS Standards - Governance, leadership and culture - Action 1.06](https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance-standard/governance-leadership-and-culture/action-106), ACSQHC, Sydney, viewed 21 July 2023, <<https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance-standard/governance-leadership-and-culture/action-106>>.

personnel, however engaged, to participate in reviews or disclosure processes following the adverse event. This is reflected in r.7A, which requires that the clinical governance protocols for the facility must provide for credentialling each health professional practising at the health service establishment, setting their scope of practice, and continually assessing their competence and performance.

Further, the department understands that some health services engaging clinical staff through external agencies may accept credentialling provided by the agency rather than conduct their own credentialling process. There may therefore be uncertainty about whether and how the hospital has set the scope of practice of these staff. While this is a business risk for the health service involved, it may also be a patient safety risk and therefore worth considering during this review of the Regulations. For example, whether the clinical governance policies of the facility must specifically address the arrangements with clinical staff other than employees (such as credentialling and scope of practice processes, participation in reviews of adverse incidents, and powers to direct).

The department is aware that these arrangements may be complex and welcomes feedback on associated risks and how they might be best mitigated.

Questions for consultation

18. Do you consider that the current use of clinical staff not directly employed, to work in private hospitals or day procedure centres, may pose a risk to patient safety? For example, by compromising the facility's direct oversight of credentialling, or undermining arrangements for incident reviews?

- a. If yes, why? If not, why not?
- b. Are there actions that can be taken to mitigate any risk?

3.6 Staff and Visiting Medical Officers fatigue

If surgical lists or work hours are excessive, staff fatigue can become an issue with consequent risks for patient safety. Current evidence suggests a systemic approach is required, not only to prevent fatigue but also to monitor for adverse impacts arising from fatigue, to inform appropriate interventions and mitigations.³⁰

There are numerous studies showing that the fatigue experienced by any person staying awake for 18 hours is similar to 0.05 alcohol concentration in the blood. Being awake for 24 hours is similar to having 0.1 alcohol concentration in the blood.³¹ These studies provide a clear indicator that excessive fatigue impacts performance. Therefore, when staff and VMOs are fatigued they are more likely to make mistakes. This could include surgical errors, medication errors, or diagnostic

³⁰ Garrubba M & Joseph C, 2019, *The impact of fatigue in the healthcare setting: A scoping review*, Centre for Clinical Effectiveness, Monash Health, Melbourne, Australia.

³¹ The National Institute for Occupational Safety and Health (NIOSH) 2020 article [NIOSH Training for nurses on shift work and long work hours](https://www.cdc.gov/niosh/work-hour-training-for-nurses/longhours/mod3/08.html) <<https://www.cdc.gov/niosh/work-hour-training-for-nurses/longhours/mod3/08.html>>, viewed 21 July 2023, provides numerous references to studies and articles as the source of these statistics.

errors. Staff and VMO fatigue can be a direct risk to patients and should be treated in the same manner as any other risk to patient safety.

The department is considering whether the Regulations should be amended to include specific requirements to manage staff fatigue. For example, the Regulations could require clinical governance policies to cover management of staff fatigue, including how the length of surgical lists will be controlled, when the facility will intervene to cap the length of the surgical list, and how cumulative fatigue over time and across campuses or facilities might be monitored.

It is not intended the Regulations would make the health service responsible for work that staff or VMOs may have performed elsewhere. However, such a scenario may still pose a risk to patients. It is worth noting that the Act holds the operator of the hospital or day procedure centre responsible for all patient treatment at its facility irrespective of who provides the treatment.

The department is aware there may be arguments made for government to set a maximum surgical list length (for example, by anticipated hours to complete the list). It is noted that in the public and private sectors this would be complex. Many factors might impact on what a maximum length should be, including the type of procedure(s) being performed. Exceptions would likely also be required including, for example, for unplanned urgent surgery, where a single procedure is expected to take more than the maximum surgical list time (for example, transplants), or where one or more patients on the list experiences complications that delay the rest of the list.

Questions for consultation

19. Do you support amending the Regulations to require that the clinical governance protocols of a health service establishment must set out how staff and VMO fatigue (including cumulative fatigue arising from work undertaken at multiple facilities) is monitored and managed? If yes, why? If not, why not?
20. Do you have any comments on the benefits and implications of setting (in clinical governance protocols or centrally in government requirements) a maximum length for surgical lists?

3.7 Nurse professional development

The department understands that approaches to the ongoing education of nursing and midwifery staff vary across private hospitals and day procedure centres.

The department is considering whether there should be specific mandatory requirements in relation to ongoing nurse education. For example, there could be a requirement for this to be addressed in clinical governance policies and procedures (and the department understands many facilities already do this).

Questions for consultation

21. Do you support amending the Regulations to include mandatory requirements for the ongoing education of nursing and midwifery staff working at private hospitals and day procedure centres. If so, why? If not, why not?

3.8 Quality and safety committees

The quality and safety protocol requirements in the Regulations (r.7A) include that the protocols must set the frequency and procedures for meetings of committees that have responsibility for the quality and safety of health services provided at the private hospital or day procedure centre (r.7A(3)(f)). In addition, the Regulations (r.48) require the proprietor of a health service to record in writing and review at least every three months information in relation to the decisions and actions taken for the purposes of improving the quality and safety of health services provided. As previously noted, private hospitals and day procedure centres are diverse in location, size, services provided, and patient acuity. Therefore, in practice, the committee responsible for quality and safety may take various forms across health services– for example, a medical advisory committee (MAC), a quality and safety committee or health service board.

The department is considering whether additional requirements for the committee with responsibility for quality and safety would improve patient safety. For example, setting a minimum meeting frequency requirement (such as once every three months) or requiring the committee Chair to have no financial (or pecuniary) interest in the health service facility. The department understands that some committees responsible for quality and safety (such as a MAC) meet annually. Some stakeholders may consider an annual meeting to be too infrequent to be able to effectively govern quality and safety in a health service.

The department seeks feedback about how committees responsible for quality and safety currently operate in diverse private hospitals and day procedure centres, whether the operation of these committees could be improved to protect patients from harm, and what additional requirements may improve patient safety.

Questions for consultation

22. How does the requirement for a committee with responsibility for quality and safety currently work in practice across diverse private hospitals and day procedure centres?
23. Could mandatory requirements in the Regulations for the committee responsible for quality and safety improve patient safety – for example, a minimum meeting frequency of once every three months or a requirement for a Chair with no financial interest in the health service?

3.9 Adjunct diagnostic services

The department is considering whether the requirements for quality and safety protocols in the Regulations (r.7A) could be amended to reflect the fact that safe and comprehensive patient care may depend on timely access to adjunct diagnostic services such as pathology or radiology. These services may be delivered by the health service establishment or may be supplied by external providers. In either case, these services should be reliable, prompt and available when needed to ensure patient safety.

The Regulations already require health service establishment protocols to include ‘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’ (r.7A(3)(e)). As this regulation does not explicitly cover adjunct diagnostic services provided off-site or by third parties, the department seeks feedback on whether an additional requirement should be introduced – for example, a requirement that health service establishment protocols include processes for assessing

the reliability, availability and timeliness of adjunct diagnostic services, whether provided by the health service establishment or an external supplier.

The department reviews health service establishments' quality and safety protocols as part of registration application and renewal processes and during other regulatory interventions where required. By including the proposed new regulation, the health service establishment would need to demonstrate to the department that it has implemented processes for assessing the quality and safety of adjunct diagnostic services.

Questions for consultation

24. Do you support amending the provisions for quality and safety protocols in the Regulations to include a requirement that these protocols include processes for assessing the reliability, availability and timeliness of adjunct diagnostic services, whether provided by the health service establishment or an external supplier? If yes, why? If not, why not?

4. Staffing requirements

4.1. Senior appointments

Senior appointments in health service establishments play a crucial role in clinical governance. Consistent with the NSQHS Standards, 'leaders of a health service organisation have a responsibility to the community for continuous improvement of the safety and quality of their services, and ensuring that they are person centred, safe and effective.'³²

The Act enables the Regulations to prescribe requirements for staffing (s.158). The Regulations currently prescribe requirements related to senior appointments in health service establishments, such as Director of Nursing (r.14), Acting Director of Nursing (r.15), Chief Executive Officer and Medical Director (r.17). To ensure these organisational leaders can fulfill their clinical governance functions, it is essential that suitably qualified and experienced individuals are in these roles.

4.1.1 Director of Nursing

Under the Regulations, a health service establishment (other than a mobile health service) must appoint a 'suitably qualified person' as the Director of Nursing (DON) (r.14(1)). The Regulations specify that a person is considered suitably qualified if they are a registered nurse, have at least one year's practical experience in nursing management, and have at least five years' clinical experience as a registered nurse (r.14(2)). It is an offence not to appoint a suitably qualified DON, with a maximum penalty of 50 penalty units (\$9,615.50)³³ for the proprietor.

4.1.1.1 Director of Nursing title

The department is considering whether to continue with the requirement for a named position of DON. In some overnight hospitals the DON is termed the Director of Clinical Services. In some day procedure centres, the position is Nurse in Charge.

Arguably, the qualifications, experience, and authority of the nurse in charge of clinical services in the facility is more important than the name of the position. It may also be preferable to allow facilities flexibility in job titles.

If the department amends the Regulations to allow job title flexibility, health services' clinical governance policies and procedures would need to set out the authority and function of the position, however named.

This proposal is consistent with the Regulations' approach to any appointed Chief Executive Officer or Medical Director, which refer to these roles as 'however titled' (rr.17-18).

Question for consultation

25. Do you support amending the Regulations so that the appointment now titled 'Director of Nursing' can be 'however titled' if the position has the qualifications, experience, and authority of the nurse who is in charge of clinical services in the facility? If so, why? If not, why not?

³² ACSQHC, [NSQHS Standards - Clinical governance standard](https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance/clinical-governance-standard), ACSQHC, Sydney, viewed 21 July 2023, <<https://www.safetyandquality.gov.au/standards/nsqhs-standards/clinical-governance/clinical-governance-standard>>.

³³ Calculated based on a penalty unit value of \$192.31 (the penalty unit value from 1 July 2023 to 30 June 2024).

4.1.1.2 Acting Director of Nursing experience and qualifications

The Regulations require that if the DON is absent, incapacitated, or the position is vacant, an Acting DON must be appointed (r.15). It is an offence not to appoint an Acting DON when required, with a maximum penalty of 50 penalty units (\$9,615.50)³⁴ for the proprietor. The Secretary must be notified of the appointment and the qualifications of someone appointed to act as DON for more than 28 days (r.16). There is currently no maximum amount of time for which a private hospital or day procedure centre can appoint an Acting DON.

The department notes the central clinical governance and safety and quality role of the DON, and the potential benefits of workforce flexibility, including using acting opportunities as appropriately supported professional development. The department is considering specifying in the Regulations criteria that an Acting DON must meet to be considered suitably qualified, and the length of time for which an Acting DON can be appointed. Three options are included for consultation:

Option 1 – status quo. This option would not make any changes to the Regulations to add any criteria (such as qualifications and experience) that an Acting DON must meet, or the maximum length of time that an Acting DON can be appointed for. Rather, private hospitals and day procedure centres would continue to use their own clinical governance policies to ensure a suitably qualified and experienced individual is appointed as the Acting DON.

Option 2 – meet the same criteria as the DON. This option would amend the Regulations to require the Acting DON to meet the same qualifications and experience criteria as for the permanent DON. These criteria include (r.14(2)) that the DON:

- is a registered nurse, and
- has at least 12 months' practical experience in nursing management,
- and has at least five years' clinical experience as a registered nurse.

Option 3 – enable the position of Acting DON to be used to upskill staff. This option would enable the Acting DON role to be used as an opportunity to upskill staff and allow a registered nurse with lesser qualifications or experience (than what is required of the permanent DON) to be appointed as the Acting DON.

If the Acting DON is to be in the role for 3 months or more, the department proposes that a written mentoring program should be put in place as part of the facility's clinical governance policies and procedures, to ensure appropriate support, training, and guidance is provided. It is proposed that if this option is adopted, it would include a requirement that an Acting DON appointment is for a maximum of 12 months.

This option recognises that the Acting DON role can be used to upskill staff when the permanent DON is on leave. However, this must not detrimentally impact on the quality and safety of health services.

Questions for consultation

26. In relation to the qualifications and experience requirements of the Acting DON, which of the below options do you support and why:

³⁴ Calculated based on a penalty unit value of \$192.31 (the penalty unit value from 1 July 2023 to 30 June 2024).

Questions for consultation

Option 1 – maintain the status quo – no qualifications or experience requirements in Regulations, and no limit on the length of time that an Acting DON can be appointed for.

Option 2 – require the Acting DON to meet the same qualifications and experience requirements of the DON, which are that they are a registered nurse, and have 12 months' practical experience in nursing management, and have at least five years' clinical experience as a registered nurse.

Option 3 – enable the position of Acting DON to be used to upskill staff.

27. If the Acting DON is *not* required to have the same level of experience and qualifications as the DON, would you support a requirement that an Acting DON appointment is for a maximum of 12 months. If so, why? If not, why not?

4.1.1.3 Director of Nursing required on-site hours

To ensure the quality and safety of health services, the department is considering whether the Regulations should be amended to include other requirements related to the role of DON such as:

- minimum on-site hours
- experienced nursing staff requirements when the DON is not on-site
- a maximum number of day procedure centres that a DON can be nominated for.

The department seeks feedback on the following options:

Option 1 – status quo. This option would not make any changes to the Regulations and would continue with the current requirements.

Option 2 – amend the Regulations to introduce minimum on-site hours as follows:

- for private hospitals (offering overnight admission), the department is considering whether the DON, or a nominated nurse in charge with the same qualifications and experience as a DON, must be on-site at all times.
- for day procedure centres, the department is considering whether the DON, or nominated nurse in charge with the same qualifications and experience as the DON, must be on-site for a minimum number of hours each week.

Option 3 – an alternative option for private hospitals and day procedure centres might be to require that a nurse with at least three years' relevant clinical experience must be on-site to supervise the provision of *medical health services*. This would give medical health services the same level of supervision currently required for surgical, maternity, obstetric, and neonatal services under the following Regulations:

- r.26A – a nurse with at least three years' relevant clinical experience must be present to supervise the provision of surgical health services to a patient and their subsequent post-operative care.
- r.26B – a registered midwife with at least three years' relevant clinical experience must be present to provide clinical oversight of maternity, obstetric or neonatal services.

The department is also considering whether there should be a maximum number of day procedure centres that a DON can be nominated for.

Questions for consultation

28. To ensure adequate nursing supervision by a suitably qualified person, which of the following options do you support, and why / why not?

Option 1 – status quo – no change to requirements in the Regulations.

Option 2 – require a DON or nominated nurse in charge with the same qualifications and experience as the DON to be:

- on-site at all times in private hospitals
- on-site for a minimum number of hours each week in day procedure centres.
What might be an appropriate number of hours?

Option 3 – for private hospitals and day procedure centres, require a nurse with at least three years' relevant clinical experience to be on-site to supervise the provision of medical health services?

29. For day procedure centres, would you support there being a maximum number of facilities that a DON can be nominated for? If so, why and what might be an appropriate number? If not, why not?

4.1.1.4 Director of nursing hours devoted to non-clinical activity

The department understands there may be some facilities where the DON's work is purely clinical during working hours and the non-clinical component is done in the DON's own time, sometimes off-site. The department wishes to consider whether this may present a risk to patient safety such that relevant requirements in the Regulations are appropriate.

As noted above, the DON is a key clinical governance role. Relevant non-clinical activities of a DON may include:

- quality and clinical governance
- policy and systems reviews
- staff performance reviews and professional development
- setting safety culture
- patient experience.

If the Regulations were amended to introduce foundational requirements to ensure attention to non-clinical activities relevant to patient safety, three options may be considered.

Option 1 – status quo. This option would not make any changes to the Regulations to mandate hours that the DON must devote to non-clinical activities. Rather, private hospitals and day procedure centres would continue to use their own clinical governance policies to ensure the DON appropriately balances clinical and non-clinical work.

Option 2 – amend the Regulations to mandate the minimum hours that the DON must devote to non-clinical activities – for example, one non-clinical day per week.

Option 3 – amend Regulations to require a health service establishment's clinical governance policy to specify how and when the DON will undertake non-clinical activities (rather than set exact requirements for non-clinical hours as proposed in option 2).

Questions for consultation

30. Would you support a requirement in the Regulations about the hours a DON must devote to non-clinical activities. If so, why, and which of the below options do you support and why:

Option 1 – maintain the status quo – no minimum non-clinical hours requirements in Regulations.

Option 2 – amend the Regulations to mandate the minimum hours that the DON must devote to non-clinical activities – for example, one non-clinical day per week.

Option 3 – amend the Regulations to require clinical governance policies to address how the DON will undertake their non-clinical duties.

4.1.2 Other appointments

The current Regulations require a health service establishment to notify the department if the service appoints a Chief Executive Officer or Medical Director (however named), and if the employment is terminated or the position becomes vacant (rr.17-18). The department must be notified within 28 days of the appointment, termination, or vacancy. It is an offence not to notify the department, with a maximum penalty of 20 penalty units (\$3,846.20).³⁵ While the Regulations require the department to be notified about these appointments, the Regulations don't require the appointments to be made.

4.1.2.1 Medical Director or Chief Executive Officer

For hospitals that are large or have high acuity patients, relying on a Medical Advisory Committee and/or corporate Medical Director alone may not be sufficient to ensure safe, quality health service delivery. As outlined above, key leadership roles play a pivotal role in ensuring robust clinical governance. The department is considering whether the Regulations should be amended to:

- include a requirement for private hospitals with 200 or more overnight beds or that have an intensive care unit, emergency department, or acute rehabilitation ward to have an on-site Medical Director (however named).
- include a requirement that an on-site Medical Director (however named) responsible for a private hospital with 200 or more overnight beds cannot be responsible for any other facilities.

It is also proposed to require each private hospital with more than 200 overnight beds to have its own appointed Chief Executive Officer (CEO) to ensure appropriate on-site leadership.

Currently there are 8 private hospitals with more than 200 beds in Victoria. It may be that all such hospitals already have an on-site Medical Director and CEO in which case the requirement may only reflect current practice and impose limited to no additional requirements on these services.

4.1.2.2 New senior appointment for midwifery

The department is considering whether hospitals that provide maternity services should be required to appoint a Director of Midwifery or a Midwife in Charge (however named). This is because the midwifery speciality is a separate qualification from nursing due to the different specialist care required. The anticipated impacts on patient safety and accessibility of services (particularly in

³⁵ Calculated based on a penalty unit value of \$192.31 (the penalty unit value from 1 July 2023 to 30 June 2024).

smaller rural maternity services) would need to be considered. The department notes that many students and recent graduates have undertaken double degrees so this issue may be less important over time.

Questions for consultation

31. Do you support including a requirement in the Regulations for private hospitals with 200 or more overnight beds or that have an intensive care unit, emergency department, or acute rehabilitation ward to have an on-site Medical Director (however named)? If yes, why? If not, why not?
32. Do you support including a requirement in the Regulations that an on-site Medical Director (however named) responsible for a private hospital with 200 or more overnight beds cannot be responsible for any other facilities? If yes, why? If not, why not?
33. Do you support requiring a private hospital to have an on-site Chief Executive Officer if it has 200 or more overnight beds? If yes, why? If not, why not?
34. Do you support any requirements for additional required senior appointments such as hospitals that provide maternity services being required to appoint a Director of Midwifery or a Midwife in Charge, or a requirement to appoint a Chief Executive Office or Medical Director (however named)? If yes, why? If not, why not?

4.2 Sufficient nursing and midwifery staff

The Regulations specify the minimum nurse-to-patient ratios for private hospitals and day procedure centres across the facility as a whole (r.27). The requirements include a general requirement that a sufficient number of nursing staff must be on duty to provide care to patients, specify what the minimum nurse-to-patient ratios to meet the 'sufficient number of nursing staff' requirement is, and what proportion of nurses can be enrolled nurses.

The *Safe Patient Care Act 2015* sets out the minimum nurse-to-patient ratios and the midwife-to-patient ratios required in Victorian public hospitals. For public hospitals, the requirements are tailored to the tier of the hospital, the service provided, the acuity of patients, specific wards, and are extensive. Public hospitals are tiered according to the acuity of patients. Private hospitals and day procedure centres are not tiered but overall treat lower acuity patients and have fewer unplanned admissions.³⁶

Nurse and midwife to patient ratios are intended to assist in maintaining the safety of Victorian patients and contribute to better patient safety outcomes. Importantly, ratios are a minimum requirement and are not intended to prevent the proprietor of a private hospital or day procedure centre from staffing a ward with additional staff beyond the minimum number required by the ratio if there is reason to do so. In addition, the ratios may be applied in a flexible way to evenly distribute workload and ensure patient safety across the whole facility, having regard for the level of care required by patients in the ward. This may legitimately result in some nurses either being assigned fewer or more patients than prescribed in the relevant ratio.

³⁶ Additional information about the requirements for public hospitals is available on the [Department of Health website](https://www.health.vic.gov.au/nursing-and-midwifery/safe-patient-care-nurse-to-patient-and-midwife-to-patient-ratios-act-2015) at <<https://www.health.vic.gov.au/nursing-and-midwifery/safe-patient-care-nurse-to-patient-and-midwife-to-patient-ratios-act-2015>>.

4.2.1 Sufficient nursing staff

For private hospitals, the Regulations require a minimum nurse-to-patient ratio of at least one registered nurse to 10 patients during the day and evening, and at least one registered nurse to 15 patients overnight across the facility. For day procedure centres, the Regulations currently require a minimum nurse-to-patient ratio of at least one registered nurse for every 10 patients. In addition, two out of every three nurses must be registered nurses (not registered as an enrolled nurse). The remainder may be enrolled nurses. There is no required midwife-to-patient ratio. However, the Regulations require that the proprietor of a private hospital or day procedure centre must ensure that a registered midwife with at least three years' relevant clinical experience must be present to provide clinical oversight of maternity services, obstetric services or neonatal services (r.26B).

When considering changes to the nurse/midwife-to-patient ratios in the private health service sector, several key guiding principles arise including:

- The safety and quality of healthcare for patients is the paramount consideration.
- The safety and quality of healthcare provided to patients in private hospitals and day procedure centres should not be any less than that provided in public health services.
- Nurse/midwife-to-patient ratios cannot be imposed to a level that makes it impossible for private hospitals or day procedure centres to comply with the Regulations.
- The diversity of private hospitals and day procedure centres must be considered, including diversity in location, size, services provided, and that private health services overall treat lower acuity patients and have fewer unplanned admissions (when compared to public hospitals).

Private hospitals and day procedure centres must fund all additional operating costs out of revenue or through increased fees for services. Therefore, it is essential that any additional costs imposed by the Regulations in relation to minimum nurse-to-patient ratios are sustainable and consider impacts on service accessibility and cost.

It is also acknowledged that there is currently a significant shortage of registered and enrolled nurses, and registered midwives. The staff that would be needed to meet increased ratios may not currently be available (especially in regional and rural areas). Therefore, if any increases to nurse-to-patient ratios were introduced there would need to be a significant lead time for implementation. Perhaps as much as five to 10 years would be required to allow for sufficient additional people to be trained and registered as nurses and midwives.

Another consideration is what level of nurse-to-patient ratio private hospitals and day procedure centres would employ in the absence of Regulations. Hospitals exist to treat patients and achieve good outcomes for them. Health professionals also have professional obligations in relation to ensuring safe and quality care for patients. It would be inconsistent with these goals and obligations for private hospitals and day procedure centres to not ensure sufficient staffing levels to provide safe quality care to patients.

As private hospitals and day procedure centres have a built-in incentive to staff according to patient needs, many facilities may already be exceeding the minimum requirements of the current Regulations. As a result, the cost impact of improving the statutory ratios may not be as severe as any regulatory change may indicate.

The department is aware of three possible or proposed approaches to ratios in the new Regulations:

Option 1 – status quo – This option would not make any changes to the Regulations and would continue with the current requirements.

Option 2 – Under this option, the following changes would be made to the Regulations to better align with the requirements for public hospitals:

- Amend the current ratio of 1:10 nurses to patients to 1:5 during the morning and afternoon shifts for private hospitals.
- Amend the current ratio of 1:15 nurses to patients to 1:10 during the night shift for private hospitals.
- Insert a requirement for a ratio of 1:2 for High Dependency Unit (HDU) patients. This number can only include a Nurse in Charge if they are dedicated to this unit and have no other responsibilities. This change may require HDUs to be defined. A suggested definition is: 'A HDU is a specially staffed and equipped area of a hospital that provides a level of care intermediate between intensive care and the general ward care.' In considering an appropriate definition, it is noted that under the framework of ratios for public hospitals there are multiple tiers of HDU with corresponding differentiated ratios. Under this option, the Regulation would also require that a HDU must be on the same site as an Intensive Care Unit (ICU). Consideration would also be given to inserting a definition of a Close Observation Unit to differentiate it from a HDU.
- Insert a requirement for a ratio of 1:1 for an ICU.
- Insert a minimum ratio of 1:3 for occupied Emergency Department cubicles. This can only include a Nurse in Charge if they are dedicated to this unit and have no other responsibilities.
- Insert a minimum ratio 1:1 for occupied Emergency Department resuscitation bays excluding a Nurse in Charge.

If this option is progressed, it will likely be necessary to consider what specific requirements for registered nurses, as compared to enrolled nurses, might be feasible.

It is noted that this option would result in a near doubling of the nursing workforce requirement as compared to the requirements in the current Regulations. Whether this would reflect the actual increase in numbers is unknown and private hospitals and day procedure centres are invited to provide advice on this point.

Option 3 – Under this option, the Regulations would require all hospitals that operate emergency departments, intensive care units or high dependency units to include policy and procedures in their clinical governance framework that determine the nurse-to-patient ratio in these areas of the hospital. The department can then review how these policies and procedures are being applied and adhered to during inspections.

Hospitals should be able to predict demand based on history and, as a result, determine baseline staffing needs for these areas of the hospital. If it is proposed to flex up staff when required, the policy must state where the staff will come from, how their availability will be ensured, and how to ensure that other ward staffing does not fall below the general mandated level.

For the remaining hospital wards and day procedure areas, a nurse-to-patient ratio of 1:8 during the day and afternoon and 1:12 overnight would be mandated.

This option provides some flexibility for private hospitals to employ staff, and flex staff according to patient acuity.

Option 4 – Under this option, the Regulations would require that the clinical governance policies and procedures of a facility must set out all staffing arrangements, including minimum nurse/midwife-to-patient ratios. Some facilities have expressed a preference for all staffing to be determined by the facility clinical governance policies. However, this option is inconsistent with the approach taken for public hospitals where minimum nurse-to-patient ratios are mandated and would also be a significant departure from the approach currently taken in the Regulations, which mandates minimum nurse-to-patient ratios as an important element for maintaining patient safety. Notwithstanding the current incentives in place outside the Regulations for private sector facilities to maintain adequate levels of staffing, this option may lead to a reduction in the level of nursing staffing that could adversely impact patient safety.

4.2.2 Sufficient midwifery staff

The department is considering whether the Regulations should mandate a minimum number of midwives to be working in antenatal, delivery suites, and post-natal wards when patients are admitted.

The department notes that many students and recent graduates have undertaken double nursing and midwifery degrees so this issue may be less important over time.

Option 1 – status quo – this would make no changes to the Regulations and the Regulations would not mandate minimum midwife-to-patient ratios.

Option 2 – Insert a minimum requirement of 2 midwives for every 3 patients in birthing suites.

Option 3 – Require hospitals that provide maternity services to ensure there is at least 1 midwife on the ward whenever there is a maternity patient admitted and at least 1 midwife working in the birthing suites when a birth is in progress. The actual staffing arrangements must be detailed through clinical governance policies.

The department notes that the preferred option for sufficient midwifery staff is likely to align with the equivalent option for sufficient nursing staff in the above section.

4.2.3 Sufficient critical care registered nurses

The department understands that some nurses have raised concerns that some facilities may not be employing enough critical care registered nurses (CCRN) for the type and acuity of the patients being treated.

Therefore, the department is considering whether the Regulations should be amended so that the number and deployment of CCRNs must be included in clinical governance policies and procedures of private hospitals, and that they be linked to the type and acuity of patients receiving health services.

Questions for consultation

Sufficient nursing staff for private hospitals

35. In relation to the minimum nurse-to-patient ratios, which of the below options do you support and why:

Questions for consultation

Option 1 – maintain the status quo – no changes to the current minimum nurse-to-patient ratios required by the Regulations.

Option 2 – increase the general minimum nurse-to-patient ratios required by the Regulations for private hospitals, and introduce minimum nurse-to-patient ratios for high dependency units, intensive care units and emergency departments.

Option 3 – amend the Regulations to require that the clinical governance policies and procedures of a facility must set out staffing arrangements, including nurse-to-patient ratios, for high dependency units, intensive care units and emergency departments, with minimum nurse-to-patient ratios for the other wards specified in the Regulations.

Option 4 – amend the Regulations to require that the clinical governance policies and procedures of a facility must set out all staffing arrangements, including minimum nurse-to-patient ratios. Current nurse-to-patient ratios in the Regulations would be removed.

Sufficient midwifery staff

36. In relation to the minimum number of midwives to be working in antenatal, delivery suites, and post-natal wards when patients are admitted, which of the below options do you support and why:

Option 1 – maintain the status quo – no changes to the Regulations and the Regulations would not mandate minimum midwife-to-patient ratios.

Option 2 – amend the Regulations to insert a minimum requirement of 2 midwives for every 3 patients in birthing suites.

Option 3 – amend the Regulations to require hospitals that provide maternity services to ensure there is at least 1 midwife on the ward whenever there is a maternity patient admitted or when a birth is in progress, with the staffing arrangements further detailed through clinical governance policies.

Sufficient critical care registered nurses

37. Do you support requiring that the number and deployment of CCRNs, linked to the type and acuity of patients receiving health services, must be included in clinical governance policies and procedures of private hospitals?

Sufficient nursing staff for day procedure centres

38. Do you think the current nurse-patient ratios for day procedure centres in the Regulations are fit for purpose? If not, why not?

4.3 Overnight clinical staff

The department understands that some private hospitals do not employ or engage medical practitioners to work overnight at hospitals where patients are kept overnight. If a medical practitioner is required, either the individual patient's consultant must be contacted or the hospital must have its own arrangements with medical practitioners.

It is understood that larger hospitals with 24-hour Emergency Departments (EDs) or Intensive Care Units (ICUs) have medical practitioners on-site in the ED and ICU but that does not mean they will be available for ward patients when needed as they may be dealing with an emergency.

This situation may pose a potential safety risk for patients as there could be time delays in contacting an external medical practitioner outside business hours, particularly overnight. This may have particular implications for a rapidly deteriorating patient – for example, smaller hospitals may rely on triple zero to transfer out deteriorating patients, which may delay necessary treatment.

Further, the department is aware there may be concerns about information asymmetry in relation to these arrangements. Patients may choose a private hospital in the mistaken belief that there is a medical practitioner on-site after hours as in most large public hospitals.

The department is considering whether the Regulations should be amended to address any risk to patients. For example, if appropriate to establish foundational regulatory standards for patient safety, the Regulations could require that all overnight hospitals are required to have a medical practitioner or nurse practitioner on-site 24 hours a day, separately from persons engaged to work in a private hospital's ED or ICU.

Questions for consultation

Sufficient overnight clinical staff

39. Do you support amendments to the Regulations requiring that all overnight hospitals must have a medical practitioner or nurse practitioner on-site 24 hours a day, separately from persons engaged to work in a private hospital's Emergency Department or Intensive Care Unit? If so, why? If not, why not? If not, would you suggest including an alternative requirement in the Regulations to address any risk to patients?

5. Pre-treatment clinical assessment and discharge of patients

5.1 Pre-treatment clinical risk assessment

The Regulations currently require registered day procedure centres and private hospitals to undertake and record in writing the *results* of a *pre-admission* clinical risk assessment for each patient (excluding emergency patients) admitted (r.20A). Registered day procedure centres and private hospitals are also required to have a procedure for assessing the scope of practice of the relevant registered health practitioner providing services to a patient. The purpose of these requirements is to ensure the quality and safety of health services being provided at the facility.

5.1.1 Pre-treatment assessment of non-admitted patients

Patients can receive prescribed speciality health services delivered by a mobile health service provider – typically anaesthesia and IV sedation delivered by a mobile anaesthetist. These mobile services are delivered in settings that are not a registered day procedure centre or private hospital, such as a dental or radiology facility. In these situations, patients are not ‘admitted’. As a result, the requirement to do a *pre-admission* clinical risk assessment under r.20A does not apply. The department understands that in practice, mobile anaesthetists conduct a pre-treatment assessment as it is an essential component of best clinical practice.

The department is considering amending the Regulations to require non-admitted patients receiving speciality health services from a mobile health service provider to undergo a pre-treatment clinical risk assessment by the mobile service provider. (See below for the department’s proposal on who can review and finalise risk assessments). This change will enhance patient safety by applying the same minimum standard irrespective of whether a patient is admitted.

5.1.2 Staff who can undertake a pre-admission clinical assessment

The Regulations do not currently specify who must undertake a pre-admission clinical risk assessment. The department is considering amending the Regulations to require that a clinical staff member (such as a registered medical practitioner, nurse or midwife) must review/assess and finalise (for example by approving or signing) the pre-admission clinical risk assessment of patients at all facilities. For reasons of patient safety, it is not considered appropriate for non-clinical staff to undertake and finalise the pre-admission assessment as they cannot be expected to understand the clinical risks associated with each procedure.

5.1.3 Requirement for anaesthetist to review a pre-admission clinical assessment

The department is considering amending the Regulations to require that the proprietor of a registered private hospital or day procedure centre must ensure the anaesthetist reviews the pre-admission assessment before the patient commences treatment for planned procedures that involve anaesthesia in a registered facility. The department understands this would generally already be occurring as part of best clinical practice.

5.1.4 Documenting and retaining pre-admission assessments

The current Regulations require a pre-admission assessment to be undertaken and the *result* of the assessment to be recorded in writing, but do not require the full assessment to be documented. The department is considering amending the Regulations to require the pre-admission clinical risk assessment to be documented and retained by the registered health service, including mobile health services. The department understands that it is likely that most if not all private hospitals and day procedure centres currently document and retain the full assessment as an essential component of best clinical practice and health record keeping.

Questions for consultation

40. Should the Regulations be amended to require that patients receiving mobile health services (such as from a mobile anaesthetist) must undergo a pre-treatment clinical risk assessment (noting that in practice this generally already occurs with patients who receive mobile anaesthetic services)? If so, why? If not, why not?
41. Should the Regulations be amended to require a pre-admission clinical risk assessment to be reviewed/assessed/finalised by a clinical staff member? If so, why? If not, why not?
42. Should the Regulations be amended to require that the proprietor of a registered private facility must ensure the anaesthetist reviews the pre-admission clinical risk assessment before a patient commences treatment for planned procedures that involve anaesthesia, noting that the department understands that in practice this generally already occurs? If so, why? If not, why not?
43. Should the Regulations be amended to require that the full pre-admission clinical risk assessment be recorded in writing and retained rather than just the result of the assessment, noting that the department understands that in practice this generally already occurs? If so, why? If not, why not?

5.2 Discharge information to be given to patients

The Regulations currently require that the proprietor of a health service establishment must ensure that a patient's written copy of the discharge summary includes a list of all medications currently prescribed for the patient, irrespective of whether the medication is prescribed in relation to the health service received at the health service establishment (r.34(3e)). This requirement has been in place since 2018.

The department is considering replacing or removing the requirement for all registered health service establishments to give the patient a full list of prescribed medications (that is all medications including those the patient has advised they were taking prior to receiving a health service at the facility as well as new medications or changes to medications made during the provision of the health service in question – also known as a drug reconciliation) as part of the discharge summary.

The department understands that this requirement, which has been in place since 2018, has not worked as intended. It has created unnecessary paperwork for health service establishments and discharge delays for patients. The department understands that a full drug reconciliation is of most benefit to patients with complex needs who typically stay at least one night in hospital. Information about changed or new medication is sufficient for patients with less complex needs who are typically discharged on the same day.

The existing requirement could be replaced with a requirement to include in a discharge summary:

- For discharge from a private hospital for patients who stay one or more nights – a full drug reconciliation.
- For discharge from a private hospital for patients discharged within one day – any change or addition to prescribed medications.
- For discharge from a day procedure centre – any change or addition to prescribed medications.

Questions for consultation

44. What impacts has the current requirement (introduced in 2018) to include all medications currently prescribed in a patient's discharge summary had on private hospitals, day procedure centres, and patients?
45. Should the Regulations be amended to replace the requirement to include all medications currently prescribed to a patient with the below requirements? If so, why? If not, why not?
- a. For private hospitals – a full list of prescribed medications, irrespective of whether the medication is in relation to the health service received at the health service establishment, must be on the patient's discharge summary if they stay one or more nights in the facility.
 - b. For private hospitals – any changes or additions to prescribed medications must be on the patient's discharge summary for patients who are discharged within one day.
 - c. For day procedure centres – any changes or additions to prescribed medications must be on the patient's discharge summary.

6. Registers and records

The Act requires a health service establishment to keep particular (or prescribed) records about individuals who receive care in the establishment and the type of care, and staff employed by the establishment (s.109). Currently, the Regulations include requirements for a patient admission and discharge register (r.35), staff register (r.36), operation theatre register (r.37), and birth register (r.38).

6.1 Operation theatre register

Currently, the Regulations require a proprietor to ensure that an operation theatre register is kept if the private hospital or day procedure centre provides surgical health services or speciality health services for the provision of endoscopy (r.37). Failure to comply carries a maximum penalty of 30 penalty units (\$5,769.30).³⁷ The purpose of the register is to record what was carried out, when, by whom, and on whom. This is important for patient safety as the register may be central to any adverse incident investigation.

From a patient safety perspective, it may not make sense for the Regulations to specify only one speciality health service (endoscopy) that must be recorded in the register while excluding other speciality health services performed in the same operating theatre or procedure room. The department understands that in practice services may already be including in the operation theatre register information related to all surgical or speciality health services provided in an operating theatre or procedure room.

The department is considering whether to amend the Regulations to require the operation theatre register be used for all procedures carried out in operating theatres and procedure rooms.

Questions for consultation

46. Should the Regulations be amended to require that the operation theatre register be used to record all surgical health services and speciality health services carried out in operating theatres and procedure rooms? If so, why? If not, why not?
47. Given advancements and changes in record keeping systems, is the specific requirement to keep an operation theatre register still fit for purpose?

³⁷ Calculated based on a penalty unit value of \$192.31 (the penalty unit value from 1 July 2023 to 30 June 2024).

7. Mandatory reporting to the department and Safer Care Victoria

7.1 Reporting of transfers out

7.1.1 Mandatory reporting to the department of transfers out

The department is considering amending the Regulations to insert a new requirement that all private hospitals and day procedure centres must report to the department on transfers out of the facility. Of particular significance will be any transfer out of a patient due to a significant deterioration. It is expected that would include all triple zero calls resulting in transfers and all transfers to emergency departments.

Currently the Regulations do not require private hospitals or day procedure centres to notify the department if a patient is transferred out due to a significant deterioration and for what reason. Significant deterioration would be intended to capture instances where the transfer out of a patient was due, for example, to an escalation in the care required to be provided rather than a progression in care required – so the patient requires a higher level of care than what was expected. It is important to note that a significant deterioration in care does not necessarily mean a clinical error or pre-admission screening error has been made. However, the department as the regulator and patient safety may benefit from having increased oversight of emergency transfers out of a facility due to a significant deterioration in a patient – especially if it is a repeat occurrence.

Hospitals receiving emergency transfers of deteriorating patients have advised the department that this is reasonably common and suggested there are gaps in the department's oversight about the prevalence or severity of these transfers.

Questions for consultation

48. Should the Regulations be amended to require private hospitals and day procedure centres to report to the department transfers out of patients? If so, why? If not, why not? What would you consider an appropriate threshold for such a reporting requirement (i.e. which transfers should be reportable)?
49. If private hospitals and day procedure centres were required to report to the department any transfer out of patients due to significant deterioration, how often or quickly should the reports be made to the department, and what key information should be provided?

7.2 Adverse patient safety events (APSE) – responding and reporting

The department is considering the current Regulations and associated legal requirements for services to report and respond to adverse events and invites input on a number of issues as set out below.

7.2.1 Background and context

In 2016, the Targeting Zero Report made a number of findings and recommendations about oversight, reporting and response to adverse events. Since then, legislative reforms have been made as part of wider changes to strengthen an open and honest culture in health services, to support identification of quality and safety risks and continuous improvement.

As part of the reforms to apply these improvements to the private healthcare sector, amendments were made to the Regulations in 2018, including:

- A new requirement for the proprietor of a health service establishment to prepare operational protocols, which must include processes for improving quality and safety of the health services, regular reviews of health practitioners' credentials and scope of practice and reviews of patient safety and quality of care provided by the establishment. This regulation (r.7A) confers the responsibility for implementation and compliance with the protocols to the proprietor.
- A requirement to put in place, publish and implement an open disclosure policy (r.32A). Although this was already required as part of the NSQHS Standards, a requirement was expressly inserted into the Regulations following the Targeting Zero Report.
- Regulations (r.48) prescribing minimum record-keeping requirements, including information relating to adverse events, sentinel events, mortality and morbidity, compliance with protocols and patient experience and staff safety survey results, and requiring that those records be reviewed at least every three months.
- A requirement for the proprietor of a health service establishment to report sentinel events to the Secretary (r. 46A). In the Regulations 'sentinel event' means an unexpected and adverse event that occurs infrequently in a health service establishment and results in the death of, or serious physical or psychological injury to, a patient as a result of system and process deficiencies at the health service establishment. Health services are expected to meet reporting timelines, review the incident, make recommendations, and implement those recommendations per the SCV [Victorian sentinel events guide](#).³⁸

To further align public and private sectors and drive continuous improvement, the department seeks feedback on current processes for review and reporting of adverse patient safety events to identify opportunities and barriers for robust and transparent processes. As outlined in the Introduction, SCV has responsibility for monitoring and improving the quality and safety of care delivered across the health system including through exercise of legislative powers of the CQSO.

7.2.2 Statutory Duty of Candour and serious adverse patient safety events (SAPSE)

In 2022, a statutory duty of candour (SDC) was introduced through amendments to the Act. The SDC builds on the principles and elements of open disclosure within the [Australian Open Disclosure Framework](#).³⁹ The SDC applies to health service entities when a patient has suffered a serious adverse patient safety event (SAPSE).

³⁸ Safer Care Victoria, 2019, [Victorian sentinel events guide](https://www.safercare.vic.gov.au/publications/sentinel-events-guide) <https://www.safercare.vic.gov.au/publications/sentinel-events-guide>.

³⁹ Australian Commission on Safety and Quality in Health Care, [Australian Open Disclosure Framework](https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework) <https://www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework>.

In the Act and the Health Services (Quality and Safety) Regulations 2020⁴⁰, SAPSE is defined as 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 harm being suffered by the patient. This includes an event that is identified following discharge from the health service entity. Sentinel events are a sub-category of SAPSE and are therefore subject to the SDC.

The SDC means that health service entities are required to:

- apologise to any person seriously harmed while receiving care
- give a written account of the facts regarding the SAPSE
- describe what action was taken and improvements put in place to prevent re-occurrence of the event.

This must be carried out in compliance with requirements and any timelines set out in the [Victorian Duty of Candour Guidelines](#).⁴¹

There are legal protections in place for apologies made in compliance with the SDC – s.128ZD of the Act provides that evidence of an apology is not admissible in any civil or disciplinary proceeding, and as such does not constitute an express or implied admission of fault or liability.

Division 8 of the Act covers SAPSE reviews. The Act states that if a SAPSE occurs, a SAPSE review may be conducted by a SAPSE review panel. The panel may be appointed voluntarily or compulsorily upon direction from the Secretary of the Department of Health (s.128P). This panel may be a joint SAPSE review panel if the event involves two or more health service entities. Membership requirements of the panel (s.128Q) ensure that the panel members are sufficiently experienced, skilled and independent from the event – including a requirement that the panel must include a person not employed or engaged by the relevant health service provider. Regulations 3C and 3D of the Health Services (Quality and Safety) Regulations 2020 specify more detail on the constitution of the panel including a requirement that if the SAPSE was a sentinel event, the panel must include a consumer representative. Sections 128R and 128S provide protection from liability for SAPSE review panel members and participants respectively.

The panel must produce a SAPSE review report covering elements of the investigation, analysis of why the event happened and any contributing factors, and recommendations for changes or improvements that could reduce the likelihood of the event happening again.

While conduct of a SAPSE review is not specifically mandated in legislation, they are a valuable quality and safety improvement process and may assist health services in fulfilling their SDC requirements. The legal protections for disclosures made during the SDC and SAPSE review processes aim to foster a culture where errors and harm are effectively identified and discussed openly, improving health outcomes by ensuring a robust and transparent response to adverse incidents, and more comprehensive and effective recommendations for improvements. SCV offers a

⁴⁰ The Health Services (Quality and Safety) Regulations 2020 are available on the [Victorian Legislation website](https://www.legislation.vic.gov.au/as-made/statutory-rules/health-services-quality-and-safety-regulations-2020) <<https://www.legislation.vic.gov.au/as-made/statutory-rules/health-services-quality-and-safety-regulations-2020>>.

⁴¹ Safer Care Victoria, 2023, [Victorian Duty of Candour Guidelines](https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour), State Government of Victoria, viewed 21 July 2023, <<https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour>>.

range of supports for services in relation to the SDC, SAPSE reviews and adverse event reporting and response.⁴²

7.2.3 Statutory Duty of Candour Reporting under the Regulations

To give effect to the changes introduced by the SDC, the Regulations were amended in June 2023, with effect from 1 July 2023. These amendments require a private hospital or day procedure centre to keep records and lodge reports/returns on metrics related to their performance with SDC obligations.

The proprietor of a private hospital or day procedure centre must report data for a 6-month reporting period on the number of SAPSEs occurring at the private hospital or day procedure centre in the first 3 months of the 6-month reporting period and, for these events, the following information for the whole 6-month period:

- the number of instances where the duty of candour process was commenced;
- the number of instances where the health service has completed the duty of candour process by providing the information specified in s.128ZC(l)(a) of the Act; and
- the number of instances where the patient/next of kin/carer has chosen not to receive the duty of candour information.

With reporting now mandatory, private hospitals and day procedure centres start reporting on SAPSEs from 1 July 2023, with the first report due to be lodged by 14 January 2024. Lodgement will be quarterly thereafter. Reporting requirements and portal are published on the SCV website.⁴³

7.2.4 Reviews of SAPSEs

As set out above, recent reforms have sought to strengthen arrangements for timely and robust review of adverse events. A recent coronial investigation has resulted in recommendations that the Regulations should be amended to introduce requirements that:

- all health facilities, public and private, are required to undertake root cause analysis reports of sentinel events and serious adverse patient safety events; and
- private hospitals be required to have an independent member on a root cause analysis panel consistent with the requirements imposed on public hospitals.

These recommendations have been accepted in principle. The department is considering how best to build on the existing arrangements outlined above, to give effect to these recommendations and ensure patient safety is prioritised and adverse events are investigated with a high level of rigour and transparency.

⁴² Safer Care Victoria, 2023, [Statutory Duty of Candour and protections for SAPSE reviews](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>> and [Adverse event review and response](https://www.safercare.vic.gov.au/support-and-training/review-and-response) <<https://www.safercare.vic.gov.au/support-and-training/review-and-response>>.

⁴³ Safer Care Victoria, 2023, [Statutory Duty of Candour and protections for SAPSE reviews](https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour), State Government of Victoria, viewed 21 July 2023, <<https://www.safercare.vic.gov.au/support-training/adverse-event-review-and-response/duty-of-candour>>.

7.2.5 Issues for consultation

An effective investigation or review process requires a robust, transparent and collaborative approach. The approach to incident management should be consistent across Victorian health services. The subsequent recommendations arising from reviews should be implemented and insights shared.

The department is aware that these processes may be hindered when health services are hesitant to:

- review sentinel events using an accepted robust methodology
- use the existing SCV reporting portal (designed to reflect a robust process and support effective monitoring of reported data by SCV)
- participate in multi-agency reviews where the investigation of an event covers more than one facility.

To address these issues and aim for consistency across the health sector, the department is considering whether to mandate the following:

- All sentinel event reporting must be made in the manner determined by the Secretary. For most health services, this change will have no effect as they already use the Sentinel event portal on the SCV website and follow the SCV [Victorian sentinel events guide](#).⁴⁴
- That all adverse patient safety events (APSEs) must be reviewed in line with SCV's [Adverse Patient Safety Events Policy](#)⁴⁵, noting that depending on the incident severity rating these reviews must be undertaken using an approved methodology (for example, root cause analysis, London Protocol, in-depth case review)

The department is aware that service providers may have a range of arrangements in place for review of APSEs, particularly following the introduction of the recent reforms to the Act, and is seeking feedback on the anticipated impact of introducing specific mandatory requirements for those reviews in the Regulations.

Finally, the department is considering the benefits and implications of broader incident reporting by health service establishments. The future goal is to have private sector health services reporting into the Victorian Health Incident Management System (VHIMS) database. This is the database used for incident reporting by public sector hospitals. It is a standardised dataset for the collection and classification of clinical, occupational health and safety incidents, near misses, hazards and consumer feedback.⁴⁶ The data reported supports quality and safety oversight by the department and SCV. The data is also analysed by the [Victorian Agency for Health Information](#) (VAHI) and reported back to health services, to inform their internal review and continuous improvement activities. Consistent reporting from across the private and public sectors would allow a system-wide

⁴⁴ Safer Care Victoria, 2019, [Victorian sentinel events guide](https://www.safercare.vic.gov.au/publications/sentinel-events-guide) <https://www.safercare.vic.gov.au/publications/sentinel-events-guide>.

⁴⁵ Safer Care Victoria, 2023, [Adverse patient safety event policy](https://www.safercare.vic.gov.au/publications/policy-adverse-patient-safety-events), <https://www.safercare.vic.gov.au/publications/policy-adverse-patient-safety-events>

⁴⁶ Victorian Agency for Health Information, 2023, [VHIMS program of reforms](https://vahi.vic.gov.au/ourwork/safety-and-surveillance-reporting/vhims-program-of-reforms#:~:text=The%20Victorian%20Health%20Incident%20Management,Human%20Services%20(the%20Department)>), State Government of Victoria, viewed 21 July 2023, <https://vahi.vic.gov.au/ourwork/safety-and-surveillance-reporting/vhims-program-of-reforms#:~:text=The%20Victorian%20Health%20Incident%20Management,Human%20Services%20(the%20Department)>.

approach to improved healthcare and provide services with the most comprehensive quality and safety dataset.

VAHI has worked to make the VHIMS system compatible/integrated with a common risk register, and to provide a free database for uploading to VHIMS to ensure accessibility for all public sector health services. However, it is acknowledged that implementing mandated reporting to VHIMS in the Regulations would be complex and may place a financial burden on health services. For example, there may be incompatibility between VHIMS and existing ICT systems including variations between how incidents are rated, and services may have to transition to new systems and processes. It is anticipated that extensive engagement with the sector, careful implementation planning and a phased approach would be required to ensure feasibility. Voluntary notifications could be introduced for services to be able to contribute their data, to benchmark their data against similar health services, prior to a staged roll-out in the future. The department welcomes feedback on the benefits and implications of mandating reporting through VHIMS in the Regulations.

Questions for consultation

50. Do you have any comments regarding the proposal to mandate sentinel event reporting via an approved pathway (currently the Sentinel event portal)?
51. Noting that amendments to the Act are beyond scope of this review, but acknowledging that the protections in the Act are relevant to any mandate for SAPSE reviews, do you find the current legislation (the Act) has sufficient protections in place to ensure rigorous and transparent review processes of adverse incidents? If not, why not?
52. Do you have any comments regarding the proposal for health service establishments to have protocols that align with SCV's *Adverse Patient Safety Event Policy*?
53. Do you foresee any barriers for health services to comply with a requirement to have an independent person on their SAPSE review panel should they choose to conduct a protected review?
54. Do you foresee any barriers for health service establishments to conduct a review using an approved methodology (for example, root cause analysis, London Protocol or in-depth case review) for all sentinel events and SAPSEs?
55. If data-reporting systems were free and/or integrated, do you see any barriers for health service establishments to report all adverse events through VHIMS? Do you see a value in receiving tailored performance reports from VAHI?
56. Do you support the Regulations being amended so that information relating to adverse events recorded and reviewed under r.48 is available to the Secretary upon request?

7.3 Open Disclosure

The Australian Open Disclosure Framework provides a nationally consistent basis for communication following a healthcare incident or adverse event. The existing provisions under r.32A regarding the preparation and implementation of an open disclosure policy must include processes by which open discussion between the health service establishment and a patient and the patient's family and carers are to occur following any adverse event that results in harm to the

patient. Open disclosure, as outlined within the Australian Open Disclosure Framework, must occur for all cases of harm and near miss.

The SDC builds upon and complements the principles and elements of open disclosure. On the occasion that an event constitutes a SAPSE, the SDC must occur as per the Act and regulations.

Questions for consultation

57. Do you have any comments regarding the proposal to maintain the existing regulation (r.32A) regarding open disclosure?

7.4 Annual data reporting by mobile health services

The definition of **health service establishment** was amended in 2018 to include ‘premises at which, or from which, a prescribed health service is provided’. The amendment was required to enable a flexible registration system that covered central premises as well as services linked to those premises. It was intended that health service establishments with smaller off-site facilities or services incorporating the same management and clinical governance arrangements as a central premises would be covered by the amended definition – for example, hospital-in-the-home.

The definition also intended to cover emerging and future innovative models of care. Unlike other health service establishments, mobile health services (usually anaesthetic and intravenous sedation services) are not required to report any Victorian Admitted Episode Data (VAED) to the department as their patients are not admitted. Typically, the patients are seen at privately owned dental clinics and radiation clinics that have contracted anaesthetic services.

Currently mobile health services are requested to report data annually via a template that is emailed to the proprietor of the mobile service health service establishment.

This retrospective baseline data supports the department’s overview of the sector and informs risk-based monitoring. The department is considering formalising this practice of data reporting from mobile services to ensure that data is received in full and in a timely manner.

The department proposes to add a regulation requiring an annual report to the Secretary on the operation of the mobile health service during the previous financial year. It is anticipated that any such annual report would contain the following information in respect of the financial year reported on, consistent with current operational arrangements:

- the number of patients treated
- the number of patients at each acuity level (patient’s preoperative physical health status using the ASA scale⁴⁷)
- nature of the anaesthesia (general anaesthesia or sedation)
- number of clinical incidents in relation to a patient while under the care of the mobile health service

⁴⁷ The American Society of Anesthesiology (ASA) Physical Status Classification of the patient’s present physical condition on a scale from 1-6 as it appears on the anaesthesia record.

- number of emergency patient transfers
- any other information that the Secretary has, by notice given to the proprietor of the mobile service health service establishment, requested the proprietor to include.

Questions for consultation

58. Do you support the Regulations being amended to require that a day procedure centre providing mobile services (such as mobile anaesthesia) is required to report annual data to the department?
59. Do you think the listed data points are appropriate? Are there other metrics that would support risk-based monitoring of the services provided?
60. Do you have any comments regarding the burden of reporting this data?

7.5 Infection control reporting

Under regulations 46(3)(a) and (4), the proprietor of a private hospital must prepare a return for each month containing data about infections acquired by patients and staff at the private hospital and infection prevention and surveillance activities implemented at the private hospital.

This requirement was introduced in the last amendments to the Regulations in 2018 to improve oversight of quality and safety and align private sector data reporting with public health services.

In practice, this is implemented by health services reporting data to the Victorian Hospital-acquired Infection Surveillance System (VICNISS). The primary aim of the VICNISS Coordinating Centre is to reduce the occurrence of healthcare associated infections (HAIs) in Victoria. The Coordinating Centre collates the data and provides reports to the department, as well as to participating hospitals. Participating hospital staff have access to their own hospital data, to aggregated data for the State and in some cases to de-identified data from other hospitals.

Questions for consultation

61. Do you have any comments regarding the current process of reporting data to VICNISS?

8. The patient experience: rights, informed care and complaints

Ensuring that individuals' rights are respected and that they can be fully informed about the care they will receive is fundamental to a safe and thriving health system. Patients also need to be satisfied that if they raise any issues or complaints regarding their treatment at a health service establishment that their concerns will be considered and current or future care uncompromised.

The Targeting Zero Report highlighted the importance of patient-centred care and transparency as well as continuous improvement. While requirements in the Regulations regarding the management of patient care and addressing complaints have been in place for some time, the requirement to capture and review patient experience data was only added as part of the 2018 regulatory amendments. In addition, the NSQHS Standards (Standard 2) set requirements for partnering with consumers. By seeking the patient experience, health services can best understand and address patient needs, and take action in response to patient concerns, benefitting both the patient and ultimately the health service. Relevant data collected, analysed and shared helps health services improve their own performance and provide a safer environment for care.

The department is considering whether changes to existing requirements, or insertion of new requirements in the Regulations, might improve regulation of foundational requirements for patient-centred care.

8.1 Care of patients – respect, dignity and privacy

The Regulations require the proprietor to take reasonable steps to ensure that the needs of patients are met promptly and efficiently by competent staff (r.28). In addition, rights-based requirements are included in the Regulations.

Regulation 20(2) lists the information to be given to patients in a statement covering patient rights.

Regulation 25 outlines the responsibility of proprietors of health service establishments to ensure that patients are treated with dignity and respect with regard to individual religious beliefs, and ethnic or cultural practices. It specifies that the patient should not be subjected to unusual routines, unless the routines are beneficial for the patient, and that meals are to be provided in accordance with cultural practices. These principles align with elements of the Victorian [Charter of Human Rights and Responsibilities Act 2006](https://www.legislation.vic.gov.au/in-force/acts/charter-human-rights-and-responsibilities-act-2006/015) (the Charter)⁴⁸, which only applies to public authorities (including public health services). Regulation 25 therefore ensures patients in private facilities are afforded similar protections of their rights.

Regulation 25 also covers personal privacy, and provides examples of when privacy should be available, such as when bathing, toileting and dressing, and when receiving health services. These requirements are consistent with other obligations private businesses may have – for example, under privacy legislation.

⁴⁸ [Charter of Human Rights and Responsibilities Act 2006](https://www.legislation.vic.gov.au/in-force/acts/charter-human-rights-and-responsibilities-act-2006/015), <<https://www.legislation.vic.gov.au/in-force/acts/charter-human-rights-and-responsibilities-act-2006/015>>.

8.2 Complaints

The management of complaints is an important part of the continuous improvement process and information about complaints received and how they were managed is an essential source of information about the quality and safety of services provided. Part 7 of the Regulations addresses how complaints are to be managed by a health service, including:

- nomination of a complaints officer – r.29(1)
- ensuring staff and patients are provided with the name of the complaints officer – r.29(2)
- dealing with complaints promptly and discreetly – r.30(1)(2)
- informing the complainant of the subsequent action that has been taken – r.30(3)
- making and retaining records of complaints for 7 years – r.31
- ensuring that patients are not adversely affected due to making a complaint – r.32.

These requirements supplement sections 71, 83 and 84 of the Act, which list complaints within the previous three years among the criteria that the Secretary must consider when considering granting or refusing an approval in principle, registration or renewal of registration of a health service establishment. Further, r.20(2)(l) specifies that in the information provided to patients on or before admission, they must be advised that they can comment or complain about the treatment or quality of the health care or services and be given the contact details of the complaints officer.

The department is interested in feedback on benefits and implications of an additional requirement, complementing the current r.31, that deidentified data about complaints received must be provided to the Secretary, to support risk-based monitoring of service safety.

8.3 Display and publication of information

Regulation 45 requires that the proprietor of a health service establishment must display in a prominent position at the entrance or reception area the certificate of registration of the premises as a health service establishment. The particulars of the certificate of registration are laid out in s.85 of the Act and include:

- the kind of health services provided at or from the premises
- the name of the proprietor
- any conditions which have been applied
- details of whether a prescribed health service may be provided at other premises
- the number of beds (if any) to which the registration relates
- the period for which the registration is granted
- if the premises are registered as a day procedure centre or private hospital:
 - the kinds of prescribed health services; and
 - the number of beds that may be used for specified kinds of prescribed health services.

Additionally, if required to be appointed under the legislation, the names of the Director of Nursing, the Chief Executive Officer or Medical Director, and the contact details of the person nominated under r.29 to receive and deal with complaints, must be displayed.

As noted in Chapter 2 – Accreditation and related standards above, the department is considering complementing this with a requirement for display of the certificate of accreditation issued under the Australian Health Service Safety and Quality Accreditation Scheme.

Further, r.7A and r.32A require that the clinical protocols and open disclosure policy of the facility be published on the health service establishment's website. The department is interested to hear about the most common and effective means of displaying this kind of information so those can be best reflected in the Regulations.

8.4 Patient experience survey data

Collecting data on the patient experience helps organisations identify areas for improvement of their patient care. Insights from the patient experience are valuable as the information is factual in nature, distinct from patient satisfaction data which is more subjective. Patient experience explores the nature of the actual care the patient received, helping to identify the system-related factors that may lead to a positive or negative experience.

In addition to other quality and safety data that proprietors must record and review, r.49 requires that patient experience data in the form of a survey must be collected and reviewed, with this data made available to the Secretary on request.

Additionally, r.48(b)(v) requires the proprietor of a health service establishment to ensure results from surveys (including patient experience) are reviewed quarterly.

8.5 Safer Care Victoria Partnering in Healthcare Framework

Consumer partnerships are central to a quality system focussed on improved health outcomes. Closely integrated and aligned with the Clinical Governance Standard (see section 3), Partnering with Consumers is the second NSQHS Standard and:

This standard, together with the Clinical Governance Standard, underpins all the other standards. The Partnering with Consumers Standard recognises the importance of involving patients in their own care and providing clear communication to patients.⁴⁹

The SCV [Partnering in Healthcare Framework](#)⁵⁰ (the Framework) was produced with extensive public health sector and consumer consultation in 2018. This best-practice resource is intended to align with existing policies and procedures within health services, helping organisations to identify issues, monitor implementation and measure progress and achievements. Adopting the Framework is a requirement for all Victorian public health services but it is a tool that could be used by other health services.

The department is interested in feedback about the benefits and implications of private health services adopting the Framework.

⁴⁹ ACSQHC, [NSQHS Standards - Partnering with consumers standard](https://www.safetyandquality.gov.au/standards/nsqhs-standards/partnering-consumers-standard), ACSQHC, Sydney, viewed 21 July 2023, <<https://www.safetyandquality.gov.au/standards/nsqhs-standards/partnering-consumers-standard>>.

⁵⁰ Safer Care Victoria, 2019, [Partnering in Healthcare Framework](https://www.safercare.vic.gov.au/publications/partnering-in-healthcare) <<https://www.safercare.vic.gov.au/publications/partnering-in-healthcare>>.

Questions for consultation

62. Do you have any feedback or suggestions for improvements or additions to any of the regulations related to patient rights, informed care and complaints? If yes, please reference the regulation number in your response.
63. Would you support a requirement in the Regulations for de-identified data about complaints to be reported, or made available, to the Secretary, to inform risk-based monitoring of service safety? If so, why? If not, why not?
64. What would be the benefits and/or implications of health service establishments adopting the Partnering in Healthcare Framework alongside their existing patient engagement policy? Would that constitute a significant shift from current arrangements?

9. Offences, penalties and sanctions

The Act and Regulations work together to provide a regulatory framework that:

- sets obligations that health service establishments must meet (for example, registration and accreditation, quality and safety protocols, senior appointments and other requirements as discussed throughout this paper)
- provides a range of powers and statutory tools for the department and SCV to monitor and enforce compliance with these obligations (for example, powers of entry for authorised officers and authorised quality and safety officers; powers for the Secretary to request information)
- defines offences, penalties and other sanctions that may be applied where serious breaches occur (for example, penalty units for various offences; registration conditions, suspensions and revocations).

Offences, penalties and sanctions will be considered as part of this review of the Regulations.

As noted earlier in this paper – for example, in Chapter 2 Consequences for non-compliance with registration and accreditation requirements – some penalties are defined in the Act, so amending these is outside the scope of this review. However, the department is still keen to hear from stakeholders if they have feedback or suggestions in relation to these.

9.1 Offences in the Regulations

The Regulations prescribe 35 offences with penalty units. The maximum penalty amounts set out in the Regulations are the maximum penalties that may be imposed by a court if a person is prosecuted for a breach of the Regulations. This is different from an infringement penalty, which is discussed in the section below. These are summarised in Appendix A – Penalties and offences in the Regulations.

The department seeks feedback from stakeholders about whether the offences and penalties are sufficient and fit for purpose. For example:

- Are the penalty amounts proportionate to the offence?
- Are the penalties effective as a deterrent to non-compliance?
- Are there any other breaches or non-compliances that should become offences under the Regulations?
- Are there other sanctions that could be more effective if remedial activities have failed to bring health services into compliance?

9.2 Infringements in the Regulations

The Act (s.155) allows an authorised officer to serve an infringement notice on a person whom the officer believes has committed a prescribed offence against the Regulations requiring the person to pay the prescribed penalty for that infringement, being an amount not exceeding one-fifth of the maximum penalty applicable to the offence.

While there are currently no infringement offences prescribed in the Regulations, the department is considering whether they could be a useful addition. Infringements are part of the contemporary regulatory ‘toolkit’ for several reasons:

- Infringements can be issued swiftly as direct punishment for clearcut offences (for example, parking fines are infringements for disobeying parking rules).
- Infringements can be issued without potentially lengthy or costly court proceedings.
- Infringement amounts are lower than penalty amounts and may therefore be proportionate to less serious offences.
- Infringements do not result in a criminal record.
- Infringements may act as a deterrent to reoffending.

Introducing infringement offences into the Regulations will give the department, as the regulator of health service establishments, more options for responding to non-compliance. This is particularly important in relation to cases of lower-level offences where court proceedings, registration suspensions, or other ‘full force of the law’ sanctions would be disproportionate to the non-compliance.

Any decision to prescribe an offence in the Regulations would need to consider, and be consistent with, the [Attorney-General’s Guidelines to the Infringements Act 2006](#).⁵¹

Questions for consultation

65. Do you have any feedback on the existing penalty offences and penalty amounts in the Regulations (as summarised in Appendix A – Penalties and offences in the Regulations)? If yes, please reference the regulation number in your response.
66. Do you have any suggestions for additional offences and penalties that could be prescribed in the Regulations?
67. Do you support the introduction of infringements to allow the department to deal with less serious breaches in a way that is swift, direct and proportionate to the offence? If yes, why? If not, why not?

⁵¹ Department of Justice and Community Safety Victoria, 2022, [Attorney-General’s guidelines to the Infringements Act 2006](https://www.justice.vic.gov.au/justice-system/fines-and-penalties/attorney-generals-guidelines-to-the-infringements-act-2006), <<https://www.justice.vic.gov.au/justice-system/fines-and-penalties/attorney-generals-guidelines-to-the-infringements-act-2006>>.

10. Other issues

10.1 Fees

This review of the Regulations is also an opportunity to consider if the fees prescribed in the Regulations remain appropriate. Fees are charged for various registration-related activities – for example, approval in principle and registration renewal. Fees differ between private hospitals and day procedure centres and are scaled to the number of beds provided at the premises. Fees are set in ‘fee units’ with a fixed value each financial year.⁵²

The fees currently prescribed in the Regulations include:

- application for approval in principle fees (s.70(2)(b) and r.8(2))
- application for transfer or variation of certificate of approval in principle fee (s.74(2) and r.9(b))
- application for registration fee (s.82(2)(b) and r.10(2))
- application for variation of registration fee (s.92(2)(b) and r.13(2))
- application for approval of alterations to clinical area (s.108(2)(b) and r.13A(2))
- annual fee (s.87(2) and r.11) (note this is currently prescribed as nil fee)
- application for renewal of registration fee (s.88(2)(b) and r.12(2))
- additional fees if an annual fee is not paid on time (s.87(2)(b)) or if a renewal of registration is not made at least 3 months prior to the registration expiring (s.88(2)(b)(ii)).

Regulations that set fees are subject to the Government’s [Pricing for Value Guide](#)⁵³, which is intended to improve consistency and capability in setting fees and charges across government. The *Pricing for Value Guide* sets out 12 Pricing Principles and requires departments to undertake pricing reviews. The Pricing Principles include principles related to cost recovery, who should bear costs (such as fees), that fees should not limit access to those with a lower ability to pay, fee structures should be easy to understand and simple to administer, and fees should be monitored and reviewed.

The Regulatory Impact Statement will provide more details about any proposed changes to fees and the proposed fees in the new Regulations. For the purposes of this discussion paper the department invites any preliminary comments on the fees.

10.2 Treatment agents must be available for clinical emergencies

Regulation 28A currently requires the proprietor of a health service establishment to have reversible agents for anaesthesia or other sedation immediately accessible when providing a health service that includes the use of anaesthesia or sedation (and where such agent exists). Anaesthesia in this context is defined as per the Regulations (r.5) and includes general anaesthesia, major regional

⁵² Fee units are set according to the *Monetary Units Act 2004*.

⁵³ Available on the [Department of Treasury and Finance website](https://www.dtf.vic.gov.au/financial-management-government/indexation-fees-and-penalties) at <<https://www.dtf.vic.gov.au/financial-management-government/indexation-fees-and-penalties>>.

anaesthetic block, intravenous sedation, or a high dose of local anaesthetic that has the potential to cause system toxicity (and does not include a dental nerve block).

The department understands that the use of the terminology ‘reversible agent’ in this section of the Regulations may unintentionally narrow the emergency medication inventory that should be required to be available on-site. In addition to the medications and agents commonly used to manage anaesthesia, health service establishments should ensure availability of treatment agents for the management of clinical emergencies that may arise.

For example, the Australian and New Zealand College of Anaesthetists (ANZCA) and the Faculty of Pain Medication Position Statement (PS55(A)) states ‘in addition, if volatile anaesthetics or suxamethonium are intended to be used, the possibility of malignant hyperthermia (MH) is present. A supply of Dantrolene appropriate to the clinical area must be stocked’.⁵⁴

The statement also specifies a minimum requirement for basic emergency medication inventories to manage emergency conditions that may arise, such as adrenal dysfunction, anaphylaxis, bronchospasm, cardiac arrest, cardiac arrhythmias, coagulopathies, hyperkalaemia, hypoglycaemia, hypotension, hyperglycaemia, hypertension, malignant hyperpyrexia, major haemorrhage, pulmonary oedema, raised intracranial pressure, respiratory depression, and uterine atony (where relevant).

Clinical emergencies may arise from other aspects of medical treatment, and it is expected that health service establishments should ensure availability of appropriate treatment agents for such events.

The department is considering amending the Regulations to require that additional treatment agents are available at the facility for the management of emergencies. The treatment agents required would be dependent on the nature of medical services provided, for example anaesthesia.

Questions for consultation

68. Do you have any preliminary comment on the fees set out in the Regulations?

69. Should the Regulations be amended so that health service establishments must ensure treatment agents are available for clinical emergencies that require pharmacological intervention – for example, treatments specific to anaesthesia. If so, why? If not, why not?

10.3 Hospital-in-the-home

Hospital-in-the-home is a growing area of medical and nursing care. The Act already permits registered facilities to provide services at or from their location, so this includes hospital-in-the-home services.

⁵⁴ Australian and New Zealand College of Anaesthetists and the Faculty of Pain Medication [*Position Statement on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations 2021*](https://www.anzca.edu.au/getattachment/7ee1b267-8c29-414e-86c2-6d0e50933d43/PS55(A)-Position-statement-on-minimum-facilities-for-safe-administration-of-anaesthesia-in-operating-suites-and-other-anaesthetising-locations-(PS55)) (PS55(A)), viewed 21 July 2023, <[https://www.anzca.edu.au/getattachment/7ee1b267-8c29-414e-86c2-6d0e50933d43/PS55\(A\)-Position-statement-on-minimum-facilities-for-safe-administration-of-anaesthesia-in-operating-suites-and-other-anaesthetising-locations-\(PS55\)](https://www.anzca.edu.au/getattachment/7ee1b267-8c29-414e-86c2-6d0e50933d43/PS55(A)-Position-statement-on-minimum-facilities-for-safe-administration-of-anaesthesia-in-operating-suites-and-other-anaesthetising-locations-(PS55))>.

The department seeks advice on what new measures, if any, could or should be included in the Regulations to ensure these services are delivered safely.

Services typically provided in the home are for chronic conditions such as palliative care, dialysis, and oncology. There may also be home births. The department is aware that this service is now being extended to heart patients by some hospitals.

As the new Regulations will have a 10-year lifespan, the department wishes to ensure they are appropriate to regulate the hospital-in-the-home patient service over the next 10 years.

10.4 Other issues

This discussion paper is an opportunity for you to raise other issues related to the Regulations that have not been specifically raised in this discussion paper. For example, this could include:

- Requirements that you may consider no longer fit for purpose (since the making of the Regulations in 2013). For example, this may be due to technological advancements, changes in clinical practice, changes in business practices, changes in community expectations, changes in other relevant regulatory schemes, or changes in regulatory burden.
- Requirements that you may consider are not effectively or efficiently achieving the desired outcome of safe, quality health services for patients.
- Requirements that you may consider essential for achieving the desired outcome of safe, quality health services for patients.

It should be noted that amendments to the Regulations are within the scope of this review but amendments to the Act are not within scope. Therefore, some issues may not be able to be considered through this review such as proposals that would require amendments to the Act.

Questions for consultation

70. Are there any other issues related to the Regulations that have not specifically been raised in this discussion paper that you would like to raise with the department?

10.5 Administrative reforms

This review of the Regulations is an opportunity for stakeholders to raise any other amendments that are of an administrative nature. This may include raising with the department any sections of the Regulations that may contain errors, are unclear, or may be duplicative.

10.5.1 Prevention of Scalding

The department proposes to repeal r.41 which imposes a specific requirement for the proprietor of a health service establishment facility to 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.

The Australasian Health Facility Design Guidelines (AusHFG) which are mandatory in Victoria (as a condition for Approval in Principle for a new build or renovation), set out requirements for the safe provision of hot water in facilities. Since 2018, the Act has also contained a general requirement to

provide a safe service (s.110B). Therefore, the department is considering removing this specific requirement from the Regulations (r.41) as it may be considered duplicative and would not impact on the outcome of delivering safe health services.

Questions for consultation

71. Do you agree that the requirements in the Regulations to prevent scalding of patients (r.41) can be removed from the Regulations without impacting on the delivery of safe health services?
72. Are there any other specific areas of the Regulations that you would like to raise with the review team as a requirement that may be duplicative, unclear or contain an error?

Appendix A – Penalties and offences in the Regulations

Table 3: Offences and penalties in the Regulations

Regulation	Offence description	Penalty units	Amount ⁵⁵
r.14(1)	Not appointing a suitably qualified person as the DON.	50	\$9,615.50
r.15	Not appointing an acting DON.	50	\$9,615.50
r.16	Not notifying the Secretary of the appointment, qualifications and experience of a DON or acting DON within 28 days.	20	\$3,846.20
r.17	Not notifying the Secretary of the appointment of a CEO or Medical Director (however titled) within 28 days.	20	\$3,846.20
r.18	Not notifying the Secretary of the termination of a CEO or Medical Director (however titled) appointment or vacancy of the position within 28 days.	20	\$3,846.20
r.19	Not allocating a unit record number to a patient on or as soon as practicable after admission.	30	\$5,769.30
r.20(1)	Not giving a patient on or before admission a statement containing information about the health care services provided by the health service establishment*; fees; and an explanation of the treatment. *r.20(2) gives an extensive list of items that must be covered in the statement.	50	\$9,615.50
r.21	Not creating and maintaining separate clinical records for each patient.	30	\$5,769.30
r.22	Not ensuring each clinical record contains the required information* *r.22(a) – (e) give an extensive list of information required – e.g. patient name, address, contact details, clinical history, diagnostic test results, etc.	30	\$5,769.30
r.23	Not ensuring a patient can be readily identified by an attached identity band or device or a photograph on their clinical record.	40	\$7,692.40
r.24(1)	Not ensuring at least 2 identity bands or devices are attached to an infant before leaving the delivery room and while it remains on the premises.	30	\$5,769.30

⁵⁵ Calculated based on a penalty unit value of \$192.31 (the penalty unit value from 1 July 2023 to 30 June 2024).

Regulation	Offence description	Penalty units	Amount ⁵⁵
r.24(2)	Not ensuring at least 2 identity bands or devices are attached to an infant if its mother is admitted as a patient immediately after giving birth.	30	\$5,769.30
r.26	Not ensuring each nurse is an enrolled or registered nurse with the professional competence, education or experience relevant to the health services being provided.	50	\$9,615.50
r.27(1)	Not ensuring a sufficient number of nursing staff* are on duty *r.27(2) gives the required nurse-to-patient ratios for private hospitals and day procedure centres.	50	\$9,615.50
r.28	Not ensuring patient needs are met promptly and effectively by nursing staff and other professionally competent registered health practitioners.	50	\$9,615.50
r.29(1)	Not nominating a person to receive and deal with patient complaints.	50	\$9,615.50
r.29(2)	Not ensuring that patients and staff are informed of the name of the person nominated to receive and deal with complaints.	50	\$9,615.50
r.30(1)	Not responding to a complaint as soon as practicable.	40	\$7,692.40
r.30(2)	Not ensuring a complaint is dealt with discreetly.	40	\$7,692.40
r.30(3)	Not informing the complainant of the action taken in respect of the complaint.	40	\$7,692.40
r.31(1)	Not keeping a written record* of every complaint *r.31(2) lists the information to be recorded.	30	\$5,769.30
r.31(3)	Not storing the record securely for 7 years.	30	\$5,769.30
r.32	Not taking reasonable steps to ensure a complainant is not adversely affected by making the complaint.	60	\$11,538.60
r.33	Not sending all information and documents relating to a transferring patient's medical condition and treatment to the receiving establishment or agency.	40	\$7,692.40
r.37(1)	Not keeping an Operation Theatre Register* where surgical health services or endoscopy is carried on *r.37(2) lists the information to be contained in the register.	30	\$5,769.30
r.38(1)	Not keeping a Birth Register* where obstetrics may be carried on *r.38(2) lists the information to be contained in the register.	30	\$5,769.30
r.38(3)	Not retaining the Birth Register for at least 25 years after date of last entry.	30	\$5,769.30

Regulation	Offence description	Penalty units	Amount ⁵⁵
r.39	Not putting signage at room entrances to indicate the room's letter or number and the number of beds and recovery chairs ordinarily in that room.	10	\$1,923.10
r.40(1)	Not operating an effective electronic communication system* at a registered premises *r.40(2) specifies the purpose and required functionality of the system.	60	\$11,538.60
r.41	Not installing a system or mechanism to control hot water temperature to avoid patient scalding.	50	\$9,615.50
r.42	Not ensuring premises are kept clean, hygienic, in proper state of repair and free of hazards or materials that may become offensive, injurious to health or facilitate fire outbreaks.	80	\$15,384.80
r.43(2)	Not ensuring facilities, equipment, furnishings and fittings are maintained in good working order and kept clean and hygienic.	80	\$15,384.80
r.44(1)	Not implementing and maintaining an Infection Control Management Plan* *rr.44(2) and 44(30) specify the purpose and requirements of the Plan.	80	\$15,384.80
r.45	Not prominently displaying the registration certificate, name of the DON and name of the CEO or Medical Director if appointed.	20	\$3,846.20
r.46A	Not reporting a sentinel event in required timeframe.	40	\$7,692.40

Appendix B – Response template

Review of the Health Services (Health Service Establishments) Regulations 2013 discussion paper – August 2023

OFFICIAL

The Department of Health (the department) is seeking feedback on the discussion paper, *Review of the Health Services (Health Service Establishments) Regulations 2013*.

You may use this template to submit your response or provide your feedback in another written format.

Any individual or organisation can make a submission.

Your submission can address one or more of the questions in the discussion paper that are relevant to you or your organisation. These questions are listed below to guide your submission. You do not need to address all the questions.

Your submission can also include feedback on any other elements of the Health Services (Health Service Establishments) Regulations 2013 (the Regulations) not covered by the questions.

Your submission may include facts, opinions, recommendations or suggested solutions to the questions.

When writing your submission, please:

- Be brief and clear. If your submission is long, it is helpful to include a summary of your key points on the first page. Please number the pages in your submission.
- Make it clear who the submission is from. If you are making a submission on behalf of an organisation, please indicate your position in the organisation and the level at which the submission has been authorised.
- Be relevant and appropriate. The department may choose not to accept a submission that is not relevant, is frivolous or contains offensive language or remarks.

Your name will only be published if you provide consent.

Material in your submission will only be published if you provide consent.

Making 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 midnight 24 September 2023.

Publication of submissions

All submissions will be considered public documents unless marked 'private and confidential'. They may be referred to in further consultation material developed by the department, including being

included in full or in summary in the Regulatory Impact Statement (RIS) that will be published on the department's website.

Clearly mark your submission 'private and confidential' if you are disclosing personal or other information that you prefer not to publish.

Alternatively, you can submit material marked 'private and confidential' in a separate attachment to non-confidential material that can be published.

You may withdraw consent for the department to publish all or part of your submission by emailing [Legislation and Regulation Reform](mailto:legandregreform@health.vic.gov.au) <legandregreform@health.vic.gov.au> before 8 October 2023.

Before publishing, the department will remove your contact details and may remove other personally identifying information from your submission.

The department reserves the right to not publish submissions for any reason including material that is offensive, potentially defamatory or out of scope for the consultation. The views expressed in the submissions are those of the individuals or organisations who submit them and their publication does not imply any acceptance of, or agreement with, these views by the department.

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.

Please read the collection notice below before completing a submission.

Privacy Collection Notice

The department is committed to protecting your personal information and privacy, and any 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 *Review of the Health Services (Health Service Establishments) Regulations 2013 – discussion paper*. This information will be used to prepare for further consultation, including a Regulatory Impact Statement (RIS) and an exposure draft of proposed Regulations.

The department may engage a third party to help develop the RIS. The department may share your submission, and any personal information you provide, with the third party. All parties are committed to protecting the personal information provided by you, in accordance with Victorian privacy laws.

If you provide your personal information (e.g. name, title, role), you can choose whether we publish these details by ticking the appropriate field in the response template.

You can choose to make an anonymous submission. However, you will need to provide your contact details if you would like the department to advise you of the outcome of the consultation.

Material in submissions – including those made anonymously – may be published unless you clearly mark it 'private and confidential'.

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:legandregreform@health.vic.gov.au) <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.

Contact details

Question	Your response
Name and title (optional)	
In what capacity are you making this submission?	Consumer of health services <input type="checkbox"/> Registered private hospital <input type="checkbox"/> Registered day procedure centre (including mobile services) <input type="checkbox"/> Member of a professional association or peak body <input type="checkbox"/> Regulator or government agency <input type="checkbox"/> Other – please state below
Organisation / association / peak body / regulator / government agency (if relevant)	
Are you authorised to provide this response on behalf of your organisation?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Email address (optional)	
Would you like to remain anonymous if material in your submission is published?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Would your organisation like to remain anonymous if material in your submission is published?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Do you/your organisation consent for material in your submission to be published on the department's website? NOTE: We will not publish any text marked 'private and confidential'.	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Do you/your organisation consent for material in your submission to be shared with a third party engaged to develop a Regulatory Impact Statement?	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>
Do you wish to be advised of the outcomes of this review? If you answer 'yes', you must provide an email address above.	Yes <input type="checkbox"/> No <input type="checkbox"/> N/A <input type="checkbox"/>

Questions for public comment

Question	Comment
Health service definitions and scope	
1.	Are the definitions for medical health service, surgical health service, speciality health service, anaesthesia, renal dialysis, and emergency medicine clear, current, workable, and effective?
2.	<p>Are additional definitions of prescribed speciality health services needed in the Regulations to address ambiguity?</p> <ol style="list-style-type: none"> If not, why? If so, can you provide details about what issues you experienced or expect due to ambiguity about the meaning of a prescribed speciality health service? If additional definitions are needed to reduce ambiguity, which speciality health services should be defined and what authoritative source should the definition draw on? Do you consider clarification is required in relation to the terms 'alcohol or drug detoxification (detoxification – acute phase)' or 'mental health services'? If so, please provide details of the ambiguity or clarification needed.
3.	Do you support amending the Regulations to define cosmetic surgery as a type of health service? If yes, why? If not, why not?
4.	Do you have any other comments about the scope of prescribed speciality health services in the Regulations and any current or anticipated future impacts on quality, safety and access to health services?
Registration and accreditation	
5.	Do you have any comments about the registration of private hospitals and day procedure centres (noting that amendments to registration criteria or other provisions in the Act are outside

Question		Comment
	the scope of this review of the Regulations)?	
6.	Do you have any comments about the role accreditation to the NSQHS Standards plays in ensuring the safety and quality of health services provided by private hospitals and day procedure centres?	
7.	In relation to the accreditation process, are there opportunities to better communicate the respective roles of the Commission, accreditation assessment bodies and the department?	
8.	Do you support amending the Regulations to require health service establishments to display their accreditation certificate in a prominent place? If not, why not?	
9.	Do you see any role for additional accreditation schemes to supplement quality and safety requirements under the Act, Regulations and NSQHS Standards? If yes, which ones and why? What would be the impact on private hospitals and day procedure centres (for example, in terms of additional costs, involvement of third-party accreditation agencies)?	
10.	Do you have any comments on the penalties and sanctions related to registration and accreditation (noting amendments to the Act are beyond scope of this review but feedback on this issue may inform decisions on any future reforms)?	
Clinical governance		
11.	Do you support private hospitals and day procedure centres being required to comply with the Safer Care Victoria Victorian Clinical Governance Framework? If yes, why? If not, why not?	
12.	Are there elements of the Victorian Clinical Governance Framework that might require clarification or adjustment in order to apply effectively to private hospitals and day procedure centres?	

Question	Comment
13. What impacts on private hospitals or day procedure centres do you anticipate this requirement would have?	
14. Do you support private hospitals and day procedure centres being required to comply with SCV's <i>Credentialing and scope of clinical practice for senior medical practitioners policy</i> ? If yes, why? If not, why not?	
15. What impacts on private hospitals or day procedure centres do you anticipate this requirement would have?	
16. Do you support mandating the <i>Guideline for providers of liposuction; best practice guideline for clinicians, and those involved in the provision of liposuction</i> through the Regulations instead of through a direction from the Secretary? If yes, why? If not, why not?	
17. Do you support a requirement in the Regulations that the clinical governance protocols of a health service must set out the roles and responsibilities of key clinical leadership positions? If not, why not? If so, which positions do you consider should be addressed in the protocols?	
18. Do you consider that the current use of clinical staff not directly employed, to work in private hospitals or day procedure centres, may pose a risk to patient safety? a. If yes, why? If not, why not? b. Are there actions that can be taken to mitigate this risk?	
19. Do you support amending the Regulations to require that the clinical governance protocols of a health service establishment must set out how staff and VMO fatigue (including cumulative fatigue arising from work undertaken at multiple facilities) is monitored and managed? If yes, why? If not, why not?	
20. Do you have any comments on the benefits and implications of setting (in clinical governance protocols or centrally in government requirements) a maximum surgical list length?	

Question		Comment
21.	Do you support amending the Regulations to include mandatory requirements for the ongoing education of nursing and midwifery staff working at private hospitals and day procedure centres. If so, why? If not, why not?	
22.	How does the requirement for a committee with responsibility for quality and safety currently work in practice across diverse private hospitals and day procedure centres?	
23.	Could mandatory requirements in the Regulations for the committee responsible for quality and safety improve patient safety – for example, a minimum meeting frequency of once every three months or a requirement for a Chair with no financial interest in the health service?	
24.	Do you support amending the provisions for quality and safety protocols in the Regulations to include a requirement that these protocols include processes for assessing the reliability, availability and timeliness of adjunct diagnostic services, whether provided by the health service establishment or an external supplier. If yes, why? If not, why not?	
Staffing requirements		
25.	Do you support amending the Regulations so that the appointment now titled 'Director of Nursing' can be 'however titled' if the position has the qualifications, experience, and authority of the nurse who is in charge of clinical services in the facility. If so, why? If not, why not?	
26.	In relation to the qualifications and experience requirements of the Acting DON, which of the below options do you support and why: Option 1 – maintain the status quo – no qualifications or experience requirements in Regulations, and no limit on the length of time that an Acting DON can be appointed for. Option 2 – require the Acting DON to meet the same qualifications and experience requirements of the DON,	

Question	Comment
<p>which are that they are a registered nurse, and have 12 months practical experience in nursing management, and have at least five years clinical experience as a registered nurse).</p> <p>Option 3 – enable the position of Acting DON to be used to upskill staff.</p>	
<p>27. If the Acting DON is <i>not</i> required to have the same level of experience and qualifications as the DON, would you support a requirement that an Acting DON appointment is for a maximum of 12 months. If so, why? If not, why not?</p>	
<p>28. To ensure adequate nursing supervision by a suitably qualified person, which of the following options do you support, and why / why not?</p> <p>Option 1 – status quo – no change to requirements in the Regulations.</p> <p>Option 2 – require a DON or nominated nurse in charge with the same qualifications and experience as the DON to be:</p> <ul style="list-style-type: none"> • on-site at all times in private hospitals • on-site for a minimum number of hours each week in day procedure centres. What might be an appropriate number of hours? <p>Option 3 – for private hospitals and day procedure centres, require a nurse with at least three years relevant clinical experience to be on-site to supervise the provision of medical health services?</p>	
<p>29. For day procedure centres, would you support there being a maximum number of facilities that a DON can be nominated for? If so, why and what might be an appropriate number? If not, why not?</p>	
<p>30. Would you support a requirement in the Regulations about the hours a DON must devote to non-clinical activities. If so, why, and which of the below options do you support and why:</p> <p>Option 1 – maintain the status quo – no minimum non-clinical hours requirements in Regulations.</p>	

Question	Comment
<p>Option 2 – amend the Regulations to mandate the minimum hours that the DON must devote to non-clinical activities – for example, one non-clinical day per week.</p> <p>Option 3 – amend the Regulations to require clinical governance policies to address how the DON will undertake their non-clinical duties.</p>	
<p>31. Do you support including a requirement in the Regulations for private hospitals with 200 or more overnight beds or that have an intensive care unit, emergency department, or acute rehabilitation ward to have an on-site Medical Director (however named)? If yes, why? If not, why not?</p>	
<p>32. Do you support including a requirement in the Regulations that an on-site Medical Director (however named) responsible for a private hospital with 200 or more overnight beds cannot be responsible for any other facilities? If yes, why? If not, why not?</p>	
<p>33. Do you support requiring a private hospital to have an on-site Chief Executive Officer if it has 200 or more overnight beds? If yes, why? If not, why not?</p>	
<p>34. Do you support any requirements for additional required senior appointments such as hospitals that provide maternity services being required to appoint a Director of Midwifery or a Midwife in Charge, or a requirement to appoint a Chief Executive Office or Medical Director (however named)? If yes, why? If not, why not?</p>	
<p>35. Sufficient nursing staff for private hospitals:</p> <p>In relation to the minimum nurse-to-patient ratios, which of the below options do you support and why:</p> <p>Option 1 – maintain the status quo – no changes to the current minimum nurse-to-patient ratios required by the Regulations.</p> <p>Option 2 – increase the general minimum nurse-to-patient ratios required by the Regulations for</p>	

Question	Comment
<p>private hospitals, and introduce minimum nurse-to-patient ratios for high dependency units, intensive care units and emergency departments.</p> <p>Option 3 – amend the Regulations to require the that the clinical governance policies and procedures of a facility must set out staffing arrangements, including nurse-to-patient ratios, for high dependency units, intensive care units and emergency departments, with minimum nurse-to-patient ratios for the other wards specified in the Regulations.</p> <p>Option 4 – amend the Regulations to require that the clinical governance policies and procedures of a facility must set out all staffing arrangements, including minimum nurse-to-patient ratios. Current nurse-to-patient ratios in the Regulations would be removed.</p>	
<p>36. Sufficient midwifery staff:</p> <p>In relation to the minimum number of midwives to be working in antenatal, delivery suites, and post-natal wards when patients are admitted, which of the below options do you support and why:</p> <p>Option 1 – maintain the status quo – no changes to the Regulations and the Regulations would not mandate minimum midwife-to-patient ratios.</p> <p>Option 2 – amend the Regulations to insert a minimum requirement of 2 midwives for every 3 patients in birthing suites.</p> <p>Option 3 – amend the Regulations to require hospitals that provide maternity services to ensure there is at least 1 midwife on the ward whenever there is a maternity patient admitted or when a birth is in progress with the staffing arrangements further detailed through clinical governance policies.</p>	
<p>37. Sufficient critical care registered nurses:</p> <p>Do you support requiring that the number and deployment of CCRNs, linked to the type and acuity of patients</p>	

Question		Comment
	receiving health services, must be included in clinical governance policies and procedures of private hospitals?	
38.	Sufficient nursing staff for day procedure centres: Do you think the current nurse-patient ratios for DPCs in the Regulations are fit for purpose? If not, why not?	
39.	Sufficient overnight clinical staff: Do you support amendments to the Regulations requiring that all overnight hospitals must have a medical practitioner or nurse practitioner on-site 24 hours a day, separately from persons engaged to work in a private hospital's Emergency Department or Intensive Care Unit? If so, why? If not, why not? If not, would you suggest including an alternative requirement in the Regulations to address any risk to patients?	
Pre-treatment clinical assessment and discharge of patients		
40.	Should the Regulations be amended to require that patients receiving mobile health services (such as from a mobile anaesthetist) must undergo a pre-treatment clinical risk assessment (noting that in practice this generally already occurs with patients who receive mobile anaesthetic services)? If so, why? If not, why not?	
41.	Should the Regulations be amended to require a pre-admission clinical risk assessment to be reviewed/assessed/finalised by a clinical staff member? If so, why? If not, why not?	
42.	Should the Regulations be amended to require that the proprietor of a registered private facility must ensure the anaesthetist reviews the pre-admission clinical risk assessment before a patient commences treatment for planned procedures that involve anaesthesia, noting that the department understands that in practice this generally already occurs? If so, why? If not, why not?	
43.	Should the Regulations be amended to require that the full pre-admission	

Question		Comment
	clinical risk assessment be recorded in writing and retained rather than just the result of the assessment, noting that the department understands that in practice this generally already occurs? If so, why? If not, why not?	
44.	What impacts has the current requirement (introduced in 2018) to include all medications currently prescribed in a patient's discharge summary had on private hospitals, day procedure centres, and patients?	
45.	<p>Should the Regulations be amended to replace the requirement to include all medications currently prescribed to a patient with the below requirements? If so, why and if not, why not?</p> <ul style="list-style-type: none"> a. For private hospitals – a full list of prescribed medications, irrespective of whether the medication is in relation to the health service received at the health service establishment, must be on the patient's discharge summary if they stay one or more nights in the facility. b. For private hospitals – any changes or additions to prescribed medications must be on the patient's discharge summary for patients who are discharged within one day. c. For day procedure centres – any changes or additions to prescribed medications must be on the patient's discharge summary. 	
Registers and records		
46.	Should the Regulations be amended to require that the operation theatre register be used to record all surgical health services or speciality health services carried out in operating theatres and procedure rooms? If so, why? If not, why not?	
47.	Given advancements and changes in record keeping systems, is the specific requirement to keep an operation theatre register still fit for purpose?	
Mandatory reporting to the department and Safer Care Victoria		

Question	Comment
48. Should the Regulations be amended to require private hospitals and day procedure centres to report to the department transfers out of patients? If so, why? If not, why not? What would you consider an appropriate threshold for such a reporting requirement (i.e. which transfers should be reportable)?	
49. If day procedure centres were required to report to the department any transfer out of patients due to significant deterioration, how often or quickly should the reports be made to the department, and what key information should be provided?	
50. Do you have any comments regarding the proposal to mandate sentinel event reporting via an approved pathway (currently the Sentinel event portal)?	
51. Noting that amendments to the Act are beyond scope of this review, but acknowledging that the protections in the Act are relevant to any mandate for SAPSE reviews, do you find the current legislation (the Act) has sufficient protections in place to ensure rigorous and transparent review processes of adverse incidents? If not, why not?	
52. Do you have any comments regarding the proposal for health service establishments to have protocols that align with Safer Care Victoria's <i>Adverse Patient Safety Event Policy</i> ?	
53. Do you foresee any barriers for health services to comply with a requirement to have an independent person on their SAPSE review panel should they choose to conduct a protected review?	
54. Do you foresee any barriers for health services to conduct a review using an approved methodology (for example, root cause analysis, London Protocol or in-depth case review) for all sentinel events and SAPSEs?	
55. If data-reporting systems were free and/or integrated do you see any barriers for private health services to report all adverse events through VHIMS? Do you see a value in	

Question		Comment
	receiving tailored performance reports from VAHI?	
56.	Do you support the Regulations being amended so that information relating to adverse events recorded and reviewed under r.48 is available to the Secretary upon request?	
57.	Do you have any comments regarding the proposal to maintain the existing regulation (r.32A) regarding open disclosure?	
58.	Do you support the Regulations being amended to require that a day procedure centre providing mobile services (such as mobile anaesthesia) is required to report annual data to the department?	
59.	Do you think the listed data points are appropriate? Are there other metrics that would support risk-based monitoring of the services provided?	
60.	Do you have any comments regarding the burden of reporting this data?	
61.	Do you have any comments regarding the current process of reporting data to VICNISS?	
The patient experience: rights, informed care and complaints		
62.	Do you have any feedback or suggestions for improvements or additions to any of the Regulations related to patient rights, informed care and complaints? If yes, please reference the regulation number in your response.	
63.	Would you support a requirement in the Regulations for de-identified data about complaints to be reported, or made available, to the Secretary, to inform risk-based monitoring of service safety? If so, why? If not, why not?	
64.	What would be the benefits and/or implications of health service establishments adopting the Partnering in healthcare framework alongside the existing patient engagement policy? Would that constitute a significant shift from current arrangements?	
Offences, penalties and sanctions		

Question	Comment
65. Do you have any feedback on the existing penalty offences and penalty amounts in the Regulations (as summarised in Appendix A – Penalties and offences in the Regulations)? If yes, please reference the regulation number in your response.	
66. Do you have any suggestions for additional offences and penalties that could be prescribed in the Regulations?	
67. Do you support the introduction of infringements to allow the department to deal with less serious breaches in a way that is swift, direct and proportionate to the offence? If yes, why? If not, why not?	
Other issues	
68. Do you have any preliminary comment on the fees set out in the Regulations?	
69. Should the Regulations be amended so that health service establishments must ensure treatment agents are available for clinical emergencies that require pharmacological intervention – for example, treatments specific to anaesthesia. If so, why? If not, why not?	
70. Are there any other issues related to the Regulations that have not specifically been raised in this discussion paper that you would like to raise with the department?	
71. Do you agree that the requirements in the Regulations to prevent scalding of patients (r.41) can be removed from the Regulations without impacting on the delivery of safe health services?	
72. Are there any other specific areas of the Regulations that you would like to raise with the review team as a requirement that may be duplicative, unclear or contain an error?	