Risk Based Regulatory Framework: Private Hospitals 2017

VICTORIA State Government | Health and Human Services

Risk Based Regulatory Framework: Private Hospitals 2017

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Introduction

Private Hospitals: Risk Based Regulatory Framework outlines the Department of Health and Human Services' (the department's) regulatory framework for private healthcare facilities required to be registered in Victoria under the *Health Services Act 1988* (the Act).

There are a broad range of areas for which state government has a regulatory oversight role. A risk-based approach allows government's resources to be utilised more effectively and efficiently, targeting resources to areas where risk and non-compliance is greatest.

This document describes the risk based regulatory approach used by the department in regulating registered Victorian private hospitals and day procedure centres, including information on regulatory compliance, the risk assessment process and tools used by the department, and regulatory activity.

A further review of this framework is planned for 2017/18 as work to implement the recommendations of *Targeting Zero* progresses (including the introduction of a new Quality and Safety Bill into Parliament to address a number of the review's recommendations).

Regulatory Compliance

The Victorian government's Regulation Reform Program aims to improve the quality of regulation in Victoria and ensure that the Government's regulatory policy objectives are achieved at the lowest cost to the community. Under this program Ministers issue a Statement of Expectations to each regulator establishing clear expectations of each regulator's focus, performance and improvement. The Statement of Expectations framework specifically promotes:

- risk based and outcomes focused regulation;
- stakeholder consultation and engagement; and
- cooperation among regulators.

Regulatory objectives

Context

Private hospitals and day procedure centres are registered to operate and are regulated by the *Health Services Act 1988* (the Act), and the *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013* (the Regulations).

The Act sets out the registration scheme and high level patient safety requirements, the Regulations prescribe the health services that can be registered and provide more detailed requirements, including requirements related to patient safety. In addition the National Safety and Quality Health Service Standards (which must be complied with as a condition of registration), set out detailed standards for patient safety and quality of care.

Purpose

To monitor that all patients in registered private hospitals and day procedure centres receive safe care.

Outcomes

The department will monitor and facilitate safe patient care for all patients admitted to a private hospital or day procedure centre providers through regulatory compliance.

The department will monitor risk indicators, including data provided by private hospitals and day procedure centres to screen for potential risks to patient safety and will escalate regulatory oversight and activity as required.

The department will monitor, through site inspections, that risks to patient safety are reviewed, managed, and supported by adequately maintained records and data that are regularly reviewed at the private hospital's or day procedure centre's highest level of governance.

Stakeholders

Registered private hospitals and day procedure centres are the key stakeholder group. There are many other organisations that form part of the broader stakeholder group including Safer Care Victoria, Better Care Victoria, the Victorian Agency for Health Information, the Commonwealth Department of Health, other jurisdictional Departments of Health, the Australian Commission on Safety and Quality in Health Care, the Australian Health Practitioner Regulation Agency, the Australian Medical Association, the Australian Society of Plastic Surgeons, the Royal Australasian College of Surgeons and other medical colleges.

The Private Hospitals Unit (the Unit) will continue to work with Safer Care Victoria and the Victorian Agency for Health Information as they continue to build on establishing their roles and functions. As this work evolves, this will further strengthen regulatory oversight of private healthcare facilities.

Risk Based Regulatory Framework

The department uses a risk based regulatory framework to identify, analyse and prioritise risks, before selecting regulatory tools and activities. A risk based regulatory framework informs how the department, as a regulator, applies the regulatory tools available and how these are prioritised in determining the appropriate regulatory response.

The department is currently developing a regulatory practice policy (*Better regulatory practice in health, human services and sport)*, with the expectation that each identified departmental regulator establishes their own published regulatory practice policy. The draft *Better regulatory practice in health, human services and sport (November 2016)* has guided the review of the Private Hospitals Unit's (the Unit's) risk based regulatory approach.

The Unit has regulatory oversight of the Private Hospital and Day Procedure Centre sector, with responsibility to monitor regulatory compliance and patient safety. The use of a risk based regulatory framework enables the department to:

- identify clear parameters for accountability and responsibility for actions to address gaps in regulatory compliance;
- ensure activities are linked to achieve outcomes in the sector and effectively manage risk;
- apply consistent frameworks to support consistent, transparent and rigorous decisions;
- reduce unnecessary burden on sector and stakeholders;
- provide analysis and recommendations on emerging issues to improve practice within the sector;
- determine the effectiveness of the regulatory frameworks;
- adapt the framework in response to emerging risks and evaluation.

Risk based assessment and monitoring

This section sets out the approach the department uses to monitor legislative compliance.

The risk based regulatory approach is centred on a risk assessment, identifying the consequences and likelihood of an adverse event or impact on patient safety. This is conducted using a *Risk Assessment Tool* (Attachment 1), drawing on a wide range of information to provide a comprehensive picture of health service legislative compliance and risk of non-compliance.

At each registration renewal period (every two years), and as required at any period should receipt of any additional information that may impact regulatory compliance become available, the department will conduct a risk assessment of registered Private Hospitals and Day Procedure Centres. Regular review of identified criteria will be used in the risk assessment for each facility. The risk assessment will inform the department's regulatory response and monitoring.

Regulatory response and monitoring

Through the department's application of the *Risk Assessment Tool* (Appendix 1) safety and quality issues or concerns with compliance are identified.

Five categories of risk indicators (Appendix 2) have been identified to facilitate the monitoring of risks affecting patient care and safety. The five categories are based on regulatory requirements in line with the Regulations and the common risk based assessment matrix developed by the national Working Group on Standardising Safety and Quality in Compliance in Private Health Facilities.

The risk indicator categories are Registration; Governance / Management; Environment; Clinical Care; and Quality Improvement.

The level of risk for each indicator (Appendix 2) in the *Risk Assessment Tool* is identified as either low, medium, major or severe. This assessment of level of risk is for departmental use only, to assist in informing and actioning a proportionate regulatory response in relation to the level of risk identified, which includes:

1) Low: desk top audit and phone call follow up. Escalation in regulatory activity as required. (If no site visit has been undertaken in four years, a site visit will be undertaken regardless of risk assessment).
2) Moderate: desk top audit, phone call follow up, on – site visit. Escalation as required.
3) Substantial: on-site visit. Escalation as required.
4) High: immediate investigation and on-site visit. Escalation as required.

As a regulator of registered private healthcare establishments, the department will consider the full range of options available in each situation and take a balanced approach, proportionate to the circumstances and risk at the time.

To determine appropriate and proportionate responses to non-compliance the department will assess the seriousness of the identified issues and implement corrective action and appropriate escalation as necessary. It will consider the following issues and provider responses or actions:

- level of risk to patient safety
- length of time of non-compliance
- whether non-compliance was foreseeable, intentional or preventable
- capacity to achieve compliance within an acceptable time frame
- compliance history
- escalation and consideration of penalties.

Authorised Officers are appointed by the department under the Act to monitor regulatory compliance. Site visits are conducted as required, informed by the use of the Risk Assessment Tool. The department seeks to resolve the issue *before* it negatively impacts patient safety.

The department works with private providers to address and resolve issues and may require the providers to submit a corrective action plan to address identified service issues such as drivers of poor performance, identified mitigation strategies, unmet accreditation outcomes, risk assessments, options and timelines for implementation.

Where escalation in regulatory response is required, this will include consultation and potential on site visits with clinical experts through Safer Care Victoria and/or the Office of the Chief Psychiatrist. In addition legislative intervention could be considered. See Table 1 for examples of levels of regulatory response, ranging from the lowest level of intervention through to more extensive measures.

Table 1: Sample tools related to levels of regulatory response

Increasing levels of regulatory response	Regulatory response
	Desk top audit and phone call follow up.
	On site visit.
	Health service and department agree on voluntary undertakings, including for example, a corrective action plan, identified mitigation strategies, and timelines for implementation.
	Meeting with Chief Executive Officer and/or management team
	Consultation with clinical experts through Safer Care Victoria and the Office of the Chief Psychiatrist.
	On site visits with clinical experts from Safer Care Victoria and/or the Office of the Chief Psychiatrist.
	Direct healthcare establishment to limit or cease provision of services until suitable remedial measures are in place.
	The Minister for Health or Secretary to the Department may exercise any power available to them under the *Health Services Act*, including for example imposing conditions on registration, or revoking registration.

Support with compliance

The Unit works with Private Hospitals and Day Procedure Centre providers to support patient safety, regulatory compliance, identify and reduce risk, encourage continual improvements and reduce unnecessary regulatory burden. With the establishment of Safer Care Victoria and the Victorian Agency of Health Information, identification of system issues, benchmarking and opportunities for improvement will be identified.

The department also encourages self-reporting by private providers if they identify issues of non-compliance and, initiate remedial action.

Communication between the department and stakeholders includes:

- forums/information sessions
- website links to relevant areas or clinical information
- clear communication of the departmental regulatory approach and how activities are conducted
- information about specific regulatory issues identified through analysis of complaints, incidents or emerging issues
- written communication following support visit or inspection.

Evaluation of Framework

In virtually all sectors, regulatory challenges are in a state of constant shift. Thus, for instance, new risks and risk creators emerge or are recognised and uncertainties can harden into risks as, for example, events occur, knowledge develops, markets change, institutional structures are reformed, political and legal obligations alter, and public expectations and preferences mutate.

A further review of this framework is planned for 2017/18 as work to implement the recommendations of *Targeting Zero* progresses (including the introduction of a new Quality and Safety Bill into Parliament this year to address a number of the review's recommendations).

Attachment 1: Risk Assessment Tool

The process to assess the level of risk to patient safety for each Private Hospital and Day Procedure Centre is based on the *Australian/New Zealand Standard AS/NZ ISO 31000:2009 Risk management – Principles and Guidelines*.

Four key steps described in subsequent sections aim to:

- Identify risks based on the risk indicators
- Determine the consequences and likelihood of risks
- Develop risk estimates to determine the level of potential harm.
- Determine appropriate response.

Step 1: Identify risks based on the risk indicators

Risk identification

Risk, in the context of regulation, can be defined as the risk of not achieving outcomes that the various standards, codes, regulations and the general direction of government policy are designed to achieve. These key risks or harms, which should concern any health and social care regulator, include:

- Risk to individuals in terms of outcomes related to quality of care and safety;
- Risk to public confidence in health and social care.

Authorised Officers of the department will review relevant data and information to identify the level of risk for each risk indicator (Appendix 2). Risk identification is based on regulatory requirements in accordance with the with *Health Services Act 1988* and *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013*, and conditions on registration.

Step 2: Determine the consequence and likelihood of occurrence

The risk matrix is used to measure the consequence and how likely it is an identified risk will occur. For each of the five risk indicators (Registration, Governance, Environment, Clinical Care and Quality Improvement), identified risks can be plotted to achieve a level of risk for that indicator by assessing the likelihood and consequence together. If a number of descriptors are identified within one risk indicator, the most serious descriptor will be used to assess the consequence and likelihood of occurrence for that indicator.

Consequences and likelihood

The possible *consequence* of risk indicators needs to be ranked on a scale from minor (minimal or no impact on patient safety). through to serious (severe or immediate impact on patient safety).

The *likelihood* an identified risk on patient safety will occur, *without new or interim controls in place*, needs to be ranked on a scale from rare (highly unlikely to occur). through to high (highly likely to occur).

Risk Matrix		Likelihood of impacting on patient safety			
		Rare	Unlikely	Possible	Likely
Consequence on patient safety	Minor				
	Moderate				
	Substantial				
	Serious				

Step 3: Determining the level of risk

The matrix above is used to identify the level of risk for each risk indicator as follows:

a. Mark the 'consequence rating' together with the 'likelihood rating'.

b. The colour coded outcome provides a rating according to the level of risk below. The steps are repeated for each risk indicator (Registration, Governance, Environment, Clinical Care and Quality Improvement), to inform the regulatory response.

Low	Moderate	Substantial	High

Step 4: Risk Assessment and regulatory activity

The regulatory response and activity is informed by the level of risk assessed for each risk indicator. The regulatory response and monitoring activities undertaken by the departments Private Hospitals Unit may involve a staged approach. To determine appropriate and proportionate responses the department will assess the seriousness of the identified issues and implement corrective action and appropriate escalation of regulatory activity as necessary. This has been discussed earlier in the document and summarised in the Table 1 '*Sample tools related to levels of regulatory response'.*

The table below demonstrates how the outcome of the risk assessment in Step 3 informs the regulatory response and activity.

Level of risk	Risk rating	Regulatory activity examples
High	• 1 or more risk indicators rated high • 3 or more risk indicators rated substantial	Immediate Investigation* & follow up
Substantial	• 1 or 2 risk indicators rated substantial • 3 or more risk indicators rated moderate	Onsite Visit
Moderate	• 2 risk indicators rated moderate	Desktop audit +/- onsite visit
Low	• 1 risk indicator rated moderate or all other risk indicators rated low	Desktop audit

Attachment 2: Risk Indicators and Descriptors

This list of risk indicators and descriptors is based on the common risk based assessment matrix developed by the national Working Group on Standardising Safety and Quality in Compliance in Private Health Facilities. Indicators of risk identified in *Targeting Zero* around Governance have also been included. As work with Safer Care Victoria and the Victorian Agency on Health Information develops, risk indicators and descriptors will be reviewed.

<table>
<tr><th colspan="3">Risk Indicator 1: Registration</th></tr>
<tr><td>Descriptors</td><td>
Registration issues:
Insolvency, other legal matters, financial problems.
Commissioning of a new facility/alterations & additions/ new services:

Lack of processes and resources e.g., insufficient staff numbers/experience
Director of Nursing (DON) not appointed or does not meet regulatory requirements
Lack of policies/procedures
Relevant certification not provided
Building works do not meet plan approval conditions
Medical Advisory Committee membership non-compliance.
Provision of high risk services (e.g. ICU, ED, CCU)
Small numbers of high risk surgery
Commencement of a new service
Rapid expansion of services
Rurality

</td><td>
Registration conditions:

Patients accommodated in unregistered areas
Closure/relocation of ward/service/beds without notice

Patient data:

Trends identified – for example hospital acquired complications, low volume complex surgery, health service outliers (currently for Perinatal Service Performance Indicators, but datasets will expand as work with Safer Care Victoria and the Victorian Health Information Agency develops)
Evidence that facility is operating outside of registration scope and conditions

Response from Registered provider:

Refers to the level of compliance demonstrated in the past by a registered provider to respond to recommendations made by the department i.e. no response, incomplete/inappropriate response, written response but actions not implemented.

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<tr><th colspan="3">Risk Indicator 2: Governance/Management</th></tr>
<tr><td>Descriptors</td><td>
Governance, leadership and culture:

A governance environment that does not :
drive improvements to performance within a culture of safety and quality
measure and monitor their own performance
respond transparently to performance issues and foster an ethic of learning
have clear accountabilities and processes for detecting and responding to performance issues when they arise
optimise and standardise processes to reduce variation in performance and maximise reliability of performance.

</td><td>
Governance:

Change in ownership of facility
Stand-alone facility

Medical Advisory Committee:

Inadequate membership
Inadequate governance processes
Inadequate health professional credentialing

Management:

Recent and high executive tenure
Long executive tenure

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<tr><th colspan="3">Risk Indicator 3: Environment</th></tr>
<tr><td>Descriptors</td><td colspan="2">Non-compliance with Australasian Health Facility Guidelines
Non-compliance with Building Code of Australia
Inadequate risk assessment and safety inspection program
Inadequate maintenance of building facilities and equipment
Inadequate maintenance program
Inadequate provision of equipment and stores for services for which the facility is registered
Inadequate communication system provided
Inadequate policies and procedures for the management of environmental issues (e.g. waste and hazardous substances, fire safety, disaster management)
No or insufficient back-up power supply</td></tr>
<tr><th colspan="3">Risk Indicator 4: Clinical Care</th></tr>
<tr><td>Descriptors</td><td colspan="2">Insufficient number of appropriately qualified staff to carry out the services provided at the facility
Reliance on locums and/or international medical graduates
Inadequate clinical record documentation
Lack of policies and procedures for the management of patient’s clinical care (e.g. identification, admission & separation, transfer, privacy)
Notifications to DHHS such as public health, communicable diseases, drugs and poisons
Information from other regulators (e.g. Australian Health Practitioner Regulation Agency, Health Complaints Commissioner)
Patient data:
Trends identified – for example hospital acquired complications, low volume complex surgery, health service outliers (currently for Perinatal Service Performance Indicators, but datasets will expand as work with Safer Care Victoria and the Victorian Health Information Agency develops).
Infection control:
Inadequate policies and procedures for the management of infection control
Decontamination systems and processes do not comply with national or international standards
Inadequate staff- infection control education</td></tr>
<tr><th colspan="3">Risk Indicator 5: Quality Improvement</th></tr>
<tr><td>Descriptors</td><td>Incidents/Root Cause Analysis (RCA):
Inadequate policies and procedures for the management of incidents/RCA
SAC 1 incident reported (voluntary)
Any other adverse event (non -SAC 1) reported to the Department that has been identified as an ongoing potential risk to patient safety
Data indicative of potential clinical care concerns (e.g. HSMR; PSPI)
Notifications to DHHS such as public health, communicable diseases, drugs and poisons
Patient data:
Trends identified – e.g. excessive number of transfers for higher level of care; HSMR, PSPI</td><td>Complaints:
Inadequate policies and procedures for the management of complaints
Complaint received by the Department for investigation and report and/or third party reports
Quality Management System:
Inadequate policies and procedures for the management of quality processes
Lack of regular compliance/outcome audits.
Notification of “significant patient risk” with the National Safety and Quality Health Service Standards
Accreditation – ‘not met’ actions or accreditation withdrawn</td></tr>
</table>

References

1. Australian/New Zealand Standard AS/NZ ISO 31000:2009 *Risk management – Principles and Guidelines.*
2. Baldwin, Robert and Julia Black. 2008 “Really Responsive Regulation,” *Modern Law Review* 71:59-94
3. Victorian Auditor-General’s Report on Patient Safety in Victorian Public Services, March 2015.
4. Department of Health and Human Services. 2016 *Governance for safe, quality healthcare. Victorian clinical governance framework 2016,* Victoria
5. Department of Health and Human Services. 2016 *Draft - Better regulatory practice in health, human service and sport,* November 2016, Victoria
6. NSW Government *Guidance for regulators to implement outcomes and risk-based regulation,* October 2016
7. Victorian Competition and Efficiency Commission *Smart regulation: grappling with risk guidance note,* April 2015