Regulatory Impact Statement for the Health Services (Health Service Establishments) Regulations 2024

Prepared for the Victorian Department of Health

29 April 2024

Contents

Glossary

Abbreviation	Stands for
AHPRA	Australian Health Practitioner Regulation Agency
The Commission	Australian Commission on Safety and Quality in Health Care
BRV	Better Regulation Victoria
The department	Victorian Department of Health
HSEs	Health service establishments
MCA	Multi criteria analysis
NSQHS Standards, the Standards	National Safety and Quality Health Service Standards
OECD	Organisation for Economic Co-operation and Development
RCA	Root Cause Analysis
RIS	Regulatory Impact Statement
SAPSE	Serious Adverse Patient Safety Event
SCV	Safer Care Victoria
SDC	Statutory Duty of Candour
SL Act	Subordinate Legislation Act 1994
Targeting Zero report	*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*
The current Regulations, the Regulations	Health Services (Health Service Establishments) Regulations 2013
The Accreditation Scheme	The Australian Health Service Safety and Quality Accreditation Scheme
The Act	Health Services Act 1988
VAHI	Victorian Agency for Health Information
VAED	Victorian Admitted Episodes Dataset

Foreword

This Regulatory Impact Statement (RIS) has been prepared with respect to the proposed Health Services (Health Service Establishments) Regulations 2024.

The RIS should be read in conjunction with the proposed Regulations, which are provided as a separate document.

This RIS sets out the objectives of the proposed Regulations, explains their effect and assesses the nature and scope of the problem that the proposed Regulations seek to address. It also sets out the likely impacts (costs and benefits) and discusses alternatives.

How to respond to the proposed Regulations

Interested individuals and organisations are invited to make submissions responding to the RIS or the proposed Regulations.

To assist stakeholders to prepare and submit a response, the Department has created a template that outlines all the updates being made to the Regulations in this process and seeks feedback in particular on anticipated impact of the proposed updates to the Regulations and any matters that should be taken into account in implementing the proposed changes. The template is optional.

The closing date for submissions is 29 May 2024.

Comments may be provided via email to the following email address: legandregreform@health.vic.gov.au

For further assistance about the public comment process, or to obtain copies of the RIS and proposed Regulations, please contact the relevant team at the Department of Health on legandregreform@health.vic.gov.au.

Executive summary

Context

Private hospitals, day procedure centres and mobile health services (known as health service establishments or HSEs) are a significant part of health service delivery in Victoria. In 2021-22, 1.08 million separations[1] in Victoria occurred in private hospitals or 37% of all hospital separations.[2]

The *Health Services Act 1988* (the Act) (primarily Parts 4 and 5A) and Health Services (Health Service Establishments) Regulations 2013 (the Regulations) for the safety and quality of patient care in Victoria's private hospitals and day procedure centres. Under the Act and Regulations, the Secretary to the Department of Health (the department) is the regulator of HSEs. A HSE cannot commence operation (or continue operation), nor admit patients unless the premises are registered under the Act.

The Regulations are due to sunset on 1 September 2024 and a Regulatory Impact Statement (RIS) is required to support development of the Health Services (Health Service Establishments) Regulations 2024 (the proposed Regulations).

The Department of Health (the department) has undertaken a sunsetting review, which has informed the development of this RIS, to determine whether the Regulations are fit for purpose and meet the objectives of the regulatory scheme.

The sunsetting review process has included extensive policy analysis of key elements of the Regulations. A discussion paper seeking stakeholder feedback on potential reforms to the Regulations was published in August 2023.[3] Following consideration of the stakeholder engagement led by the department and an analysis of options, this RIS presents the case for remaking the Regulations, with a number of targeted improvements to address issues that arose in the review. As set out below a further period of consultation and policy development will be undertaken to inform a second set of updates to the Regulations to address other issues that arose in the review. This will ensure the Act and Regulations can continue to operate as intended and provide for foundational requirements for the safety and quality of patient care.

The Act and the Regulations for private hospitals and day procedure centres were last significantly reviewed and amended in 2017 and 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)[4], which

[1] Separation - The process by which an episode of care for an admitted patient ceases (AIHW definition https://meteor.aihw.gov.au/content/327268)

[2] Australian Institute of Health and Welfare (2023) *Admitted patient care 2021-22 2 How much admitted patient activity?* Australian Government.

[3] *Review of the Health Services (Health Service Establishments) Regulations 2013 Discussion Paper – August 2023*, Department of Health, August 2023.

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

recommended a range of improvements to the hospital sector overall. The 2018 amendments to the Regulations were designed to reduce the risk of patient harm.

Problem analysis

The Regulations in their current form aim to address two main (and related) problems:

1. An underlying knowledge, information and power imbalance between patients and HSEs.
2. The need for system-wide information and system management.

While most healthcare in Victoria leads to good safety and quality outcomes, this is not always the case. Preventable adverse events do occur across the health system. Patients are not able to assess and control many relevant risk factors when seeking and receiving treatment, so they rely on effective safety and quality systems to be in place (at the facility and health-system level) to ensure risk of harm is minimised.

Additionally, if the Regulations were allowed to expire and no replacement Regulations put in place, the Act would not be able to operate as intended. For example, the registration scheme defined in the Act would not have meaning without the prescribed health services, and forms and fee schedules set out in the Regulations and more detailed foundational quality and safety requirements would not be imposed or enforceable. This would increase the risks to the safety and quality of care of patients receiving health services in HSEs.

Objectives

The proposed Regulations are made under the *Health Services Act 1988*, the purpose of which is to make provision for the development of health services in Victoria, for the carrying on of hospitals and other health care agencies and related matters.

The primary objective of these Regulations is to provide for the safety and quality of care of patients receiving health services in HSEs.

The secondary objective of the Regulations is to prescribe fees, forms and other matters as required under the *Health Services Act 1988* in relation to HSEs. This provides the mechanisms by which HSEs meet their requirements under the Act.

Preferred option and options analysis

The department has undertaken detailed policy analysis across many elements of the Regulations. This has drawn on research and stakeholder engagement on proposals as set out in the department's discussion paper, published in August 2023.

The preferred option is to remake the Regulations largely in their current form and structure, with targeted improvements as set out in Table i below. In addition, reform proposals raised in the review and consultation, which related to workforce requirements in the Regulations and to the services that are prescribed and defined as in scope of the Regulations, are being considered further. The department will undertake additional consultation and impact assessment on these matters. Any amendments to the Regulations to address those matters will be progressed separately after the proposed updated Regulations are made, and will then be subject to appropriate impact assessment.

Options for changing the Regulations were compared with a Base Case (allowing the Regulations to sunset) and an alternative option (remaking the Regulations with no targeted amendments). These options were assessed against their impact on the following criteria:

- protects the safety and quality of care of patients receiving health services in HSEs
- cost to HSEs; and cost to government.

The proposed amendments to the Regulations build on the program of regulatory reform that has been occurring in the Victorian health sector in recent years since the Targeting Zero Report.

Table i Proposed amendments to the Regulations

Topic area	Proposed amendments
Clinical governance	Regulation 7A would be re-made, with the following amendments: • add regulations allowing the Secretary to review the required clinical governance protocols and issue directions for updates to the protocols[5]. For transparency, the Secretary may have regard to best practice guidance that has been formally identified by the Secretary as relevant for such reviews • include additional matters that must be addressed in the protocols that HSEs are required to have in place.
Sentinel events reporting and review	• Amend regulation 46A to specify that sentinel events must be reported in the manner directed by the Secretary. It is intended that the Secretary will direct the SCV Online Portal as the mechanism for reporting • Insert a new provision that requires the proprietor of the HSE to ensure that each sentinel event is subject to a review and reports from the review are provided to the Secretary, with the review process requirements and timeframes for reporting to be specified by the Secretary. It is intended that the requirements to be specified will be those set out in the SCV Sentinel Events Guide and Adverse Patient Safety Event Policy.
Admissions assessment	Regulation 20A would be remade with the following amendment: • clarify the pre-admission clinical risk assessment must be completed by a registered health practitioner • require the matters considered and assessed in the pre-admission clinical risk assessment to be recorded (not just the results) • clarify that for a HSE that does not formally admit patients, but which provides prescribed services, a pre-presentation clinical risk assessment must be completed and recorded at least 24 hours prior.
Infringements	New infringement offences would be prescribed in the Regulations.

[5] HSEs are currently required to prepare health service protocols for quality and safety under regulation 7A. 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.

Fees	Remake the currently prescribed fee units with no change except for the introduction of a fee for applications to use particular land or premises as a private hospital or day procedure centre, which is a minor change.

Implementation

The proposed Regulations remake the existing Health Services (Health Service Establishments) Regulations 2013, with amendments as considered in this RIS. Based on the analysis in this RIS, the department is recommending remaking the Regulations with targeted improvements.

The department will be primarily responsible for implementation of the proposed changes.

Key aspects of the implementation plan are:

1. finalise the remade Regulations
2. develop and implement the proposed additional oversight of clinical governance through review of protocols by the Secretary (see proposed amendment in section 6.1)
3. develop and implement new compliance and enforcement policy
4. education and communication with industry on the amendments to the Regulations.

It is proposed that the commencement of substantial new provisions in the Regulations may be some time after the new Regulations are made to allow time for the department and facilities to prepare for implementation. Responses to this RIS on implementation issues will inform final decisions on the commencement date for relevant provisions.

Evaluation

The department will develop an evaluation plan including consideration of how to best ensure a baseline dataset to allow comparative analysis for any future proposed reforms. This will include considering available data and data gaps to assess any potential gaps in evidence.

1. Background

This chapter outlines the multi-faceted regulatory framework applying to HSEs, the context for regulatory changes being considered, and the need for and approach to undertaking this RIS.

Following analysis of options and a stakeholder engagement process led by the Department of Health, this RIS presents the case for remaking the Regulations with a number of targeted improvements. These build on significant regulatory reforms undertaken in recent years.

1.1 Context

1.1.1 Victorian private hospitals and day procedure centres

Private hospitals, day procedure centres and mobile health services (health service establishments, HSEs) are a significant part of health services delivery in Victoria. In 2021-22, 1.08 million separations[6] in Victoria occurred in private hospitals or 37% of all hospital separations.[7]

HSEs are facilities where patients are treated by a doctor of their own choosing and pay a fee for services (patients may have private health insurance to cover costs). They exist in response to a patient's willingness to pay to choose their own doctor and facilities, and to receive faster access to services compared to the public healthcare system. In 2021-22, 83% of hospitalisations in private hospitals across Australia involved privately insured patients.[8]

As of November 2023, there were 76 private hospitals, 97 day procedure centres and 28 mobile anaesthesia services registered in Victoria.[9] Private hospitals are owned and managed by private organisations – either by for-profit companies or not-for-profit non-government organisations (religious, charitable or community organisations). Day procedure centres tend to be operated on a for-profit basis. See Table 1 below for more detail.

[6] Separation - The process by which an episode of care for an admitted patient ceases (AIHW definition https://meteor.aihw.gov.au/content/327268)

[7] Australian Institute of Health and Welfare (2023) *Admitted patient care 2021-22 2 How much admitted patient activity?* Australian Government.

[8] Spending on admitted patients - Australian Institute of Health and Welfare (aihw.gov.au)

[9] Department of Health data. Note these figures include 3 bush nursing private hospitals, 3 alcohol and other drug establishments, and 1 Day Procedure Centre focussed solely on liposuction. These figures do not include 10 Approval in Principle establishments.

Table 1 Number of private hospitals and day procedure centres

	For profit	Not for profit	Total
Private hospitals	50	26	76
Day procedure centres	95	2	97
Mobile anaesthesia services	28	-	28
Total	**173**	**28**	**201**

HSEs are an important part of the provision of planned surgery[10] for both public and private patients.[11] Across Australia, 70% of planned surgeries in 2021-22 were performed in private hospitals.[12] One contributing factor is that total admissions involving planned surgery for public patients in private hospitals across Australia have increased significantly since the start of the Covid-19 pandemic, from 33,400 in 2019–20 to 52,100 in 2020–21 and then to 57,400 in 2021–22.[13] The pandemic caused unprecedented demand on emergency departments, hospital beds and the workforce, creating significant delays to planned surgery. Private hospitals were a significant part of the response to Covid-19 patients and to overall health system demand in Victoria.

This remains so: the Victorian Government has invested $1.5 billion to boost surgical activity, including working with the private sector to enable more patients to receive surgery in private hospitals as part of the Victorian Government's *COVID Catch-Up Plan*.[14]

How private HSEs differ from public hospitals

The health sector is diverse, with services provided differing greatly in their size and nature. Public hospitals are funded by both the state and federal governments, while private hospitals and day procedure centres are funded by many sources, including: federally-funded Medicare, the Department of Veteran's Affairs and the Pharmaceutical Benefits Scheme; as well as private health insurance funds, third party insurers, and patients.[15]

Relative to public hospitals, private hospitals treat lower acuity patients and have fewer unplanned admissions. The public hospital sector predominantly manages acute care separations, including those

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[10] In 2023, the department began using the term 'planned surgery' instead of 'elective surgery'. Planned surgery refers to planned surgical procedures that can be booked in advance. Source: Victorian Department of Health. *Planned Surgery Reform Blueprint*. October 2023.

[11] Elective surgery is planned surgery that can be booked in advance as a result of a specialist clinical assessment. Elective surgery is considered medically necessary, and may be required urgently, but is not conducted as a result of an emergency presentation. Source: Australia Institute of Health and Welfare, https://www.aihw.gov.au/.

[12] https://www.aihw.gov.au/getmedia/71d19036-8c1e-485d-9d93-6618780346ae/australia-s-hospitals-at-a-glance.pdf

[13] Spending on admitted patients - Australian Institute of Health and Welfare (aihw.gov.au)

[14] Victorian Department of Health. *Media release: COVID catch-up plan to deliver for patients*. 3 April 2022 (https://www.premier.vic.gov.au/covid-catch-plan-deliver-patients)

[15] https://www.betterhealth.vic.gov.au/health/servicesandsupport/hospitals-in-victoria

typically admitted through emergency departments—in 2021–22, just over 3 in 4 acute care separations in public hospitals were medical as opposed to surgical.[16] The public hospital sector accounts for most regional and remote hospitals. HSEs are more prevalent in metropolitan regions, with a concentration on surgical procedures which are planned or elective, with 94% of all surgical hospitalisations in private hospitals elective in 2021-22.[17]

Public and private healthcare services may be subject to different financial incentives as they receive funding from different sources. Differences in hospital size, location, and service offerings between public and private hospitals are influenced by factors such as their respective business models, legislative and other government requirements, and community expectations and preferences.

The Victorian government aims to ensure that public and private hospitals provide equally safe and high-quality care.[18]

1.2 Regulation of private hospitals and day care procedure centres

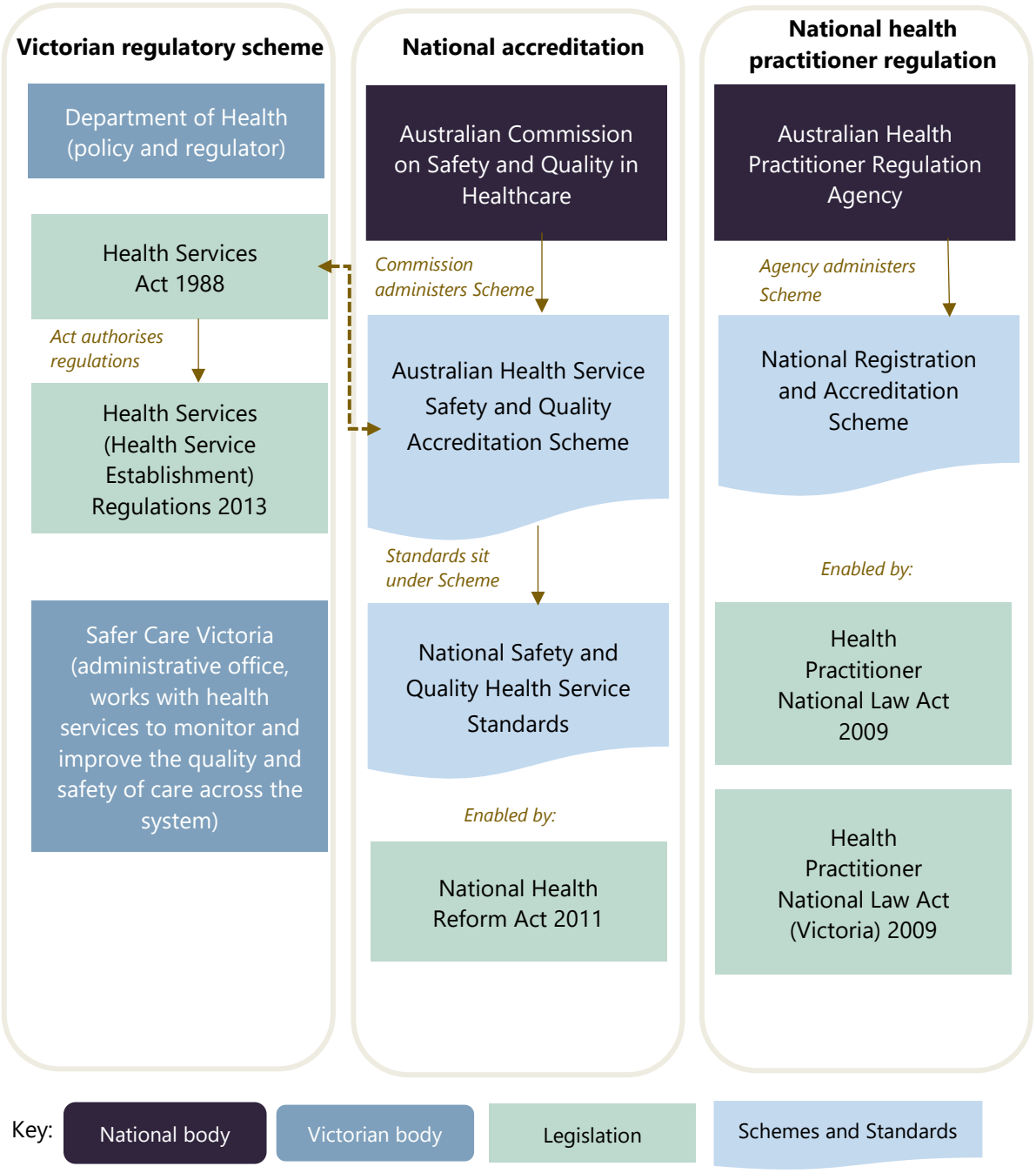
Victorian HSEs are subject to a range of regulatory and safety requirements. The Victorian regulatory scheme, established under the *Health Services Act 1988* (the Act) and Health Services (Health Service Establishments) Regulations 2013 (the current Regulations), works together with the Australian Health Service Safety and Quality Accreditation Scheme (the Accreditation Scheme) to safeguard patients receiving health services from risk of serious harm. National Law, relating to health practitioner regulation and accreditation, is also applicable.[19]

Figure 1 sets out a high-level overview of the quality and safety legislative framework for HSEs in Victoria. The dotted arrow represents the relationship between the Act and the Accreditation Scheme - namely, the Act allows for the approval of an Accreditation scheme under section 107, which HSEs must follow.

(Note that the above description and the below diagram do not cover all legislation applicable to HSEs (e.g. occupational health and safety laws) and are intended to give an overview understanding of the legislative framework for the purpose of this RIS.)

[16] https://www.aihw.gov.au/reports-data/myhospitals/intersection/activity/apc
[17] Ibid.
[18] Victorian Government. *Better Safer Care: Delivering a world-leading healthcare system.* October 2016.
[19] *Health Practitioner Regulation National Law Act 2009*.

Figure 1 High-level overview of quality and safety legislative framework in Australia (developed by Sapere for purpose of this RIS)



1.2.1 The Victorian regulatory scheme

The department administers a registration-based regulatory scheme for HSEs that is set out in:

- The *Health Services Act 1988* (the Act)
- The Health Services (Health Service Establishments) Regulations 2013 (the Regulations).

The purpose of the Act is to make provision for the development of health services in Victoria, for the operation of hospitals and other health care agencies and related matters.

Parts 4 and 5A of the Act establish the foundational requirements for the safety and quality of patient care in Victorian private hospitals and day procedure centres.

Under the Act, HSEs must be registered by the department before health services may be provided. In considering whether to register an HSE, the Secretary of the department is required by the Act to take a number of factors into account. These include whether the proprietor is a fit and proper person to carry on the establishment, the suitability of the premises, its design and construction, whether the proposed arrangements for the management and staffing are satisfactory and whether appropriate arrangements have been, or will be, made for evaluating, monitoring and improving the quality of the health services provided by the establishment.[20]

The Regulations are made under section 158 of the Act. The main objective of the current Regulations is to provide for the safety and quality of patient care in HSEs. The Regulations support this objective by setting requirements for key drivers and safeguards of quality and safety, including in relation to

- clinical governance arrangements to be documented, established and complied with (being the systems and processes for monitoring, maintaining and improving quality and safety of services provided at the facility)
- arrangements to be in place regarding qualifications and competence of staff and adequacy of workforce
- clinical assessments to be conducted and recorded prior to treatment
- clinical records to be kept for management of patient care and organisational records to be kept and reviewed for management and improvement of quality and safety of care at the facility
- requirements for care to be patient-centred – for example requirements for information to be provided to patients in relation to their care and related costs, and in relation to the facility, and requirements to consider and accommodate patient attributes and needs and have a process for patient complaints
- premises, equipment, operational plans and consumable supplies to be in place
- reporting data and information to the Secretary, to allow monitoring and oversight of safety and quality indicators and of compliance with the Act and Regulations.

[20] The criteria which must be considered by the secretary are set out fully in section 71 of the Act.

This regulatory scheme provides the department with legal powers to monitor and enforce foundational requirements for patient safety and quality of care requirements. Under the scheme, the department:

- manages the lifecycle of approvals-in-principle for registration, 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).

The department – for a time through the Victorian Agency for Health Information (VAHI) and since February 2024 through its eHealth Division – also collects and manages data about hospital performance. This includes analysis and production of reports to inform oversight of quality, safety and performance, and to allow information to be shared across government and the healthcare system to build an accurate picture of hospital and health service performance.

1.2.2 Other Victorian government bodies

The department's role as regulator of HSEs is complemented by the functions of other Victorian government bodies 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 (SCV)

SCV was established in 2017 as an administrative office of the department, in response to the *Targeting Zero Report – a review of hospital safety and quality assurance in Victoria* (the Targeting Zero Review – see discussion of this review in section 1.3). It works with health services to monitor and improve the quality and safety of care delivered across the Victorian health system.

Health Complaints Commissioner (HCC)

The Health Complaints Commissioner (HCC) receives and manages complaints about healthcare and the handling of health information in Victoria. The purpose of the HCC is to support the consumer's voice and learn from complaints to help drive ongoing improvement in the quality of health services in Victoria. The HCC acts independently and impartially to investigate matters and review complaints data.

1.2.3 Australian Health Service Safety and Quality Accreditation Scheme

The Act requires that the proprietor of an HSE:

- must not, without reasonable excuse, fail to comply with the requirements of an applicable approved accreditation scheme (Section 107A)
- if notified that the proprietor's application for accreditation under an approved accreditation scheme is refused, must give notice of the refusal to the Secretary within 24 hours after receiving the notification (Section 107B).

For the purposes of these provisions, an approved accreditation scheme is one that has been approved by the Secretary under section 107 of the Act, by notice published in the Government Gazette and on the department's website.

The Australian Health Service Safety and Quality Accreditation Scheme (Accreditation Scheme) was approved by the Secretary in 2010.[21] The Accreditation Scheme is administered by the Australian Commission on Safety and Quality in Health Care (the Commission)[22].

The Accreditation Scheme provides for the national coordination of accreditation processes and sets out the responsibilities of accrediting agencies for assessing health service organisations against safety and quality standards. This includes the National Safety and Quality Health Service Standards (the Standards.

The Standards aim to protect the public from harms and improve the quality of health service provision. Implementation is mandated in all hospitals, day procedure services and public dental services across Australia. The second edition of the Standards has eight Standards which provide a nationally consistent statement about the level of care that consumers can expect from their health service provider:

- Clinical Governance Standard
- Partnering with Consumers Standard
- Preventing and Controlling Infection Standard
- Medication Safety Standard
- Comprehensive Care Standard
- Communicating for Safety Standard
- Blood Management Standard
- Recognising and Responding to Acute Deterioration Standard.

The Standards were developed through a collaboration of the Commission, the Australian Government, states and territories, the private sector, clinical experts, patients and carers.

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[21] Under Gazette Notice G 34, 23 August. This was agreed by Health Ministers in 2010.

[22] The Australian Commission on Safety and Quality in Health Care (the Commission) was formed under the *National Health Reform Act 2011*.

Australian, state and territory governments determine the health service organisations required to be assessed against the Standards. They receive data on the outcomes of assessment[23] of health service organisations and respond to emerging issues.

1.2.4 Role of the Victorian regulatory scheme and the National Accreditation Scheme

Both the Standards and the Regulations target the safety and quality of healthcare, addressing common issues like infection control, clinical records, and staffing requirements. However, the emphasis differs.

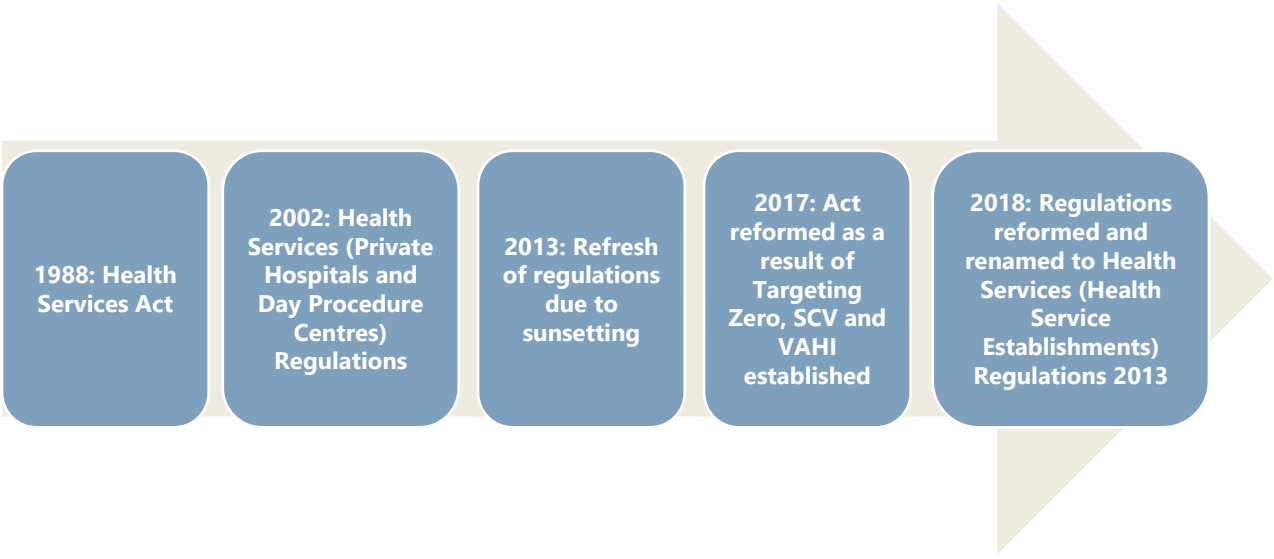
The Accreditation Scheme provides a quality assurance mechanism for HSEs. Accreditation assesses whether relevant systems are in place to meet the expected level of safety and quality standards and serves as a quality improvement tool to help facilities achieve developmental goals.

The Victorian regulatory scheme sets minimum compliance requirements for HSEs, and provides the department with a monitoring, oversight and enforcement framework. The department receives Standards accreditation reports for each HSE, including details about any actions that are 'not met' at initial assessment, in addition to assessment outcomes data reports. This data supplements the regulator's own compliance monitoring activities and informs its risk-based approach.

1.3 The history of legislative reform of HSEs in Victoria

Since the inception of the current Regulations, there has been a significant program of regulatory reform undertaken by the department to improve safety and quality of patient care outcomes.

Figure 2 Historical reform timeline since the introduction of the Health Services Act 1988[24]



[23] Qualified third parties approved by the Commission conduct the accreditation assessments and certifications.
[24] The predecessor legislation (prior to 1988) was the *Hospitals and Charities Act 1958*.

State government intervention in the Victorian hospital system over the past decade has been shaped by recommendations made following the cluster of perinatal deaths that occurred at Djerriwarrh Health Services in 2013 and 2014.

In March 2015 the Department of Health and Human Services was notified that a cluster of perinatal deaths had occurred at Djerriwarrh Health Services during 2013 and 2014. An expert review into the deaths was subsequently undertaken by a senior obstetrician, Professor Euan Wallace. Professor Wallace identified that seven of the deaths were avoidable or potentially avoidable, with many of them involving common and recurring deficiencies in care. The review identified that the health service had inadequate clinical governance and was not monitoring and responding to adverse clinical outcomes in a timely manner.

In response to this expert review the department commissioned a detailed and extensive analysis into how the department oversees and supports quality and safety of care across the Victorian hospital system, culminating in the 2016 report Targeting zero, the review of hospital safety and quality assurance in Victoria. The review found that the department had "relied too heavily on health services achieving accreditation to assure itself of quality and safety across the health system". The department has since classified accreditation as a requirement for public health services and has included additional quality and safety indicators in their service agreements (see further on regulatory amendments below the text box).

In response, the Victorian Government published *Better, safer care: Delivering a world-leading healthcare system* in 2016. The report set out a blueprint for achieving the recommendations set out by Targeting zero, and created new organisations, including SCV and VAHI.

As part of the Victorian Government's work to implement Targeting zero review recommendations, amendments to the Regulations were made in 2018[25], alongside reforms of the Act in 2017.[26] These reforms:[27]

- extended the scope of registration requirements to include what were then unregulated activities
- changed the focus of regulation so that the type of health service provided determines whether it must be registered, rather than the quantity of the service provided
- enabled registration requirements to be made broader and more flexible, and allowed for independent mobile services to be registered
- allowed the secretary to consider patient safety and quality at all times and allowed authorised officers to carry out inspections and investigations in response to safety and quality concerns
- strengthened the requirements for private sector services to maintain adequate safety and quality accreditation, enabling the secretary to publish in the Government Gazette an approved and mandated accreditation scheme and require private hospitals and day procedure centres to be accredited by such a scheme.

[25] Amended by the Health Services (Private Hospitals and Day Procedure Centres) Amendment Regulations 2018
[26] Amended by the Health Legislation Amendment (Quality and Safety) Act 2017
[27] Health Legislation Amendment (Quality and Safety) Bill, second reading speech, 21 June 2017

The now-proposed 2024 amendments to these Regulations, discussed in following sections of this RIS, build on the 2018 amendments and seek to improve the effectiveness of the response.

1.4 Sunsetting review

The **Regulations will expire (or 'sunset') on 1 September 2024**. To support the remaking of the Regulations and any potential changes to improve the Regulations, the department is undertaking a sunset review to assess whether the Regulations are fit for purpose and meet the objectives of safe, quality patient care. The review has included extensive policy analysis supported by a discussion paper in August 2023 seeking stakeholder feedback on potential reforms to the Regulations.[28]

The discussion paper requested feedback via 72 questions on current arrangements and policy proposals in relation to:

- Health service definitions and scope
- Registration and accreditation
- Clinical governance
- Staffing requirements
- Pre-treatment clinical assessment and discharge of patients
- Registers and records
- Mandatory reporting to the department and SCV
- The patient experience: rights, informed care and complaints
- Offences, penalties and sanctions
- Other issues including fees

Forty-six written submissions were received, with most submissions from either private hospitals or professional associations and peak bodies.

While varied views were expressed on different topics, a general theme across submissions was that the Regulations (together with the Accreditation Scheme[29]), remain fit for purpose in achieving the objectives of safety and quality of care of patients. Recommendations were made by some stakeholders about significant changes to staffing requirements, while there was some support for more prescriptive clinical governance requirements. The private hospital sector generally opposed significant change to the Regulations with some noting that there are already Standards and appropriate mechanisms in place to meet governance requirements in the Standards by the Commission and that implementation of proposed Regulation changes would cause further duplication both in reporting and oversight.

The department also engaged the Health Issues Centre (HIC) to consult people with lived experience about their expectations and experiences of regulation, and safety and quality in HSEs. Key themes from consumers were centred around communication, information, staff competence/expertise, timely response to adverse events and complaints, clinical governance, and fees. The department considers

[28] *Review of the Health Services (Health Service Establishments) Regulations 2013 Discussion Paper – August 2023*, Department of Health, August 2023.

[29] Which is out of scope of this RIS but is a critical element of the Victorian regulatory scheme.

that key themes cited as important by consumers are reflected in the current Regulations and align with the department's proposed improvements.

> The HIC's Consumer Interviews Report (December 2023) found that "it is clear…that consumers have a lot to say when it comes to quality and safety in health care. The key themes regarding communication and information, competence and expertise of staff, patient centred care, timely response to adverse events and complaints, clinical governance and fees show that consumers have significant experience and expertise in helping to inform the review of the Regulations."

Following this consultation program, the department undertook additional detailed analysis and targeted information sessions and consultations with key stakeholders to further refine its policy proposals. Key areas of policy development were around clinical governance, workforce and staffing requirements and the scope of the Registration scheme (see discussion below).

Drawing on this extensive review, the department considers that the current Regulations are necessary to ensure the Act can continue to operate as intended. For example, the registration scheme defined in the Act would not have meaning without the prescribed health services, forms and fee schedules set out in the Regulations.

The review has also identified the ongoing need for regulations to set requirements for key elements of quality and safety, as they currently do.

The review identified some areas of the Regulations that should be updated and strengthened as set out in this RIS, to ensure that the relevant objective of the Regulations is best achieved.

In addition, the review considered the elements of the Regulations that set out workforce and staffing requirements and those that determine the scope of the Registration scheme in the Act (that is, the provisions that list and define the types of services that must be provided in a registered facility). Consultation and policy analysis raised important questions about the best settings of the Regulations to achieve the desired safety outcomes without undue restriction on service delivery:

- On workforce requirements, there has been feedback that the minimum staffing requirements currently in the Regulations do not reflect the workforce arrangements necessary to support patient safety. There has also been feedback about the potential adverse impact of general and prescriptive regulatory requirements on these matters, including on the viability of facilities and therefore availability of services.
- On the services that are listed and defined in the Regulations to determine the scope of the Registration requirement, there has been feedback on a range of possible clarifications or additions, including in relation to cosmetic surgery, which raise factual and policy questions about how best to define the services that should only be delivered in or from a registered facility.

In light of this, updates to those elements of the Regulations are still under active consideration. The department will conduct further consultation and policy analysis to inform proposals for further updates to the Regulations, which will then be subject to appropriate impact assessment.

1.5 Purpose of this Regulatory Impact Statement

Under the *Subordinate Legislation Act 1994* (SL Act), a RIS is required to be prepared for proposed regulations that are expected to have a significant impact. The responsible Minister must ensure a RIS is prepared for public consultation.

The department engaged Sapere Research Group to prepare this RIS in accordance with Better Regulation Victoria's (BRV) Victorian Guide to Regulation[30] and the SL Act.

The key purpose of this RIS is to assess the impact of different options for replacing the current Regulations. The rigorous assessment of regulatory proposals within a RIS ensures that regulation best serves the Victorian community. The general approach to the assessment, as per the Guide to Regulation, is:

1. Identify the problem	2. Identify options to achieve the objectives	3. Options analysis	4. Assess other impacts	5. Implement and evaluate
We considered the nature and extent of the problem that the proposed Regulations aim to address	Options that could address the defined problems were identified	Costs and benefits of options were assessed, and a preferred option was identified	We considered the likely small business and competition impacts of the preferred option	The arrangements for implementation and evaluation of the preferred option are described

1.5.1 Stakeholder consultation

Further feedback on the proposed Regulations and RIS will be sought through a public comment process.

1.5.2 Public comment

The proposed Regulations and this RIS will be released for 28 days to provide individuals, organisations regulated under the proposed Regulations and other key stakeholders the opportunity to provide feedback. The process for responding to the RIS is outlined in the foreword to this report.

The department welcomes and will consider all submissions received during the period of public comment. The department will prepare a Response to Public Comment summarising the submissions

[30] Office of the Commissioner for Better Regulation, 2016, Victorian Guide to Regulation: A handbook for policy makers in Victoria, Department of Treasury and Finance, Melbourne.

received and its response, including a decision on whether any amendments to the proposed Regulations are needed. Submissions to the review, and the Response to Public Comment document, will also be made available on the department's website.

Interested parties are encouraged to provide any views on the proposed Regulations. In particular,

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

2. Nature and extent of the problem

The Regulations, proposed to be retained with targeted improvements, aim to address two main (and related) problems:

1. An underlying knowledge, information and power imbalance between patients and HSEs
2. The need for system-wide information and system management.

While most healthcare in Victoria leads to good safety and quality outcomes, this is not always the case. Preventable adverse events do occur across the health system. Patients are more vulnerable when seeking treatment, and hence their interests need to be protected.

This section outlines the implications of each problem, as well as the ways regulation addresses and mitigates against risks of patient harm; that is, on the underlying need for the Regulations. Specific problems to be addressed through targeted improvements are discussed in more detail in chapters 5 to 10.

2.1 Information asymmetry between patients and HSEs

Knowledge imbalance or 'information asymmetry' occurs when a service provider has more information or knowledge than the consumer of those services. In the case of healthcare, patients may not have access to the information they require to make decisions that are in their best interests. They rely on those delivering the services and the arrangements in place for management of the facility to keep them safe and informed.

Health services require specialist expertise provided by health practitioners who have substantially more relevant knowledge and information than the consumer of the services. Most patients are not clinical experts, so they rely on health practitioners (e.g. doctors, specialists, nurses, midwives) for information about their condition, treatment options, risks, likely outcomes and ongoing care.

In addition, the nature of the services means that patients do not control all the factors that might minimise the risk that they will be harmed while receiving care. This is not only because of the patient's relative lack of clinical expertise, but also because the services are such that patients are not always able to determine or change how they are delivered. This means patients rely on there being systems and processes in place to ensure that risk is identified and minimised.

In addition, healthcare patients are severely unwell, physically and/or psychologically, which makes them more vulnerable than consumers of many other goods and services. While some procedures like cosmetic surgery are voluntary, many patients need to engage with healthcare services due to health conditions that are largely out of their control. Patients may have limited choice about the urgency or duration of their treatment, even in situations where surgery is 'elective' or planned. Patients' choice of healthcare provider may also be limited to facilities where their specialist practitioner has admitting rights, as frequently occurs in the private health sector. Choice of location may be further limited by the distribution of facilities across metropolitan and regional areas and the range of services they offer, and other factors.

Healthcare services also differ from other types of goods and services because of their inherent risk and the potential for adverse outcomes that may significantly affect consumers' health and wellbeing.

With this significant knowledge and power imbalance and with so many factors beyond the understanding or control of patients, there is a clear role for regulation.

2.1.1 Need for regulation to safeguard consumers

Regulation can address these issues by setting specific requirements for information to be provided to patients by service providers. It can also do so by setting other requirements for safe and quality care, and by ensuring that government can oversee compliance with those requirements and take action to enforce them.

Patients are becoming more aware of information asymmetry and are increasingly empowered to ask questions. They can access a wide range of information online about treatments and alternative options as well as about their rights as patients. However, there is still a significant knowledge differential in people being able to interpret and apply this information to their circumstances. Patients are also aware of the role of regulation in driving quality and safety, and expect that relevant regulatory requirements will be in place and will allow oversight and intervention by government to minimise risk of harm.

As part of the HIC's consultation process, consumers were asked to rate dimensions of safe and high-quality care in order of importance. Information and knowledge about health service providers appeared as a strong theme in the consumers' responses.

The HIC's Consumer Interviews Report (December 2023) found that the top 5 dimensions of safe and high-quality care are, as rated by the consumer participants in order:

- You know if the health service you are in has a requirement to be registered or accredited with a government or expert body [rated extremely important]
- You know that the staff treating you have the right qualifications and experience
- You receive information before the health care experience about fees, treatment and patient rights
- There is quick and easy access to someone at the health service who has decision making authority and skills to activate a response in a timely way
- Health services display their accreditation and registration certificates in a prominent place [rated mid-level importance]

Consumers rated highly the importance of knowing that HSEs are registered and accredited to make them feel safe when accessing health services. Together, the Act and the Regulations set out specific quality and safety obligations on health providers about a range of matters for them to achieve and maintain registration. Knowing that HSEs are registered acts as a signal for consumers regarding service safety quality and provides them with assurance that foundational safety standards are in place. The problem of information asymmetry can be offset by consumers' confidence that, through the registration scheme, providers are required to comply with foundational safety standards, and government has clear oversight of HSEs' compliance with those requirements, as well as the power to act if required to protect consumers.

Other dimensions of safe and high-quality care cited by consumers are also enabled by the current Regulations – e.g. regulations relating to clinical governance; senior appointments; credentialling of clinicians; nursing and professional care; pre-admission clinical assessments; patient transfers and discharge; and display of information. Under existing Regulations, HSEs are required to provide patients with information before admission about health services, costs and their rights, and with information about medications and follow-up care upon discharge. Many of these Regulations were discussed during the HIC-led consumer workshop in February 2024. Consumers clearly voiced their support for these Regulations to be retained as they currently appear or amended as proposed. These are discussed throughout this RIS.

The Regulations operate in an environment where healthcare quality and safety are also influenced by a range of other factors. For example, registered health practitioners must meet and comply with requirements for registration, including working under codes of conduct meeting a range of clinical standards. They want the best clinical outcomes for their patients, and this requires access to high-quality facilities and other staff. Specialist health practitioners therefore have an incentive to seek admitting rights at HSEs with excellent records on safety and quality. Similarly, HSEs develop a brand and reputation to secure relationships with health practitioners, health insurers and patients. It follows that HSE proprietors have a commercial incentive to maintain high levels of quality and safety and to minimise the occurrence of adverse events. However, market forces alone are not sufficient to ensure patient safety.

In the public sector, the State Government uses funding and service agreements with each public health service to set requirements for quality and safety. However, similar mechanisms are not available in the private sector. The only way in which HSEs can be compelled by government to meet quality and safety requirements is by legislation and regulation.

2.2 The benefits of system-wide information

To ensure consistency in quality and safety across the healthcare system, it is not sufficient to only look at data at the individual HSE level. A whole-of-system view is needed to understand how public and private health services can provide safe and accessible healthcare for the whole population, and to identity systemic issues and emerging trends in the quality of health services being provided. In Victoria, the department relies on data and information provided by health services to fulfil its role as whole-of-system manager across public and private health services. The *Targeting Zero* Review report described the role as follows:

> *"System managers can help hospitals to prevent harm, as well as detecting it. They have a vantage point that allows them to act as system leaders, using their resources to help hospitals benchmark against each other, share the lessons of top performers and international research, strengthen the incentives for hospital executives to prioritise and invest in safe care, and drive improvement in overall safety and quality of care over time."*[31]

[31] Ibid.

2.2.1 Regulation to support system management

The current Regulations ensure that all HSEs comply with the same set of foundational service quality and safety requirements. This shared set of expectations underpins the framework that empowers the department to monitor compliance and act where services do not meet the required standards.

In addition to setting quality and safety obligations that apply to all HSEs, the Regulations also prescribe requirements for recording and reporting information. Consistent reporting enables meaningful analysis of comparable data across the health sector. This is important at the national, state and individual HSE level:

- Victoria has performance data reporting obligations under national agreements such as the National Health Information Agreement and the Australian Health Care Agreement. Under the current Regulations, proposed to be retained, HSEs provide the department with information about the utilisation and performance of their services to meet these obligations. This information assists with health service planning at a national level.
- At the state level, the department uses a variety of information reported by public and private healthcare providers in its role as system manager. For example, data reported into the Victorian Admitted Episodes Dataset (VAED) dataset provides useful information about patient admissions, separations, diagnoses and other characteristics (e.g. age, sex). Reporting under the SCV Sentinel Events Program provides information about the most serious adverse patient safety events across the state. The department also shares data and insights back to healthcare providers for benchmarking purposes and makes some information available to the public for greater transparency about the health sector's performance (e.g. the SCV Sentinel Events Annual Report). The current Regulations that enable this reporting are proposed to be retained and/or strengthened because of the valuable insights they provide.
- At the individual level, under the current Regulations, HSEs are required to record a variety of information, not just to meet state or national reporting requirements, but also to drive their own continuous improvement. For example, HSEs are required to record and regularly review information about adverse events, sentinel events, mortality, morbidity, compliance with clinical governance protocols and patient and staff survey results.[32] As described in chapter 9, the current Regulations are proposed to be amended to require an additional item to be reviewed and recorded (transfers out for escalation of care) and to allow the Secretary access to this information upon request.

Consistency of regulatory obligations and information recording, reporting and review fosters comparison, benchmarking and service improvement. This in turn supports improvements in care and outcomes for patients, and more informed consumer decision-making and higher quality system manager planning.

[32] Regulation 48 of the Regulations.

2.3 Risks and costs of non-intervention

Additionally, if the Regulations were allowed to expire and no replacement Regulations put in place, the Act would not be able to operate as intended. For example, the registration scheme defined in the Act would not have meaning without the prescribed health services, and forms and fee schedules set out in the Regulations and more detailed foundational quality and safety requirements would not be imposed or enforceable. This would increase the risks to the safety and quality of care of patients receiving health services in HSEs.

While most healthcare in Victoria leads to good safety and quality outcomes, this is not always the case. The Australian Commission on Safety and Quality in Health Care notes:[33]

> *Although most health care in Australia leads to good outcomes, patients do not always receive the care that is most appropriate for them, and preventable adverse events occur across the Australian health system. Lapses in safety and quality, and unwarranted variation in health care provided to different populations within Australia have substantial costs, in terms of both the effect on people's lives and finances.*

A range of harms can result from safety and quality problems in health services, such as:

- loss of life
- decreased quality of life
- longer-term or additional treatment
- longer-term care and rehabilitation
- financial impact on patients, family and carers
- cost of investigations and inquiries
- cost of legal action and negligence claims.

The cost of adverse events is significant. The Commission reports that in 2013, approximately 12% to 16.5% of total hospital activity and expenditure in Australia was the direct result of adverse events.[34] In the financial year 2017–18, admissions associated with hospital-acquired complications were estimated by the Commission to cost the public sector $4.1 billion or 8.9% of total hospital expenditure (public hospitals only).[35]

An OECD paper, *The Economics of Patient Safety*, concludes that the available evidence suggests that 15% of hospital expenditure and activity in OECD countries can be attributed to treating safety failures (and notes that this is likely to be a conservative figure). The paper notes that "patient harm is felt in the broader economy through lost capacity and productivity of patients and their carers. In the political economy, the cost of safety failure includes loss of trust in the health systems, in governments and in social institutions."[36]

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[33] Australian Commission on Safety and Quality in Health Care, *The state of patient safety and quality in Australian hospitals 2019*, p.6.

[34] No data on the costs of adverse events is available for Victoria specifically.

[35] Ibid.

[36] *The Economics of Patient Safety*, OECD, March 2017.

The 2013 RIS for the then-proposed Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013[37] considered it realistic that the proposed Regulations could prevent approximately 4,400 adverse events per year at a cost per event of $6,826.[38] This level of avoided adverse events would break even with the estimated total cost of the Regulations at approximately $30 million per year.[39]

2.4 The specific problems being addressed in this RIS

As set out above the Regulations are an important safeguard for patients accessing care in HSEs, setting foundational requirements and empowering a regulator to monitor compliance and take action where services do not meet the required standards.

In undertaking the review of the Regulations, the department considers that the key elements of the current Regulations are necessary to achieve this objective, and to ensure that the registration scheme in the Act operates effectively.

The review has identified some areas of potential risk to patient safety and quality of care which could be addressed through changes to the Regulations. There are specific areas where there is evidence that requirements should be set out in clearer detail, and/or the department is constrained in how well it can perform its monitoring, oversight and enforcement role, due to either insufficient information being reported or lack of a robust and transparent mechanism for departmental review of a specific area of compliance. These problem areas, discussed in detail in chapters 4 and 5 of this RIS, are:

- **Clinical governance**, where the current Regulations do not sufficiently enable oversight by the department to ensure HSEs have established and are demonstrating key elements of effective clinical governance. (see chapter 4)
- **Sentinel events reporting and review**, where there are opportunities to improve the sentinel events reporting process and review requirements (see section 5.1)
- **Admissions assessment** (see chapter 6)
- **Infringement penalties** (see chapter 7).

In addition, there are several discrete elements of the Regulations that require clarification or amendment to improve the effectiveness of the Regulations, as described in chapter 9.

As noted in section 1.4 above, the review has also considered the elements of the Regulations that set out workforce and staffing requirements and those that determine the scope of the Registration scheme in the Act (that is, the provisions that list and define the types of services that must be provided in a registered facility). Consultation and policy analysis has raised important questions about the best settings for these Regulations to achieve the desired safety outcomes without undue restriction on service delivery. The department will conduct further consultation and policy analysis to inform proposals for further updates to the Regulations, which will then be subject to appropriate impact assessment.

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[37] These regulations became the Health Services (Health Services Establishments) Regulations 2013.

[38] Department of Health, *Regulation Impact Statement for the proposed Health Services (Private Hospitals and Day Procedure Centres), Regulations 2013*, July 2013.

[39] Not inflated for 2024 dollars.

3. Objectives

The proposed Regulations are made under the *Health Services Act 1988*, the purpose of which is to make provision for the development of health services in Victoria, for the carrying on of hospitals and other health care agencies and related matters.

The primary objective of these Regulations is to provide for the safety and quality of care of patients receiving health services in HSEs.

The secondary objective of the Regulations is to prescribe fees, forms and other matters as required under the *Health Services Act 1988* in relation to HSEs. This provides the mechanisms by which HSEs meet their requirements under the Act.

4. Overview of options development and approach to analysis

This chapter explains how options for the RIS were identified and the overall approach to option design. Details of options for each individual area of change being considered in the RIS are outlined in following chapters.

4.1 How options have been developed

As part of the RIS process, it is important to consider different options that could achieve the Victorian Government's objectives. The Subordinate Legislation Act 1994 and its Guidelines (the guidelines), and the Victorian Guide to Regulation recommend that this includes considering a range of approaches, including non-regulatory options (such as national accreditation schemes), approaches in other jurisdictions, and improvements to existing regulatory regimes and regulatory practice.

In considering options it is noted that the guidelines state:

> *In most cases, when a responsible Minister is considering making a statutory rule or legislative instrument, the authorising Act or statutory rule will dictate what kind of instrument may be created. For example, where the authorising legislation provides for fees to be prescribed in statutory rules, there may be no discretion to set those fees by another method.*

The authorising Act, in this case the *Health Services Act 1988,* sets down a regulatory framework requiring registration of HSEs. Provisions in the Act establish that forms, fees or registers will be prescribed in regulations.

In addition, section 158 provides that the Governor-in-Council may make regulations to prescribe matters including (amongst other things): the kinds of care which may be provided in HSEs; requirements, guidelines and standards to be complied with in relation to governance; cleanliness and hygiene; quality and safety; staffing; facilities and equipment; record keeping; and provision of statistical information.

Following detailed policy analysis by the department across many elements of the Regulations, drawing on research and stakeholder engagement on a broad range of proposals, and set out in the department's published discussion paper (see section 1.4), the department is proposing to remake the Regulations in their current form and structure. Most elements of the Regulations are not proposed to change as part of the remaking of the Regulations.

Targeted improvements are proposed in the following areas:

1. Clinical governance
2. Sentinel events reporting and review
3. Admissions assessment
4. Infringements
5. Fees
6. Administrative changes and clarifications

As set out above, further updates to the Regulations are under active consideration, in relation to workforce requirements and the services listed and defined in the Regulations. The department will conduct further consultation and policy analysis to inform proposals for further updates to the Regulations, which will then be subject to appropriate impact assessment.

4.2 Overall structure of options design for each area of change being assessed

The analysis in this RIS focuses on the proposes changes to the Regulations that represent a material incremental cost on the sector compared to the current Regulations. Analysis of each area of change is presented in chapters 5 to 9.

Each area of change being considered presents a Base Case and two or three alternative options depending on the nature of the problem being assessed:

- **Base Case**: The current Regulations for the area being assessed (e.g. sentinel reporting) lapse in September 2024 and are not replaced. Provisions in the Act establishing that forms, fees or registers will be prescribed in regulations which are currently operative would cease to have an effect going forward. The Base Case is included as an option against which to compare other options (that is, a counterfactual) and is not considered to be a feasible option
- **Option 1: Remake current Regulations (status quo)**: This option would keep the current Regulations for the area being assessed, largely in their current form, except for a small number of minor clarifications
- **Option 2: Remake current Regulations plus a targeted proposal for improvement**: The RIS identifies a proposal for improving the Regulations in the area being assessed to address the problem identified—for example, additional sentinel reporting requirement added to existing sentinel reporting requirement
- **Option 3: Remake current Regulations plus a targeted proposal for improvement**: The RIS identifies an alternative option of change to the Regulations to address the problem identified.

As noted in section 3.1, it is proposed that most of the Regulations will be remade without any change. No options are considered for areas of the Regulations where no change is proposed.

4.3 Assessment of options

The options in this RIS have been assessed using Multi-Criteria Analysis (MCA) supported by quantitative information where available. A separate analysis is undertaken for each area of proposed change because they are discrete areas of the Regulations being considered and it enables stakeholders to understand the rationale for the proposed changes and alternatives considered. An MCA is used instead of a Cost-Benefit Analysis due to lack of quantifiable information on both costs and benefits. The MCA provides a structured and transparent way of evaluating the options given the limited quantitative data that is available to assess the benefits of the options.

MCA requires judgement on how the proposed options will contribute to a series of criteria that are chosen to reflect the benefits and costs associated with each option. Each criterion is assigned a

weight reflecting its importance to the policy decision, and a weighted score is then derived for each option. The option with the highest weighted score is the preferred option.

The criteria and weightings used to assess options for this RIS are shown in the table below. These draw on the objectives for the Regulations identified in section 3.

Table 2 Criteria and weightings

Criteria	Weighting
Protects the safety and quality of care of patients receiving health services in HSEs	50%
Cost to HSEs; and cost to government	50%

The criteria for costs groups costs to HSES and government together, as costs to government are very small.

Each of the feasible options has been scored against each criterion above. The score can range from -10 to +10, with the scores then weighted by the above weightings. The scores reflect how well the option improves (a positive score) or worsens (a negative score) each criterion objective relative to the Base Case.

Table 3 MCA scale

Score	Description
-10	Much worse than the Base Case
-5	Somewhat worse than the Base Case
0	No change from the Base Case
+5	Somewhat better than the Base Case
+10	Much better than the Base Case

5. Clinical governance

Strengthening of the department's ability to review and monitor clinical governance protocols under regulation 7A is proposed.

5.1 The nature and extent of the problem to be addressed

The underlying problem being addressed is that there is evidence of some facilities not meeting expectations for sound clinical governance without close engagement and oversight through the accreditation process or through risk-based compliance monitoring by the regulator under the Act and Regulations.

According to the Commission's National Model Clinical Governance Framework, clinical governance is:

> *…the set of relationships and responsibilities established by a health service organisation between its department of health (for the public sector), governing body, executive, workforce, patients and consumers, and other stakeholders to deliver safe and high-quality health care. It ensures that the community and health service organisations can be confident that systems are in place to deliver safe and high-quality health care, and continuously improve services.*

Clinical governance is well established as a key foundation for mitigating risks and supporting service quality and safety. Implementation of effective clinical governance can identify and manage clinical risks for patients, prevent harm, and improve the processes of clinical care, leading to better clinical outcomes and improved wellbeing.

In its submission to DH's Discussion Paper, the Commission says:

> *With the NSQHS Standards and a clinical governance framework in place, health service organisations reduce the risk of harm to patients from hospital-acquired infections, the wrong medicines, falls, pressure injuries, or failures to communicate or identify and manage acute deterioration. They can also ensure better care for Aboriginal and Torres Strait Islander people and patients with cognitive impairment, mental illness or at the end of life.*[40]

The Commission has identified clinical governance as a preventive barrier to stop sentinel events from occurring.[41]

In 2015, in a national survey of public and private health services (coordinated by the Commission) about the impacts of the Standards on safety and quality governance approximately 76% said that

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[40] Australian Commission on Safety and Quality in Health Care submission to DH Discussion Paper, September 2023.

[41] Australian Commission on Safety and Quality in Health Care, *Australian Sentinel Events List (version 2) Specifications*, April 2020, p.5. The Commission states that "Sentinel events will be considered 'wholly preventable' in the context of preventive barriers being available to stop the event from occurring. Preventive barriers may include: the National Safety and Quality Health Service (NSQHS) Standards (2) (such as NSQHS Standard 1: Governance for Safety and Quality in Health Service Organisations and NSQHS Standard 2: Partnering with Consumers), policy documents or clinical protocols, documents providing safety guidance, safety recommendations or both, on how the event can be prevented."

patient safety had improved, and 64% said that the quality of patient care at their health service had improved.[42]

Concerns about performance against NSQHS Clinical Governance Standard

The Clinical Governance Standard requires HSEs to define and implement a clinical governance framework that ensures HSEs have safety and quality systems in place to minimise risks of patient harm (based on the 33 action points prescribed under the Standard).

The Clinical Governance Standard is assessed against evidence of performance of the HSEs self-defined clinical governance framework. At initial assessment, the accrediting agency rate actions for a HSE as 'not met', 'met with recommendations', 'met', not applicable or not assessed for each Standard[43]. When a HSE is awarded 'not met' and/or 'met with recommendation' rating/s, there is a remediation period of 65 business days from the initial assessment. At the end of the remediation period, a final assessment is conducted, and a determination made on the awarding of accreditation. All assessed actions must be met for accreditation to be awarded. If one or more actions are not met following final assessment, accreditation is not awarded or is withdrawn.[44]

Between January 2019 and October 2023, 80% of the 170 Victorian HSEs assessed had all actions assessed as 'met' or 'met with recommendations' at the initial assessment.[45]

However, analysis of at the Clinical Governance Standard, at initial assessment shows less than half (47%) were rated 'met' for all actions in this Standard. A further 35% achieving 'met with recommendations' (see Figure 3). Breaking this down, 64% of private hospitals and 37% of day procedure services achieved a 'met' assessment initially against the NSQHS Clinical Governance Standard, indicating performance was a relatively greater issue for day procedure services.

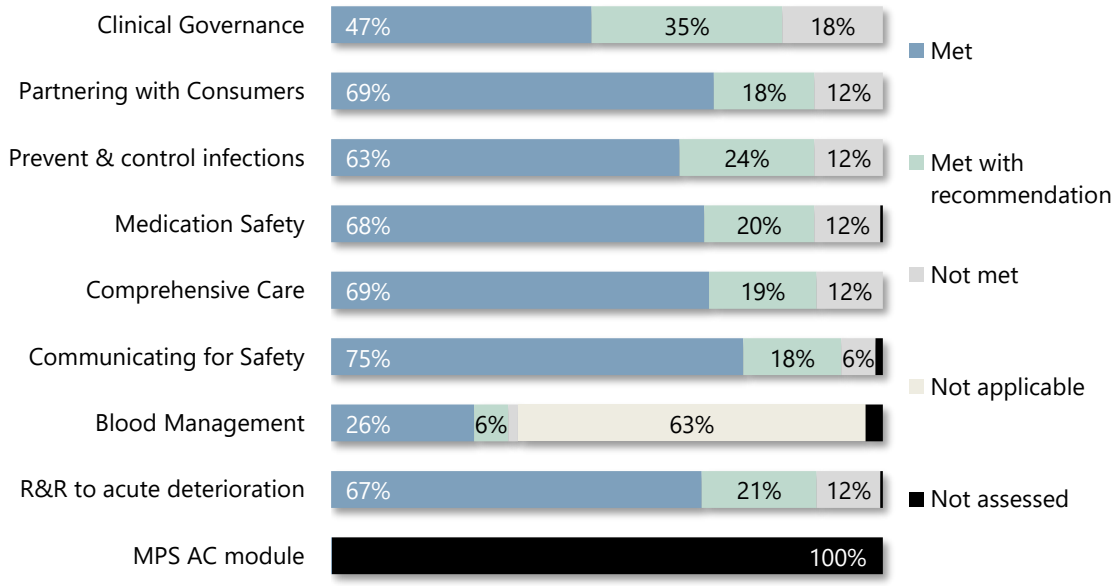
[42] Commission national self-report survey of hospital board members - *Safety and Quality Governance Survey*, 2015.

[43] 'Met with recommendations' means that the requirements of an action are largely met, with the exception of a minor part of the action in a specific service or location in the organisation, where additional implementation is required.

[44] https://www.safetyandquality.gov.au/standards/nsqhs-standards/nsqhs-standards-assessment-outcomes.

[45] Data provided to the department by the Commission but not published.

Figure 3 Outcome at initial assessment by Standard (Victorian private hospitals and day procedure centres), assessments finalised between January 2019 and October 2023



Two of the Top 5 Actions related to clinical governance most frequently rated as 'not met' at initial assessment during the same period as the data above. These are outlined in Table 4.[46]

Table 4 Accreditation data for Action 1.10 and 1.27 Clinical governance – number rated as "not met" out of 170 Victorian HSEs

Action	Detail	No. rated as not met[47]
Clinical Governance Standard: Action 1.10	*Risk management* – The HSE identifies and documents organisational risks; uses clinical and other data collections to support risk assessments; acts to reduce risks; regularly reviews and acts to improve the effectiveness of the risk management system; reports on risks to the workforce and consumers; and plans for, and manages, internal and external emergencies and disasters.	15
Clinical Governance Standard: Action 1.27	*Evidence-based care* – The HSE has processes that provide clinicians with ready access to best-practice guidelines, integrated care pathways, clinical pathways and decision support tools relevant to their clinical practice; and support clinicians to use the best available evidence, including relevant clinical care standards developed by the Commission.	15

[46] The other Top 5 Actions related to Standard 2 Action 2.11 Partnering with consumers and Standard 5: Action 5.13 Comprehensive care.

[47] Note that there is crossover in these numbers i.e. some HSEs did not meet both Action 1.10 and Action 1.27.

There are many reasons why facilities might not be assessed as meeting a Standard initially, ranging from substantive issues with compliance through to administrative process errors. However, it is notable that the Clinical Governance Standard has significantly poorer outcomes at the initial assessment stage than other Standards (as shown in Figure 3)[48].

In its submission to DH's Discussion Paper, the Commission states:

> *Clinical governance continues to be an area where significant improvements can and should be made. Assessment reports show it as the area of consistently poorer performance within the NSQHS Standards. The Commission supports strategies to improve processes and structures for clinical governance in health service organisations.*[49]

The department is concerned about poor performance on clinical governance during the accreditation process as there is a demonstrated relationship between clinical governance and patient safety and quality of care.

Current coverage of Regulations in addition to NSQHS accreditation standards

The Act and Regulations have provisions that require appropriate clinical governance processes and systems to support safe and quality patient care and continuous improvement. This includes the requirement under the Regulations for HSEs to prepare health service protocols for quality and safety (regulation 7A(3)). Matters that must be included in these protocols include (but are not limited to):

- Processes for assessing the credentials (both to practice and to undertake certain procedures at facilities) of each health professional practising at the health service every three years
- 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.

Under the Regulations, these protocols must be documented in writing, published on the HSE's website, made available to the Secretary on request, and implemented and complied with.

In assessing compliance with regulation 7A to support its monitoring and enforcement role, the department requests the HSE provide the protocols. HSEs also must provide a copy of each accreditation assessment report to the department[50], while the Commission provides the department aggregated data on assessments of all Victorian HSEs against the Standards. However, there's no explicit and robust review mechanism, including a mechanism to further engage and monitor HSEs on

[48] Blood management has a lower met assessment at but is not applicable to 63% of HSEs.
[49] Commission submission to DH Discussion Paper, September 2023.
[50] Under regulation 46(6), the report must be provided to the Secretary within 14 days of receipt.

their clinical governance protocols. This is a concern given the relatively poor performance of HSEs against the Clinical Governance Standard.

Separately, some key elements of clinical governance are not currently specified as matters that must be dealt with in the protocols of a facility, in regulation 7A(3). To address this the department has considered including additional matters in Regulation 7A. Most of those are reflected in the NSQHS Standards, as identified in the square brackets in the list below:

- The description and allocation of safety and quality roles of the health service establishment [Key tasks under Action 1.06 in National Standard 1: Clinical Governance, and Action 1.25 in National Standard 1]
- Processes for:
  - ensuring availability of appropriate adjunct diagnostic services
  - review of adverse patient safety events, including participation of all relevant personnel in the review (whether employees or not) [Action 1.11 in National Standard 1]
  - addressing the specific needs of Aboriginal and Torres Strait Islander people [Action 1.02 and 1.33 in National Standard 1]
  - recognising and responding to deteriorations in the condition of patients [Action 1.27 under National Standard 1, Standard 8 under the National Standards, in particular Action 8.01 which links back to the Clinical Governance Standard (Standard 1) regarding identification and management of acute deterioration].

The absence of an explicit and robust review mechanism in the Regulations hinders the department from effectively monitoring compliance with the clinical governance requirements in the Regulations and the quality of the protocols in place, hampering efforts to strengthen clinical governance and mitigate risks to patient safety and quality of care within HSEs. Separately, certain key elements of clinical governance lack oversight by the department because they are not included as protocols in Regulation 7A(3).

5.2 Options for addressing the problem

This section outlines options for addressing the problem.

5.2.1 The Base Case

A Base Case is presented for the purpose of comparison against feasible options.

Under the Base Case, the current Regulations lapse in September 2024 and are not replaced. In the absence of regulations, HSEs would no longer be required to prepare protocols for quality and safety as specified in regulation 7A. HSEs would also no longer be required to make available the protocols to the Secretary on request.

HSEs would still be required to be accredited to the Standards, including the clinical governance and other standards, under section 107 of the Health Services Act. HSEs would still need to implement the actions required to meet the Standards.

5.2.2 Option 1: replication of current regulations (status quo)

Option 1 is a continuation of the current regulatory approach to require appropriate clinical governance processes and systems to support safe and quality patient care and continuous improvement in addition to the Standards.

Regulation 7A would be re-made in its current form with no amendments.

In addition, related regulation 48 would be re-made in its current form. Regulation 48 requires that HSEs 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.

5.2.3 Option 2: current Regulations plus additional clinical governance protocols and Secretary oversight mechanism

Regulation 7A would be re-made, with amendments to improve oversight of clinical governance to better support patient safety and quality of care.

Key changes proposed are to add regulations allowing the Secretary to review a HSE's regulation 7A-required protocols and make directions for updates to the protocols. For transparency, the Secretary may have regard to best practice guidelines that have been formally determined by the Secretary as relevant for such reviews, to inform the review and any direction for an update to the protocols.

It is also proposed to include in the Regulations additional matters that HSEs would be required to document in their protocols, as follows:

- The description and allocation of safety and quality roles of the health service establishment
- Having regard to the kind or kinds of health services being provided at, or from, the health service establishment, processes and procedures for:
    - the availability of appropriate adjunct diagnostic services
    - review of adverse patient safety events, including participation of all relevant personnel in the review (whether employees or not)
    - addressing the specific needs of Aboriginal and Torres Strait Islander people
    - recognising and responding to deterioration in the condition of patients.

It is expected that the new additional requirements will come into effect after the new Regulations are made. This is to allow time for appropriate communication and consultation about how reviews of clinical governance protocols will be conducted, to identify any best practice guidelines that will be used to inform the reviews, and to allow time for facilities to prepare and comply.

5.2.4 Option 3: Option 2 additions and mandating the Victorian Clinical Governance Framework and Credentialing policy

Option 3 would mandate through the protocols the adoption by HSEs of the *Victorian Clinical Governance Framework*[51] and *Credentialing and scope of clinical practice for senior medical practitioners policy*[52], both published by SCV. This option was presented for feedback in the department's discussion paper.

The *Victorian Clinical Governance Framework* (VCGF) is designed for public health services to complement the governance requirements in the NSQHS Standards.

The *Credentialing and scope of clinical practice for senior medical practitioners policy* (Credentialling policy) details Victorian requirements for senior medical practitioner credentialing 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 the VCGF and Credentialing policy, however the documents are only recommended for HSEs.

If this option was preferred, the VCGF and Credentialing policy would have to be reviewed and amended to align more strongly to clinical governance settings in HSEs and as needed to reflect their mandatory nature under the Regulations.

5.3 Assessing the options

The section assesses the options against the criteria outlined in chapter 4.

5.3.1 Protects the safety and quality of care of patients receiving health services in HSEs

Base Case

Under the Base Case, HSEs would no longer be required to prepare protocols for quality and safety as specified in regulation 7A or to make the protocols available to the Secretary on request.

However, HSEs would still be required to be accredited to the NSQHS Standards, including the clinical governance and other standards, under section 107 of the Health Services Act.

There would still be drivers for HSEs to have clinical governance in place, however the department's monitoring and enforcement capabilities would be reduced in the absence of specific obligations under the Regulations and a mechanism for the department to monitor or enforce compliance, including by requesting protocol information.

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[51] *Delivering high-quality healthcare Victorian clinical governance framework*, Safer Care Victoria, June 2017.
[52] *Credentialing and scope of clinical practice for senior medical practitioners policy*, Safer Care Victoria, April 2020.

There has been no stakeholder support for this option.

The Base Case is scored a 0.

Option 1

Option 1 maintains the current arrangements with no proposed amendments.

Regulation 7A is a key foundation for regulating standards for clinical governance in Victoria. However, the current arrangements do not provide a transparent and robust mechanism for oversight and engagement on protocols of HSEs by the regulator, or a sufficient oversight framework to review the certain key elements of clinical governance.

This limits the ability of the department to make assessments about whether a HSE will provide safe and quality care to patients. For example, Commission data on the accreditation may show a HSE did not meet several actions at the initial assessment stage and there was a remediation process undertaken to achieve a met rating. The department would be able to request the HSE's protocols but would not have a transparent and robust process set out in the Regulations for engaging further with the HSE and monitoring compliance.

Feedback received via consultation on proposed changes to clinical governance is mixed: between the private health sector who are mostly in favour of maintaining the current clinical governance arrangements and some peak body and regulatory stakeholders who are in favour of making the clinical governance requirements more prescriptive, for example by mandating the Victorian Government Clinical Governance Framework and SCV credentialling policy.

Option 1 is assessed as somewhat better than the Base Case (+5).

Option 2

Review mechanism

Under the Regulations, the Secretary can currently request the protocols, but there is nothing prescribed about reviewing a HSE's protocols, including how the Secretary can engage further with the HSE or make directions for improvement. This option addresses concerns about clinical governance performance under current arrangements.

During consultation with private hospital stakeholders, feedback was not negative on the headline proposal of having a review mechanism *however* there was strong concern about the granting of power to the Secretary to effectively nominate best practice clinical governance arrangements against which a facility's protocols will be reviewed, and then effectively require the facility to amend its protocols to adopt those arrangements. Private hospitals are concerned about the level of uncertainty of the proposed regulation. Private hospitals questioned whether providing the Secretary with the power to nominate best practice may be a way for the Secretary to indirectly mandate the Victorian Clinical Governance Framework and the SCV Credentialing policy (without explicitly mandating these in regulations, and if best practice was defined to incorporate review against the Victorian Clinical Governance Framework and SCV Credentialing Policy).

Best practice is not currently defined in the Regulations so there are limits to which the potential impacts of this element of the proposal can be assessed in this RIS. The best practice guidelines

considered by the Secretary in assessing the protocols a facility has in place, which may inform directions aimed at improving the protocols, could result in different impacts on HSEs and patients depending on the content of those guidelines.

However, the department intends that these provisions will align with, and supplement, accreditation assessments against the Standards, and the current risk-based compliance monitoring by the Secretary as regulator under the Act and Regulations. It is not intended to operate as an indirect mechanism for the Secretary to mandate specific operational or clinical arrangements.

So, for the purpose of this RIS, it is expected that best practice guidelines referred to for reviews of protocols under the amended Regulations would align to current intent and best practice; therefore resulting in no major changes to current actual clinical governance requirements. However, there remains a degree of uncertainty about the proposal until the design and implementation is complete. As part of this implementation, and the ongoing operation of the proposed new provisions, it is expected that prior to determining any best practice resource as one that can be referred to for the purposes of a review of a facility's protocols, there would be stakeholder consultation to build transparency.

Additional matters to be dealt with in a facility's protocols

Including additional matters in the required elements for protocols under the Regulations is intended to strengthen governance in facilities by making explicit that these key matters must be addressed in the protocols developed and followed by each facility and also thereby providing the Secretary as regulator with a clear basis to engage with facilities to ensure that those matters are appropriately addressed, hence improving oversight of clinical governance.

Private hospitals raised concerns that the proposal would create misalignment or additional complexity (relative to Option 1). However, with the exception of the proposed adjunct diagnostic services element, the proposed additions to the clinical governance protocols each relate directly to a specific action under the Standards. It is expected that HSEs will already have policies and procedures in place for these matters and that the impact in developing protocols under the Regulations will not be significant. In the Stakeholder Information Session with private hospitals in January 2023, there was no strong objection to formalising these requirements through the protocols[53].

There is no equivalent requirement in the Standards to the proposed requirement in the Regulations for protocols to set out processes for ensuring appropriate access to adjunct diagnostic services[54], taking into account the services provided at the facility. However, the Australian Private Hospitals Association noted in submission that "availability of adjunct diagnostic services are reviewed during routine regulatory visits by the Department of Health and by the delegated surveyors tasked with assessing compliance against the National Standards". There has been feedback from sector peak

[53] Private hospitals expressed concerns about including a staff fatigue protocol in section 7A, but that is not being considered under this proposal (see discussion in chapter 1).

[54] The inclusion of an adjunct diagnostics services protocol aligns to the intention of Standard 8 (Recognising and Responding to Acute Deterioration Standard), which supports the provision of appropriate and timely care to patients whose condition is acutely deteriorating. It requires that systems are in place to detect, recognise and respond to acute deterioration in physiological or mental state. However, this alignment is not as clear and explicit as for the other proposed additions.

bodies that this is typically reflected in the clinical capability framework of available services, formal or informal service level agreements or arrangements and adjunct policies. Clinical governance practices for adjunct diagnostic services are therefore already likely to be in place at HSEs, although effort may be required by HSEs to document a protocol for the purposes of the proposed Regulations. That said, there was no objection from private hospitals to formalising this requirement[55].

Overall, the proposed changes to clinical governance requirements under this option are expected to have a moderate positive impact on patient safety and care by strengthening foundational requirements for, and oversight of, clinical governance. This assumes moderate change to current clinical governance requirements already in place in most HSEs, but recognises the uncertainty of the proposed new power of the Secretary to determine what best practice is.

Option 2 is assessed as slightly better than Option 1 (+7).

Option 3

The option to require HSEs to comply with the VCGF and Credentialling Policy, which was canvassed in the discussion paper, received support from some stakeholders.

> *"We note that effective clinical governance is essential for the health and safety of the public. Any guidance and/or frameworks that assist health services and individual practitioners to correctly understand their professional responsibilities in relation to clinical governance helps to ensure safe and professional practice as well as the safety and quality of health services that are being provided by those practitioners."*
>
> *"The Safer Care Victoria Victorian Clinical Governance Framework arose out of significant system failures at Djerriwarrh Heath Services. The Framework provides a broad set of principles to promote quality and safety and to reduce clinical risk. Requiring private hospitals and day procedure centres to comply…mean that irrespective of the health care settings, all Victorians have access to high quality care referenced against one yardstick or framework for clinical governance.*"

The private health sector generally expressed the view that prescriptive requirements in the Regulations proposed under Option 3 would not necessarily be appropriate, or effective at supporting quality and safety. It was argued that optimal and feasible arrangements for a facility will depend on various factors, including the services provided, the acuity of patients, and organisational and corporate governance.

> *"Initial reviews by health services have indicated there are already Standards and appropriate mechanisms in place to meet governance requirements in the National Standards by the Australian Commission on Safety and Quality in Health Care's and suggest implementation of proposed Regulation changes would cause further duplication both in reporting and oversight."*

[55] Private health sector stakeholders objected to the proposal in the discussion paper that the protocol includes assessing the reliability, availability and timeliness of adjunct diagnostic services, whether provided by the HSE or an external supplier. The main objection was that HSEs are not best positioned to assess quality of adjunct diagnostic services. However, the department has refined the proposal to include only the availability of adjunct diagnostic services.

> *"Duplication or overlaying of governance expectations where there are already National Standards may inadvertently create confusion, misunderstand/misinterpretation and ultimately unnecessary risks."*
>
> *"The SCV's credentialing and scope of clinical practice policy would not be appropriate in the private sector. There are already safeguards as part of licencing regulation for the private hospital sector including the need to establish a Medical Advisory Committee and Credentialling Committee."*

There were exceptions, for example one large private hospital provider said:

> *[Our] revised framework is already centred on the SCV clinical governance framework. We are aware that variation exists between the SCV Clinical Governance framework and NSQHS standard 1… The [Credentialing] policy represents a thorough and standardised approach. [We] follows the principles outlined in the policy already.*

For benefits, this option has been scored the same as Option 2 (+7). It strengthens the oversight mechanisms available to the department, as per Option 2. There might be some additional benefit in mandating the VCGF and Credentialing policy in that it would provide for more consistency and potentially raise clinical governance standards, however the prescriptive approach might not be optimal across the wide spectrum of HSEs.

5.3.2 Cost to HSEs; and cost to government

Base Case

There would be no direct costs to HSEs under the Base Case.

Government's regulatory role is more limited as the Secretary is unable to request protocols as it can currently, or undertake a review (as per Option 2), so costs to government could decrease. However, the department is still required to fulfil its monitoring and enforcement role under the Act and other elements of the Regulations.

It is likely to fulfil this role less efficiently in the absence of specific requirements in the Regulations in relation to clinical governance as there may not be direct means of engaging with a facility to assess clinical governance arrangements and related issues of compliance with the Act and Regulations, and risk to the quality and safety of services being provided. Over time there could be an increase in costs to government as the department is unable to intervene early to address problems in clinical governance, which could lead to poorer outcomes over time that government needs to respond to - for example the cost of responding to HCC complaints or adverse events, or costs associated with more significant regulatory interventions such as infringements, or suspension or revocation of registration.

The Base Case is scored a 0.

Option 1

This option requires HSEs to develop protocols, provide protocols to the Secretary on request, and implement and comply with the protocols.

The required elements for the protocols generally align with the Standards so the need to develop these for the purpose of the Regulations is minimised. There will be some work to do to develop the required protocols plus administrative work in providing protocols to the Secretary (compared to the Base Case).[56]

While no estimated dollar costs are available on the current cost of complying with current regulation 7A, feedback from the sector does not indicate the cost of current clinical governance requirements under the Regulations is significant or disproportionate.

For government, there will be a cost of requesting access to the protocols and otherwise monitoring compliance with the requirement to establish and implement the protocols, however this cost is likely to be small. Offsetting this, there could be a cost saving versus the Base Case where over time there is less need for the government to respond to poorer outcomes as a result of poor clinical governance.

This option is scored a -3, which represents a moderate small cost to industry and government.

Option 2

HSEs would need to develop additional protocols under regulation 7A and provide these on request to the Secretary, implement and comply with them. Most of the proposed additional elements for the protocols align with actions in the Standards, so development of the protocols is expected to impose only a small incremental cost on HSEs. Development of a protocol for ensuring appropriate access to adjunct diagnostic services does not explicitly align with any action in the Standards so is likely to take more effort for HSEs to develop.

When private hospitals were requested to provide feedback on the costs of developing these protocols in the Stakeholder Information Session held by the department (January 2023), no stakeholders expressed concern about the costs, although there was more general feedback about potential duplication and incremental costs across requirements in the Standards and the Regulations.[57]

The cost of the new review mechanism for any given facility will depend on the details of the review process, the detail of any best practice guidelines determined by the Secretary for the purposes of such review by the Secretary and the detail of any updates to facility protocols directed by the Secretary. Some stakeholders were concerned about the uncertainty in how the mechanism will be implemented.

HSE costs of providing information to the Secretary (or delegate) for a review of protocols is not expected to be more onerous than complying with requests from the department for information under the current Regulations. HSE costs associated with updating the protocols in response to a direction from the Secretary following a review will depend on the extent to which a facility's pre-existing protocols are inconsistent with the requirements in the Regulations and any identified best practice guidelines.

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[56] In practice existing HSEs have already developed protocols so will not have to develop these again. New HSEs would need to develop protocols.

[57] Stakeholders expressed strong concerns about the potential inclusion of staff fatigue in the list of protocols, but this is not being considered as part of this RIS (see section 1.4).

So, under the proposed mechanism, costs are most likely to arise in instances where improvement to clinical governance protocols is needed to protect patients. To allow appropriate transparency about this, it is expected that the provisions allowing for reviews will not come into operation for some time after the remaking of the Regulations, to allow for consultation and communication about the best practice guidelines to which the Secretary may refer for the purposes of a review. It is expected that decisions about which best practice guidelines will inform reviews will consider existing resources such as the Standards and relevant industry practice.

For government, there will be a cost of undertaking reviews and requesting information on additional protocols, however this could be offset in terms of efficiency benefits to be gained from having a clear oversight mechanism established and over time less need for the department to respond to poorer outcomes as a result of poor clinical governance.

Overall, the cost of this option is likely to be slightly larger than the cost of Option 2 but will depend on design and implementation (-4).

Option 3

Mandating the VCGF and Credentialing policy could involve HSEs having to make material changes to policies and procedures, and implementation and compliance with any changes. This would impose significant costs on those HSEs that have clinical governance frameworks not closely aligned to these already. Some HSEs might incur only minor costs, such as a large private health service which states in its response to the discussion paper that its clinical governance framework already aligns strongly with the VCGF.

Compared to Option 2, this is a blunter and less efficient regulatory approach, as it requires all HSEs to adopt the VGCF and Credentialling Policy (which would require review and update in relation to applicability for HSEs), potentially allowing some regulatory action for non-compliance with that requirement where there are concerns about clinical governance in a facility. In contrast, Option 2 allows flexibility in relation to identifying relevant best practice guidelines, impacts only those who are subject to a review by the Secretary (and where a facility's protocols are more likely to be inconsistent with the requirements in the Regulations and any identified best practice guidelines) and allows nuanced and targeted directions to be made.

As no cost data is available from HSEs to estimate the costs of this option, the assessment of the cost of this option to industry is based on judgement about the relative cost versus the Base Case and other options, supported by findings of stakeholder engagement.

For government, the department would need to tailor the VGCF and Credentialling Policy to align more strongly to clinical governance settings in HSEs. This would involve a review and engagement with the sector. Over time, as per Option 2, the cost of this implementation could be offset by there being less need for the department to respond to poorer outcomes as a result of poor clinical governance.

Overall, this is considered to have a significant cost compared to other options and the Base Case (-7.

5.4 Summary of MCA scores and preferred option

Table 5 presents the MCA scores for clinical governance options**. Option 2 is given the highest score and preferred** as it best balances the strengthening of clinical governance of HSEs to best support safety and quality of care of patients with the regulatory burden imposed on industry and government. An implementation plan for the development of the review mechanism is proposed by the department as set out in Chapter 11.

Table 5 Summary of MCA scores for clinical governance

	Base Case	Option 1	Option 2	Option 3
Protects the safety and quality of care of patients receiving health services in HSEs (50%)	0	+5	+7	+7
Cost to HSEs; and cost to government (50%)	0	-3	-4	-7
Net weighted score	**0**	**+1**	**+1.5**	**0**

6. Reporting and review of sentinel events

Effective oversight and review of sentinel events is a key foundation of continuous monitoring and improvement of quality and safety at the facility and system level. This section assesses options to strengthen the current regulatory framework relating to sentinel events.

6.1 The nature and extent of the problem to be addressed

The Regulations define a sentinel event as an unexpected and adverse event that occurs infrequently in a HSE 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 HSE. Sentinel events reporting is important because it:

1. enables individual HSEs to identify and address immediate patient safety risks, track safety trends over time and address any systemic issues to improve their safety performance
2. facilitates learnings from adverse outcomes to be shared across the health system to improve quality and safety
3. helps government monitor safety and quality at the facility level to inform appropriate interventions and to compile insights from reviews at the system level to learn from past events of harm to prevent future events of harm.

The Commission states that the purpose of sentinel event reporting is to ensure public accountability and transparency and drive national improvements in patient safety.[58] The Commission published a revised national sentinel event category list that came into effect on 1 July 2019. In addition to the 10 national sentinel event categories, in Victoria a category 11 sentinel events is included in the list of sentinel event categories: All other adverse patient safety events resulting in serious harm or death.[59]

SCV oversees the sentinel event program in Victoria. All sentinel events must be reported to SCV by all public and private health services. SCV has a role in supporting health services to review and recommend improvements to health services in relation to SAPSEs, including sentinel events. SCV analyses sentinel event data to identify system trends and emerging risks; this information is shared in the SCV annual sentinel event report to facilitate health-sector-wide sharing and improvement.

Each year, SCV reports sentinel events that fit the national criteria to the independent hospital pricing authority (IHPA), and national sentinel event numbers are reported annually by the Australian Government's Productivity Commission.

In 2021-22, there were 240 sentinel event notifications to SCV (from both public and private health services), an increase of 43% from 168 in 2020-21. SCV's 2021-22 Sentinel Events Annual Report notes

[58] https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/incident-management-and-sentinel-events.

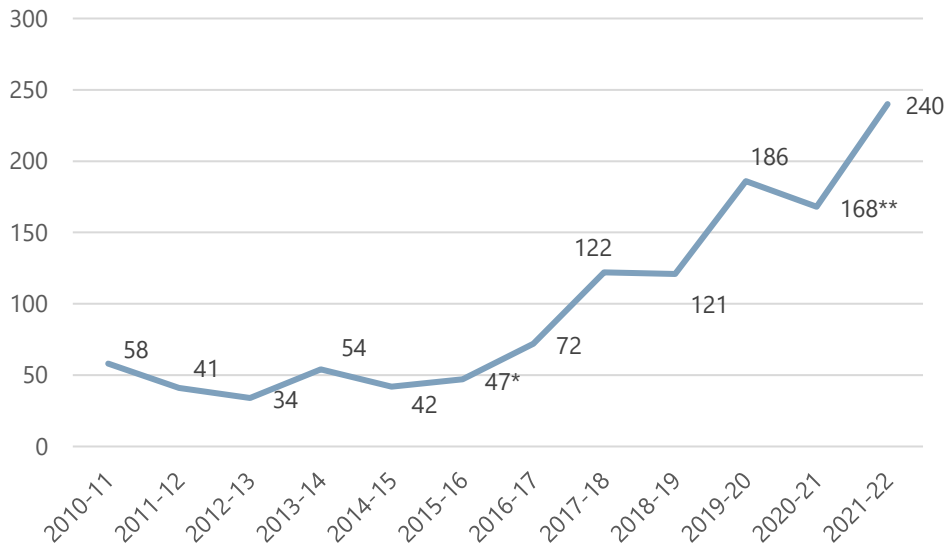
[59] https://www.safercare.vic.gov.au/best-practice-improvement/publications/sentinel-events-guide

that this increase is consistent with the upward trend seen since 2017 when SCV was established and began oversight of the sentinel events program.[60]

> *The upturn in sentinel event notifications is consistent with the improving recognition, notification and review of sentinel events. This demonstrates an ongoing, and increasing transparency from the health sector, illustrating that safety culture is evolving.*[61]

In 2020-21, 25 sentinel events were reported by HSEs and 143 were reported by public hospitals (a total of 168).[62] In 2019-20, 22 sentinel events were reported by HSEs and 164 were reported by public hospitals (a total of 186).[63] The same data is not available for 2021-22.

Figure 43 Sentinel event notifications – 1 July 2010 to 30 June 2022[64]



* On 1 July 2017, SCV began oversight of the sentinel events program from the department.

** There was a small reduction in notifications between 2019/20 (186) and 2020/21 (168) which has been associated with the impact of the COVID-19 pandemic.

The actual number of sentinel events may be higher than the number reported to SCV. The 2021-22 Sentinel Events Annual Report states:

> We know from wider data sets around patient harm that sentinel events are likely to be under-reported. For this reason the year-on-year increase in sentinel event notifications is a welcome sign that health services across the state are increasingly dedicated to creating a safer healthcare system.

[60] 2021-22 Sentinel Events Annual Report, p.11.
[61] Ibid.
[62] 2020-21 Sentinel Events Annual Report.
[63] 2019-20 Sentinel Events Annual Report.
[64] Ibid.

However, the reporting requirement is not changing as a result of changes being made through the remaking of the regulations so any future increase in costs that arises from an increase in rates of compliance with the reporting requirement is not dealt with in this RIS.

Requirements for the reporting and review of sentinel events have been strengthened over recent years, however there are some gaps and issues in the framework that proposed amendments to the regulations seek to address.

Reporting process to support system-level monitoring

Under regulation 46A, the proprietor of an HSE must report in writing a sentinel event that occurred at the HSE to the Secretary within the time determined by the Secretary (three business days). The Regulations do not prescribe how the HSE must report to the Secretary, including what detail must be reported or the mechanism for reporting.

In in practice most sentinel event reports from HSEs are received through the SCV Online Portal[65]. The Portal requires specific information about sentinel events to be reported in a prescribed format. This acts as a data validation process enabling SCV and the department to generate key indicators that are used for system-level surveillance. These indicators may flag potential concerns with specific HSEs or provide system-wide insights on sentinel events. Consistency of input to the SCV Online Portal maintains the integrity of the data used to undertake compliance monitoring and enforcement activities.

It is not mandatory for HSEs to report sentinel events in a particular way to the department, although most HSEs do so using SCV's Online Portal. There is a risk for SCV and the department in that they cannot be assured that all HSEs will report through the Portal. Key information on the sentinel event may not be collected, or may be collected in the incorrect format, impacting the quality of its system-wide oversight and learnings provided.

Methodologies used in reviews of sentinel events

Reviews of sentinel events are important to understand what happened, why it happened, and what system improvements can be made to prevent recurrence of similar adverse events or to minimise the harm if they do reoccur.[66]

Reviews of sentinel events are critical to support system-wide improvement of the safety of care, and there is a range of legislation, regulation, guidance and policy reflecting this. However, it is not mandatory for HSEs to use formal review processes for sentinel events.

The Standards include actions for appropriate analysis of incidents to inform continuous improvement in safety, and for policies and processes for appropriate communication with patients and next of kin where incidents have occurred (open disclosure) – under Standard 1 Clinical Governance.

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[65] https://www.safercare.vic.gov.au/report-manage-issues/sentinel-events/about-the-sentinel-events-portal.
[66] Safer Care Victoria, *Adverse Patient Safety Event policy*.

The Act sets out requirements in relation to how reviews of serious adverse patient safety events (SAPSEs) are undertaken, of which sentinel events are a sub-category.

Under section 128ZC of the Act, if a patient suffers a SAPSE while receiving health services, the health service entity (including HSEs) responsible for providing those services owes a Statutory Duty of Candour (SDC) to the patient. The *Victorian Duty of Candour Guidelines* require that the health service entity must apologise to any person seriously harmed while receiving care, give a written account of the facts regarding the SAPSE, and undertake a review of the SAPSE and produce a report describing what action was taken and improvements put in place to prevent re-occurrence of the event.[67] Under the Victorian Duty of Candour Guidelines, the report produced has to be given to the patient and/or families but not the Secretary. While the Guidelines require a review of the SAPSE to be undertaken, they do no set out requirements for how the review must be conducted, such as setting out specific review methods.

Under Part 5A Division 8 of the Act, if a SAPSE occurs, a 'SAPSE review' (referred to here as a 'protected SAPSE review'[68]) 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. This means a protected SAPSE review is not mandated specifically in legislation.

If a protected SAPSE review is undertaken there are mandated requirements for a panel, including that panel members must be sufficiently experienced, skilled and independent from the event, and 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.

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. A SAPSE review report must be made available to the Secretary on request.

While not mandatory for HSEs[69], SCV's *Victorian Sentinel Event Guide* provides information to help health service entities fulfil their obligations when managing and reporting sentinel events[70]. This includes guidance for reviewing and analysing a sentinel event using root cause analysis (RCA) methodology and reporting timing requirements. For sentinel events, SCV reviews and provides feedback on the RCA reports that are produced by health services entities, and on risk reduction action plans arising from these reviews.

[68] Referred to as a protected SAPSE review due to protections from liability provided in the Act for SAPSE review panel members and participants.

[69] The Guide is mandatory for public health services but not mandatory for HSEs.

[70] While the national list provides guidance on 10 main event categories, it isn't comprehensive and the guide aims to fill the gap particularly for sub-categories of adverse patient safety events that fall outside the 10 main categories.

SCV published the *Adverse Patient Safety Events policy (2023)* to support Victorian health services to improve systems for delivering care in response to adverse events including sentinel events. SCV recommends the policy as best practice for HSEs to meet the review requirements for Statutory Duty of Candour and the Sentinel Events Program. The policy provides a best practice guide for the adverse patient safety events management process, including review and improvement. The policy describes review types which might be chosen and =examples of formal review methods (RCA, London Protocol, AcciMap and in-depth case review). The policy is not mandatory for HSEs.

The department understands that most HSEs that report a sentinel event under regulation 46A are subsequently completing a review and reporting outcomes from the review in line with the Duty of Candour (supported by the Victorian sentinel event guide and Adverse Patient Safety Events policy). However, this is not formally mandated and there is a risk that a HSE does not apply these processes if a sentinel event occurs.

The absence of a mandatory and consistent approach to the conduct and review of outcomes of sentinel event reviews impacts the effectiveness of SCV's system-wide oversight and sharing of learnings to improve patient care.

A coronial investigation was undertaken into the death of Antoinette O'Brien, who died of sepsis after delivering her stillborn baby in 2017. The Coroner's 2023 report considered the role of SCV and its role in reviewing sentinel events in Victoria, including consideration of the voluntary participation of health services in sentinel event reviews. The Coroner found:

> *It is clear that at the time of Annie's passing, SCV lacked the legislative power to compel the cooperation of health services in undertaking its review of sentinel events and relied on their voluntary cooperation. I am satisfied that the enhanced legislative powers which come into effect last year, will allow SCV to be more proactive in managing their interactions and engagement with health services. I am however concerned that root cause analysis reports are not required for all SAPSEs. I am of the view that root cause analysis reports should be mandatory for all SAPSEs and sentinel events regardless of whether they occur in a public or private health service.*

The Coroner made recommendations that the Regulations should be amended to introduce requirements that:

- all health facilities, public and private, be required to undertake RCA reports of SAPSEs, including sentinel events
- private hospitals be required to have an independent member on a RCA panel consistent with the requirements imposed on public hospitals.[71]

The recommendations of the Coroner have been accepted in-principle by the department.

Timelines for reporting requirements

The Victorian Sentinel Event Guide sets out timelines for sentinel event reporting:

- notify SCV within three business days of the service becoming aware of the event

[71] Coroners Court of Victoria, Court reference COR 2017 004055.

- review and analyse the sentinel event using root cause analysis (RCA) methodology
- submit an RCA report (parts a and b) within 30 business days of the notification
- submit recommendations from the RCA (part c) within 50 business days of the notification
- submit a recommendation monitoring report within 120 business days of the notification.

The department notes stakeholder feedback and other evidence that there can be challenges in convening a panel as specified, which can lead to delays in completing the reviews on time.

Table 6 sets out SCV reporting on the Sentinel Events Program that shows rates of compliance with requirements for review teams and timelines for reporting (for all health services, not just HSEs). Most reports are not received on time and over 50% of health services request timeline extensions.

Table 6 Compliance rates for all health services vs Victorian Sentinel Events Guide

Annual report period	21/22	20/21	19/20	18/19	17/18
Review team composition					
- Consumer representatives	88%	47%	51%	33%	17%
- External independent member	*	91%	85%	85%	80%
- Included a Consumer rep, external member and involved the affected Consumer	*	18%	13%	*	*
RCA reporting timeliness					
- Parts A and B received on time (30 days)	*	42%	40%	36%	18% (22 of 120)
- Part C received on time (50 days)	*	77%	72%	*	*
- Requests for extensions	*	54%	57%	60%	64%

Source: compiled from SCV reports by the department.
Note: * Indicates data not available in the SCV annual reports.

6.2 Identification of options

6.2.1 The Base Case

Under the Base Case, HSEs would not be required to report sentinel events to the Secretary (as is currently required under regulation 46A). Requirements under the Act in relation to Duty of Candour (section 128ZC of the Act) and SAPSE reviews (Part 5A Division 8) would continue to apply. HSEs would continue to be required to maintain accreditation against the Standards which include elements about analysis of incidents and open disclosure about adverse events.

6.2.2 Option 1: remake current regulations with no changes

Regulation 46A of the current Regulations would be remade. Requirements under the Act in relation to Duty of Candour (section 128ZC of the Act) and SAPSE reviews (Part 5A Division 8) would continue

to apply. HSEs would continue to be required to maintain accreditation against the Standards which include elements about analysis of incidents and open disclosure about adverse events.

6.2.3 Option 2: current Regulations plus new event review process requirement and reporting to the Secretary requirements

This option includes two elements in addition to Option 1:

1. Amend regulation 46A to specify that sentinel events must be reported in the manner directed by the Secretary—intended to be the SCV Online Portal
2. Insert a new provision that requires the proprietor of the HSE to ensure that each sentinel event is subject to a review, with the review process requirements and reporting timeframes to be specified by the Secretary and reports from the review to be provided to the Secretary. It is intended that the requirements to be specified will be those set out in the Victorian Sentinel Events Guide and Adverse Patient Safety Event Policy, namely:
    - the review must be done according to an SCV-approved methodology such as Root Cause Analysis, London Protocol, AcciMap
    - the panel/team conducting the review must consist of at least three persons that:
        - include a member not employed or engaged by the proprietor to work at the facility
        - include a consumer representative
        - not include any person involved in the sentinel event
    - the report on the findings of the review (parts A and B) must be provided to the Secretary within 30 business days of the sentinel event being notified
    - the recommendations from the review (part C) must be submitted to the Secretary within 50 business days of the sentinel event being notified
    - a report on implementation of the recommendations from the review must be submitted to the Secretary at 6 months and 12 months following notification of the sentinel event
    - the proprietor may seek, and the Secretary may grant, an extension of the submission deadlines for the reports above. This happens currently across the Sentinel Events Program as a practical response to the difficulties health services experience in timely completion of reviews, typically as a result of challenges resourcing the review panel.

It is proposed that the commencement of these provisions may be six to twelve months after the new Regulations are made to allow time for facilities to prepare for implementation.

6.3 Assessing the options

The section assesses the options against the criteria outlined in chapter 4.

6.3.1 Protects the safety and quality of care of patients receiving health services in HSEs

Base Case

Under the Base Case, HSEs would not be required to report sentinel events to the Secretary (as is currently required under regulation 46A). Requirements under the Act in relation to Duty of Candour and SAPSE reviews under Part 5A Division 8 of the Act would continue to apply.

In the event of a sentinel event, HSEs may voluntarily follow the Victorian Sentinel Events Guide, even though it is not mandatory. But there is a risk that a HSE would not use an accepted methodology for review of a sentinel event. This could impact on the quality of learnings from sentinel event reviews and improvements to be made in response, at the facility level.

HSEs would not be required to report to the Secretary about the outcomes of the reviews. This would impact on the capacity of the department and SCV to monitor incidence and causes of sentinel events at the facility level. It would also compromise oversight of how facilities review sentinel events and how they identify and implement improvements based on those reviews, which are key activities for supporting safety and quality of care at the facility. It would also undermine system-wide learnings about causes of sentinel events and improvements to be made in response.

The Base Case, as the counterfactual, is scored 0.

Option 1

Option 1 improves on the Base Case as it requires reporting to the Secretary. This supports system-wide learning of lessons and improvement, although reporting via the SCV Online Portal is not mandatory under Option 1 and so there is a risk of incomplete or non-comparable information.

Option 1 is given a score of +2, which is a moderate improvement versus the Base Case.

Option 2

For most HSEs, the proposed changes under Option 2 will have little or no impact on how they respond to sentinel events, as they already use the SCV online portal on the SCV website and follow the Victorian Sentinel Events Guide. However, by formalising these requirements, Option 2 addresses the risk that a HSE might do neither of these things.

There was reasonable stakeholder support for the proposals in responses to the discussion paper, while no private hospitals raised concerns about the changes. The peak private hospitals body, AHPA, supported reporting via an approved pathway or portal and the use of an approved methodology, noting an in-depth review is the likely tool of choice for many health services for a range of incidents. It noted that:

> *Experienced and mature health services are largely familiar with other methodologies such as root cause analysis and London Protocol, and ensures their staff are appropriately rained.*

AHPA did note though, there could be differences across types of HSEs in how they can comply with the requirements:

> *There may be significant barriers with smaller sites with very infrequent incidents requiring investigation. The training required, turn-over of staff and recency of practice may result in insufficient trained staff to support an investigation.*

This concern is noted in the assessment of Small Business and Competition impacts (chapter X).

Option 2 also addresses an issue with the timeline requirements under the Victorian Sentinel Event Guide by allowing HSEs to seek, and the Secretary to grant, an extension of the timelines for sentinel event reporting. This should allow time for HSEs to constitute a panel in the necessary timeframe. This

is a small change that formalises and makes more transparent a process that is currently occurring in practice.

Option 2 is given a score of +5.

6.3.2 Cost to HSEs; and cost to government

Base Case

Under the Base Case, HSEs would not incur any costs associated with reporting sentinel events to the Secretary (as is currently required under regulation 46A).

The Base Case, as the counterfactual, is scored 0 against this criterion.

Option 1

In Option 1, there would be an additional cost of reporting (notifying) a sentinel event to the Secretary under regulation 46A (as compared to the Base Case). This would apply to about 25 sentinel events a year at HSEs (assuming the same number as in 2020-21).

Reporting (notifying) a sentinel event via the SCV Online Portal Patient (or via another method such as a written document) requires a HSE to provide patient details, event details, and details of those reporting the event. The information requested should be information that is collected by the HSE as part of management of a sentinel event. The requirement for reporting (notifying) is therefore largely an administration cost, which is the cost of time for providing details to the Secretary (through the SCV) about the sentinel event (by fillings in fields in an online form in the Portal or another method chosen by the HSE).

If there are 25 sentinel events reported per year, and for each of these a senior professional at the HSE spent half a day preparing and submitting the sentinel event notification report, this would add up to 12.5 days in total. A cost of time of $3,435 per week ($685 per day) is assumed, based on ABS data for average weekly blended earning earnings data of senior professionals in the health profession who would be likely to be working on a sentinel event review[72]. Applying this rate, the cost of this requirement would be about $42,000.

The absence of mandatory reporting requirements including how sentinel events are reported to the Secretary may mean there is some variation in the costs of reporting. Stakeholder engagement has not indicated any disproportionate or unnecessary regulatory burden associated with these reporting requirements and so is assumed to be moderate.

For government, there would be costs relative to the Base Case to review information provided in sentinel event notifications and undertake follow up requests as required, and to undertake compliance monitoring and enforcement to ensure HSEs are meeting prescribed sentinel event reporting requirements. On the other hand, costs to government would be lower over time than under the Base Case as reporting matures and contributes to improved patient care and quality. Overall, the cost to government is expected to be small.

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[72] Including anaesthetists, specialist physicians, surgeons, other medical practitioners, managers, corporate services manages, CEOs// Managing directors.

This option is scored a -1, which represents a moderate cost to industry and government.

Option 2

Option 2 will impose an additional cost on some HSEs compared to Option 1, as a small number of HSEs that do not use the SCV Online Portal or follow the Victorian Sentinel Event Guidelines will be required to do so. The change will not affect most HSEs because they already follow these processes.

During consultation with private hospital stakeholders, industry made no specific comment relating to the cost of this proposal, although did request that requirements for sentinel events are aligned as much as possible to those for SAPSEs to minimise regulatory burden. The department noted this point but observed that there were limitations on how this could be achieved as sentinel events are by nature more serious than SAPSEs and may therefore have different requirements to reflect this.

The costs of undertaking a sentinel event review in accordance with the Victorian Sentinel Event Guidelines is likely to vary due to a number of factors, including the nature of the harm suffered and the surrounding clinical and operational circumstances. Further, not all the costs of conducting these reviews are attributable to including the proposed review requirements in the Regulations, given other requirements that create an imperative for HSE to conduct a review of each sentinel event that occurs (including relevant parts of the Standards, open disclosure policies and the Statutory Duty of Candour). The cost has therefore been estimated using some assumptions.

Under the Victorian Sentinel Event Guide, Report A and B must be submitted within 30 business days of notification and Report C must be submitted within 50 business days. The panel conducting the review must consist of at least three persons (per the SCV Adverse Patient Safety Event Policy. As such, a rough estimate of the cost of time spent on the report can be developed using assumptions. Assuming a review takes 50 days from beginning to end, that there are three people conducting the review and that they each spend 50% of their time on the review, this adds up to 75 days for conducting the review. If there are 25 sentinel events per year, this adds up to a total of 1,875 days per year by HSEs conducting sentinel event reviews. A cost of time of $3,435 per week ($685 per day) is assumed, based on ABS data for average weekly blended earning earnings data of senior professionals in the health profession who would be likely to be working on a sentinel event review[73]. This results in an overall cost of roughly $1.3 million per year. While this may in some cases overestimate the time spent by members of the formal review panel, it will likely appropriately cover time spent by (other) personnel of the facility who work to support the review as part of their role at the facility, some of which time may be attributable to the specific review requirements that it is proposed will be formalised in updates to the Regulations. Given that a significant proportion of HSEs are already undertaking sentinel events using the in accordance with the Victorian Sentinel Event Guide the cost of Option 2 is likely to be much lower.

For government, the application of only one reporting platform is expected to generate a small cost saving as information is quicker and easier to access and assess. Similarly, the introduction of more

[73] Including anaesthetists, specialist physicians, surgeons, other medical practitioners and quality and safety experts, managers, corporate services managers, CEOs/Managing directors.

prescriptive review and reporting requirements means that it is quicker and easier for the relevant data to be collated and analysed to generate insights which inform continuous improvement.

Overall, Option 2 is given a score of -3, slightly worse than Option 1.

6.4 Summary of MCA scores and preferred option

Table 7 presents the MCA scores for sentinel event reporting. **Option 2 is the preferred option** as it best balances the protection of safety and quality of care of patients with costs to industry and government.

Table 7 Summary of MCA scores for sentinel events reporting and review

	Base Case	Option 1	Option 2
Protects the safety and quality of care of patients receiving health services in HSEs (50%)	0	+2	+5
Cost to HSEs; and cost to government (50%)	0	-1	-3
Net weighted score	**0**	**+0.5**	**+1**

7. Admissions information and assessment

This section addresses existing lack of clarity in the current Regulations in relation to pre-admission assessments of patients.

7.1 The nature and extent of the problem to be addressed

Pre-admission assessment allows for planning and management of any identified patient concerns and/or comorbidities by treating health practitioners.[74] Appropriate pre-admission assessments can also prevent late cancellations, which can be distressing to the patient and cause delays in treatment.

The failure to properly assess a patient prior to admission can result in the patient receiving treatment without the treating health practitioners being prepared for any significant clinical risk factors. This means that decisions about the care to be provided may be compromised and an appropriate risk management and escalation plan may not be put in place. The absence of a pre-admission clinical assessment could also result in the patient being admitted to a facility that does not have the capability to manage their risk.

Regulation 20A states that, for the purpose of ensuring the quality and safety of health services provided at a HSE, the proprietor of the HSE must ensure in relation to each non-emergency patient admitted to the HSE that:

a. a pre-admission clinical risk assessment is carried out for each patient before admission
b. the results of the pre-admission clinical risk assessment are recorded in writing, not less than 24 hours before admission
c. the procedure for which the patient is admitted is assessed in relation to the scope of practice of the relevant registered health practitioner providing health services to that patient at the HSE.

Requirements for pre-admission assessments in the Regulations align with NSQHS Standard 5: Comprehensive Care. This Standard aims to ensure that patients receive comprehensive health care that meets their individual needs.[75] Action 5.10 states that clinicians use relevant screening processes:

- on presentation, during clinical examination and history taking, and when required during care
- to identify cognitive, behavioural, mental and physical conditions, issues, and risks of harm
- to identify social and other circumstances that may compound these risks.

[74] Victorian Department of Health (2023). *Perioperative service capability framework for Victoria,* https://www.health.vic.gov.au/health-system-design-planning/perioperative-service-capability-framework-for-victoria. Accessed December 2023.
[75] https://www.safetyandquality.gov.au/standards/nsqhs-standards/comprehensive-care-standard

Under strategies for improvement, the Standard suggests that in Day Procedure Service settings, this Action mostly relates to processes for pre-admission screening. Action 5.11 states that clinicians comprehensively assess the conditions and risks identified through the screening process.

In a survey of 20 Victorian consumers (either a patient and/or a loved one who has had an experience of a private hospital or day procedure centre), having a pre-treatment risk assessment done by an appropriately qualified person (e.g. an anaesthetist or nurse) was rated high in importance (8.7 (weighted average) on a scale of 1-10).[76]

Proposed amendments to the Regulations being assessed in this RIS address the following problems:

- Potential lack of clarity in the requirements about who must undertake a pre-admission clinical risk assessment
- Potential lack of clarity about what information relating to the pre-admission clinical risk assessment must be recorded
- Pre-admission clinical risk assessment requirements in regulation 20A do not apply in instances where patients are not formally admitted to a health service establishment (e.g. to receive outpatient radiation oncology services or sedation from a mobile anaesthetist in a dentist's surgery).

Staff who can undertake a pre-admission clinical risk assessment

Regulation 20A does not specify who must carry out the pre-admission clinical risk assessment. However, the intent of the regulation is to require assessments be conducted by appropriately qualified clinical personnel to ensure patient safety, as implied by the term "clinical" in "clinical risk assessment".

This is consistent with relevant National Standards, for example Action 5.11 states that clinicians comprehensively assess the conditions and risks identified through the screening process.

The regulator reports that while currently a relatively high number of assessments are done by suitably qualified clinical personnel, during regulatory monitoring a small number of facilities have been identified as not complying with the intent of the Regulation. For example, the department identified a day procedure centre that, across multiple sites, used administration staff to undertake pre-admission assessments. Additionally, the regulator observed a potential risk in the pre-admission assessment process in some HSEs, where the establishment allowed administrative staff to collect pre-admission information which was then referred to a clinical person for assessment. The referral to a clinician was indicated by a tick box. If the tick box was not ticked, the pre-admission assessment may not have been conducted by a clinician. These two examples illustrate the need for appropriate processes and clarifications to be put in place to ensure pre-admission assessments are conducted by appropriately qualified personnel.

[76] Health Issues Centre (2023). Health Services Establishments Regulations Review: Consumer Interviews Report. Melbourne, Victoria.

Record-keeping requirements

The current Regulations require the *results* of a pre-admission assessment to be recorded in writing, but do not explicitly require any information about the matters considered and assessed to be documented.

Comprehensive documentation of the assessment aligns with the Documentation of information criterion under the Communicating for Safety Standard in the NSQHS Standards which requires that essential information is documented in the healthcare record to ensure patient safety. For documentation to support the delivery of safe, high-quality care, it should (among other things) include information about assessments, action taken, outcomes, reassessment processes (if necessary), risks, complications and changes.[77] Action 6.11 under this same Standard states:[78]

> *The health service organisation has processes to contemporaneously document information in the healthcare record, including:*
>
> - *Critical information, alerts and risks*
> - *Reassessment processes and outcomes*
> - *Changes to the care plan.*

The intent of Action 6.11 is to ensure relevant, accurate, complete and timely information about a patient's care is documented in the healthcare record to support safe patient care.[79] To support this aim, the standard suggests that the documentation include information about assessments and outcomes. The strategies for improvement for Action 6.11 recommend that documents provide enough information and justification to explain recommendations and instructions (actions to be taken and why), rather than just listing them.

It is understood that comprehensive documentation of clinical assessments is current practice for many HSEs, but regulatory monitoring has identified some instances where this has not been the case and clarification of the requirement in the regulation would assist with further compliance monitoring and enforcement.

Site coverage requirements

Patients can receive prescribed speciality health services delivered by a registered mobile health service provider e.g. anaesthesia and IV sedation delivered by a mobile anaesthetist. In 2021-22, a total of 6,036 patients received services from a mobile health service provider.[80] These mobile services can be 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 regulation 20A does not apply.

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[77] https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/documentation-information

[78] https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/documentation-information/action-611

[79] https://www.safetyandquality.gov.au/standards/nsqhs-standards/communicating-safety-standard/documentation-information

[80] DH data on Mobile Services Activity Summaries, provided December 2023.

While the department reports high levels of compliance by registered mobile services with respect to clinical assessment requirements, the department understands there may be a small number of registered facilities who may be interpreting this provision as not applying to patients treated at those sites.

There are also situations where patients receive a prescribed health service at a registered premises but they are not formally 'admitted' – for example, patients receiving outpatient radiation oncology treatments. This means that the requirement to conduct a pre-*admission* risk assessment under regulation 20A would not apply. The proposed amendment would address this unintended gap.

7.2 Identification of options

7.2.1 The Base Case

The Base Case is no regulations. HSEs would still be required to be accredited to the NSQHS standards, under Section 107 of the Act, so will be assessed against relevant actions relating to pre-admission clinical risk assessments and documentation of information that are included in the Standards, as part of obtaining and maintaining accreditation.

7.2.2 Option 1: Remake current regulations

Section 20A of the Regulations would be remade. Under Section 107 of the Act, HSEs would still be required to be accredited to the NSQHS standards.

7.2.3 Option 2: proposed regulations

Regulation 20A would be remade with the following amendments:

- clarify the pre-admission clinical risk assessment must be completed by a registered health practitioner
- require the matters considered and assessed in the pre-admission clinical risk assessment to be recorded (not just the results)
- clarify that for a HSE that does not formally admit patients, but which provides prescribed services, a pre-presentation clinical risk assessment must be completed and recorded at least 24 hours prior.

7.3 Assessing the options

The section assesses the options against the criteria outlined in chapter 4.

7.3.1 Protects the safety and quality of care of patients receiving health services in HSEs

Base Case

There will be no regulation requiring a pre-admission clinical risk assessment to be carried out and recorded in writing, however NSQHS Standards will apply. There would still be drivers for HSEs to have

pre-admissions processes in place, however there might be some HSEs that would not meet the expected standard in the absence of an explicit requirement in the Regulations. The department's capability to monitor and enforce capabilities would be reduced in the absence of the regulations.

The Base Case is scored 0.

Option 1

Requiring a pre-admission clinical risk assessment in the Regulations makes explicit that the assessment must be undertaken and supports the department's monitoring and enforcement role on this matter. This will have a small positive impact on patient safety and care compared to the Base Case.

Option 1 is given a score of +2 compared to the Base Case.

Option 2

Option 2 clarifies the requirements for who must do the pre-assessment and what information needs to be recorded.

Stakeholder feedback to the consultation indicates that these proposed changes generally reflect current clinical practice, therefore most HSEs won't be impacted.

In 2021-22, over 1 million separations occurred in private hospitals in Victoria.[81] Hypothetically, if the proposed amended requirements affect 5% of pre-admission processes, this proposal has the potential to impact over 50,000 pre-admission processes each year. This example gives an indication of the potential size of impact on patient safety, which is potentially feasible and not immaterial. It should be noted though, these practices are already required in the Standards and the proposed amendments are for clarification only.

There was some support for and some against these proposals in submissions to the discussion paper. In relation to the requirement for pre-admission risk assessments to be comprehensively documented, a private healthcare provider supported the proposal and said it reflected best practice. On the proposal to require a registered health practitioner to do the assessment, the private healthcare provider said:

> *Yes. [our] current preadmission service does this already. Any significant cases trigger a response, which involves alerting the anaesthetist regarding the complexity/ risk of the case.*

The main reason for not supporting these two proposals was that it is already covered in the Standards. However, it is noted that the proposed amendments are being made to clarify the current Regulations and improve alignment with the Standards.

The requirement for clinical assessments for HSEs that do not formally admit patients addresses a current gap in regulations in relation to mobile health service providers (e.g. anaesthetists). The department understands this proposed requirement is current practice by most mobile health service providers so the impact is likely to be small, but will address the risk of some providers not currently

[81] In 2022/23, there were 1,031,819 planned/elective admissions (source: Victorian Admitted Episodes Dataset)

doing so. There was general stakeholder support for the proposal, as shown below by two private healthcare providers:

> *[Private Healthcare Provider] supports the requirements of a pre-procedural risk assessment for anaesthetics being conducted outside of a health service. Risk assessments are beneficial to foresee any actual or potential anaesthetic complications and ensuring the patient's safety who is receiving an anaesthetic agent out of a typical hospital setting.*
>
> *Yes, any health service provider should do this as a basic standard of care.*

Similarly, extending the requirement for a clinical risk assessment to be conducted for patients receiving treatment at a registered HSE without being formally admitted is also intended to address a current gap in the Regulations.

Overall, Option 2 is expected to have a small to moderate positive impact on patient safety and care and is therefore scored +4 relative to the Base Case.

7.3.2 Cost to HSEs; and cost to government

Base Case

There would be no direct costs to HSEs under the Base Case.

Over time, if there are no regulations in place, costs to the government are likely to increase because of the need to respond to complaints and adverse events due to increased risks to patient safety and quality of care.

The Base Case is given a score of 0.

Option 1

The cost to HSEs of Option 1 is expected to be small as Regulation 20A aligns to what is required under the Standards. It is understood that most HSEs currently meet these requirements. HSEs are generally in compliance with the current requirements of Regulation 20A and there has been no feedback from industry that the requirements impose an unreasonable cost.

This option is scored as -2, a small negative impact.

Option 2

As noted previously, the changes being proposed in Option 2 are already current practice for most HSEs and therefore will not impose additional costs compared to the current Regulation.

There will be some costs however for those HSEs that need to change their practices in relation to who undertakes pre-admission clinical risk assessments and what needs to be documented. HSEs currently using administration staff instead of a clinician to undertake the pre-admission clinical risk assessment will incur additional staff costs. Similarly, documenting the matters considered and assessed rather than just the results of an assessment will take more time for each admission. *One* stakeholder noted that the requirement for recording the assessment, rather than the outcome, will be a significant departure from current practice, requiring behavioural change by physicians, in addition to process and system changes including larger data storage and security. Industry is encouraged to provide further information on the cost of this proposal during the public feedback stage on this RIS.

For over 1,000,000 admissions, if changes in pre-admission assessment processes are required for even a small proportion of these, the potential impact on costs is not immaterial. Industry is encouraged to provide further information on the cost of this proposal during the public feedback stage on this RIS.

The requirement for mobile health services to do pre-presentation clinical risk assessments is an additional requirement compared to Option 1. Feedback from industry and input from the department indicates that most mobile health services are already doing pre-presentation clinical risk assessments, so the impact of this change is likely to be small. In 2021-22, a total of 6,036 patients received services from a mobile health service provider.[82] This is a very small proportion of all services provided by HSEs.

The cost to government of this proposal is expected to be small.

Option 2 is given a score of -3, a small additional cost compared to Option 1.

7.4 Summary of MCA and preferred option

Table 8 presents the MCA scores for admissions information and assessments**. Option 2 is given the highest score and preferred** as it provided for increased assurance in relation to the safety and quality of care of patients.

Table 8 Summary of MCA scores for admissions information and assessment

	Base Case	Option 1	Option 2
Protects the safety and quality of care of patients receiving health services in HSEs (50%)	0	+2	+4
Cost to HSEs; and cost to government (50%)	0	-2	-3
Net weighted score	**0**	**0**	**+0.5**

[82] DH data on Mobile Services Activity Summaries, provided December 2023.

8. Infringements

Section 155 of the Act allows an authorised officer to serve an infringement notice on a person whom the officer believes has committed a prescribed offence against the Regulations. However, no infringement offences (or penalties) are currently prescribed in the Regulations. This section considers making this power to serve infringement notices under the Act operational and thereby providing greater options for regulatory compliance and enforcement actions.

8.1 The nature and extent of the problem to be addressed

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

- sets obligations that HSEs must meet
- 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; 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).

Section 155 of the Act 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 the infringement, being an amount not exceeding one-fifth of the maximum penalty applicable to the offence.

Infringements are an important part of the compliance and enforcement toolkit for regulators. Consistent with the Attorney-General's guidelines to the Infringements Act 2006:[83]

- Infringements can be issued swiftly as direct consequence for lower-level and clear offences, thereby addressing non-compliance more quickly than other enforcement options, including by prompting remediation and by deterring future non-compliance, by the HSE or more generally. Increased compliance is expected to have the benefit of reducing risk of harm to patients in HSEs.
- Infringements can be issued without potentially lengthy or costly court proceedings.
- Infringement amounts are lower than the maximum penalty amounts imposed through prosecution and may therefore be proportionate to less serious offences.
- Infringements do not result in a criminal record.

No infringement offences (or penalties) are currently prescribed in the Regulations, which means the power to serve infringement notices under section 155 of the Act is not operational. This leaves a gap

[83] 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>.

in the current regulatory compliance and enforcement toolkit, as the Act and Regulations currently only provide for the most extreme 'full force of the law' methods for dealing with non-compliance. These include court proceedings, which may be extremely costly to all parties and disproportionate to the compliance breach, or registration suspensions or revocations, which would interrupt service delivery (by removing legal authority for operation of the facility).

8.2 Identification of options

8.2.1 The Base Case

The Base Case is no regulations. No offences or penalties would be included in the Regulations. HSEs would still be subject to penalties for offences set out in the Act, which would be enforced through court proceedings, and to other regulatory action (such as suspension or revocation of registration) for non-compliance with obligations under the Act. HSEs would also still be required (under the Act) to maintain accreditation against the Standards.

8.2.2 Option 1: current regulations are remade

Under Option 1, 36 offences[84] and associated penalty units prescribed in the regulations are remade and apply to HSEs, however no infringement offences and penalties would be included in the Regulations. The penalties for non-compliance set out in the Regulations would only be enforced through court proceeding. Some other regulatory actions for non-compliance with the regulations would be available under the Act (for example such as suspension or revocation of registration). HSEs would also be required (under the Act) to maintain accreditation against the Standards.

8.2.3 Option 2: current regulations with the addition of prescribed infringement offences

Under Option 2, 29 new infringement offences will be prescribed in the regulations. These offences are set out below under the current Regulations, with the proposed new regulations included in blue for clarity:

- reg 14(1) [proposed reg 18(1)] – not appointing a suitably qualified person as the DON [Director of Nursing]
- reg 15 [proposed reg 19] – not appointing an acting DON
- reg 16 [to be split into two offences in proposed regs 20(1) and 20(2)] – not notifying the Secretary of the appointment, qualifications and experience of a DON or acting DON within 28 days

[84] If the current regulations are remade under Option 1, the total number of penalty offences will change because regulation 41 'Prevention of scalding' is proposed to be deleted from the Regulations and two other regulations that currently contain two offences (regulations 16 and 21) will be split into separate regulations, each with their own offence penalty, but with no substantive change to the nature of the offences or the associated penalty units.

- reg 17 [proposed reg 21] – not notifying the Secretary of the appointment of a CEO or Medical Director (however titled) within 28 days
- reg 18 [proposed reg 22] – not notifying the Secretary of the termination of a CEO or Medical Director (however titled) appointment or vacancy of the position with 28 days
- reg 19 [proposed reg 23] – not allocating a unit record number to a patient on or as soon as practicable after admission
- reg 20(1) [proposed reg 24(1)] – not giving a patient on or before admission a statement containing information about the health care services provided by the HSEs[85]; fees; and an explanation of the treatment
- reg 21 [to be split into two offences in proposed regs 27(1) and 27(2)] –not creating and maintaining separate clinical records for each patient
- reg 23 [proposed reg 29] – not ensuring a patient can be readily identified by an attached identity band or device or a photograph on their clinical record
- reg 24(1) [proposed reg 30(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
- reg 24(2) [proposed reg 30(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
- reg 26 [proposed reg 32] – not ensuring each nurse is an enrolled or registered nurse with the professional competence, education or experience relevant to the health services being provided
- reg 27(1) [proposed reg 35] – not ensuring a sufficient number of nursing staff are on duty[86]
- reg 29(1) [proposed reg 38(1)] – not nominating a person to receive and deal with patient complaints
- reg 29(2) [proposed reg 38(2)] – not ensuring that patients and staff are informed of the name of the person nominated to receive and deal with complaints
- reg 30(3) [proposed reg 39(3)] – not informing the complainant of the action taken in respect of the complaint
- reg 31(1) [proposed reg 40(1)] – not keeping a written record of every complaint[87]
- reg 31(3) [proposed reg 40(3)] – not storing the record securely for 7 years
- reg 33 [proposed reg 42] – not sending all information and documents relating to a transferring patient's medical condition and treatment to the receiving establishment or agency
- reg 37(1) [proposed reg 47(1)] – not keeping an Operation Theatre Register[88] where surgical health services or endoscopy is carried on
- reg 38(1) [proposed reg 48(1)] – not keeping a Birth Register[89] where obstetrics may be carried on
- reg 38(3) [proposed reg 48(3)] – not keeping a Birth Register for at least 25 years after the date of the last entry

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[85] Regulation 20(2) gives an extensive list of items that must be covered in the statement.
[86] Regulation 27(2) gives the required nurse-to-patient ratios for private hospitals and day procedure centres
[87] Regulation 31(2) lists the information to be recorded
[88] Regulation 37(2) lists the information to be contained in the register.
[89] Regulation 38(2) lists the information to be contained in the register.

- reg 39 [proposed reg 50] – 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
- reg 40(1) [proposed reg 51(1)] – not operating an effective electronic communication system[90] at a registered premises
- reg 44(1) [proposed reg 56(1)] – not implementing and maintaining an Infection Control Management Plan[91]
- reg 45 [proposed reg 57] – not prominently displaying the registration certificate, name of the DON and the name of the CEO or Medical Director if appointed
- reg 46A [proposed reg 66] – not reporting (in writing) a sentinel event to the Secretary within the time determined.

This is additional to the remaking of 36 offences[92] and penalty units specified in the Regulations that may be imposed by a court if a person is prosecuted for a breach of the Regulations.

The offences that are suitable for being an infringement offence (that is, an offence where contravention may result in a fine being issued) are selected by reference to the *Attorney General's Guidelines to the Infringement Act 2006 (2022 Edition)*. These require consideration of several factors, including whether the relevant behaviour should be criminalised, the gravity of the offence, and whether the elements of the offence are all sufficiently clear (unambiguous) such that there is only limited discretion for the officer issuing an infringement notice. The Guidelines also set parameters for the maximum amount of an infringement. In addition, the Act specifies that these can only be 20% of the maximum penalty for the relevant offence.

To assist transparency, as part of the implementation process for the Regulations the department will develop and communicate guidelines about the exercise of the powers to issue infringement notices.

8.3 Assessing the options

This section assesses the options against the criteria outlined in chapter 4. Scores are not awarded for each option as both the costs and benefits to government and HSEs are difficult to predict because they will differ from case to case and over the range of offences and penalties. Further, the options are not binary, rather they illustrate the relative efficiency of the existing range of tools that the department currently has to respond to non-compliance with the regulations, as compared with the preferred option where an additional existing power is operationalised to enable a fuller range of proportionate enforcement activity consistent with established principles of best practice regulation.

8.3.1 Protects the safety and quality of care of patients receiving health services in HSEs

Base Case

[90] Regulation 40(2) specifies the purpose and required functionality of the system.
[91] Regulation 44(2) and regulation 44(30) specify the purpose and requirements of the Plan.
[92] There will be 36 penalty offences if regulation 41 is deleted from the Regulations, and regulations 16 and 21 are each divided into two regulations with associated penalty offences.

Under the Base Case, the offences and associated penalties specified in the regulations would no longer apply to HSEs. However, HSEs would still be subject to other offences and penalties set out in the Act.

Option 1

Option 1 maintains the current arrangements with no proposed amendments. There continues to be no mechanism for an authorised officer to serve an infringement notice for non-compliance with penalty provisions in the regulations, as no infringement offences are prescribed in the regulations.

Thirty-six offences and associated penalty units that are currently set out in the regulations[93] would be remade and apply to HSEs. The maximum penalty amounts set out in the regulations could only be imposed by a court through a prosecution proceeding. In addition to prosecution to impose those penalties, the department would retain the powers (in the Act) to suspend or revoke registration if the proprietor of an HSE has failed to comply with the regulations, or is not likely to continue to carry on the HSE in compliance with the regulations.

Although this option is an improvement on the Base Case, the actions available to the department to regulate and enforce compliance with the relevant provisions of the regulations are limited.

Prosecution and court proceedings are often not the most appropriate regulatory response to non-compliance. Not only can they be protracted, onerous and costly, but they might also be a disproportionate course of action given the level of non-compliance. This can deter the use of such action, which significantly limits how the regulator can enforce compliance through offences and penalties. Suspension and revocation of registration, which affect the legal authority of the HSE under the Act to provide services, are likewise significant regulatory interventions that may not be proportionate to the nature and scale of non-compliance with the relevant provisions in the regulations.

All enforcement action is intended to drive compliance to best achieve the quality and safety benefits of the relevant regulations. This option limits the avenues for enforcement as compared to Option 2 (see below) so on the quality and safety of care criterion it is not preferred.

Option 2

Prescribing infringements offences in the Regulations will provide the department, as the regulator of HSEs, an additional mechanism to address non-compliance. This should bridge a current gap in dealing with lower-level offences, where court proceedings, registration suspensions, or other 'full force of the law' sanctions are disproportionate to the nature and level of non-compliance. This may provide a more appropriate (timely and proportionate) tool to address some non-compliance. This also supports an alternative to criminal prosecution where appropriate.

Feedback received via consultation on the proposed changes was largely non-supportive: various stakeholders suggested that punitive measures should be reserved for extreme cases, but non-

[93] There will be 36 penalty offences if regulation 41 is deleted from the Regulations, and regulation 16 and 21 are each divided into two regulations with associated penalty offences.

punitive methods were preferred to ensure transparency (e.g., willingness to self-report errors without fearing a fine).

As permitted under section 155 of the Act, the proposed infringement amounts have been calculated at 20% of the current penalty amounts in the Regulations[94]. They range from 2 penalty units (currently $385) up to 12 penalty units ($2,308). These amounts take into account the nature and potential consequences of any non-compliance and are intended to have a deterrent effect. For example:

- The highest proposed amount of $2,308 is the penalty for not having an operational electronic communications system (reg 40(1)) or not implementing and maintaining an Infection Control Management Plan (reg 44(1)). This amount reflects the potentially serious impacts of non-compliance on an entire facility, staff, patients and carers in the absence of an operational communications system or effective Infection Control Management Plan
- The mid-range amounts ($1,538-$1,923) relate to senior appointments (DON), nurse credentialling, sufficient staffing levels, information on fees and services for patients, and some complaints-related matters. Any non-compliance with these regulations could significantly compromise quality and safety across the whole facility (e.g. from unqualified staff) or significantly impact individuals (e.g. a patient not fully informed about costs or treatments, or about the outcome of their complaint)
- The lower-range amounts ($385-$769) are largely related to administrative non-compliances (e.g. not notifying the Secretary about senior appointments, not displaying information prominently). As direct impacts on patient safety and service quality from these non-compliances would be minimal, the infringement amounts reflect this reduced risk of harm.

Further, as set out above, the offences to be prescribed have been selected in accordance with the *Attorney General's Guidelines to the Infringement Act 2006 (2022 Edition)*, which provide for consideration of various factors including the gravity of contravention and clarity of the elements of the offence, to ensure that the issue of a fine is a reasonable and proportionate regulatory response. Further, to assist transparency the department will develop and communicate guidelines about the exercise of the powers to issue infringement notices.

Compared to the Base Case and Option 1, Option 2 provides more scope to enforce compliance with the regulations, from low-level administrative non-compliances – such as not displaying information prominently – which will incur a smaller financial penalty, through to more serious offences – such as not implementing and maintaining an Infection Control Management Plan - which will incur a larger financial penalty. The power to prosecute and undertake court proceedings, or suspensions or revocations of registration, will still be available as per Option 1.

Having an operationalised power to issue infringement notice for non-compliance with these requirements would allow earlier and more proportionate regulatory intervention to address non-compliance. This is expected to improve rates of compliance, by prompting remediation of non-compliance and acting as a specific and general deterrent for future non-compliance. Higher

[94] Except for regulation 44, where the proposed infringement penalty of 12 penalty units is less than 20% of the penalty amount.

incidence of compliance makes it more likely that the intended quality and safety benefits of the relevant regulations will be realised.

8.3.2 Cost to HSEs; and cost to government

Base Case

Under the Base Case there would be no direct costs to HSEs apart from the cost of complying with national standards and with obligations in the Act (including penalty provisions). The cost incurred by the department would be minimal as they have limited ability to monitor compliance.

Option 1

Under this option, where HSEs are compliant with the relevant regulations there are no costs to HSEs or to government for enforcement of the penalties for non-compliance.

It is expected that court proceedings to impose penalties for offences set out in the Regulations would be very costly for both HSEs and government. These would include court fees, fees for legal services (advice and representation) and costs associated with compilation and production of evidence (in documentary or testamentary form). These costs could vary considerably depending on the matters at issue in the proceeding, related evidentiary requirements, and decisions made by the parties, about their position in the proceedings and about the legal advice and representation they seek. Prosecutions may not be pursued very often, given regulatory experience is of relatively high levels of compliance overall, and given prosecution may not be the most appropriate regulatory response to all instances of non-compliance. This may mean that in practice the cost of prosecutions is not very high overall across the entire registration scheme. However, the costs to HSEs and to government of prosecution as a means of imposing penalties for the relevant offences (this Option 1) are much higher than the costs for issuing and paying infringements under Option 2 (below), where the costs described above are significantly less likely to arise.

Option 2

Under this option, where HSEs are compliant with the relevant regulations there are no costs to HSEs or government associated with enforcing the penalties for non-compliance. Under this option, the department may incur more costs in the short term as compared with Option 1 and the Base Case. The department would be able to issue infringement notices under Option 2, which would be a new area of regulatory activity not currently undertaken. There may also be initial administrative costs to the department, associated with establishing the systems and processes for issuing infringement notices. However, the costs of issuing infringement notices are expected to be lower than the cost of pursuing prosecution to impose penalties for the relevant offences as the legal costs described for Option 1 are much less likely to arise. Further, in the longer term, where introduction of infringement notices allows earlier intervention to rectify non-compliance or to deter non-compliance, it may reduce the number of compliance breaches that the department needs to respond to and thereby reduce enforcement costs overall. Overall, efficiencies in government costs are expected over time as regulatory activity is appropriately streamlined and focussed, with higher-resource activity focussed on instances of highest risk to patients, and more serious or complex non-compliance.

Under this option, costs to HSEs are expected to be lower than under Option 1. Responding to an infringement notice will not incur the legal process costs associated with a prosecution (as discussed

in Option 1 above). Where an HSE is non-compliant with a relevant provision of the regulations and an infringement notice is issued the HSE will incur the costs specified in the notice (see section 8.3.1.1 above for examples of dollar amounts). The existence of an additional enforcement option for the regulator may mean that, due to the prospect of an infringement notice, or the issuing of an infringement notice, more non-compliant HSEs may take steps to ensure they become compliant (as compared to Option 1).

The cost to HSEs of taking such actions is not considered in assessing the preferred option in this section as HSEs are already expected to be compliant with requirements, meaning that to factor in these costs would be contrary to the objectives of the decision-making criteria. However, the benefits of these actions are considered in assessing the preferred option because improved compliance will support the quality and safety objectives of the regulatory framework. Moreover, the addition of infringement notices as an additional enforcement tool for the regulator is expected to allow earlier intervention to address non-compliance, often non-compliance that is less serious and would not form the basis of prosecution action. It is therefore considered that Option 2, allowing a fuller range of proactive and proportionate enforcement responses, is overall the more efficient way to drive improvements in compliance. This may include prompting actions to improve compliance at earlier stages so those actions are less costly.

8.4 Summary of preferred option

Option 2 is the preferred option as it allows a more proactive and efficient approach to enforcing compliance with relevant requirements in the regulations to achieve intended safety and quality benefits. The precise costs to government and HSEs may depend on how the proposed infringement notice approach is implemented. Information on this will be developed and published as part of the implementation of the updated regulations. It is expected that the compliance and enforcement approach taken by the department will consider the level of risk to patient safety, the HSE's compliance history and willingness to engage in remedial activities, and which enforcement tool will most efficiently and effectively address the non-compliance. The regulator will continue to use lower-level interventions to address non-compliance, including providing guidance to HSEs and making written recommendations for how compliance can be achieved. Infringement penalties are likely to be used where non-punitive approaches have failed and where stronger sanctions (such as prosecution or suspension or revocation of registration) would not be necessary or appropriate. Overall this is expected to better ensure that costs relating to enforcement of the relevant regulations are proportionate to the quality and safety risk arising from non-compliance.

9. Administrative changes and clarifications

This section addresses administrative changes and clarifications to the Regulations in relation to:

- Regulation 20(1) – Information about fees and services.
- Regulation 20(2) and regulation 25 – Addition of 'gender identity'
- Regulation 28A – Reversible agents
- Regulation 34(3)(e) – Discharge information to be given to patients
- Regulation 37 – Operation Theatre Register
- Regulation 41 – Prevention of scalding
- Regulation 45 - Information to be prominently displayed
- Regulation 46 – Returns and reports to be given to the Secretary
- Regulation 48 – Review of quality and safety of health services provided

A detailed analysis is not undertaken for these changes.

9.1 Regulation 20(1) – Information about fees and services

The current Regulations require patients to be provided with information about fees and services, including information about fees to be charged by the HSE and any likely out of pocket expenses which may be incurred by the patient (under regulation 20(1)(b)).

In 2022-23, the HCC had 6,128 recorded issues against non-general health service providers (i.e. providers providing health services that require a registered health practitioner under the National Law[95]). Of these, 8% related to fees, costs and billing, and 6% related to communication.[96]

In a survey of 20 Victorian consumers[97], the provision of pre-admission information on fees, services and procedures was rated the most important type of information and communication.[98] A follow up consumer workshop on this matter identified that consumers would like more information about third party fees (e.g. pathology, pharmacy, patient transport, surgeon, anaesthetist costs). Consumers indicated setting an expectation ahead of time about the type of fees that may arise helps in patient decision-making regarding their care.[99] Third party fees are additional to the fees for health services charged by HSEs, and are charged to the patient separately by the third party. Third party fees can be a significant cost to patients.

Proposed amendment to the Regulations

- Regulation 20(1)(b) would be amended to require that information to be provided about fees charged includes fees that may be charged by third parties (i.e. separate to fees charged by

[95] *Health Practitioner Regulation National Law Act 2009*.
[96] HCC, Annual Report 2022-23. Found at https://www.hcc.vic.gov.au/sites/default/files/media-document/HCC%20Annual%20Report%202022-2023_0.pdf
[97] Either a patient and/or a loved one who has had an experience of a private hospital or day procedure centre.
[98] Health Issues Centre (2023). Health Services Establishments Regulations Review: Consumer Interviews Report. Melbourne, Victoria.
[99] Consumer consultation workshop held February 2024.

the HSE) in relation to the services provided at the HSE. This would be a statement informing of potential fees from third parties rather than the HSE being required to provide an estimate of the fee for any items.

9.2 Regulation 20(2) and regulation 25 – Addition of 'gender identity'

Regulation 20(2)(c) requires a statement to be provided to patients that contains information about the consideration of a patient's beliefs and ethnic, cultural and religious practices. Regulation 25(a) requires that the proprietor of a HSE must ensure that a patient is treated with dignity and respect, and with due regard to his or her religious beliefs and ethnic and cultural practices.

Discrimination against someone because of their gender identify is against the law in Victoria. Under the *Equal Opportunity Act 2010* (Vic) a person must not discriminate against someone because of their gender identity (Part 2, Section 6 of the Act). There is also a duty under Part 3 to eliminate discrimination, sexual harassment or victimisation, i.e. rather than responding after a complaint has been made.

The *Sex Discrimination Act 1984* (Cth) makes it unlawful to treat people less favourably than another person in a similar situation because of their gender identity (section 5B).

Under the Standards, Partnering with Consumers Standard Action 2.03, health services organisations are to have a charter of rights that is consistent with the Australian Charter of Healthcare Rights, and easily accessible for patients, carers, families and consumers. Consideration of gender identity aligns with this action.

Ensuring that health services are inclusive and do not discriminate against someone on the basis of their gender identity was rated highly by consumers in consultation. [100]

Proposed amendment to the Regulations

- Regulation 20(2)I and Regulation 25(a) would be amended to include the words 'gender identity'. This aligns with the positive duty under the Equal Opportunity Act to eliminate discrimination, sexual harassment or victimisation, not just respond to it. The gender neutral pronoun 'their' will also replace 'his or her' in Regulation 25(a).

9.3 Regulation 28A – Reversible agents

The current regulations refer to 'reversible agents' in regulation 28A. However, there is evidence that the term 'reversal agents' is currently used in anaesthesia practice e.g. in the Australasian Anaesthesia 2023 publication.[101]

[100] Consumer consultation workshop held February 2024.

[101] Australian and New Zealand College of Anaesthetists (2023). Australasian Anaesthesia (aka the Blue Book). Accessed December 2023 at https://www.anzca.edu.au/getattachment/9ec71c61-8a66-4f81-b0f8-c87d65e36298/Australasian-Anaesthesia-2023

According to the Subordinate Legislation Act 1994 Guidelines, regulations must be expressed in a language that is clear and unambiguous.[102] Ensuring that the regulations are kept up-to-date with the latest terminology is important to ensure the regulations are easily understood.

Proposed amendment to the Regulations

- Regulation 28A would be amended to "reversal agents must be available" from "reversible agents" to more accurately reflect accepted terminology.

9.4 Regulation 34(3)(e) – Discharge information to be given to patients

Medications are the most common treatment in healthcare. They are associated with a higher incidence of errors and adverse events, compared to other healthcare interventions, and these events can be costly in terms of morbidity, mortality and resources.[103] Changes to a patient's medication regimen during a hospital stay are common, and many medicine-related incidents that may cause harm occur at transitions of care.

Reflecting its importance, medication management is addressed directly in NSQHS Standard 4 – Medication Safety. Under Action 4.12, health service organisations must have processes to provide patients on discharge with a current medicines list and the reasons for any changes.[104]

The Regulations require that a list of all medications currently prescribed be provided as part of the discharge summary for all admitted patients, irrespective of whether the medication is in relation to the health service received (regulation 34(3)(e)). The purpose is to ensure appropriate continuity of care for the patient, whether they are transferred to another facility or discharged home (including ongoing primary care).

Regulation 34(3)(e) applies to all admitted patients, including those undergoing day procedures. In 2021-2022, there were 1,083,287 separations in private hospitals in Victoria. Of these, almost 70 per cent (748,180) were discharged on the same day.[105] Many day procedures are exploratory (e.g. endoscopy) or minor, and do not involve any changes to a patient's medications. Unlike with overnight or extended hospital admissions, when a patient undergoes a day procedure, the HSE does not take over their medication management. They are, however, expected to have processes in place to communicate any medication changes.

The Medication Safety Standard's strategies for improvement with respect to day procedure centres note that the requirement to provide a medications list is not applicable for day procedure services if they provide evidence that they are not changing or altering patients' medicines during an episode of care. This indicates that the Standards do not envisage day procedure centres providing detailed

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[102] Victorian Department of Premier and Cabinet (2023). Subordinate Legislation Act 1994 Guidelines. Accessed December 2023 at https://new.parliament.vic.gov.au/4a7aed/globalassets/tabled-paper-documents/tabled-paper-7465/subordinate-legislation-act-1994-guidelines-september-2023.pdf

[103] Australian Commission on Safety and Quality in Health Care. *National Safety and Quality Health Service Standard 4: Medication Safety Standard*.

[104] Ibid.

[105] AIHW admitted patient care data, Table S2.1: Separation statistics, public and private hospitals, 2021-22.

medication information on discharge if no changes are made to the patients' current medication, though the Department understands it would still be expected that the discharge summary note that no changes had been made.

Feedback from the sector was that the existing requirement for patients staying overnight is also unnecessarily prescriptive and does not reflect the risk-based approach included in the Standards and adopted by most health services. They argue the current requirement is burdensome when applied to patients who are deemed low risk with no relevant medication changes, and note that the process of transcribing medications lists can introduce a risk of errors. The Commission has advised that the Standards outline safety and quality outcomes that a health service organisation must achieve, while allowing health service organisations the flexibility to decide how to achieve these outcomes in a way that is appropriate for their context. Discharge information will vary between patients, and organisations need to identify those patients most at risk and ensure they receive the information they need.

The proposed amendments to the regulations remove the requirement for day procedure centres or private hospitals who discharge patients within one day to provide a full medication list. It is also proposed that the requirement for private hospitals to provide overnight patients with a full medication list on discharge be amended to instead require a 'medication summary', where assessed as clinically safe and appropriate. Using the term 'summary' would allow hospitals the option of providing a statement rather than documenting a full medication list for patients they deem as low risk (e.g. a summary could say "No changes to pre-existing medication list"). For many patients where the risks are higher, for example, due to complexities in the patient's condition or the types and combinations of medications being prescribed, a full medication list would still be necessary and appropriate to ensure their safety. All discharge summaries would be expected to clearly document any changes, cessations or additions to prescribed medications that occurred during the patient's time at the facility. These amendments are intended to reduce unnecessary regulatory burden on HSEs and align the Regulations with the Standards.

Proposed amendment to the Regulations

- Regulation 34(3)(e) – information to patients on discharge regarding lists of medications – would be amended to require the following:
  - For private hospitals:
    - a summary of current medications including details of any cessations, variations or additions made to the regular prescribed medication for patients that stay one or more nights in the facility.
    - any cessations, variations or additions to prescribed medications must be on the patient's discharge summary for patients who are discharged within one day.
  - For day procedure centres:
    - any cessations, variations or additions to prescribed medications must be on the patient's discharge summary.

9.5 Regulation 37 – Operation Theatre Register

This amendment is proposed to ensure that the title of the regulation reflects the intention of the provision, which is that the register requirement is not limited to procedures conducted in an operating theatre but rather covers all 'surgical services' and speciality endoscopy services, wherever in the facility they are performed.

Proposed amendment to the Regulations

- Regulation 7 - Amend title and provision to refer to 'Surgical Procedure Register' rather than 'Operation Theatre Register'.

9.6 Regulation 41 – Prevention of scalding

Regulation 41 states that the proprietor of a HSE must ensure that every bath, shower and hand basin used by patients is installed with a system or mechanism to avoid the risk of scalding by controlling the outlet temperature of hot water.

Regulation 41 is duplicative of existing national and state-based legislative requirements. Plumbing work (including water temperature requirements) in Victoria is regulated through a framework which includes the *Building Act 1993*, *Plumbing Regulations 2018*, the National Construction Code, Plumbing Code of Australia, and referenced documents. These requirements are also set out in the Victorian Health Building Authority (VHBA) Engineering Guidelines.

Proposed amendment to the Regulations

- Regulation 41 – prevention of scalding – would be deleted.

9.7 Regulation 45 – Information to be prominently displayed

Under the current regulations, there is no requirement to display the accreditation certificate issued under the accreditation scheme that is approved by the Secretary under section 107 of the Act. HSEs are only required to display their registration certificate issued under section 85 of the Act. Displaying the accreditation certificate alongside the registration certificate may help ensure patients are further informed about the safety and quality of the services provided at the facility.

The requirement to display the accreditation certificate supplements information already published by the Commission about the accreditation status of facilities. There is evidence from sector stakeholders that, in practice, the accreditation certificate is already displayed.

In the HIC-led consumer interviews and workshop, there was strong interest in knowing about an HSE's accreditation when accessing their health services. Consumers supported making accreditation information about HSEs more available to consumers by having the certificate displayed in a prominent place. There was a range of views about the ideal location, including foyers and reception areas, waiting rooms, nurses' stations and elevator areas.

Proposed amendment to the Regulations

- Regulation 45 – information to be prominently displayed in facility - would be amended to include the certificates(s) issued in respect of the facility under the accreditation scheme approved by the Secretary under Section 107 of the Act.

9.8 Regulation 46 – Returns and reports to be given to the Secretary

Unlike other HSEs, mobile health services (usually anaesthetic and intravenous sedation services) are not required to report any Victorian Admitted Episode Data 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 to the department annually via a template that is emailed to the proprietor of the mobile health service establishment. It is proposed to formalise this arrangement to ensure data is received in a full and timely manner, thus supporting the department's oversight of the sector and risk-based monitoring.

Proposed amendment to the Regulations

- Regulation 61 - Insert additional provision to allow the Secretary to direct statistical returns from mobile HSEs (i.e. those registered HSEs where services are provided primarily from—rather than at—the registered premises) – in the form and within the timeframes directed by the Secretary.

9.9 Regulation 48 - Review of quality and safety of health services provided: adding a requirement for transfers out for escalation of care

Transfers out are critical for supporting the safety and effectiveness of the Victorian health system. In instances where patients require a higher level of care than can be safely provided by an HSE, they may be transferred out of the HSE to an emergency department in another hospital to receive the care they need.

Transfers are often the safe and appropriate thing to do given the patient's condition and the capability of the HSE to escalate care accordingly. It may be standard protocol at many facilities for certain cohorts of patients to be transferred out if their condition deteriorates. During consultation, the sector pointed to neonatal transfers and mental health transfers as examples of this.

While these types of transfers would not be viewed as indicators of poor performance or delays in recognising or responding to patient deterioration, other types of transfers out may indicate that unexpected circumstances have arisen that the HSE was not prepared for and cannot manage - for example, if patient risk indicators are missed during pre-admission clinical assessments. Transfers out could also indicate that HSEs are admitting certain cohorts of patients for certain types of procedures or treatments that are beyond the HSE's capability framework.

VAED data shows that transfers out are a common occurrence in the private sector. In 2021-22 there were 19,302 transfers out of private hospitals and day procedure centres, and in 2022-23 there were 18,827.[106] However, as no clinical reason for transfers is collected, it is not possible to know how many were due to patients requiring escalated care. Public hospitals receiving emergency transfers for escalation of care have advised the department that such transfers are reasonably common and suggested there are gaps in the department's oversight about the prevalence or severity of these transfers.

As transfers may, in some situations, indicate underlying systemic issues at an HSE, the department proposes to amend the regulations to require HSEs to record and review transfers out for escalation of care as part of their regular quality and safety review processes. The department proposes to add this requirement to existing regulation 48, which requires HSEs to record and review at least every 3 months other information related to patient incidents, such as adverse events, sentinel events, mortality and morbidity. As a complement to an HSE's current overall quality and safety monitoring, regular internal reviews of this cohort of transfers out may provide useful insights and lessons.

Proposed amendment to the Regulations

- Regulation 48 - require the proprietor to record in writing and review at least every 3 months all patient transfers from the health service establishment to another health service establishment or health care agency for the escalation of patient care.

Under Regulation 35(c)(viii) HSEs are already required to record in the patient admission and discharge register, if a patient is transferred to another health service establishment or health care agency, the name of that establishment or agency and the reason for the transfer. In practice, the sector has advised that transfers out are recorded in internal incident management systems, along with data relating to SAPSEs, sentinel events and other incidents. Some HSEs have also indicated that transfers out are routinely examined as part of their quality and safety review processes.

In terms of impact of this proposed change, the department considers this to be a minor amendment as it will formalise current practices for most HSEs that are already likely to be collecting and reviewing this data. However, HSEs are encouraged to quantify any incremental costs in their response to this RIS.

It is anticipated this requirement will come into effect some time after the new Regulations are made, to allow further consultation and communication. Feedback received in response to this RIS will inform assessment of the timeframe reasonably required to prepare for implementation.

[106] Data from the Victorian Admitted Episodes Dataset.

9.10 Regulation 48 - Review of quality and safety of health services provided: adding a requirement to provide information to the Secretary on request

Under the Act (section 147), during a site inspection of a HSE, an authorised officer can request access to records and documents, which includes any records that are currently required to be kept and reviewed under Regulation 48. It is proposed to amend the Regulations to provide a streamlined and transparent mechanism for the Secretary to request records kept under Regulation 48 at any time upon request, not just during a site visit of the facility.

These requests will not be for routine, regular reports to be provided by every HSE. During consultation, the sector noted a high reporting burden overall, including reporting through various mechanisms at various times. For this reason, the department has proposed an 'upon request' model for HSEs to provide information. The Secretary may request data from individual HSEs on occasion, for example during a registration renewal assessment or as part of its risk-based approach to compliance monitoring. This may expand the department's understanding of matters related to compliance under the Regulations and also provide a means for the Secretary to obtain more information if there are concerns about a HSE operating outside its capability or about its quality and safety performance.

Proposed amendment to the Regulations

- Regulation 48 - Amend to specify that information recorded and reviewed under this Regulation must be made available to the Secretary on request.

In terms of impact of this proposed change, the department considers this to be a minor amendment as HSEs are already required to record the matters set out in existing Regulation 48. There may be incremental costs related to the proposed additional recording of transfers out for escalation of care under this amended regulation although, as described in 9.6.3 above, HSEs are already required to record all transfers out under Regulation 35(c)(viii).

One sector stakeholder advised that the process of extracting records from internal incident management software is likely to be manual and may therefore introduce a cost burden. However, this feedback was provided when the department was considering a periodic reporting model rather than the current proposal for information to be provided only upon request. Under the current proposal, any additional burden would be infrequent – for example, it may only occur at registration renewal, and the information requested will likely be confined to a limited time period. However, HSEs are encouraged to quantify any potential costs in their response to this RIS.

It should also be noted that the department and SCV plan to continue working together to enhance analysis of existing datasets (e.g. VAED, VEMD) and develop meaningful performance indicators to drive improvements across the public and private health sectors. The department will also continue to seek opportunities to improve data collection mechanisms to minimise reporting burdens on HSEs.

10. Fees

This chapter outlines proposed fees for recovering the costs of regulation of HSEs. It is proposed to remake the Regulations with no change to the current fee arrangements, except for the introduction of a fee for applications to use particular land or premises as a private hospital or day procedure centre, which is a minor change.

10.1 Why are fees needed

The department's costs of administering the HSEs registrations process and other costs of regulating the establishments that give rise to the need for the department's regulatory activities are estimated to be $1,415,800 per annum (see detail in section 10.3).

This section sets out the legal authority for setting fees under the Act, considerations under the Pricing for Value Guidelines for setting fees, and the rationale for setting fees in the regulations.

10.1.1 Legal authority to set fees

The Act enables the department to set fees to recover the costs associated with regulation of HSEs. Specifically, it provides for the department to prescribes fees for the following:

Power to set prescribed fee	Act reference
An application for AIP of: • the use of particular land or premises as a specified kind of HSE; • premises proposed to be constructed for use as a HSE of a particular kind; or • alterations or extensions to premises used or proposed to be used as a HSE.	s 70(2)(b)
An application for AIP of a variation of the registration of a HSE for: • an alteration in the number of beds to which the registration relates; • in the case of a day procedure centre or private hospital: - a variation of the kinds of prescribed health services that may be carried on at, or from, the premises - a variation of the number of beds that may be used for specified kinds of prescribed health services.	s 70(2)(b)
An application for transfer or variation of certificate of AIP	s 74(2)
An application for registration of premises as a HSE of a particular kind	s 82(2)(b)
Prescribed annual fee for registration	s 87(2)
An application for renewal of registration of HSE	s 88(2)(b)
An application for variation of registration of HSE	s 92(2)(b)

The department currently prescribes fees in the Regulations for all of the items that the Act enables fees to be charged for except a prescribed annual fee for registration.

10.1.2 Pricing for Value considerations

The Department of Treasury and Finance's *Pricing for Value* guide establishes the pricing principles that can be used for setting fees and charges, as well as a playbook which is a step by step 'how-to' guide for undertaking a review of an entity's fees and charges. As the relevant Victorian Government guidance, the Pricing for Value Guide is used to inform the analysis of fees in this RIS. The MCA framework is not used in considering fees, partly because it would be difficult to score the quality and safety criterion given fees may not directly impact patient outcomes.

The Pricing for Value principles are as follows:

How much does the service cost?	**1**	Agencies should aim to recover the full costs of service provision to promote efficient consumption
	2	The cost of service provision should be borne by those who benefit from the service
	3	Services creating broad benefits for the community should be priced to support efficient consumption
Who benefits from the service?	**4**	The cost of interagency services should be borne by the user agency
	5	The price of services should not limit access to those with a lower ability to pay
How do different users value the service?	**6**	Users should pay for differentiated service based on the value created by that differentiation
	7	The public should share in the value generated by pricing based on user differentiation
How will the price of the service impact behaviour?	**8**	Pricing should support positive behaviours
	9	Pricing should ensure sustainable usage of public services and reflect the value of natural resources
Are there alternatives to this service?	**10**	Where services are in competition with the private sector, pricing should be relative to market prices
How many different prices are there?	**11**	Pricing structures should be easy to understand and simple to administer
Are prices up to date?	**12**	Pricing arrangements should be monitored annually and reviewed periodically

For this review of fees and charges for HSEs, cost recovery is the key focus. Principles under the Pricing for Value guide relating to innovative pricing and sharing value are not relevant to the Regulations being considered.

Other key issues in respect of cost recovery and fee setting for this RIS are:

- What costs need to be recovered
- Whether fees should be established, and if so what level of cost recovery they should achieve.
- The structure and level of the fees.

Each of these issues is considered in the following sections.

10.2 Objectives

The desired outcome is to facilitate efficient administration of the Act by ensuring fees are received appropriate to the cost of Regulation activities. The objectives of prescribing fees are to:

- effectively recover the costs to the department of administrating the Act
- equitably distribute the costs incurred by the department across the registered HSEs.

10.3 The department's recoverable costs

This section estimates the department's costs of administering the department administering the Act as it relates to AIP and registration applications and associated tasks. Outputs and activities are identified, then the cost of each output is estimated.

10.3.1 The department's outputs and activities

The department's outputs and activities in relation to administering the Regulations are outlined in Table 9, with further detail provided in Appendix A.

All of the outputs and activities align to applications that are provided for in the Act, and for which fees are prescribed in the current Regulations, except for a proposed new fee, for an application for an AIP to use particular land or premises as a private hospital or day procedure centre. There is power to prescribe a fee for this – being an application made under section 70(2)(b) of the Act - but a fee has not currently been set for these types of applications because they were historically not received. Current operational experience is that the Regulator now receives these type of applications so it is proposed to prescribe a fee for this. The costs of administering this aspect of the regulatory scheme (that is of assessing the application and making a decision as to whether approval in principle will be granted) are similar to those for an application for AIP to construct premises for use as a private hospital.

Table 9 The department's outputs and activities

Regulation	Output	Department activity
AIP		
reg 8(2)[107]	**Application for an AIP** (a) to use particular land or premises as a private hospital or day procedure centre (b) to construct premises for use as a private hospital (c) to make alterations or extensions to a premises used or proposed to be used as a private hospital (d) to construct premises for use as a day procedure centre	Decide whether to grant or refuse an application for an AIP in accordance with prescribed criteria

[107] Under Regulation 8(2) currently except for (a) to use particular land or premises as a private hospital or day procedure centre, which is proposed for inclusion.

Regulation	Output	Department activity
	(e) to make alterations or extensions to a premises used or proposed to be used as a day procedure centre (f) to use premises as a health service establishment from which health services are to be provided at premises other than the first-mentioned premises (g) to vary the registration of a health service establishment	
reg 9(b)	**Application for transfer or variation of certificate of AIP**	Decide whether to grant or refuse an application for transfer or variation of AIP certificate in accordance with prescribed criteria
Registration		
reg 10(2)	**Application for registration** (a) for a HSE with 0 to 26 beds (b) for a HSE with 27 to 50 beds (c) for a HSE with 51 to 75 beds (d) for a HSE with 76 to 100 beds (e) for a HSE with 101 to 150 beds (f) for a HSE with 151 to 200 beds (g) for a HSE with 201 to 300 beds (h) for a HSE with 301 to 400 beds (i) for a HSE with 401 to 500 beds (j) for a HSE with 501 or more beds	Decide whether to register or refuse to register premises as HSE in accordance with prescribed criteria
reg 12(2)	**Application for renewal of registration** (a) for a HSE with 0 to 26 beds (b) for a HSE with 27 to 50 beds (c) for a HSE with 51 to 75 beds (d) for a HSE with 76 to 100 beds (e) for a HSE with 101 to 150 beds (f) for a HSE with 151 to 200 beds (g) for a HSE with 201 to 300 beds (h) for a HSE with 301 to 400 beds (i) for a HSE with 401 to 500 beds (j) for a HSE with 501 or more beds	Decide whether to renew registration or refuse to renew registration in accordance with prescribed criteria
reg 13(2)	**Application for variation of registration** (a) for the transfer of the certificate to another person who intends to become the proprietor (b) for any other case	Decide whether to vary or refuse to vary registration in accordance with prescribed criteria

10.3.2 Estimating costs

Direct costs are incurred exclusively for specific activities and can be specifically attributed to specific activities. The department's direct costs of undertaking the activities set out in Table 10 were estimated using an activity-based costing method. This involved, for each activity:

- identifying the tasks required to be undertaken
- estimate of time for each activity based on the department's expectation of performance, drawing on current and historical experience
- identifying the cost per hour for undertaking each activity, drawing on VPS salary grades of the person(s) undertaking the task or contracted rates for external suppliers
- calculating the sum of the cost of tasks to give the total cost of undertaking an activity.

Detail on the estimation of direct costs is provided in Appendix A.

The department also incurs fixed costs in undertaking its regulatory activities, which are less able to be attributed to specific activities. The estimate of fixed costs for 2024-25 is $158,471. These include staff costs associated with development of policy and guidance materials, complaints and incident review and management, contract management, compliance and enforcement, website and information management, oversight of high risk facilities and management of issues identified. These costs are included in the recoverable cost by allocating to outputs directly where possible or allocating to outputs based on proportion of costs.

Table 11 shows estimated total costs split by direct costs and fixed costs. Total costs for the first year of the regulations, 2024-25, are expected to be $1,415,800.[108]

Table 10 Department's costs of regulating HSEs, $2024-25

	2024-25 $
Direct costs	1,257,329
Fixed costs	158,471
Total costs	**1,415,800**

Table 12 shows estimated costs by output (including both direct and fixed costs).

[108] Costs are likely to change over time, for example an increase would be likely due to wage increases under Victorian Public Service Enterprise Agreements. The indexation of fee units by the Treasurer is intended to increase fees in line with inflation so that fees do not decrease in real terms (see section 10.4).

Table 11 Department's estimated costs of regulating HSEs, by output, 2024-25

Output	Estimated cost per application $	Forecast number of applications	Total cost $
Approval in principle			
Application for an AIP			
(a) to use particular land or premises as a private hospital or day procedure centre	5,511	1	5,511
(b) to construct premises for use as a private hospital	5,511	1	5,511
(c) to make alterations or extensions to a premises used or proposed to be used as a private hospital	5,511	9	49,595
(d) to construct premises for use as a day procedure centre	5,511	3	16,532
(e) to make alterations or extensions to a premises used or proposed to be used as a day procedure centre	5,511	2	11,021
(f) to use premises as a health service establishment from which health services are to be provided at premises other than the first-mentioned premises	5,511	3	16,532
(g) to vary the registration of a health service establishment	797	20	15,945
*Application for transfer or variation of certificate of A*IP	797	-	-
Registration			
Application for registration			
(a) for a HSE with 0 to 26 beds	5,235	8	41,562
(b) for a HSE with 27 to 50 beds	5,235	1	4,442
(c) for a HSE with 51 to 75 beds	5,235	1	4,759
(d) for a HSE with 76 to 100 beds	5,235	0	1,586
(e) for a HSE with 101 to 150 beds	5,235	1	3,490
(f) for a HSE with 151 to 200 beds	5,235	0	1,904
(g) for a HSE with 201 to 300 beds	5,235	1	3,173
(h) for a HSE with 301 to 400 beds	5,235	0	1,269
(i) for a HSE with 401 to 500 beds	5,235	-	-
(j) for a HSE with 501 or more beds	5,235	0	635
Application for renewal of registration			
(a) for a HSE with 0 to 26 beds	11,923	66	780,936
(b) for a HSE with 27 to 50 beds	11,923	7	83,459
(c) for a HSE with 51 to 75 beds	11,923	8	89,420

Output	Estimated cost per application $	Forecast number of applications	Total cost $
(d) for a HSE with 76 to 100 beds	11,923	3	29,807
(e) for a HSE with 101 to 150 beds	11,923	6	65,575
(f) for a HSE with 151 to 200 beds	11,923	3	35,768
(g) for a HSE with 201 to 300 beds	11,923	5	59,613
(h) for a HSE with 301 to 400 beds	11,923	2	23,845
(i) for a HSE with 401 to 500 beds			-
(j) for a HSE with 501 or more beds	11,923	1	11,923
Application for variation of registration			
(a) for the transfer of the certificate to another person who intends to become the proprietor	654	40	26,174
(b) for any other case	5,163	5	25,814
Total cost			**1,415,800**

10.4 Fee revenue

10.4.1 Current fees

Current prescribed fees under the sunsetting Regulations are outlined in Table 13. Fees are set in terms of fee units, where the value of fee unit is fixed by the Treasurer under the *Monetary Units Act 2004*. The value of a fee unit commencing 1 July 2023 is fixed at $15.90.[109] The value of a fee unit is revised each year to ensure that its original value is maintained.

Table 12 Current prescribed fees

Regulations	Output	Prescribed fee units	2023-24 $ fee
Approval in principle			
reg 8(2)	***Application for an AIP***		
	(a) to construct premises for use as a private hospital	325	$5,167.50
	(b) to make alterations or extensions to a premises used or proposed to be used as a private hospital	290	$4,611.00
	(c) to construct premises for use as a day procedure centre	285	$4,531.50
	(d) to make alterations or extensions to a premises used or proposed to be used as a day procedure centre	276	$4,388.40
	(e) to use premises as a health service establishment from which health services are to be provided at premises other than the first-mentioned premises	91	$1,446.90
		16.1	$256.00

[109] Victoria Government Gazette No. S 256 23 May 2023.

Regulations	Output	Prescribed fee units	2023-24 $ fee
	(f) to vary the registration of a health service establishment		
reg 9(b)	***Application for transfer or variation of certificate of AIP***	16.1	$256.00
Registration			
reg 10(2)	***Application for registration***		
	(a) for a HSE with 0 to 26 beds	366	$5,819.40
	(b) for a HSE with 27 to 50 beds	405	$6,439.50
	(c) for a HSE with 51 to 75 beds	445	$7,075.50
	(d) for a HSE with 76 to 100 beds	484	$7,695.60
	(e) for a HSE with 101 to 150 beds	543	$8,633.70
	(f) for a HSE with 151 to 200 beds	623	$9,905.70
	(g) for a HSE with 201 to 300 beds	701	$11,145.90
	(h) for a HSE with 301 to 400 beds	820	$13,038.00
	(i) for a HSE with 401 to 500 beds	978	$15,550.20
	(j) for a HSE with 501 or more beds	1175	$18,682.50
reg 12(2)	***Application for renewal of registration***		
	(a) for a HSE with 0 to 26 beds	366	$5,819.40
	(b) for a HSE with 27 to 50 beds	405	$6,439.50
	(c) for a HSE with 51 to 75 beds	445	$7,075.50
	(d) for a HSE with 76 to 100 beds	484	$7,695.60
	(e) for a HSE with 101 to 150 beds	543	$8,633.70
	(f) for a HSE with 151 to 200 beds	623	$9,905.70
	(g) for a HSE with 201 to 300 beds	701	$11,145.90
	(h) for a HSE with 301 to 400 beds	820	$13,038.00
	(i) for a HSE with 401 to 500 beds	978	$15,550.20
	(j) for a HSE with 501 or more beds	1175	$18,682.50
reg 13(2)	***Application for variation of registration***		
	(a) for the transfer of the certificate to another person who intends to become the proprietor	47.8	$760.00
	(b) for any other case	16.1	$256.00

10.4.2 Proposed fees

10.4.2.1 Level of cost recovery

Cost recovery generally supports the concept that users that derive private benefit from government goods or services should pay for the cost of those services, rather than have them funded by others (typically through general taxation). Full cost recovery promotes the efficient consumption of services and, in turn, the efficient allocation of resources by sending appropriate price signals about the value of resources that are required to provide the good or service.

The *Pricing for Value* guide sets out principles for supporting different levels of cost recovery:

Above 100% cost recovery	Pricing should promote positive behaviours
	Services creating broad community benefits should be priced to support efficient usage
	Pricing should promote positive behaviours
100% cost recovery	Entities should recover full cost of delivery to promote efficient usage
	Cost of service should be borne by those who benefit from the service
Below 100% cost recovery	Services creating broad community benefits should be priced to support efficient usage
	The price of services should not limit access to those with a lower ability to pay

As part of this sunsetting review the department has considered the appropriate level of cost recovery.

Under the current prescribed fees (plus the addition of a proposed new fee for an application for an AIP to use particular land or premises as a private hospital or day procedure centre, as discussed in section 10.3.1), it is estimated that revenue of $883,639 would be collected in the first year of the regulations, 2024-25, as shown in Table 14. This represents an estimated cost recovery level of 62% (versus estimated total costs of $1,415,800).

The department considers that fees should recover at least some amount of the department's costs of administering the registrations framework and other regulatory activities related to HSEs. This is consistent with the principle that the cost of service should be borne by those who benefit from the service.

To achieve full cost recovery, there would need to be a uniform increase in fees of about 60%. Application fees for AIP to build a private hospital would increase to $8,268 and to build a day procedure centre would increase to $7,378. Application fees for registration and renewals would increase to between $9,311 for a HSE with 0-26 beds to $29,892 for a HSE with 501 or more beds.

This would remove the under-recovery and ensure that the private health sector pays the full costs of its regulation.

However, stakeholder feedback from the sector raised concerns about the impact of regulatory burden on financial viability of facilities, arguing this could ultimately adversely impact capacity of facilities to offer safe and high-quality services. It has been considered that the large fee increase required for full cost recovery could impact the ability to pay of some HSEs, particularly smaller day care procedure centres. While the fee level may be negligible for some large HSEs compared to total costs of health establishment operation, if a large increase impacts viability it could potentially compromise operation of the facility, which could negatively impact the quality and safety of patient care

Full cost recovery could be achieved by setting relatively higher fees for larger HSEs instead of a uniform fee increase (thus increasing the level of cross-subsidy between larger and smaller HSEs – see below for discussion of fee structure). However, given that most applications are in relation to HSEs with 0-26 beds, the increase required for larger HSEs to fully subsidise smaller HSEs is very large and is not considered reasonable e.g. an increase of around 150% would be required, increasing registration and renewals fees to nearly $22,000 for a HSE with 101-150 beds and nearly $47,000 for a HSE with 501 or more beds.[110]

The department therefore proposes to maintain a partial level of cost recovery. Having regard to the feedback received about possible impact from regulatory burden on quality and safety of services, setting fees at this time below the level required to fully recover the Department's costs also reflects the fact that where HSEs can offer safe and high quality patient care on a sustainable financial basis this provides broader public benefit.

It is noted that the assumption underpinning the analysis in this RIS is that the department must be funded to deliver its statutory obligations to regulate and administer the Act and Regulations. The hypothetical base case scenario is that if no new fees are established under the Regulations, the department would seek funding from the Consolidated Fund to ensure it can deliver on its statutory obligations.

Table 13 Fee revenue with proposed fees, $2024-25

Output	Fee per application $	No. of applications	Fee revenue $
Approval in principle			
Application for an AIP			
(a) to use particular land or premises as a private hospital or day procedure centre	5,168	1	5,168
(b) to construct premises for use as a private hospital	5,168	1	5,168
(c) to make alterations or extensions to a premises used or proposed to be used as a private hospital	4,611	9	41,499

[110] Different scenarios could be modelled. This modelled example is where there is 150% increase for all AIP applications and registration and renewal application for HSEs with 100 beds of more, but zero increase for other fees.

Output	Fee per application $	No. of applications	Fee revenue $
(d) to construct premises for use as a day procedure centre	4,532	3	13,595
(e) to make alterations or extensions to a premises used or proposed to be used as a day procedure centre	4,388	2	8,777
(f) to use premises as a health service establishment from which health services are to be provided at premises other than the first-mentioned premises	1,447	3	4,341
(g) to vary the registration of a health service establishment	760	20	15,200
Application for transfer or variation of certificate of AIP	256	-	-
Registration			
Application for registration			
(a) for a HSE with 0 to 26 beds	5,819	8	46,203
(b) for a HSE with 27 to 50 beds	6,440	1	5,464
(c) for a HSE with 51 to 75 beds	7,076	1	6,432
(d) for a HSE with 76 to 100 beds	7,696	0	2,332
(e) for a HSE with 101 to 150 beds	8,634	1	5,756
(f) for a HSE with 151 to 200 beds	9,906	0	3,602
(g) for a HSE with 201 to 300 beds	11,146	1	6,755
(h) for a HSE with 301 to 400 beds	13,038	0	3,161
(i) for a HSE with 401 to 500 beds	15,550	-	-
(j) for a HSE with 501 or more beds	18,683	0	2,265
Application for renewal of registration		**-**	
(a) for a HSE with 0 to 26 beds	5,819	66	381,171
(b) for a HSE with 27 to 50 beds	6,440	7	45,077
(c) for a HSE with 51 to 75 beds	7,076	8	53,066
(d) for a HSE with 76 to 100 beds	7,696	3	19,239
(e) for a HSE with 101 to 150 beds	8,634	6	47,485
(f) for a HSE with 151 to 200 beds	9,906	3	29,717
(g) for a HSE with 201 to 300 beds	11,146	5	55,730
(h) for a HSE with 301 to 400 beds	13,038	2	26,076
(i) for a HSE with 401 to 500 beds	15,550	-	-
(j) for a HSE with 501 or more beds	18,683	1	18,683
Application for variation of registration			

Output	Fee per application $	No. of applications	Fee revenue $
(a) for the transfer of the certificate to another person who intends to become the proprietor	760	40	30,401
(b) for any other case	256	5	1,280
Total cost			**883,639**

10.4.3 Fee structure

It is proposed that the current fee structure will be maintained in the proposed Regulations. It is anticipated that the fees will continue to achieve a similar level of cost recovery as the existing Regulations, noting that the precise level of cost recovery may vary in practice with changing fee revenues and costs.

The tiered fee structure for application for an AIP, registration and renewals aligns with the principle of setting fees so that access is not limited for those with a lower ability to pay, who are more likely to be smaller day care procedure centres. It also encourages positive behaviours amongst smaller HSEs, by not setting fees so high for smaller HSEs as to result in undesired behaviours such as evading regulatory obligations and illegal activities.

Over time there is no evidence that larger HSEs with more beds impose a higher administrative cost on the department than smaller ones. While inspections of larger faculties can take longer and there can be more information to review (because for example they have more a more complex range of services, more rooms etc) they are also more likely to have more advanced business and quality systems and be less reliant on advice or guidance by the department with less need for follow-up inquiries. The department can spend relatively more time responding to incidents and managing issues identified at smaller HSEs.

10.5 Comparison to interstate arrangements

As part of the review of fees, we have compared the proposed fees for Victorian HSEs to those charged in other Australian jurisdictions, as shown in Table 14.

In any such comparison judgement needs to be used because different jurisdictions have different fee structures. Given the differences and complexity of fees charged in different jurisdictions, the table only shows key fee items and does not show all the additional small fees that some jurisdictions charge.

Assessed against the fees shown in Table 15, Victoria's fees are not noticeably different from fees charged in other jurisdictions in terms of type of fees charged, structure and fee level.

Table 14 Fees charged in other jurisdictions

	Victoria	Queensland[111]	Western Australia[112]	New South Wales[113]	South Australia[114]
AIP	$4,532-$5,168	$1,761.19-$5,284.63	$8,960-$19,110	$7,931	$5,345 - $10,690[115]
Variation or transfer of AIP	$256	$525.76	-	$4,041	-
Registration fee	$5,819-$18,683	$2,642.58-$8,810.19	$1,360	$7,065-$17,374	$5,345 - $10,690
Registration renewal	$5,819-$18,683	$525.76-$4,226.22	$4,000-$9,000	$7,065-$17,374	$1,603-$11,759
Variation or transfer of registration	$256-$760	$1,055.23-$1,761.19	-	$4,660	$1,603-$3,741

[111] Private Health Facilities Regulation 2016.
[112] Private Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987.
[113] Private Health Facilities Regulation 2017.
[114] Private hospitals licensed under Part 10 of the Health Care Act 2008 and Private day procedure centres licensed under Part 10A of the Health Care Act 2008.
[115] Licence application fee and fee for grant of licence.

11. Competition and small business impacts

This section assesses the competition and small business impacts of the preferred option.

11.1 Competition impacts

The Victorian Guide to Regulation requires a RIS to assess the impact of regulations on competition. Regulations can affect competition by preventing or limiting the ability of businesses and individuals to enter and compete within particular markets.

A measure is likely to have an impact on competition if any of the questions in the Table 16 can be answered in the affirmative.

Table 15 Analysis of competition impacts

Test question	Assessment	Reason
Is the proposed measure likely to affect the market structure of the affected sector(s)	No	The regulatory scheme for HSEs imposes restrictions on service providers entering a market. The restrictions are effectively imposed by the Act. The Act makes it an offence to operate a HSE without registration, defining 'HSE' by reference to services provided at or from the premises, and where a charge is made. These services are prescribed in the Regulations. Prescribing them is necessary to give effect to the registration scheme in the Act. The proposed 2024 regulations do not change the scope of these prescribed services, as compared to the current 2013 regulations. The proposed Regulations also set out some detail to the regulatory requirements for registered facilities and otherwise give practical effect to the Act.
Will it be more difficult for new firms or individuals to enter the industry after the imposition of the proposed measure?	No	The proposed Regulations introduce new requirements. Stakeholder feedback provided to the review of the Regulations did include general comments that warned continued or significant increase in regulatory burden may affect the financial viability of facilities. However, this concern was not raised in relation to key elements of the proposed 2024 regulations discussed in this RIS. On this basis it is not

Test question	Assessment	Reason
		considered likely that those new requirements will lead to either HSEs exiting the market, or new participants being reluctant to enter the market.
Will the costs/benefits associated with the proposed measure affect some firms or individuals substantially more than others (e.g. small firms, part-time participants in occupations etc.)?	Minimal	Larger HSEs may find it easier to create the processes needed to comply with requirements in the proposed Regulations. However, there is also some flexibility for HSEs adhering to the Regulations (and the National Standards) depending on nature of size, acuity level of patients etc.
Will the proposed measure restrict the ability of businesses to choose the price, quality, range or location of their products?	Not applicable	Health care is considered a service, rather than a product.
Will the proposed measure lead to higher ongoing costs for new entrants that existing firms do not have to meet?	No	The costs imposed on new entrants will be the same as for existing businesses. It is acknowledged that some mature businesses may have processes in place already or more efficient processes in place already which will lower their upfront costs. However, the ongoing costs are expected to be the same for new entrants.
Is the ability or incentive to innovate or develop new products or services likely to be affected by the proposed measure?	No	The proposed regulations do not restrict the ability or incentive to innovate or develop new services. Any new services developed need to consider the quality and safety of patient care.

11.2 Small business impacts

The Victorian Guide to Regulation also considers it good practice for a RIS to consider the impacts of proposed Regulations on small businesses. Small businesses may experience disproportionate effects from regulation for a range of reasons. This may include that the requirement applies mostly to small businesses, or because small businesses have limited resources to interpret compliance requirements or meet substantive compliance requirements compared to larger businesses. Small businesses may also lack the economies of scale that allow regulatory costs to be spread across a large customer base.

Smaller HSEs may be impacted more than larger HSEs when developing processes to comply with the new Regulations, as larger HSEs have more resources available to develop and interpret new compliance requirements. However, most of the proposed changes reflect current practice in HSEs, and are already part of the NSQHS Standards, which HSEs are required to be accredited against.

Given that the proposed Regulations represent a continuation of the Regulations that have been in place for over 20 years, the department does not expect significant implementation issues or unintended consequences for smaller HSEs.

12. Implementation and evaluation

This chapter discusses key issues to be considered in the implementation and evaluation of the Regulations.

12.1 Implementation

The proposed Regulations remake the existing Health Services (Health Service Establishments) Regulations 2013, with amendments as considered in this RIS. Based on the analysis in this RIS, the department is recommending remaking the Regulations with a number of targeted improvements. As noted in sections 1.4 and 2.4 above, additional matters that arose in the review of the Regulations are still under active consideration and will be subject to further consultation and subsequent reform processes.

The department will be primarily responsible for implementation of the proposed changes discussed in this RIS.

Key aspects of the implementation plan are:

- Finalise the remade Regulations
- Develop and implement the processes for proposed additional oversight of clinical governance through review of protocols by the Secretary (see proposed amendment in section 6.1)
- Education and communication with industry on the amendments to the Regulations.

It is proposed that the commencement of substantial new provisions in the Regulations may be some time after the new Regulations are made to allow time for the department and facilities to prepare for implementation. Responses to this RIS on implementation issues will inform final decisions on the commencement date for relevant provisions.

Finalise the remade Regulations

The release of the proposed Regulations and this RIS for a 28-day public comment period will provide key stakeholders and members of the public the opportunity to consider the proposed changes to the Regulations and provide feedback. At the conclusion of the public comment period, the department will review and consider each submission and take account of the feedback on both the proposed Regulations and the RIS in finalising the Regulations.

The department will prepare a document, which will discuss the comments provided in in response to this RIS and respond to those comments.

The Office of Chief Parliamentary Council will review and settle the Regulations, which will then be submitted to the Minister for Health for approval.

Develop and implement the clinical governance Secretary oversight mechanism

As noted above it is proposed that new additional requirements for clinical governance will come into effect after the new Regulations are made. This is to allow time for appropriate communication and

consultation about how such reviews will be conducted, which best practice guidelines will be used to inform the Secretary's assessment, and time for facilities to prepare and comply.

Key steps in implementation of the oversight mechanism will be:

- Development of the department's proposed approach to conducting Secretary reviews, including review processes and which best practice guidelines will be used
- Consulting with key stakeholders on the proposed approach
- Finalising the approach to conducting Secretary reviews
- Informing stakeholders about the changes being made.

Refresh and communicate compliance and enforcement processes

Reflecting the proposed introduction of prescribed infringement offences and penalties in the Regulations, the department will undertake a refresh of its existing compliance and enforcement arrangements. This will include setting out the department's approach to compliance and enforcement, including arrangements for issuing infringements for non-compliance.

The will provide clarity on how the department will exercise its regulatory powers, including how it will apply the new powers in the Regulations in relation to infringement notices and penalties.

Education and communication plan

The department will develop and deliver a high level education and information campaign to promote industry and community awareness of the new regulatory framework.

12.2 Evaluation

The Regulations will sunset 10 years after the commencement of the Regulations. The department will actively monitor and evaluate the effectiveness and efficiency of the Regulations throughout the life of the Regulations (including provisions that are updated after the Regulations are remade as a result of issues raised in the current sunsetting review). A structured evaluation of the Regulations will be undertaken before the sunsetting of the Regulations. To support this evaluation the department will develop an evaluation plan including evaluation questions, available data and data gaps to assess any potential gaps in evidence.

Key evaluation questions will be designed to align with the Department of Treasury and Finance Resource Management Framework, such as:

- *Problem justification*: What is the evidence of continued need for the Regulations and role for government?
- *Effectiveness*: To what extent has the primary objective of these Regulations, which is to provide for the safety and quality of care of patients receiving health services in HSEs, been achieved?
    - Have the Regulations been effective in reducing the likelihood of adverse events?
    - How well have the changes to the Regulations been understood and implemented?
- *Efficiency*: do the Regulations achieve the objectives in the most efficient way?

Data assessment will include consideration of ensuring appropriate baseline data for performance indicators to enable a comparison of the current state versus future state.

In terms of existing data sources:

- The department will continue work to optimise analysis of VAED data.
- The department will continue to work with SCV to optimise use of data that is reported or otherwise available on quality and safety indicators to inform ongoing regulatory monitoring and enforcement and future assessment of regulatory settings and reform proposals (it is noted that amendments to the Regulations discussed in the RIS designed to improve oversight will assist in this regard).
- The regulator will continue to visit HSEs, with these inspections providing compliance data that will feed into the overall picture of quality and safety in HSEs.
- The department will continue to receive accreditation data from the Commission, which supports monitoring of facilities and system-wide monitoring and management.

Appendix A Cost estimations for fees

Direct cost estimation, for fees estimates

The following tables show time allocation and staff cost per hour for each key output, direct costs only.

All staff time costs for VPS staff include on-costs of 75% of hourly wage, as per Victorian Department of Treasury and Finance guidance.[116]

For fee calculations, it is noted that fixed costs are allocated to estimate the total cost of each output. A total of $135,820 is allocated. Most of this is allocated to registration renewals reflecting the ongoing compliance and monitoring work that is included as part of the renewals and registration function.

AIP

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Telephone/email enquiries	VPS 4	1	103.15	103.15
Pre-AIP meeting with proprietor	VPS 5	1	123.28	123.28
Receive application and review for completeness	VPS 5	0.5	123.28	61.64
File application and update AIP spreadsheet	VPS 4	0.25	103.15	25.79
Follow up with applicant if documents outstanding	VPS 4	0.25	103.15	25.79
Raise invoice	VPS 4	0.17	103.15	17.54
Allocate design review to architect panel	VPS 5	0.25	123.28	30.82
Design review by architect	Contract	5	300.00	1,500.00
Full review of application and design review by senior compliance officer (note 2)	VPS 5	3	123.28	369.84
Design review feedback letter drafted and issued to applicant	VPS 5	0.5	123.28	61.64
Further design review if required – architect or senior compliance officer	Contract	1	300.00	300.00
	VPS 5	1	123.28	123.28
Preparation of memo, cert and letter of approval	VPS 4	1	103.15	103.15
Memo, Certificate and Letter reviewed by manager	VPS 6	1	159.86	159.86
Decision by delegate (director)	EO3	1	259.34	259.34
Email of cert and letter of approval to applicant	VPS 4	0.25	103.15	25.79
Save documents to TRIM and update AIP tracking sheet	VPS 4	0.25	103.15	25.79
Contact applicant to arrange AIP site inspection.	VPS 4	0.25	103.15	25.79

[116] https://www.dtf.vic.gov.au/reducing-regulatory-burden/regulatory-change-measurement-manual.

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Email applicant with information required prior to inspection	VPS 4	0.25	103.15	25.79
Arrange inspection with applicant and architect	VPS 4	0.25	103.15	25.79
AIP inspection by authorised officer(s) and architect	VPS 5	4	123.28	493.12
	Contract	4	300.00	1,200.00
Architect issues post inspection report. Reviewed by authorised officer	VPS 5	1	123.28	123.28
Further correspondence to applicant following report if required	VPS 5	0.5	123.28	61.64
Receive proof of any outstanding works and documents	VPS 5	1	123.28	123.28
Approval to occupy emailed to facility	VPS 4	0.25	103.15	25.79
Update TRIM and AIP tracking sheet	VPS 4	0.17	103.15	17.54
Variation of registration or registration may be required. See later sections.		As per variation		
Total				**5,438.69**

Variation of transfer of AIP

Task	Staff tariff	Time (hrs)	Staff cost per hr	Cost $
Telephone/email enquiries	VPS 4	0.17	103.15	17.54
Receive application and review for completeness	VPS 4	0.25	103.15	25.79
File application and update AIP spreadsheet	VPS 4	0.25	103.15	25.79
Follow up with applicant if documents outstanding	VPS 4	0.25	103.15	25.79
Raise invoice	VPS 4	0.17	103.15	17.54
Further design review by architect if required (contract)	Contract	1	300.00	300.00
Full review of application	VPS 5	0.5	123.28	61.64
Preparation of memo, cert and letter of approval	VPS 4	0.5	103.15	51.58
Memo, Certificate and Letter reviewed by manager	VPS 6	0.5	159.86	79.93
Decision by delegate (director)	EO 3	0.5	259.34	129.67
Email of cert and letter of approval to applicant	VPS 4	0.25	103.15	25.79
Save documents to TRIM and update AIP tracking sheet	VPS 4	0.25	103.15	25.79
Total				**786.82**

Initial registration

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Telephone/email enquiries	VPS 4	0.5	103.15	51.58
Receive application and review for completeness and regulatory compliance	VPS 5	8	123.28	986.24
File application and update AIP and master spreadsheet	VPS 5	0.25	123.28	30.82
Follow up with applicant if documents outstanding and provision of feedback	VPS 5	1	123.28	123.28
Raise invoice	VPS 4	0.17	103.15	17.54
Arrange for facility inspection	VPS 5	0.17	123.28	20.96
Pre-inspection preparation	VPS 5	8	123.28	986.24
On-site inspection by authorised officer(s)	VPS 5	7	123.28	862.96
Complete post-inspection file note	VPS 5	8	123.28	986.24
Preparation of memo, cert and letter of approval	VPS 5	1.5	123.28	184.92
Memo, Certificate and Letter reviewed by manager	VPS 6	2	159.86	319.72
Decision by delegate (director)	EO 3	2	259.34	518.68
Email of cert and letter of approval to applicant	VPS 4	0.25	103.15	25.79
Save documents to TRIM and update spreadsheets	VPS 4	0.25	103.15	25.79
Advice of new registration sent to internal and external stakeholders	VPS 4	0.25	103.15	25.79
Total				**5,166.53**

Registration renewal

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Telephone/email enquiries	VPS 4	1	103.15	103.15
Generation of reminder email and invoice	VPS 4	0.83	103.15	85.61
Risk based assessment and determination of renewal schedule	VPS 5	38	123.28	4,684.64
Arrange inspection and provide advice documents	VPS 5	1	123.28	123.28
Pre-inspection preparation	VPS 5	7.6	123.28	936.93
Inspection	VPS 5	13	123.28	1,602.64
Post inspection filenote	VPS 5	8	123.28	986.24
Preparation of post inspection rectification letter	VPS 5	3	123.28	369.84
Post inspection letter reviewed and signed by manager.	VPS 6	1	159.86	159.86
Letter filed in TRIM and issued to facility. Databases updated.	VPS 5	0.25	123.28	30.82

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Authorised officer review of facility action plan.	VPS 5	0.5	123.28	61.64
Acceptance of action plan and/or further communication with facility	VPS 5	2	123.28	246.56
Receive application, file and enter into database	VPS 4	1	103.15	103.15
Check for completeness and assess against checklist	VPS 4	1.5	103.15	154.73
Follow up applicant by phone/email if required	VPS 4	0.5	103.15	51.58
Processing payment of fee	VPS 4	0.5	103.15	51.58
Prepare certificate, memo and letter	VPS 4	1	103.15	103.15
Application package reviewed by manager	VPS 6	1	159.86	159.86
Decision by delegate (director)	EO 3	0.67	259.34	173.76
Update all files	VPS 4	0.42	103.15	43.32
Email cert and letter to applicant	VPS 4	0.17	103.15	17.54
Advice sent to relevant stakeholders	VPS 4	1	103.15	103.15
Total				**10,353.01**

Variation of registration

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Telephone/email enquiries	VPS 4	0.25	103.15	25.79
Receive application and review for completeness. File.	VPS 4	0.5	103.15	51.58
Follow up with applicant if documents outstanding	VPS 4	0.17	103.15	17.54
Raise invoice	VPS 4	0.17	103.15	17.54
Application assessed by Authorised Officer if variation is for addition of clinical services	VPS 5	2	123.28	246.56
Preparation of memo, certificate and letter of approval	VPS 4	0.5	103.15	51.58
Memo, Certificate and Letter reviewed by manager	VPS 6	0.5	159.86	79.93
Decision by delegate (director)	Director (EO3)	0.33	259.34	85.58
Email of cert and letter of approval to applicant	VPS 4	0.17	103.15	17.54
Save documents to TRIM and database	VPS 4	0.17	103.15	17.54
Advise sent to internal and external stakeholders	VPS 4	0.25	103.15	25.79
Total				**636.94**

Transfer of registration

Task	Staff tariff	Time (hrs)	Staff cost per hr $	Cost $
Telephone/email enquiries	VPS 4	0.5	103.15	51.58
Receive application and review for completeness and regulatory compliance	VPS 5	8	123.28	986.24
File application and update master spreadsheet	VPS 5	0.25	123.28	30.82
Follow up with applicant if documents outstanding and provision of feedback	VPS 5	1	123.28	123.28
Raise invoice	VPS 4	0.17	103.15	17.54
Arrange for facility inspection	VPS 5	0.17	123.28	20.96
Pre-inspection preparation	VPS 5	8	123.28	986.24
On-site inspection by authorised officer(s)	VPS 5	7	123.28	862.96
Complete post-inspection filenote	VPS 5	8	123.28	986.24
Preparation of memo, cert and letter of approval	VPS 5	1.5	123.28	184.92
Memo, Certificate and Letter reviewed by manager	VPS 6	2	159.86	319.72
Decision by delegate (director)	EO 3	2	259.34	518.68
Email of cert and letter of approval to applicant	VPS 4	0.25	103.15	25.79
Save documents to TRIM and update new reg spreadsheet and master database	VPS 4	0.25	103.15	25.79
Advice of transfer of registration sent to internal and external stakeholders	VPS 4	0.25	103.15	25.79
Total				**5,166.53**

About Sapere

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For more information, please contact:

Sally Carrick, Director
Mobile: 0412 454 653
Email: scarrick@thinkSapere.com

Wellington	Auckland	Sydney	Melbourne	Canberra	Brisbane	Perth
Level 9 1 Willeston Street PO Box 587 Wellington 6140	Level 8 203 Queen Street PO Box 2475 Shortland Street Auckland 1140	Level 18 135 King Street Sydney NSW 2000	Level 5 171 Collins Street Melbourne VIC 3000	GPO Box 252 Canberra City ACT 2601	L18, 324 Queen Street Brisbane QLD 4000	PO Box 1210 Booragoon WA 6954
P +64 4 915 7590	P +64 9 909 5810	P +61 2 9234 0200	P +61 3 9005 1454	P +61 2 6100 6363	t +61 7 2113 4080	P+61 8 6186 1410

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