health

Regulatory impact statement

For the proposed Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013

July 2013

State Government Victoria

Department of Health

Regulatory impact statement

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July 2013

Proposed Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013

Regulatory impact statement

In accordance with the *Victorian Guide to Regulation*, the Victorian Government seeks to ensure that regulations are well targeted, effective and appropriate, and that they impose the lowest possible burden on Victorian businesses and the community.

The regulatory impact statement (RIS) process involves an assessment of regulatory proposals and allows members of the community to comment on proposed regulations before they are finalised. Such public input provides valuable information and perspectives, and improves the overall quality of regulations.

The proposed regulations are made under Section 158 of the *Health Services Act 1988*.

This RIS has been prepared to facilitate public consultation on the proposed Health Services (Private Hospitals and Day Procedure Centres) Regulations 2013. A copy of the proposed Regulations is attached to this RIS.

Submissions are now invited on the proposed Regulations. Unless requested by the author, all submissions will be treated as public documents and may be made available to other parties.

Written comments and submissions should be forwarded by no later than 5 pm Monday12 August 2013 to:

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privatehospitals@health.vic.gov.au

Contents

Abbreviations

ACSQHC	Australian Commission on Safety and Quality in Health Care
the Act	Health Services Act 1988
APET System	Admitted Patient Entry and Transmission System
the current Regulations	Regulations 2002
the department	Department of Health
DoHA	Commonwealth Department of Health and Ageing
DoN	director of nursing
HCP data	Hospital Casemix Protocol data
HSC	health services commissioner
IFC	informed financial consent
ISO	International Standards Organisation
JAS-ANZ	Joint Accreditation Scheme of Australia and New Zealand
the proposed Regulations	Regulations 2013
MCA	multi-criteria analysis
the national standards	National Safety and Quality Health Service Standards
NCP	National Competition Policy
NMBA	Nursing and Midwifery Board of Australia
OHSC	Office of Health Services Commissioner
PHDB Data	Private Hospital Data Bureau
PHIO	Private Health Insurance Ombudsman
Premier's guidelines	*Subordinate Legislation Act 1994 Guidelines*
QAHC study	Quality in Australian Health Care Study
RIS	regulatory impact statement
the secretary	Secretary to the Department of Health
VAED	Victorian Admitted-Episodes Dataset
VCEC	Victorian Competition and Efficiency Commission
VPCD	Victorian Perinatal Data Collection
VSL	value of a statistical life
VSLY	value of a statistical life year

Summary

Private hospitals and day procedure centres are currently regulated under Part 4 of the Health Services Act 1988 (the Act) and the Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002 (the Regulations).

This regulatory framework mandates requirements to ensure patient safety and quality of care in health service establishments. It establishes requirements for premises and equipment, infection control and appropriate staffing.

The current regulations are due to expire on 10 September 2013.

In 2012 the Department of Health (the department) committed to a review of Part 4 of the Act under the Victorian Government's Red Tape Reduction Strategy. The intention is to replace Part 4 with a new Act and policy framework to regulate private hospitals and day procedure centres. The department has commenced this review, and the introduction of a new Act and new Regulations is anticipated in 2014.

In order to maintain continuity in the regulatory coverage of private hospitals and day procedure centres, it is necessary to make new regulations during this interim period.

In accordance with the requirements of the *Subordinate Legislation Act 1994* and the *Victorian Guide to Regulation*, this regulatory impact statement (RIS) is required to assess proposed Regulations in terms of their objectives and their effects, alternative approaches to achieving those objectives, and an assessment of the costs and benefits of the regulations and the alternatives.

Objectives

The primary objective of these regulations is to provide for the safety and quality of care of patients receiving health services in private hospitals and day procedure centres. The Regulations set minimum requirements, with the aim of minimising the risk of harm to patients.

The secondary objective of the regulations is to prescribe fees, forms and other matters required to be prescribed under the Health Services Act 1988 in relation to health service establishments. This provides the mechanisms by which establishments can meet their requirements under the current Act.

There are specific objectives in relation to certain parts of the proposed Regulations detailed in the table below.

Area of regulation	Objective
Providing for senior appointments	To ensure a suitably qualified person is appointed as the director of nursing.
Specifying minimum standards for staffing	To ensure that the standard of care patients receive at private health premises is adequate, suitable and timely
Specifying information to be provided to patients	To ensure patients receive adequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services.
Specifying fees for applications	To facilitate efficient administration of the Act by ensuring fees received are appropriate to the cost of Regulation activities.

Nature and extent of the problem being addressed

Victoria has a high quality health care system in which most of the population receives high quality care, most of the time.

Regulation applied to private hospitals and day procedure centres is motivated by the desire to ensure adequate and targeted protections for the public. In doing so the government acknowledges that:

- patients are more vulnerable when seeking treatment, and hence their interests need to be protected
- appropriate regulation is essential to ensure a minimum standard of safety and provision of quality care
- safety-related incidents or issues that produce adverse patient outcomes do occur
- there are benefits to the community as a whole in ensuring high quality private health care
- there are market failures that warrant intervention.

Common types of 'market failure', where there is a case for the government to intervene, relevant to the private health care sector include:

- Addressing information and power asymmetries in the health care system:

  Patients are reliant on treating and referring practitioners to provide them with the information required to make decisions that are in their best interests. During this time of vulnerability, they may be unable, or uncomfortable in accessing, additional information about treatment options and alternative providers.

- Addressing public health and safety:

  There is an expectation in the community that the government has a role in ensuring minimum standards of safety and quality in health care.

In addition, the government has an interest in a high quality, strong private health care sector to complement the state-funded public health system. Without it, we would see increased demands placed on the public health and community services system.

Quantifying the extent of a 'quality problem' in the health care sector is difficult, both due to the differing definitions and perceptions of what may constitute 'quality' as well as a lack of quality performance data for private health care services.

Government intervention is intended to reduce the risks associated with health care and the number of negative consequences with social and economic costs that may arise, affecting individuals, the community and the sector, including:

- 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 data provided in this RIS supports a role for government intervention in both the public and private health care setting, to ensure minimum standards of patient safety and quality are met.

Summary of costs and benefits of the proposed measures

The estimated costs of the proposed Regulations are indicated in the following table. They reflect costs that are additional to a hypothetical base case of no regulation. That is, they represent the cost of imposing the proposed Regulations on the private health care sector if there were no current regulations. However, for private hospitals and day procedure centres, where regulations have been in place for many years, the costs of the proposed Regulations would largely be incremental.

Area of Regulation	Total costs per year $	Discounted 10-year cost $
Providing for senior appointments	3,273,110	29,323,149
Specifying minimum standards for staffing	9,016,297	80,775,936
Specifying information to be provided to patients	10,288,327	92,171,901
Specifying fees for applications	149,532	1,339,639
Submission of data to the department	7,318,873	65,568,915
TOTAL	**30,046,139**	**269,179,540**

In total, these regulations impose additional costs of **$30,046,139** per year to private hospitals and day procedure centres.

One approach of judging the net benefits of the proposed Regulations is to use a 'break-even' analysis. This involves placing a value on certain undesirable outcomes, and determining how many of these undesirable outcomes would need to be avoided due to the Regulations in order to justify the costs of the Regulations. The undesirable outcomes in relation to patients at private hospitals or day procedure centres are adverse events leading to loss of life, decreased quality of life or longer-term or additional treatment. As noted previously, these are very difficult to quantify.

Of the above regulation costs, the majority (approximately $22,577,734 per year) are attributable to measures aimed at ensuring minimum levels of safety and ensuring quality care (that is, senior appointments, adequate staffing, and provision of information to patients).

The Department of Health has estimated the cost of each adverse event in Victoria is $6,826.[1]

Using these figures, it is possible to conduct a break-even analysis.

At a total cost of **$30,046,139** per year, the proposed Regulations would need to prevent approximately 4,400 adverse events per year in order to break even.

The department considers this a realistic outcome of the proposed Regulations, considering data provided by the Australian Institute of Health and Welfare estimated 32,465 patient separations per year in private hospitals resulted in an adverse event[2] and that it has been estimated that over 50 per cent of adverse events are preventable.[3] The current rate of adverse events for Victorian private hospitals is 3.5 per 100 separations, and this includes the effect of the Regulations currently in effect. Therefore, the Regulations would need to account for approximately 0.5 per 100 separations to break even (that is, 0.005 × total number of separations per year [917,000] = 4,400). This appears to be reasonable, given that the variation in adverse events among other states and territories is from 3.3 to 6.5 per 100 separations and the national average is 3.9 per 100 separations.[4]

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[1] Department of Health, September 2010, Introduction to Safety and Quality Principles*, Adverse events*, http://www.health.vic.gov.au/qualitycouncil/safety_module/page04.htm

[2] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011–12*, http://www.aihw.gov.au/publication-detail/?id=60129543133

[3] Wilson R, Runciman W, Gibberd RW, Harrison BT, Newby L, Hamilton JD, 1995, 'The Quality in Australian Health Care Study' *Medical Journal of Australia* vol. 163 pp. 458–471.

[4] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011–12*, http://www.aihw.gov.au/publication-detail/?id=60129543133

However, it is also noted that ideally, the break-even analysis would compare the (4,400) with the subset of adverse events attributable to the noncompliant group of the sector (that is, not 32,465). However, this figure is unknown.

In addition, this break-even analysis does not allow for the likelihood that a proportion of those adverse events will be critical, causing serious harm or death. What percentage this equates to is not available for Victorian private hospitals. By comparison, a report from Western Australia notes that in their public hospital system the proportion of adverse events that was critical was approximately 1 in 20.[5] However, this RIS relied on a multi-criteria analysis (MCA) as the decision rule in assessing cost-benefit analysis of the components of regulation, recognising that such break-even analysis is very sensitive to assumptions and it is difficult to directly attribute causes and effects in most cases. The MCA analysis therefore focuses on whether or not the proposed Regulations provide for the safety and quality of services provided to patients.

The MCA scores for each of the options considered in the RIS are noted in the table below. It is acknowledged that in some cases scores between options are close.

Options for senior appointments	MCA score
Option A: the proposed Regulations These require that the proprietor appoints a suitably qualified person as the director of nursing. Define a person as being 'suitably qualified' if they have a qualification or practical experience in nursing management and they are a registered nurse. If a director of nursing is absent, incapacitated or the position is vacant, the proprietor must appoint a person to act as the director of nursing. Require that the proprietor notify the secretary in writing of the name, qualifications and experience of any person appointed by the proprietor as the director of nursing, acting DON chief executive officer or medical director within 28 days after the appointment has been made.	+2.0
Option B: the alternative regulatory option Require that the proprietor appoint a suitably qualified person as the director of nursing.	+1.25

Options for staffing	MCA score
Option A: the proposed Regulations The proprietor must ensure that each nurse is professionally competent through education or experience to provide nursing care at the hospital or centre, having regard to the kind or kinds of health service being provided. The proprietor must ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care for those patients. A sufficient number of appropriately educated or experienced nursing staff is on duty if — in the case of a private hospital — at least one registered nurse is on duty for each 10 patients or fraction of that number during day and evening shifts; and at least one registered nurse is on duty for each 15 patients or fraction of that number during night shifts; or, in the case of a day procedure centre, not fewer than one registered nurse is on duty for each 10 patients or fraction of that number. In determining the number of nurses on duty, if three or more nurses are on duty at a private	+2.0

[5] Auditor-General of Western Australia, 2007, *First Do No Harm: Reducing Adverse Events in Public Hospitals*.

hospital or a day procedure centre during a shift, one-third may be enrolled nurses.	
Option B: the alternative regulatory option — principle based The proprietor must ensure that each nurse is professionally competent through education or experience to provide nursing care at the hospital or centre, having regard to the kind or kinds of health service being provided. The proprietor must ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care for those patients.	+1.59
Option C: the alternative regulatory option — risk based on class of service Option C specifies specific classes of services and prescribes staffing requirements for each. The classes of services are based on those that are characterised with particular or specific risks, and include: anaesthesia class; rapid opioid detoxification class, emergency class private health facilities; intensive care (Level 1 or Level 2) class private health facility; paediatric class private health; facilities; rehabilitation class private health facilities; maternity class (Level 1 or 2) private health facility; and mental health class.	+1.5

Option	MCA score
Option A: the proposed Regulations The proprietor of a private hospital or day procedure centre must ensure that on or before admission each patient of the hospital or centre is given: 1. a statement containing information in relation to the health care services provided 2. information about fees to be charged by the hospital or centre and any likely out-of-pocket expenses that may be incurred by the patient and 3. a clear explanation of the treatment and services to be provided to the patient. A statement referred to must contain information about the following matters: the quality or standard of health care and services provided; courteous treatment of patients; consideration of a patient's beliefs and ethnic, cultural and religious practices; consideration of a patient's special dietary needs, if any; a patient's privacy; that a patient may request the names and roles of the key health workers involved in the patient's care; a patient's entitlement to ask for a referral if they want to seek another medical opinion; that any personal information or identifying material about a patient is dealt with in a confidential manner except: 1) where necessary to enable another health care worker to assist in the patient's care; or 2) when authorised by or under a law; a patient’s consent to treatment; that a patient may refuse the presence of health workers not directly involved in the patient’s care; that a patient may discharge themselves at any time despite the advice of the attending health care practitioner or staff of the hospital or centre; that a patient may comment on or complain about the treatment or the quality of the health services or care being provided, including to whom any complaint should be made.	+1.5
Option B: the alternative regulatory option The proprietor of a private hospital or day procedure centre must ensure that on or before admission, each patient of the hospital or centre: has access to a document which explains their rights and responsibilities; is given information about fees to be charged by the hospital or centre and any likely out-of-pocket expenses that may be incurred by the patient.	+1.4

Option for fees	MCA score
Option A: full cost recovery	+ 2.65
Option B: partial cost recovery (proposed Regulations*)	+ 2.9

**The proposed fees are set at the same rate as the current fees.*

Why other approaches are not appropriate

The proposed Regulations were assessed against identified feasible alternatives in each of the main areas. In each case, the proposed Regulations were considered to be superior, because they received a higher overall score (although small in some cases) when assessed against an MCA, which assists comparing options where costs and benefits are not able to be fully calculated.

The proposed Regulations will ensure continuity of the regulation regime during this interim phase while a new Act to regulate private hospitals and day procedure centres is being developed.

Higher-level regulatory options relating to the overall regulation of the private health care sector will be considered in the development of that Act. Therefore, this RIS does not assess options, such as negative licensing instead of registration, or education campaigns instead of prescribing requirements.

Consultation

A primary function of the regulatory impact statement (RIS) process is to allow members of the public to comment on the proposed Regulations before they are finalised. Public input provides valuable information and perspectives and improves the overall quality of regulations. Accordingly, feedback on the proposed Regulations is welcomed and encouraged.

All interested parties are invited to provide comment on this RIS. Parties may wish to respond to any part of this RIS or the draft Regulations, although particular comment is invited on: whether there are any specific unforeseen impacts of the proposed Regulations; and if the assumptions used in calculating costs and benefits of the proposed Regulations are reasonable. More specific areas for comment may include the following:

Rationale for government intervention

The objective of the proposed Regulations is to provide for the safety and quality of care of patients receiving health services in private hospitals and day procedure centres. In considering the rationale for the proposed Regulations:

- What is the nature and extent of information constraints faced by consumers?
- To what extent is it the role of government to address residual safety risks, given the high level of voluntary compliance with the existing Regulations?
- In the absence of the Regulations, would other incentives be sufficient to minimise the incidence of adverse events and achieve appropriate safety outcomes? To what extent do Regulations contribute to safety outcomes?

Base case

Based on interaction with the sector, it is the department's view that there is a high degree of compliance with requirements in the Regulations; however, the Regulations are required to ensure and enforce compliance. In this regard:

- In the absence of the Regulations, is the assumed level of compliance referred to in the RIS reasonable? To what extent would health service establishments comply with the proposed requirements as part of standard business practice?

Senior appointments: director of nursing

- The proposed Regulations aim to ensure that a suitably qualified person is appointed as the director of nursing, as defined as having nursing management experience and is a registered nurse, but does this provide sufficient clarity to proprietors about what is 'suitably qualified'?
- The proposed Regulations require proprietors to send notification to the department of senior appointments. Is this a reasonable expectation to assist in implementing the requirements of the Act? Are the estimated time costs to provide this information realistic?
- The RIS describes prescriptive versus principle-based options for requirements around senior appointments within this analysis. Have all relevant costs and benefits have been considered?

Staffing

- The proposed Regulations place requirements on proprietors regarding the sufficient number of appropriately educated or experienced nursing staff. Does this provide sufficient clarity to proprietors?
- Are there circumstances where the Regulations do not offer sufficient flexibility to proprietors? If so, what is the additional cost of this? Are there alternative staffing options, either in regard to ratios or skill mix, which should be explored?
- The RIS describes three options for requirements around staffing within this analysis. Have all relevant costs, benefits and implementation issues been considered? Are the assumptions made in calculating the incremental costs of these requirements reasonable?

- In considering requirements in relation to staffing, do you have any comments on the cost-effectiveness of staffing requirements compared to other safety measures?

  Provision of information

  - The proposed Regulations place requirements on proprietors regarding the provision of information to patients. Staff time is also the major cost factor in calculating the cost of providing patients with fee information. Were the assumptions used to calculate these costs reasonable?

  Other

  - The proposed Regulations aim to clarify what proprietors are expected to do to meet the requirements under the Act. Do the proposed Regulations give sufficient clarity to proprietors? If not, in relation to which part of the Act or Regulations would greater clarity be useful?
  - The department considers that via break-even analysis, the impact of the Regulations could reasonably be attributable to the prevention of at least 4,400 adverse events per year (compared with an absence of regulations). Is this realistic?
  - Some Regulations were not analysed in this RIS because they are considered 'business as usual' for the sector (see Section 8). Is this a reasonable assumption? Are there further incremental costs attributable to these Regulations which are not addressed?
  - Do the proposed Regulations have any impacts on competition not identified in this RIS?
  - Overall, are there any practical difficulties in meeting any of the requirements set out in the Regulations?
  - Overall, are there any transitional or implementation issues associated with the proposed Regulations?
  - These Regulations are intended to be revoked on commencement of a new Act to regulate private health establishments and supporting Regulations. Do you have any comments on broader options relating to approaches in regulating the sector?

Stakeholders and the public will also have an opportunity to comment on the development of the new Act, and the future Regulations developed under the reformed approach.

Responses are to be received by the department no later than **5pm Monday 12 August 2013.**

1 Introduction

1.1 Regulation of private hospitals and day procedure centres

Private hospitals and day procedure centres (health services establishments) in Victoria are regulated under Part 4 of the Health Services Act 1988 (the Act). Under the Act, health services establishments must be registered by the department before health services may be provided.

In considering whether or not to register a health services establishment, 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.[6] Proposed premises may also be approved in principle prior to construction, in which case registration is subsequently granted on terms that are consistent with the approval.

Regulation under the Act is supported by the Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002 (the 2002 Regulations), which are intended to provide for the safety and quality of care of patients receiving treatment in health services establishments.

The 2002 Regulations:

- set minimum standards of requirements relating to staffing, appropriateness of premises and equipment and infection control
- specify consumer protection arrangements, including consumer information and complaints resolution requirements
- detail a range of requirements to support the secretary's regulatory functions in Part 4 of the Act, such as registration, application forms, registration fees and annual fees
- set data provision requirements to support input from the private sector into the Victorian Admitted-Episodes Dataset (VAED).

1.2 Purpose of this regulatory impact statement

The 2002 regulations were originally due to sunset on 10 September 2012. A 12-month extension of the Regulations was granted under Section 5(4) of the Subordinate Legislation Act 1994, and the extended regulations are now due to sunset on 10 September 2013.

In accordance with the requirements of the Subordinate Legislation Act 1994 and the *Victorian Guide to Regulation*, an RIS is required to assess the proposed Regulations in terms of their objectives and their effects, alternative approaches to achieving those objectives, and an assessment of the costs and benefits of the regulations and the alternatives. An assessment should also be undertaken of the implications of the proposed Regulations on competition.

In assessing the most effective option to achieve the identified objectives, the RIS must determine decision criteria to assess each option. These criteria must relate directly to the objectives of the proposed Regulations and the Act.

By virtue of the framing of the Act, the 2002 Regulations and the proposed Regulations respond specifically to particular provisions of the Act rather than being self-contained. Therefore, the assessment

[6] The criteria which must be considered by the secretary are set out fully in Section 83(1) of the Act.

of the costs and benefits of the proposed Regulations is only on the 'incremental' costs and benefits arising from the proposed Regulations and not the impacts that are attributable to the provisions of the Act.

In 2012 the development of the new Act to replace Part 4 of the Health Services Act 1988 was approved as a project under the Victorian Government's Red Tape Reduction Initiative.

The Regulations will require revision as a result of the development of the new Act. A thorough review of the Regulations is proposed once the key reforms to the Act have been identified. The new Act and Regulations are expected to be in place by mid to late 2014.

To minimise transition costs for the sector, and to maintain business continuity, it is considered preferable to defer any substantial changes to when the future Regulations are prepared in accordance with the new Act. Consequently, the proposed Regulations substantially remake the provisions of the 2002 Regulations. While it is anticipated that the proposed Regulations will be in place for approximately twelve months, the department received advice that preparing time-limited or further interim Regulations, was not possible under the Subordinate Legislation Act. Therefore, the analysis in this RIS considers the cost-benefits over the ten year lifespan set down in the Subordinate Legislation Act.

A copy of the proposed Regulations is at Appendix F.

2 The reasons for regulation

2.1 Background

Victorian private hospitals and day procedure centres

Private hospitals and day procedure centres (health service establishments) play a significant role in the delivery of health services in Victoria. In 2010–11, 876,000, or more than 36 per cent of all hospital separations in Victoria, occurred in private hospitals.[7] This included more than 61 per cent of all elective surgery carried out in Victoria.

Health service establishments are privately owned and operated institutions, catering for patients who are treated by a doctor of their own choice. Patients are charged fees for accommodation and other services provided by the establishments and relevant medical and paramedical practitioners. Health service establishments exist in response to patients' willingness to pay for a choice of doctor, private ward facilities and relatively faster access to services.[8]

Characteristics of health service establishments

Health service establishments differ greatly in size, function and management. Currently there are 164 registered health service establishments in Victoria, of which half are day procedure centres. Day procedure centres in Victoria are typically small practices operated for profit. Private hospitals are either operated by religious, charitable and community organisations on a not-for-profit basis, or are commercial organisations for profit. The latter category includes hospitals owned by publicly listed companies (including national hospital chains) and independently owned hospitals.

Approximately 80 per cent of patients treated in health service establishments are privately insured, and the majority of private hospital funding is received from private health insurers for treating their members.

Health service establishments operate under fee-for-service funding models that reward additional activity. Therefore, there is an incentive to maximise throughput. Health service establishments, particularly the for-profit sector, seek to maximise returns on their capital investment and labour force, for the benefit of owners or shareholders. Meanwhile, the not-for-profit private hospitals return revenue to upgrade facilities and equipment.

The majority of the services delivered in health service establishments are elective procedures. These may range from highly complex and/or high-risk procedures, through to those which are minimally invasive. Some larger private hospitals also offer a broader range of services comparable to those provided in public sector tertiary hospitals.

How are health service establishments different from public hospitals?

Public and private health services are driven by different operational motives, typically treat different types of patients, and deliver different suites of services.[9] Differences between public and private hospitals in terms of hospital size, location and services are, in part, a function of their business models, government and legislative requirements and community expectations.

The public hospital sector handles the majority of acute care separations, with activity concentrated on medical cases (including those typically admitted through emergency departments), and accounts for most regional and remote hospitals.

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[7] Australian Institute of Health and Welfare, 2012, *Australia's Hospitals 2010–11 at a glance*, http://www.aihw.gov.au/publication-detail/?id=10737421715.

[8] Australian Institute of Health and Welfare, 2011, *Australian Hospital Statistics 2009–10*, http://www.aihw.gov.au/publication-detail/?id=10737418863

[9] Productivity Commission, 2009, *Research report: Public and Private Hospitals*, http://www.pc.gov.au/projects/study/hospitals/report

Health service establishments are more concentrated in metropolitan areas, are concentrated on surgical (typically elective) procedures and are more likely to treat patients of higher socioeconomic advantage.[10] Simultaneously, the boundaries between public and private services are becoming increasingly blurred, and given public hospitals can provide services to private patients, health service establishments may provide services to public patients under government contracts; while emergency care, education and training may be provided by both.[11]

Given the increasing demand for hospital services, in a resource-constrained environment, current policy platforms are focused on greater quality and efficiency across both public and private hospitals. This is reflected in the creation of the Australian Commission on Safety and Quality in Health Care (ACSQHC). The ACSQHC is a government agency, established by the Commonwealth with the support of state and territory governments, to lead and coordinate national improvements in safety and quality in both the public and private health services sector. The phased implementation of common national standards for accreditation from 2013 is a key consideration in reviewing the regulatory approach in Victoria.

The new national standards will replace the existing choice of health standards for accreditation. Currently, hospitals may be accredited against either the standards developed by the Australian Council on Healthcare Standards (ACHS using the EQuIP standards) or the International Standards Organization (ISO 9001) combined with the Core Standards for Safety and Quality in Health Care, which were developed by a committee of the Joint Accreditation Scheme of Australia and New Zealand (JAS-ANZ).

At present, all Victorian public hospitals and 95 per cent of health service establishments are accredited. It is a requirement under the *Private Health Insurance Act 2007* (Commonwealth) for a provider to be accredited in order to be declared a 'hospital', and therefore access funding via the private health insurance system. The five per cent of health service establishments that are not accredited are those which do not access the private health insurance system. Typically, these are cosmetic day surgery centres which receive payment directly from the patient.

Both the national standards and the Regulations are aimed at safety and quality of health care, and the frameworks address common issues such as: infection control, clinical records, staffing requirements and so on. However, the Regulations are focused on compliance with minimum requirements, whereas accreditation provides a quality assurance mechanism for health service establishments. That is, accreditation that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met, and a quality improvement mechanism that enables them to realise developmental goals.

Victorian public hospitals are required to be accredited in accordance with the *Victorian Health Policy and Funding Guidelines.* The guidelines and *Statements of Priorities*, along with the *Victorian Health Performance Monitoring Framework*, provide the mechanisms by which the department ensures public hospitals meet their accountability requirements.

Under the requirements of the Private Health Insurance Act 2007*,* facilities must meet state-based regulation requirements in order to receive payments by private insurers for service.

Victorian approach to regulation

As noted previously, the department administers a registration-based regulatory scheme for health service establishments that is set out in:

- Part 4 of the Health Services Act 1988 (the Act)
- the Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002 (the 2002 Regulations).

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[10] Ibid.

[11] Productivity Commission, 2009, *Research report: Public and Private Hospitals*, http://www.pc.gov.au/projects/study/hospitals/report

This regulatory framework mandates requirements for the safe provision of services to patients receiving health services in health service establishments. It establishes requirements for premises and equipment, infection control and appropriate staffing. In addition, any proposed construction, alteration or extensions of, or to, a health service establishment must also be approved in principle by the department before building works may commence. The Regulations prescribe registration fees, forms and other administrative matters required under the Act.

The department has responsibility for administering these regulatory functions, and conducts formal inspections of all private hospitals once every two years (at a minimum) to assess compliance with the Act and Regulations.

Other regulatory requirements

In addition to the above, health service establishments are also subject to:

- the *Building Act 1993* and the Building Code of Australia, in determining what elements the design must incorporate in the construction of a hospital or day procedure centres
- the *Planning and Environment Act 1987*, for determining the suitability or amenity of the location of facilities
- the *Health Services (Conciliation and Review) Act 1987*
- the *Drugs, Poisons and Controlled Substances Act 1981* and the Drugs, Poisons and Controlled Substances Regulations 2006
- the *Occupational Health and Safety Act 2004*
- the *Health Practitioner Regulation National Law Act 2009* (Victoria).

2.2 Rationale for government intervention

Victoria has a high quality health care system in which most of the population receives high quality care, most of the time.

The review of the Act and Regulations is motivated by ensuring adequate and targeted protections for the public, and simultaneously decreasing unnecessary regulatory burden on health service establishments. In doing so the government acknowledges that:

- patients are more vulnerable when seeking treatment, and hence their interests need to be protected
- appropriate regulation is essential to ensure the provision of safety of services
- safety-related incidents or issues that produce adverse patient outcomes do occur
- there are benefits to the community as whole in ensuring safe, high quality private health care
- there are market failures that warrant intervention.

Risk to the community

The primary driver for regulation by government is to set minimum standards of safety that must be observed by the operators of all registered health service establishments

A variety of mechanisms, such as funding and service agreements, are available to government to ensure that public hospitals provide quality health care. Similar mechanisms are not available in the private sector. The only certain way in which health service establishments can be compelled by government to meet safety requirements is by regulation.

It is difficult to quantify the extent of the risk to patients in receiving hospital services, because accurate data is not yet available on safety performance indicators. This reflects a lack of publicly available data on health service performance generally, particularly in relation to private health services.

However, across the Australian health system in 20011–12:[12]

- there were 917,810 separations from health service establishments in Victoria, with a total of 2,261,615 patient days
- 5.3 per cent of total separations in public and private hospitals resulted in an adverse event
- this included 3.9 per cent of separations in private hospitals and 6.1 per cent of separations in public hospitals.

Market failures

The second reason why continued regulation is considered necessary for health service establishments is to counterbalance the information and power asymmetry in the health care system.

In a typical market, consumers have access to the information they require to make decisions that are in their best interests. For example, information on the quality or content of the products they are considering purchasing, and the ability to compare available products.

The concept of 'information asymmetry' describes when the seller of the product has more information or knowledge than the buyer.

Unlike most other markets, private health care patients generally rely on their primary health service provider (general practitioner) for advice and information on treatment options, and specialist referrals, at a time when they are vulnerable and may be either unable, or unwilling, to access additional information about treatment options and providers. Often, the particular specialist a patient is referred to limits the choice of private health establishment, because they will only have treating or operating rights at one or two facilities.

In addition, if a patient wishes to be treated by a particular medical practitioner, the patient may have limited choice from the hospital or centre where they will be treated. It is acknowledged that a patient's choice of private health insurance may also limit their choice of hospitals; however, this is beyond the influence of Victorian regulatory regime.

For some small private health care providers, the treating practitioner may also be the proprietor of the business. In these cases, providers may have less incentive to compete on quality, particularly where it is difficult for patients to move between providers.

It is acknowledged that community expectations in the delivery of services are increasing, patients are becoming increasingly empowered to ask questions, and are able to access the information online and so on, However, there is still a significant knowledge differential in people being able to interpret and apply this information to their circumstances, and feel comfortable to challenge treating practitioners.

The use of regulations, for example, to require health service establishments to provide patients with verbal explanations and written information on the costs of their care, potential out-of-pocket expenses and their rights as patients, is intended to counterbalance these asymmetries.

Further, addressing these asymmetries and actively involving patients in decisions about their care is an important factor in ensuring the quality of health care. This 'patient-centred' approach, where the delivery

[12] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011–12*, http://www.aihw.gov.au/publication-detail/?id=60129543133

of healthcare is responsive to the needs and preferences of patients, has been defined as a dimension of safety and quality'.13

The department also acknowledges that the majority of health care providers are motivated to provide quality care, and to some extent, market drivers will have an effect. Specialist medical practitioners or surgeons want the best clinical outcomes for their patients, and therefore have an incentive to seek treating rights at private health establishments with good records on safety and quality. Similarly, private health establishments develop a brand and reputation they want to market to treating medical practitioners, health insurers and patients. It is further acknowledged that proprietors have a financial incentive to minimise the occurrence of adverse events; however, given the number of connected variables contributing to the rate of adverse events, and that performance data in this regard is not available to patients, is suggested that this in itself is not a strong enough driver of adequate safety outcomes.

Social priorities

The third reason continued regulation is considered necessary is to enable Victoria to meet its obligations under various national agreements.

These include the National Health Information Agreement and the Australian Health Care Agreement. Without legislation, the private health care sector could not be compelled to provide the information required by the department to comply with these agreements and to monitor the utilisation and performance of health services. This information assists with health service planning at a state and national level.

The government has an interest in a high quality, safe, strong private health care sector to offer alternatives to the state-funded public health system. Without it, increased demands would be placed on the public health and community services system.

2.3 Nature and extent of the problem

Quality and safety

When enacted in 1988, the Act was designed to promote management and accountability structures within health care agencies which encourage safety, quality, equity and efficiency in service delivery.

While the majority of health services (public and private) provide safe, quality health care services to the community, there remains a need, and a community expectation, that government will act to ensure that minimum requirements are in place.

Australian health ministers endorsed the *Australian Safety and Quality Framework for Health Care* in 2010 (the framework). The framework specifies three core principles for safe and high quality care: that care is consumer centred; driven by information; and organised for safety.

In considering quality in health care, one study,[14] cited by the Department of Health and Ageing, has classified safety and quality problems into three categories:

1. overuse — providing a service when its risk of harm exceeds its potential benefit
2. underuse — failure to provide a service when it would have produced favourable outcomes
3. misuse — avoidable complications of appropriate health care.

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[13] The Australian Commission on Safety and Quality in Health Care, 2012, *National Safety and Quality Health Service Standards*, http://www.safetyandquality.gov.au/publications/national-safety-and-quality-health-service-standards/, accessed April 2013.

[14] Chassin, MR, 1998, 'Is Health Care Ready for Six Sigma Quality?' *Milbank Quarterly* vol. 76(4).

As a result, a number of negative consequences with social and economic costs may arise, affecting individuals, the community and the sector, including:

- 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

Prevention of harm

Quantifying the extent of a 'quality problem' in the health care sector is difficult, both due to the differing definitions and perceptions of what may constitute 'quality' as well as a lack of quality performance data for private health care services.

Ideally, all health care interventions would be timely, evidence based, affordable and appropriate for the patient's condition and cause no further harm.

However, and in reality, this is not always possible, and the data available supports a role for government intervention in both the public and private health care setting, to ensure minimum requirements of patient safety are met.

The landmark *Quality in Australian Health Care Study* (QAHC study), released in 1995, demonstrates the incidence of adverse events in health care occurred in (or resulted in) approximately 16.6 per cent of admissions.[15] Adverse events are defined as incidents in which harm resulted to a person receiving health care. They include infections, falls resulting in injuries, and problems with medication and medical devices.[16] The QAHC study also found that of the adverse events identified:

- 51 per cent were considered preventable
- 77.1 per cent had a resultant disability that resolved within 12 months
- 13.7 per cent had a resultant disability that was permanent
- in 4.9 per cent of cases the patient died
- all such events accounted for an average of 7.1 additional days in hospital per patient.

A Victorian study examined the incidence of adverse events in Victorian Hospitals from 979,834 admitted episodes in 2003–04 and found that 6.88 per cent had at least one adverse event. These admissions were on average 10 days longer and had over seven times the risk of in-hospital death than those without complications.[17]

AIHW 2011–12 data reports Victoria had 32,465 adverse events in that year, which is equal to 3.5 adverse events per 100 separations.[18]

Costs

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[15] Wilson R, Runciman W, Gibberd RW, Harrison BT, Newby L, Hamilton JD, 1995, 'The Quality in Australian Health Care Study' *Medical Journal of Australia* vol. 163 pp. 458–471.

[16] Australian Institute of Health and Welfare, 2011, *Australian Hospital Statistics 2009–10*, http://www.aihw.gov.au/publication-detail/?id=10737418863

[17] Ehsani J, Jackson P, Duckett S, 2006, 'The Incidence and Cost of Adverse Events in Victorian Hospitals 2003–04' *The Medical Journal of Australia* vol. 184(11) pp. 551–555.

[18] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011–12*, http://www.aihw.gov.au/publication-detail/?id=60129543133

Several studies have examined the cost of adverse events in hospitals, with differing estimates being provided.

- In Victoria the total cost of adverse events in this study's 2003–04 dataset was $460 million, representing an additional 18.6 per cent of the total inpatient hospital budget.[19]
- Another estimate puts the cost of treatment of illness resulting from medical examination or treatment as $1.2 billion annually across Australia.[20]
- A further report by the Australian Patient Safety Foundation estimated the immediate cost to the Australian health care system is of the order of $2 billion each year.[21]

In addition to the direct economic cost to the health care system there are other indirect tangible costs, for example, dollars spent on legal action. It has been reported that annually in Australia, $400 million or one per cent of the total amount spent on health, is consumed by legal expenses and compensation arising from medical misadventure.[22] Further, the cost of providing an insurance system, involving the legal system and treatment for adverse events injuries diverts resources away from the core business health care, leading to lost opportunities.

Ultimately, it is the personal and human cost that is both the most devastating to individuals and difficult to quantify. These costs include pain and suffering, disability, and decreased productivity, which in turn impact on relatives, caregivers and friends.

Other studies have examined high-profile cases where there has been a systemic failure to meet safety and quality expectations, and which has been subject to investigations and inquiries.[23] It was noted in these investigations that:

> None of the substantiated problems had been uncovered or previously resolved by extensive accreditation or national safety and quality processes; in each instance, the problems were exacerbated by a poor institutional culture of self regulation, error reporting or investigation.[24]

Data from inspections of health service establishments

Information collected by the department from inspections of registered establishments gives some indication of the nature of the challenges in providing quality care. The department uses a risk-based approach in determining the frequency of inspections. Estimated levels of risk in a health service establishment are assessed against pre-established criteria, with consideration given to the potential effect of adverse events on the patient.

Data from 2011 indicates:

- 85.9 per cent of health service establishments had a 'low' assessed level of risk level, placing them in a two-year inspection timeframe
- 14.1 per cent of health service establishments had a 'medium' to 'high' assessed level of risk level, placing them in a six- to twelve-monthly inspection timeframe
- no health service establishments were assessed as having a 'critical' risk level.

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[19] Ibid.

[20] Rigby K, Clark R, Runciman W, 1999, 'Adverse events in health care: setting priorities based on economic evaluation' *Journal of quality in clinical practice* vol. 19 pp. 7–12.

[21] Runciman W, Moller J, 2001, *Iatrogenic injury in Australia*, a report prepared by the Australian Patient Safety Foundation for the National Health Priorities and Quality Branch of the Department of Health and Aged Care of the Commonwealth Government of Australia, at: http://www.apsf.net.au/Iatrogenic%20Injury.pdf, accessed Jan 2013.

[22] Ibid.

[23] Department of health (Queensland). *Safety and quality Issue paper for Bundaberg Hospital Commission of Inquiry*. July 2005, http://www.health.qld.gov.au/inqui r y/submissions/safety_quality.pdf, accessed Jan 2013.

[24] Faunce A, Bolsin S, 2004, 'Three Australian whistle-blowing sagas: lessons for internal and external regulation' *Med J Aust* vol. 181 pp. 44–47.

Up until to 2012, where one or more instances of noncompliance with the Regulations were identified following inspection by the department, 'recommendations' were made to health service establishments. From 2012, the department has issued 'requirements' where noncompliances with the regulations have been found, in place of recommendations.

In 2011 the department made 271 recommendations following inspections. Health service establishments were required to submit action plans in response to these recommendations. Also in 2011, 30.26 per cent of health service establishments inspected were found not to have implemented all actions in response to the recommendations made in the previous inspection, all of which were issues identified with noncompliance to regulations.

2012 data shows that:

- the department placed 296 requirements on registered establishments following inspections.
- 92 per cent had of facilities had at least one requirement identified
- 81 per cent of facilities had up to five identified requirements
- 9.82 per cent of facilities did not complete the actions required of them by the department following the previous inspection (an improvement from 30.26 per cent in 2011).

Of the issues identified during facility inspections, 81 per cent related to four regulations. These were:

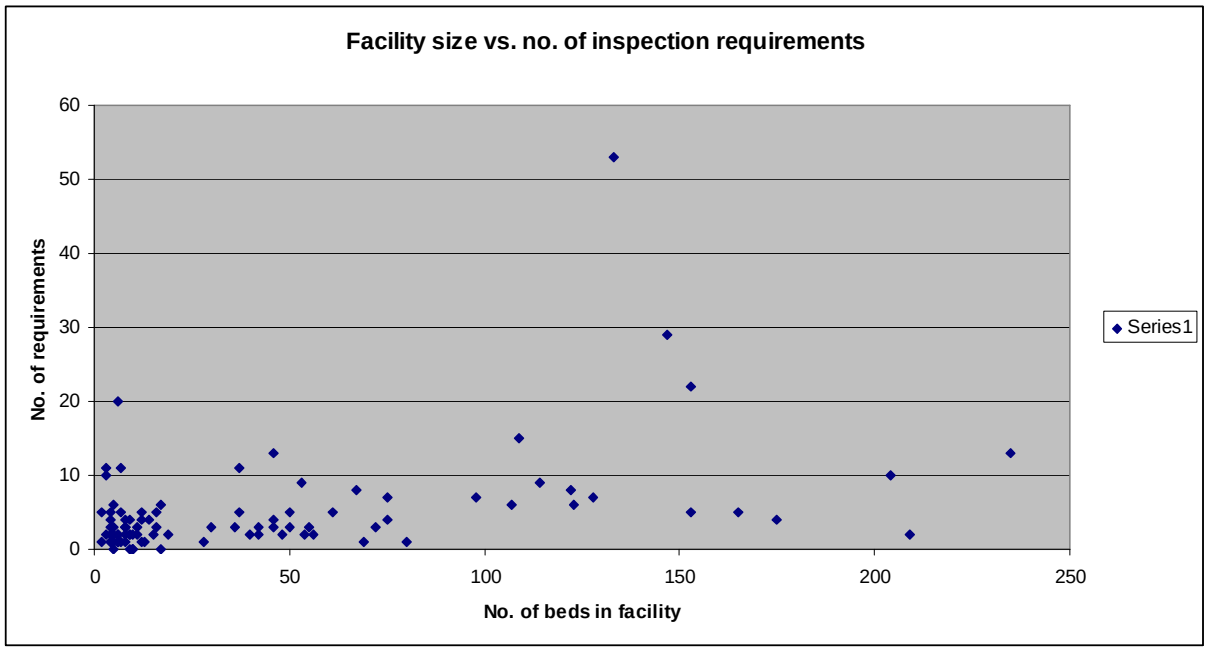
1. Regulation 28: skilled and appropriately qualified health professionals (credentialling of medical practitioners)
2. Regulation 42: Repair and cleanliness of premises
3. Regulation 43: Suitability and cleanliness of facilities, equipment etc.
4. Regulation 45: Infection control management plan.

Private hospitals compared with day procedure centres

The current (and proposed) regulations apply equally to both day procedure centres and private hospitals. While there is a difference in the types of services, treatments and patient profile seen across these settings, they share common baseline requirements for safety and quality; for example, infection control, clinical records and so on. The review of the Act currently underway is considering if an alternative framework that describes classes of facilities by service type may be option. This has been implemented in New South Wales and Tasmania.

Inspection data collected by the department indicates that is not possible to generalise about risk and performance between private hospitals and day procedure centres, or by the size of a facility.

The graph below plots the number of post-inspection requirements the department requested in response to noncompliances versus bed capacity at facility for 2012 (from 94 facilities visited in that year).



The department has observed that the strongest indicator of performance/compliance with the regulations is the governance arrangements in the facility, and this is consistent across smaller, stand-alone day surgeries and large for-profit private hospitals. Strong governance arrangements include the appointment of a suitably qualified person as the director of nursing.

Directors of nursing are accountable for the governance and practice standards of nurses, the development and effectiveness of systems to support, evaluate and consistently improve nursing and midwifery practice and health work environments.

The department has observed a correlation between an effective director of nursing and compliance with the Regulations.

3 Identification of options

3.1 Objective

The prime objective of these regulations is to provide for the safety and quality of care of patients receiving health services in registered private hospitals and day procedure centres. The 2002 Regulations set down minimum requirements with the aim of minimising the risk of harm to patients

The secondary objective of the regulations is to prescribe fees, forms and other matters required to be prescribed under the Health Services Act 1988 in relation to health service establishments. This provides the mechanisms by which health service establishments meet their requirements under the current Act.

3.2 Base case

The 'base case' scenario is one where the current Regulations lapse in September 2013 and are not replaced.

The *Victorian Guide to Regulation* requires the base case to be defined for the purposes of comparison (that is, what are the potential costs and benefits compared to the situation where the proposed approach is not adopted).

The removal of regulations for private hospitals would result in resource savings to government associated with applying and assessing registration, inspecting and monitoring. The health service establishments would experience a resultant decrease in compliance costs. It is possible that this scenario would also lead to increased competition, through additional service providers entering the market and additional treatments offered. However, the savings are likely to be limited and not of sufficient quantum to influence a decision on whether or not to enter the market.

In a non-regulated environment there is a risk that providers will pursue a competitive advantage that may result in decreased safety and quality. As described in Section 2 under 'Nature and extent of the problem' there is evidence that health care markets fail to operate efficiently when left to their own devices. This market failure is associated with the following:

Information asymmetries: health care consumers do not necessarily have sufficient information to make informed decisions about the type, quality and price of the treatment they will receive. They are predominantly reliant on the providers of health care to advise what is required, and may not have the ability to ask questions or seek other options and opinions.

Consumers' access to the market: the circumstances under which consumers seek health care is different from a normal market arrangement; there may be urgent need for treatment and therefore no opportunity to choose providers.

Limited price signals: in a standard market situation a consumer can select a product, taking into consideration the price; however, the costs of health products can be unpredictable in the private sector via insurance arrangements.

Supplier-induced demand: the risk that practitioners promote the use of their services or treatments to consumers.

The above, market-driven scenario would not enable government to meet its primary objective of ensuring minimum standards of safety and quality of health care for Victorians.

In addition, under the base case, the private health care sector would still be subject to Part 4 of the Health Services Act. The Act would continue to require health service establishments to be registered and pay a prescribed fee, but with no mechanism in regulations to provide for this. In this scenario, government would not be able to administer the current Act. Consequently, health service establishments would not be able to meet Victorian requirements, and this would impact on their ability to

qualify under the Commonwealth Private Health Insurance Act 2007 to receive payments by private insurers for services. This would create significant barriers to operation.

In the absence of Regulations, there would still be drivers for health service establishments to provide for patient safety and quality. These include the national standards for health care, against which health service organisations will be accredited commencing 2013 (referred to in Section 2), as well as professional codes of conduct and specialist practice guidelines. While these drivers promote safety and quality, under the base case there is no power for government to act or intervene in circumstances where it is found that these requirements are not being met.

3.3 Options to achieve the objectives

In considering options it is noted that:

The *Subordinate Legislation Act 1994 Guidelines* (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 health service establishments.

A number of provisions in the Act prescribe 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 relating to: safety, cleanliness and hygiene; staffing of health service establishment; requirements for facilities and equipment; record keeping; and provision of statistical information.

In accordance with the Act and guidelines, remaking of the regulations for these provisions is the only viable option to give effect to the Act. Therefore, alternative regulatory options (for example, negative licensing instead of registration, or guidance notes to proprietors in place of Regulations) are not considered in this RIS. Similarly, options involving information, such as league tables or benchmarking, while arguably addressing information asymmetries, are not viable, because this type of performance information is not available. As a result, options to be considered and assessed for the purposes of the RIS focus on those regulations that represent an incremental cost on the sector. These have been identified as:

- senior appointments
- staffing
- information provided to patients on fees and services
- fees.

These aspects of the proposed Regulations are discussed in Sections 4–7, where the nature and extent of the problems particular to those areas, as well as the arrangements in other jurisdictions, are discussed. All Australian states and territories register or license private hospitals, and all but South Australia and the Northern Territory register day procedure centres.

In addition, the Regulations' objectives and options will be examined. The cost-benefit for each option will be assessed using multi-criteria analysis, resulting in a preferred approach.

The rationale for other regulations that are either a low impact to the sector or where the cost is attributable to the Act and not the Regulations is set out in Section 8.

Regulation requirements compared with national standards for accreditation

As stated previously, both the regulation and accreditation of private health establishments is aimed at ensuring the safety and quality of services provided. There are areas of commonality between the proposed Regulations and the accreditation standards, but the Regulations do not address everything in

the national standards and vice versa. There are points of difference, and in some areas the Regulations are more specific. The Regulations needs to specify those requirements for the purpose of enforcement and compliance. Appendix D provides further information on the national standards and compares them with the proposed Regulations.

4 Senior appointments

4.1 The nature and extent of the problem to be addressed

Section 2.3 outlined the broad 'nature and extent of the problem' that is to be addressed by a regulation of private hospitals and day procedure centres.

The safety and quality of care provided in all health service establishments is the major concern of all stakeholders, services users and the community.

There are risks and adverse outcomes associated with health care, and these have significant personal, social and economic costs. As a result, there is significant investment and attention by all health care providers and governments to ensure that there are mechanisms in place to ensure that standards of safety are met and quality processes are effective.

Public hospitals operate under legislation that provides for governance of the public hospital system. The Victorian Government applies comprehensive policies and programs addressing safety and quality in their public hospitals.

In the private health care sector safety and quality is addressed through registration and regulation.

Section 83 of the Act sets down the criteria the secretary must consider in determining whether to register a premises as a health service establishment, including:

> (h) whether the proposed arrangements for the management and staff of the establishment are suitable; and
>
> (i) whether appropriate arrangements have been or will be made for maintaining the quality of health services provided by the establishment.

Appropriate governance arrangements, including the administrative management and clinical leadership, are important factors in achieving safety and quality of services. Commonly, these roles are fulfilled by the director of nursing (DoN), also known as director of clinical services, as well as a medical director and/or chief executive officer or general manager.

The Act does not define 'suitable' or 'appropriate' arrangements, and the intention is to provide some clarity on this in the Regulations and to ensure the regulator can have confidence this is being complied with.

The nature and size of regulated entities varies widely. At a hospital, a wide range of personnel may have clinical leadership responsibilities related to safety and quality. At the other end of the spectrum, small day procedure centres may have only one nurse manager on duty at any one time, who has a range of clinical and management responsibilities, and who works directly with the proprietor of the centre on a day-to-day basis. While the scope of the role may differ between a large corporate hospital and a small day procedure facility, the DoN role remains central to the clinical governance and management of the facility. In a larger facility the DoN may have responsibility for the implementation of clinical governance and quality across multiple teams and departments. In a smaller facility, the DoN, in addition to having a patient caseload, may also ensure systematic and day-to-day implementation of clinical quality and management of the facility.

The DoN has a key role in providing appropriate clinical and administrative leadership of nursing services, and has been a requirement in Victorian Regulations for many years. Directors of nursing are accountable for the governance and practice standards of nurses, the development and effectiveness of systems to support, evaluate and consistently improve nursing and midwifery practice and health work environments.

There is minimal data available on the performance of private hospitals, and it is acknowledged that there is no Victorian data to show the relationship between noncompliance with the DoN requirement and adverse safety outcomes.

The Australian Nursing Federation and some private health establishments have emphasised the need to have a DoN role with the authority and responsibility to provide operational leadership and achieve safety and quality outcomes. In addition, it has been reported that this leadership role is associated with:

- nurse autonomy and control over practice settings and superior outcomes[25]
- positive leadership behaviours, increased patient satisfaction and reduced adverse events[26]
- improved organisation of other staff and support services, and the climate and culture[27]

Data collected by the department indicates that the majority of registered hospitals and day procedure centres employ DoN with extensive clinical nursing and administrative management experience to undertake this pivotal role. In larger establishments, the role may involve full-time clinical management responsibilities; in smaller establishments it is like a dual role combined with direct clinical care. However, on small number occasions (approximately two to three occasions per year) the department is advised of an appointment of a DoN who, on assessment, does not have the requisite skills and experience for the role. On this basis, the likelihood of an adverse outcome (safety being placed at risk and being below community expectations) is low; however, the consequences in such circumstances could be moderate to high. As a result, the proposed the Regulations are designed to target a small group of providers that may not chose to appoint a DoN and/or appoint a DoN that is not suitably qualified.

The role of the CEO (however named) is responsible for the overall management at a private hospital or day procedure centre. The business management of registered services is not a matter for intervention by government, and it is not the intention to dictate the management structure of the health services establishments. However, to date there has been a requirement for registered health service establishments to notify the department of any appointments made. This enables communication between the department and the individuals responsible for ensuring the operation of the health service establishment and the delivery of safe and quality care.

4.2 Objectives

The primary objective of the Regulations is to provide for the safety and quality of care of health services in private hospitals and day procedure centres.

This objective of the regulation providing for senior appointments is to ensure a suitably qualified person is appointed as the director of nursing.

4.3 Interstate arrangements

Table 4.1 shows the requirements in place in other Australian states that apply to the staffing or senior management of private hospitals and/or day procedure centres.

[25] Aiken L, Clarke S, Sloane DM, Lake ET, Cheney T, 2008, 'Effects of hospital care environment on patient mortality and nurse outcomes' *J Nurs Adm* vol. 38(5) pp. 223–229.

[26] Wong A, Cummings C, 2007, 'The relationship between nursing leadership and patient outcomes: a systematic review' *J Nurs Adm* vol. 15(5) pp. 508–21.

[27] Clarke S, Donaldson N, 2008, *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*, Agency for Healthcare Research and Quality.

Table 4.1 Arrangements in other Australian jurisdictions

Jurisdiction	Legislation / Regulations	Requirements
New South Wales	*Private Health Facilities Act 2007* Private Health Facilities Regulation 2010	Requires that a registered nurse is appointed as a director of nursing of the facility. Prescribes the minimum necessary qualifications for director of nursing as: (a) five years post-basic or postgraduate nursing experience, and (b) two years administrative experience in a position of, or more senior than that of, nursing unit manager in a hospital.
Queensland	*Private Health Facilities Act 1999* Private Health Facilities (Standards) Notice 2000	The licensee must comply with relevant standards; Standard 4 relates to 'management and staffing'. A registered nurse at the facility is appointed in charge of the nursing staff. Staffing must be in accordance with *Guide to Clinical Services Capability Framework — Public*.
Tasmania	Health Care Act 2008 Health Service Establishments Regulations 2011	Requires there is a person who carries out the duties of chief nurse of the establishment and that person is a registered nurse and has such experience as the secretary considers necessary. The licensee must notify the secretary in writing of the full name and the qualifications of the chief nurse.
South Australia	Health Care Act 2008	The minister may attach such conditions to a licence under this Part as the minister thinks fit. Minister may impose conditions in respect of a licence requiring that the premises be in the charge of a person with specified qualifications, and otherwise regulating the staffing of the premises.
Northern Territory	*NT Private Hospitals Act*	An application for a licence must include particulars of the name of the person proposed to be director of nursing of the private hospital.
Western Australia	*Hospitals and Health Services Act* Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987	A licence holder shall ensure that the person occupying the post of director of nursing of the private hospital to which the licence relates or, in their absence, a responsible person holding qualifications approved by the CEO for the purposes of this paragraph is at all times present at, and in charge of, that private hospital.

4.4 Identification of options

Table 4.2 details two regulatory options.

Table 4.2 Regulatory options

Option A: the proposed Regulations	Option B: the alternative regulatory option
Require that the proprietor appoint a suitably qualified person as the director of nursing. Define a person suitably qualified if they have a qualification or practical experience in nursing	Require that the proprietor appoint a suitably qualified person as the director of nursing.

management and they are a registered nurse. If a director of nursing is absent, incapacitated or the position is vacant, the proprietor must appoint a person to act as the director of nursing. Require that the proprietor notify the secretary in writing of the name, qualifications and experience of any person appointed by the proprietor as the director of nursing; acting DON chief executive officer or medical director within 28 days after the appointment has been made.	

Option A is a continuation of the current regulatory approach applied to senior appointments. It defines 'suitably qualified' as being both a registered nurse and having qualifications or experience in nursing management. In addition, the Regulation requires that acting DoN arrangements need to be put in place, and the secretary must be advised of any senior appointments (DoN, acting DoN or medical director) within 28 days.

Option B takes a more 'principle-based' approach to this Regulation, requiring only that the proprietor appoint a suitably qualified person as the DoN.

Principle-based regulation has been described as 'moving away from reliance on detailed, prescriptive rules and relying more on high-level, broadly stated rules or principles to set the standards by which regulated entities must operate'.[28]

Arguably, Option B may be sufficient in meeting the objective of the Regulation and allow for greater flexibility in how private hospitals and day procedure centres comply. It has been suggested that this type of high-level approach to regulation may allow for more substantive compliance and achieving outcomes and less on simply following procedures or process.[29] Given the broad range of facilities that come under Regulation this may be an efficient approach.

Option B is similar to the equivalent arrangements regulating private hospital's in South Australia. Under the Health Care Act 2008 (SA) there is a high-level provision reserving the power that the 'Minister may impose conditions in respect of a licence requiring that the premises be in the charge of a person with specified qualifications'. This creates the expectation and an option for compliance and enforcement, without prescribing how to meet this requirement.

Critics of principle-based approaches suggest that the approach can fail to provide certainty, predictability, or to provide adequate protection to consumers and others; however, it is acknowledged that there is no evidence that such approaches are linked to worse safety outcomes.

Option A, while arguably more prescriptive and process driven, attempts to offer increased public protection by requiring a DoN with clinical and management experience to be in charge, and for the department to be advised of these senior appointments. This is similar to the approach in Queensland and Tasmania.

The NSW approach, which defines the minimum necessary qualifications for a DoN as (a) five years post-basic or postgraduate nursing experience, and (b) two years administrative experience was considered. It offers the benefit of clarity around what the department would assess as 'suitable qualified', but was thought to be more prescriptive than is necessary to meet the objective for the Regulation. Feedback from the sector is that less prescriptive regulation is preferred.

[28] Black J, Hopper M, Band C, 2007, 'Making a Success of Principles Based Regulation' *Law and Financial Markets Review* vol. 1(3) pp. 191.
[29] Ibid.

It is also noted that the Act that underpins these Regulations is currently being reviewed, and this may result in changes to the structure of the regulatory framework; for example, whether a 'tiered approach' should be introduced to better target regulation of particular classes of services, or types of facilities. Should these changes occur, there would be a resultant effect to the regulation of senior appointments in approximately 18 months to three years' time. Therefore, maintaining the current approach is considered optimal for business continuity.

4.5 Assessing the options

A multi-criteria analysis was used to assess the costs and benefits of the identified options. The criteria and their weightings is shown in Table 4.3 below.

Table 4.3 Multi-criteria analysis criteria and weightings

Criterion	Weighting
Protecting the service users through effective levels of safety and quality	50%
Cost	50%

These criteria reflect the objectives of the Regulations as they relate to the identified problem in this RIS about having appropriate senior appointments in place to ensure the required clinical and administrative management.

Because providing for the safety and quality of care of service users is the primary objective of the Regulations, it is accorded the benefit criteria weighting of 50 per cent. Costs are weighted at 50 per cent to ensure that costs and benefits are given balanced consideration in the analysis.

4.5.1 The base case

Under the base case, in order for private hospitals and day procedure centres to be registered they must demonstrate that their arrangements for the management and the staff of the establishment are suitable and that there are appropriate arrangements made for maintaining the quality of health services.

In addition, the majority of services will be seeking accreditation under the National Safety and Quality Health Service Standards (the national standards). National Standard 1 relates to 'Governance for Safety and Quality in Health Service Organisations', which picks up actions relating to 'Performance and skills management' to ensure that 'managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high quality health care'.[30]

In addition, there is an expectation from within the nursing profession that there is a DoN in place who is 'accountable for the governance and practice standards of nurses and midwives, the development and effectiveness of systems to support, evaluate and consistently improve nursing'.[31]

The department estimates that approximately 80 per cent of the registered health service establishments would appoint a suitably qualified DoN in the absence of the Regulations. This assumption has been informed by interactions between the department and the sector and in consideration of the other frameworks and drivers for having a DoN appointed. This assumption has not been tested with stakeholders, consultation on rates of compliance in the absence of regulations is unlikely to reliable.

Under the base case, the department would provide advice to proprietors about what suitable and appropriate arrangements need to be in place in regards to senior appointments.

[30] The Australian Commission on Safety and Quality in Health Care, 2012, *National Safety and Quality Health Service Standards*, http://www.safetyandquality.gov.au/publications/national-safety-and-quality-health-service-standards/, accessed April 2013.

[31] Australian Nursing Federation, 2012, *ANF position statement — management of nursing and midwifery services*, http://anf.org.au/documents/policies/PS_Management_nursing_midwifery_services.pdf, accessed April 2013.

4.5.2 Option A: the proposed Regulations

The proposed Regulations require that proprietors of private hospitals and day procedure centres:

- appoint a suitably qualified person as the DoN
- if the DoN is absent, appoint a person to act as the DoN
- notify the department in writing of the name, qualifications and experience of any person appointed by the proprietor as the DoN; acting DoN chief executive officer or medical director within 28 days after the appointment has been made

The incremental costs of the proposed requirements for Option A are shown in Table 4.4 below.

Table 4.4 Additional costs attributable to proposed Regulations 2012–13

Requirement	Annual cost $ per year	Cost $ per facility impacted per year	Discounted cost per facility impacted over 10 years
Employing a suitably qualified DoN (20% not included in base case)	2,920,790	89,048 (32.8 facilities)	797,772
Appointing an Acting DoN (20% not included in base case)	350,495	10,658 (32.8 facilities)	95,484
Notify the Secretary in writing of the senior appointment	1,825	11.13 (164 facilities)	99.70
TOTAL	**3,273,110**	**99,745**	

Table 4.4 provides a summary of the anticipated total costs of these regulations for 2012–13. The estimated costs across the sector for the regulations are **$3,273,110.** A series of assumptions are made in calculating these incremental costs (see Appendix A and A (i) for full details). These include:

- Costs are estimated for the estimated 20 per cent of health service establishments that would not appoint a suitable DoN (and an acting DoN) in the absence of Regulations.
- In this 20 per cent it is expected that half would have some form of management structure in place, whether it be a junior nurse or non-clinical manager; therefore, the appointment of a DoN in these cases does not equate to the employment of an additional staff member, but employment of a DoN at a higher rate of pay.
- That the department receives an average number of 52 notifications of senior appointments per year.
- The average time for health service establishments to complete a one-page notification form and attach appointee's CV is 30 minutes.
- Using the formula provided in the *Victorian Guide to Regulation* as a proxy for valuing an hour of a person's time the hourly rate would be $70.21.

Table 4.5 considers the 10-year cost of the proposed Regulations to be $**29,323,149**. This was calculated by:

- Assuming the number of private hospital and day procedure centres in Victoria to grow by 1.75 per cent per year. This figure is based on the growth in registrations between 2001 and 2012.
- Using a real discount rate of 3.5 per cent per the *Victorian Guide to Regulation.*

Table 4.5 Estimated total costs of proposed Regulations 2012–13 to 2022–23

Year	Cost $	Discounted cost
2013–14	3,273,110	3,162,425
2014–15	3,330,389	3,108,954
2015–16	3,388,389	3,056,133
2016–17	3,447,973	3,004,709
2017–18	3,508,313	2,953,905
2018–19	3,569,708	2,903,960
2019–20	3,632,178	2,854,859
2020–21	3,695,741	2,806,588
2021–22	3,760,416	2,759,134
2022–23	3,826,224	2,712,482
TOTAL	**35,432,441**	**29,323,149**

Multi-criteria analysis scores

As recommended by the *Victorian Guide to Regulation*, a symmetric scoring scale ranging from -10 to +10 was used because it is simple to apply and understand, as well as allowing enough scope for differences across options to be distinguished.[32]

The proposed Regulations provide assurance that a suitably qualified DoN will be appointed at all times at the health service establishment, and that the department will receive timely notification of this in order to act if there are concerns. Given the department has observed a correlation between the appointment of an effective DoN and compliance with the Regulations, it is assumed this will strongly contribute towards the provision for safety and delivery of quality care, and as such it is scored +8 for this criterion.

The annual average additional cost is approximately **$3,273,110** across the sector.

Given the recurrent expenditure for Victorian private hospitals and day procedure centres in 2009–10 was reported as $2,478,000,000[33] this amount is acknowledged as an impost, but not a significant one to the sector. On this basis it was scored +4 on the cost criterion.

Table 4.6 MCA scores for Option A: the proposed Regulations

Criterion	Weighting	Score	Weighted score
Protecting users through effective levels of safety and quality	50%	+8	+4
Cost	50%	- 4	- 2
TOTAL	**100%**		**+2**

[32] Government of Victoria, 2011, *Victorian Guide to Regulation*, Department of Treasury and Finance, Melbourne.
[33] Australian Bureau of Statistics, 2012, *Private Hospitals, Australia 2010–11*, cat. no. 4390.0, Canberra: ABS.

4.5.3 Option B: the alternative regulatory option

Option B, the alternative regulatory option is a principle-based approach. It is a high-level requirement for private hospitals and day procedure centres to appoint a suitably qualified DoN, but does not expand on this by, for example, by requiring an acting DoN.

The additional costs for this option are only the cost of the 20 per cent of health service establishments appointing a DoN. These are summarised in Table 4.7.

Table 4.7 Incremental costs for Option B

Requirement	Annual cost	Cost per registered premises	Discounted cost $ total 10 years
Employing a suitably qualified DoN (% not included in base case)	2,920,790	89,048	797,772 per facility

The estimated costs across the sector for the regulations are $2,920,790, or $89,048 per impacted health service establishments. The discounted rate of 10 years is equal to $797,772 per impacted health service establishments, or $26,166,921 in total.

Multi-criteria analysis scores

The alternative Regulations require that a suitably qualified DoN will be appointed. While this enables the department to intervene if it finds circumstances where proprietors have not been compliant, it does not provide a mechanism for the department to be aware of new appointees in real time. As a result, it would be possible for some health service establishments not to have adequate arrangements in place, and for the department to not become of aware of this until the next inspection visit.

In the absence of any data, it is the department's view that this scenario would involve risks to safety in a limited number of cases and does not offer effective assurance that standards of safety and delivery of quality care will have been met. The department is of the view that this approach does not protect uses as effectively as Option A. Therefore, it is scored +6 for this criterion, compared with +8 for the proposed Regulation.

The annual additional cost is approximately $2,920,790. Because this figure is 12 per cent cheaper than the cost of Option A, it was scored 12 per cent lower for cost, which is equal to -3.5.

Table 4.8 MCA scores for Option B: the alternative regulatory option

Criterion	Weighting	Score	Weighted score
Protecting users through effective levels of safety and quality	50%	+6	+3
Cost	50%	-3.5	- 1.75
TOTA	**100%**		**+1.25**

4.6 The preferred approach

Based on this analysis, the department considers that the proposed Regulations are preferable to the alternative option assessed, as shown in Table 4.9.

Table 4.9 Summary of MCA scores for options

Option	MCA score
Option A: the proposed Regulations	+2
Option B: the alternative regulatory option	+1.25
Base case	0

5 Staffing

5.1 The nature and extent of the problem to be addressed

In a health service, establishment safety and quality is addressed through registration and regulation.

Section 83 of the Act sets down the criteria the secretary must consider in determining whether to register a premises as a health service establishment, including:

> (h) whether the proposed arrangements for the management and staff of the establishment are suitable.

The problem to be addressed is how to minimise risks to patients and provide for patient safety and quality of private health care.

The importance of nurse staffing and skill mix to the delivery of high-quality patient care and patient outcomes has been acknowledged.[34] As such, ensuring that there is a sufficient number of suitably qualified and experienced staff on duty is essential.

In Victoria, there are two principal groups of nurses:

- registered nurses, who have been educated to a bachelor degree level in university
- enrolled nurses, who have undertaken a Certificate IV in Health (Nursing) course.

Registered and enrolled nurses are regulated under the *Health Practitioner Regulation National Law (Victoria) 2009* and must be registered to practice with the Nursing and Midwifery Board of Australia (NMBA). The NMBA maintain and promote professional standards of nursing practice by all nurses in order to protect the health and safety of the public.

Enrolled nurses provide nursing care beside registered nurses, who coordinate and supervise nursing activities. An enrolled nurse retains responsibility for their own actions while remaining accountable to a registered nurse for delegated activity.

Over the past decade there has been a change in the composition of the nursing workforce, including a move towards greater professional specialisation. There has been development in the skill level and qualifications for enrolled nurses. Since 2004 enrolled nurses in Victoria have been able to do additional training to administer some forms of medicines, and from 2006 this has been part of all enrolled nurses courses. From 1 July 2010 there are changes to the way enrolled nurses who cannot administer medicines are recognised by a notation on their registration.[35]

The NMBA has determined that as of July 2014 new graduate enrolled nurses will require a diploma qualification while certificate courses are being phased out.[36]

As well as the developments in enrolled nursing, there has been an increase in employment of Assistants in nursing in health care settings to enable registered nurses to focus on more clinically orientated tasks. Assistants in nursing also work under the supervision of the registered nurses.

Initiatives in Victoria have considered how greater utilisation of an assistant workforce may support workforce sustainability and improve the system's capacity to meet the community's health needs into the future.[37] This has also been explored at a national level.[38]

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[34] Hughes RG (editor), 2008, *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*. Rockville (MD): Agency for Healthcare Research and Quality, US.

[35] Service and Workforce Planning, Department of Human Services, 2004, *Nurses in Victoria: A Supply and Demand Analysis 2003–04 to 2011–12*, Melbourne, Victorian Government.

[36] Ibid.

Victoria's Better Skills Best Care Strategy sought to trial ways to improve workforce capacity and utilisation, while also improving quality of outcomes, efficiency and worker satisfaction. The key objective was noted as ensuring:

> The right people with the right skills are in the right place at the right time to deliver quality care to patients.[39]

This is also relevant, given the skills shortages across the health professions, including for registered nurses, midwives and enrolled nurses.[40]

The skill mix, including the proportion of registered nurses, is directly related to ensuring safety and quality of care.

Research funded by the NSW Department of Health found that:[41]

- a skill mix with a higher proportion of RNs produced statistically significant decreased rates of negative patient outcomes such as, sepsis, shock, pulmonary failure as well as 'failure to rescue'
- skill mix is more critical to patient outcomes than hours of nursing provided.

This has also been demonstrated internationally with:

- staffing of RNs below target levels was associated with increased mortality[42]
- higher rates of RN staffing were associated with a 3–12 per cent reduction in adverse outcomes, depending on the outcome.[43]

In addition, there is also research on the size of the relationship between nurse-to-patient ratios and safety outcomes.

Findings from a study into evidence on effectiveness of nurse staffing on patient outcomes in public hospitals by Professor Christine Duffield at the University of Technology, Sydney, was referred to in NSW Parliament during debate on nursing ratios.[44] It was noted that:

- patients cared for under a one-to-eight nurse-to-patient ratio experience a 30 per cent greater chance of dying than those under a one-to-four ratio
- mandated nurse-to-patient ratios in Victoria were introduced 10 years ago and resulted in both a safer environment for patients, and improved morale for the nursing workforce.

Further research has focused on the cost-effectiveness of nurse to patient ratios and found that:

- Savings were made due to reduced overtime costs, reduced patient care costs, quicker patient recovery, reduced staff turnover costs and reduced patient infections. Investment in additional

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[37] Department of Health, 2012, *Growing your assistant workforce*, http://www.health.vic.gov.au/workforce/reform/assistant.htm, accessed April 2013.

[38] Health Workforce Australia, March 2012, *Health Workforce 2025 — Doctors, Nurses and Midwives*, volume 2, https://www.hwa.gov.au/sites/uploads/HW2025Volume2_FINAL-20120424.pdf, accessed April 2013.

[39] PriceWaterhouseCoopers, 2011, Evaluation of three Better Skills Best Care pilot projects, http://www.health.vic.gov.au/workforce/reform/workforce.htm, accessed April 2013.

[40] Labour Economics Office Victoria, Department of Education, Employment and Workplace Relations, December 2010, *Skills Shortages Australia*, p. 38.

[41] University of Technology Sydney, 2007, *Glueing it Together: Nurses, Their Work Environment and Patient Safety*, Department of Health (NSW), http://www0.health.nsw.gov.au/pubs/2007/nwr_report.html, accessed April 2013.

[42] Needleman J et al., 2011, 'Nurse Staffing and Inpatient Hospital Mortality' *N Engl J Med* vol. 364 pp. 1037–1045.

[43] Stanton MW, 2004, *Hospital Nurse Staffing and Quality of Care, Agency for Healthcare Research and Quality*, at: http://www.ahrq.gov/research/findings/factsheets/services/nursestaffing/nursestaff.pdf, accessed April 2013.

[44] New South Wales Parliamentary Debates, Legislative Council, 24 November 2010, http://www.parliament.nsw.gov.au/prod/parlment/hansart.nsf/V3Key/LC20101124013

nursing care hours better prepares patients for discharge, which results in a projected savings of improved RN staffing and decreased overtime costs of $11.64 million and $544,000 annually.[45]

- Improving RN-to-patient ratios from 1:8 to 1:4 would produce significant cost savings and is less costly than many other basic safety interventions common in hospitals, including clot-busting medications for heart attacks and PAP tests for cervical cancer.[46]
- Potentially preventable adverse events (pneumonia, pressure ulcer, UTI, wound infection, patient fall/injury, sepsis and adverse drug event) were all associated with increased costs. For example, the cost of care for patients who developed pneumonia while in the hospital rose by 84 per cent. Treating pneumonia raised total treatment costs by $22,390 to $28,505, while the length of stay increased 5.1–5.4 days and the probability of death rose 4.67–5.5 per cent.[47]

The Australian Nursing Federation has reported that:[48]

- adverse events are estimated to cost $4 billion annually
- short-staffed units have higher costs and patients have a longer length of stay
- it is estimated that 26.7 per cent of all infections could be avoided by appropriate nurse-to-patient ratios
- cost per case of adverse events (US$2,384 per case)
- registered nursing care is positively associated with reducing adverse events like pneumonia, a complication which adds five days to a patient's average length of stay and is estimated to cost US$4,000–$5,000 per additional day.

It is acknowledged that private health establishments are, in the main, funded through private insurance arrangements, and not government funds. Private health establishments have individual contract arrangements with private health insurers, but the department understand these do not specify staffing or skill-mix requirements, or any other specific safety and quality measures.

As noted in Section 2, to be eligible for this health insurance funding, the private health establishments must meet the requirements of the (Commonwealth) Private Health Insurance Act 2007 (PHI Act) to receive a provider number from the Department of Health and Ageing. The Commonwealth does not specify staffing requirements, but requirements for a hospital to be 'declared' and therefore, access funding, under Section 121–5 (7) of the PHI Act, include that:

- the necessary approvals by a State or Territory, or by an authority of a State or Territory, have been obtained in relation to the facility; and
- whether the accreditation requirements of an appropriate accrediting body have been met.

Standard 1 of the national standards — Governance for Safety and Quality in Health Service Organisations, includes a criterion on 'Performance and skills management' that states: 'managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high quality health care'.

The standards describe the systems required to achieve this, and actions required. These are detailed in the table below.

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[45] National Nurses United, March 2013, *RN-to-Patient Ratios — A Cost-Effective Solution for Hospitals*, at: http://nurses.3cdn.net/e73fe5c9828a8b42b1_nrm6bzj4h.pdf

[46] 2005 *American Journal of Public Health* vol. 95(8) pp. 1304–1304.

[47] Stanton MW, 2004, *Hospital Nurse Staffing and Quality of Care*, Agency for Healthcare Research and Quality, http://www.ahrq.gov/research/findings/factsheets/services/nursestaffing/nursestaff.pdf, accessed April 2013.

[48] Australian Nursing Federation, 2009, *Issues Paper: Ensuring quality, safety and positive patient outcomes — Why investing in nursing makes $ense*, at: http://anf.org.au/documents/reports/Issues_Ensuring_quality.pdf

Table 5.1 National standards in relation to staffing

This criterion will be achieved by:	Actions required:
1.10 Implementing a system that determines and regularly reviews the roles, responsibilities, accountabilities and scope of practice for the clinical workforce	1.10.1 A system is in place to define and regularly review the scope of practice for the clinical workforce 1.10.2 Mechanisms are in place to monitor that the clinical workforce are working within their agreed scope of practice 1.10.3 Organisational clinical service capability, planning and scope of practice is directly linked to the clinical service roles of the organisation 1.10.4 The system for defining the scope of practice is used whenever a new clinical service, procedure or other technology is introduced 1.10.5 Supervision of the clinical workforce is provided whenever it is necessary for individuals to fulfil their designated role
1.11 Implementing a performance development system for the clinical workforce that supports performance improvement within their scope of practice	1.11.1 A valid and reliable performance review process is in place for the clinical workforce 1.11.2 The clinical workforce participates in regular performance reviews that support individual development and improvement
1.12 Ensuring that systems are in place for ongoing safety and quality education and training	1.12.1 The clinical and relevant non-clinical workforce have access to ongoing safety and quality education and training for identified professional and personal development
1.13 Seeking regular feedback from the workforce to assess their level of engagement with, and understanding of, the safety and quality system of the organisation	1.13.1 Analyse feedback from the workforce on their understanding and use of safety and quality systems 1.13.2 Action is taken to increase workforce understanding and use of safety and quality systems

Some stakeholders have indicated that the above standards and systems should be sufficient in ensuring there is sufficient and appropriately trained staff in health services establishment, and that they should not be further regulated. The counter view is that the standards detail quality mechanisms but do not necessarily provide a clear minimum standards to provide for safety in relation to nursing staffing and — as noted in the above literature — this is linked to patient safety outcomes.

It is also acknowledged that there is a significant data gap in relation to safety indicators across health generally, and in particular, the private market. This makes it difficult to link ratios with safety outcomes in Victoria. As noted previously in the RIS AIHW 2011–12 data reports,[49] Victoria had 32,465 adverse events in that year, which is equal to 3.5 adverse events per 100 separations. This is the second-lowest rate of adverse events in Australia (with WA having the lowest rate at 3.2 and South Australia the highest at 5.2). While this may indicate a correlation between the current regulatory approach and adverse events, there are multiple variables, and a direct link could not be established, particularly because adverse event data is not available at an individual hospital level.

[49] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011-12*, at: http://www.aihw.gov.au/publication-detail/?id=60129543133

Performance data has not been regularly collected from private hospitals to date, although a small number participate in reporting schemes voluntarily. In the public system, performance data has been collected as a result of funding arrangements. In future, it is intended to move to a process of nationwide consistent indicators across health sectors, public and private. In November 2009 health ministers endorsed the Australian Commission on Safety and Quality in Health Care's recommendation that hospitals routinely monitor and review a succinct set of indicators. This is to be achieved by the establishment of the National Health Performance Authority (the authority) and the Performance and Accountability Framework (the framework).

The authority, established under Commonwealth legislation, began operations on 21 October 2011. They released a draft framework in May 2012 for consultation. In part, the framework establishes the conceptual basis for the authority to fulfil its role in developing and producing reports on the performance of hospitals and health care services, including private hospitals. Further information on these is provided in Section 9.

It is currently not mandatory for private hospitals to provide this information. Moving towards this has been contentious, with private hospitals raising issues of commercial sensitivity. It is not clear at this stage when the framework will be fully realised.

5.2 Objectives

The objective of this Regulation aligns with the overall objective of the Regulations; that is, to provide for the safety and quality of care in private hospitals and day procedure centres.

Specifically, the objective is to ensure that the standard of care patients receive at private health premises is adequate, suitable and timely. The Regulation seeks address the risk that an unregulated market will lead to pressure to retain fewer and less qualified/experienced staff than are necessary to deliver services safely.

5.3 Interstate arrangements

Table 5.2 shows the requirements in place in other Australian states that apply to the staffing or senior management of private hospitals and/or day procedure centres.

All jurisdictions have staffing requirements described, either via legislation or regulations, for registered health services establishments. While there is a range of ways these requirements are expressed, common themes include that staff are: 'sufficient or adequate' in number; and 'qualified' and 'experienced'. Both New South Wales and Tasmania include additional staffing requirements for some specialised classes of services. For example, in NSW an 'anaesthesia class private health facility' and in Tasmania a 'surgical hospital', must provide staffing in accordance guidelines issued by the Australian and New Zealand College of Anaesthetists.

Table 5.2 Arrangements in other Australian jurisdictions

Jurisdiction	Legislation/Regulations	Requirements
New South Wales	Private Health Facilities Act 2007	Requires that the licensee must: ensure that a registered nurse is on duty at the facility at all times during which there is a patient at the facility.
	Private Health Facilities Regulation 2010	Requires a facility must have a sufficient number of qualified and experienced staff on duty, at all times, to carry out the services provided by the facility, and nursing staff holding qualifications and experience appropriate for the services provided by the facility. Schedule 2 identifies additional requirements: sedation and anaesthesia, emergency, intensive care.
Queensland	Private Health Facilities Act 1999	The licensee must comply with Standard 4, which relates to 'management and staffing'. A registered nurse at the

	Private Health Facilities (Standards) Notice 2000	facility is appointed in charge of the nursing staff. And staffing must be in accordance with the *Guide to Clinical Services Capability Framework Public.*
Tasmania	Health Care Act 2008 Health Service Establishments Regulations 2011	Schedule 1 requires sufficient qualified nursing staff are employed to adequately and safely meet the needs of patients. The nursing staff must include persons having qualifications and experience appropriate for each class of private hospital or day procedure centre specified in the licence for the private hospital or day procedure centre. Additional requirements are then specified for 'surgical hospitals'.
South Australia	Health Care Act 2008	Minister may impose conditions in respect of a licence regulating the staffing of the premises.
Northern Territory	NT Private Hospitals Act	An application for a licence must include particulars of the nursing qualifications that will be required of staff to be employed for the purpose of caring for patients in the private hospital.
Australian Capital Territory	ACT Healthcare Facilities Code of Practice 2001	A health care facility must be staffed by an adequate number of health care professionals to ensure that occupant safety and care is maintained while the facility is operating.

By comparison, the *Victorian public sector nurses and midwives enterprise agreement 2012–2016*[50] sets down a range of ratios depending on the patient profile and clinical risks (see Table 5.3 below). These ratios apply to the combined number of nurses, both registered and enrolled. The agreement also specifies up to 20 per cent enrolled nurses, except for specified rural hospitals that are not restricted.

Table 5.3 Nurse ratios in Victorian public sector nurses and midwives enterprise agreement 2012–2016

Health care setting	Shift	Ratio*
General medical/surgical — Level 1	AM	1:4
	PM	1:4
	Night	1:8
General medical/surgical — Level 2	AM	1:4
	PM	1:5
	Night	1:8
General medical/surgical — Level 3	AM	1:5
	PM	1:6
	Night	1:10

[50] Department of Health, 2012, *Victorian Public Sector Nurses and Midwives Agreement 2012-2016*, at: http://www.health.vic.gov.au/enterpriseagreements/nurses.htm, accessed April 2013.

Acute	AM	1:6
	PM	1;7
	Night	1:10
Aged care	AM	1:7
	PM	1:8
	Night	1:15

**Does not include nurse in charge.*

The ratios in Table 5.3 do not apply in respect of chemotherapy, dialysis, admission centres and day procedure centres. Enterprise agreements for private health sector do not specify nursing ratios.

It is important to note that the public sector ratios above are not translated to the private health service establishments due to the difference in patient profile, acuity and complexity.

5.4 Identification of options

Three regulatory options are described below in Table 5.4. Because the Act requires the department to consider if the staffing arrangements are suitable in order to register a private hospital or day procedure centre, non-regulatory options were not explored.

The options analysed are a continuation of the current approach, with minimum ratios of registered nurses and skills mix prescribed (Option A), a general principle-based approach (Option B) and class-of-services approach, similar to that in place in NSW (Option C).

Table 5.4 Regulatory options

Option A – Proposed Regulations
The proprietor must ensure that each nurse is professionally competent through education or experience to provide nursing care at the hospital or centre having regard to the kind or kinds of health service being provided. The proprietor must ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care for those patients. A sufficient number of appropriately educated or experienced nursing staff is on duty if- a) in the case of a private hospital- (i) at least one registered nurse is on duty for each 10 patients or fraction of that number during day and evening shifts; and (ii) at least one registered nurse is on duty for each 15 patients or fraction of that number during night shifts; or b) in the case of a day procedure centre, not less than one registered nurse is on duty for each 10 patients or fraction of that number In determining the number of nurses on duty, if 3 or more nurses are on duty at a private hospital or a day procedure centre during a shift, one-third may be enrolled nurses.

Option B: principle-based Regulations
The proprietor must ensure that each nurse is professionally competent through education or experience to provide nursing care at the hospital or centre having regard to the kind or kinds of health service being

provided.

The proprietor must ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care for those patients.

Option C: classes of services

The proprietor must ensure that a registered nurse is on duty at the facility at all times during which there is a patient at the facility.

The proprietor must ensure a facility has a sufficient number of qualified and experienced staff on duty, at all times, to carry out the services provided by the facility, and nursing staff holding qualifications and experience appropriate for the services provided by the facility.

In addition, prescribe the following eight classes of services and place further requirements for each class in relation to staffing as follows:

1. Anaesthesia class

Must provide staff to assist an anaesthetist in accordance with the recommendations of the Australian and New Zealand College of Anaesthetists in its publication *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations*.

2. Rapid opioid detoxification class service

Must have a medical practitioner on staff or on-call at all times who has experience in opioid treatment and in the management of detoxification (including severe withdrawal management), and:

- must have a medical practitioner on site for the first four hours following the carrying out of any induction procedure on any patient

and

- must have a medical practitioner on-site or on-call between four and 48 hours following the carrying out of any induction procedure on any patient.

Must have sufficient nursing staff on duty at all times, including:

- a nursing staff-to-patient ratio of at least 1:2 in the first eight hours following the carrying out of any induction procedure on any patient, and
- a nursing staff to patient ratio of at least 1:4 between eight hours and 24 hours following the carrying out of any induction procedure on any patient.

3. Emergency class service

- an appropriately qualified and experienced medical practitioner appointed as director of the emergency service,
- appropriately qualified specialists available on call at all times,
- a sufficient number of appropriately trained and experienced staff on duty at all times.

4. Intensive care (Level 1 or Level 2) class service

- a medical practitioner with appropriate qualifications appointed as director of the unit, the appropriate qualifications being (in the case of an intensive care (Level 2) class private health facility) a recognised postgraduate qualification in intensive care

and

- in the case of an intensive care (Level 1) class private health facility — a medical practitioner on duty at the private health facility at all times, with priority for attendance on patients in the intensive care

unit

and

- in the case of an intensive care (Level 2) class private health facility — a medical practitioner with an appropriate level of experience present in the unit at all times, and sufficient nursing staff on duty at all times, being:
    - a nursing staff to patient ratio of at least 1:1 for all critically ill patients

    and

    - in the case of an intensive care (Level 2) class private health facility — at least 50 per cent of whom are registered nurses with intensive care certification.

5. Paediatric class service

- have a paediatric physician available for consultation

and

- have a registered nurse on duty at the facility who has appropriate paediatric experience or qualifications.

6. Rehabilitation class service

- must have sufficient appropriate therapists for the services provided

and

- must have sufficient registered nurses with appropriate rehabilitation qualifications or experience on duty at all times.

7. Maternity class (Level 1 or Level 2) service

For normal risk pregnancies:

- obstetricians, anaesthetists and a paediatrician on call at all times
- a medical practitioner at the facility at all times
- experienced midwives on duty at all times
- established links with clinical nurse consultants or clinical nurse educators in midwifery and neonatal nursing.

For a moderate risk pregnancy:

- the facility has appropriate support services and infrastructure and has staff with clinical expertise relevant to the risk factors of particular patients, including:
    - obstetricians, anaesthetists and a paediatrician on call at all times

    and

    - a medical practitioner at the facility at all times

    and

    - experienced midwives on duty at all times

    and

    - established links with clinical nurse consultants or clinical nurse educators in midwifery and neonatal nursing.

8. Mental health class service

- must have access at all times to a psychiatrist

- must have access to a general practitioner and relevant specialists for consultation

and

- must have sufficient registered nurses with appropriate psychiatric qualifications or experience on duty at all times.

All options require that a proprietor ensure that:

- nurses are competent and experienced in the kind of health services being provided
- there is a sufficient number of appropriately educated or experienced nursing and other health professional staff on duty to provide care for those patients.

Option A provides a definition of 'sufficient' staffing requiring as a minimum:

- one registered nurse for 10 patients for morning and afternoon/evening shifts in private hospitals (1:10)
- one registered nurse for 15 patients for night shifts in private hospitals (1:15)
- one registered nurse for 10 patients at a day procedure centre (1:10).

The definition refers to the registered nurses, who have supervisory responsibility for any enrolled nurses also on duty. The regulation also notes that, in determining the number of nurses on duty, if three or more nurses are on duty at a private hospital or a day procedure centre during a shift, one-third may be enrolled nurses.

It is worth noting that the concept of nursing ratios has been in place in the Victoria public health system since an Australian Industrial Relations Commission decision in 2000. Ratios are not as prevalent in other states and territories either in the public or private health care system.

The ratios described in Option A equate to minimum levels of staffing. The 1:10 and 1:15 ratios represent a negotiated position balancing the recommendations of the nursing profession, demands on private health establishments and the department's view of minimum requirements to provide for patient safety, rather than independent research.

Under the structure of the current Act, there is a wide variety of health care services subject to the same Regulations. This may vary from acute medical, emergency and intensive care services, all the way through to rehabilitation and minor day procedures. In the majority of cases, acute private health care settings would have staff in excess of these ratios. We may also expect there to be higher numbers of RNs in place due to the profile of the nursing profession in Victoria (over 75 per cent of the total profession being RNs).[51]

Some regulated entities have suggested that nurse–patient ratios are inflexible and do not reflect contemporary practice for all types of health services. That said, where there is safety risk due to understaffing in a small number of noncompliant health service establishments, it is the department's view that this requires minimum levels of staffing to be specified.

The department is currently reviewing the Act and is considering options to better classify service or facility types in order to apply targeted requirements. The department is of the view that the Act needs to be reviewed and potentially restructured in order to best explore this 'tiered' approach. However, Option C considers this model, similar to the NSW approach, with classes or types of services specified and particular staffing requirements prescribed.

The current Act allows the Regulations to prescribe a kind of health service for the purposes of defining a private hospital or day procedure centre. Currently the Act does not contain a head of power to allow the

[51] Nursing and Midwifery Board of Australia, April 2013, *Nurse and Midwife Registrant Data: March 2013*.

department to declare separate classes of private hospitals or day procedure centres; for example, Level A, B, C, based on risk or compliance performance and then apply separate requirements on this basis. While not viable under the current Act, this may be an option in development of new legislation.

It is also noted that there are limitations with Option B, and C to the extent where they do not specify what sufficient staffing would be in all settings. The department has received advice that without prescribing this in the Regulations, it may not be possible to attach an offence provision of the Regulations, and therefore potentially limit the effectiveness and enforceability of the Regulation.

5.5 Assessing the options

A multi-criteria analysis was used to assess the costs and benefits of the identified options. The criteria and their weightings are shown in Table 5.5 below.

Table 5.5 Multi-criteria analysis criteria and weightings

Criterion	Weighting
Protecting the service users through effective levels of safety and quality	25%
Practicality of Implementation	25%
Cost	50%

5.5.1 The base case

Under the base case, health service establishments seeking registration under the Act would be required to demonstrate that their staffing arrangement are suitable, but they would not be subject to any Regulations.

In the absence of Regulations, it is reasonable to expect that 'business as usual' would still see the majority of proprietors employ sufficient, qualified staff, with the required skill mix. This can be expected due to:

- contemporary clinical governance arrangements
- the national standards, which require 'the clinical workforce have the right qualifications, skills and approach to provide safe, high quality health care'[52]
- regulation of health practitioners
- guidelines and policy issues by professional colleges.

However, there would be potential for a proportion of health service establishments to seek to put in placer a lower level of staffing that may be expected by the department or the community.

Based on engagement, an interaction with the sector the department estimates the base case equal to:

- 90 per cent of proprietors employing staff who are professionally competent to provide nursing care, having regard to the kind of health service being provided; therefore, 10 per cent of the cost of the sector meeting this requirement is attributable to the Regulations
- similarly, 90 per cent of health service establishment's rostering staff with required qualifications and skill mix relevant to the service being provided, to ensure patient safety; therefore, 10 per cent of the cost of the sector meeting this requirement is attributable to the Regulations
- 80 per cent of proprietors employing sufficient number of nursing staff on duty.

[52] The Australian Commission on Safety and Quality in Health Care, 2012, *National Safety and Quality Health Service Standards*, http://www.safetyandquality.gov.au/publications/national-safety-and-quality-health-service-standards/

These assumptions have been informed by the department's discussions with proprietors and staff, as well as data and information collected during inspections. Compliance rates with staffing ratios and skill mix is generally high. The major area of noncompliance for staffing involves credentialling of medical practitioners, Although 80 per cent compliance could be considered high, the risk posed by the noncompliant 20 per cent is considered significant.

Compliance with the skill mix is also noted as high. One of the reasons for that is there are significantly more RNs in Victoria than ENs. As of March 2013 there were approximately 306,000 nurses (RNS and ENs) registered for practice in Australia, approximately 80 per cent of which were RNs. Victoria has a slightly lower proportion of RNs as percentage of the profession, at 76 per cent.[53]

5.5.2 Option A: the proposed Regulations

The incremental costs of the proposed requirements for Option A are shown in Table 5.6 below.

Table 5.6 Additional costs attributable to proposed Regulations

Requirement	Annual cost $	Average cost $ equal to
Ensure that each nurse is professionally competent through education or experience to provide nursing care for the health service being provided.	1,329,894	154 per nurse
Ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care. For a private hospital: • one RN: 10 patients — day & evening shifts • one RN: 15 patients — night shift	3,101,822	189,085 per facility 211 per bed 17 per separation
For a day procedure centre: • not fewer than 1 RN: 10 patients.	119,628	7,924 per facility 818 per bed 3.02 per separation
In determining the number of nurses on duty, if three or more nurses are on duty at a private hospital or a day procedure centre during a shift, one-third may be enrolled nurses.	$5,794,847	
TOTAL	**9,016,297**	

Full calculations are provided in Appendix A (ii).

[53] Nursing and Midwifery Board of Australia, April 2013, *Nurse and Midwife Registrant Data: March 2013*.

The cost of ensuring that each nurse is professionally competent is estimated at $1,329,894. In making this estimation, it was assumed that as a result of multiple other drivers requiring appropriately qualified and trained staff, only 10 per cent of this cost is attributable to the proposed Regulations.

The second requirement of the proposed Regulations is that proprietors provide sufficient staff to provide care, with sufficient nursing staff defined as per RN: patient ratios.

For private hospitals the ratio is prescribed as 1:10 for the morning and afternoon shifts and 1:15 for night shifts. For day procedure centres, this is prescribed as 1:10.

The department has estimated the costs of this component of the Regulation as being $3,101,822 per year for private hospitals and $119,628 per year for day procedure centres.

Option A also seeks to ensure an appropriate skill mix of nursing staff by providing that, if three or more nurses are on duty at a health service establishment during a shift, one-third may be enrolled nurses. This provision is particularly relevant to ensure safety in smaller establishments that do not have the option to draw from wider staffing resources on site. As one example, the majority of day procedure centres provide surgical and endoscopic services and have fewer than 10 beds. On a daily basis there would be patients undergoing a procedure in theatre, as well as patients being monitored through stages of recovery.

If the 1:10 ratio noted in Option A is applied to this scenario in isolation, one RN may be considered sufficient. However, in reality, one RN would not be able to adequately treat and monitor patients, as well as support and supervise EN, in an operating theatre and recovery suite simultaneously. The skill mix component of the proposed Regulation is designed to ensure that there is a sufficient mix of RN and ENs to ensure patient safety.

This requirement aligns with the perioperative nursing guidelines[54] set down by Australian College of Operating Room Nurses, which requires that a registered nurse must be present in both theatre and recovery. Similar guidelines aimed ensuring safe skill mixes are also provided by the Australian and New Zealand College of Anaesthetists and the Gastroenterological Nurses College of Australia.

Because the base case estimates 80 per cent of health service establishments would meet this requirement in the absence of the Regulation, the incremental cost has been calculated for the 20 per cent of the registered health service establishments that would be required to do more under the proposed Regulation.

There is no data available that can indicate what ratios would likely be if they were not prescribed in Victoria. Therefore, a further series of assumptions was made in order to quantify this cost, and the calculations associated with these are set out in Appendix A (ii). In summary, based on the interactions with the sector, it was assumed that the nature of noncompliance was not the absence of nurses altogether, but the employment of fewer registered nurses and more enrolled nurses. Within that 20 per cent it is difficult to know the degree of difference that would be in place. In order to quantify, the department has assumed that this 20 per cent would, on average, have 50 per cent less RNs. Therefore, a ratio of 1:20 rather than 1:10 would apply. This allows the incremental costs between these two ratios to be estimated.

The third component relates to the skill mix, and provides that one-third of the nurses on duty may be enrolled nurses. The incremental cost of this was calculated by determining the number of additional RNs needed to meet the required skill mix proportionate to the Regulation. The skill-mix component has been calculated relative to the regulated staff ratios because it is the department's view that these components of the Regulation are strongly related and need to be considered together.

[54] Australian College of Operating Room Nurses, 2010, *ACORN Standards for Perioperative Nursing: 2010-2011*, Adelaide.

The Department of Health is of the view that options that remove the skill-mix component of the Regulations is not viable at this point, particularly considering the review of the Act. However, comments are sought on the incremental costs associated with this Regulation, and any alternatives, as part of consultation.

Full calculations are at Appendix A (ii). The cost of this component is estimated at $5,794,847. This represents the most costly component of the proposed staffing requirements, but is also expressed by some stakeholders as the most critical to ensuring for safety and quality. As noted in Section 5.1, there is extensive literature on the connection with nursing skill mix and improved outcomes for patients. In addition there is some research that indicates that increased expenditure on nursing staff does not equate to a significant decrease in hospital profits. One study found that a one per cent increase in RN full-time equivalents increased operating expenses by approximately 0.25 per cent, but resulted in no statistically significant effect on profit margins. In contrast, higher levels of non-nurse staffing caused higher operating expenses as well as lower profits.[55]

Arguably, this can be seen in the available data on Victoria's performance compared to other states and territories. Victoria is the only state that has ratios in its Regulations and has the second-lowest adverse event rate in private hospitals in Australia. For overnight separations, the Victoria had the lowest proportion of separations with an adverse event.[56] There are additional benefits to be considered, such as improved nurse retention, nurse satisfaction and reduced overtime costs.[57] It is acknowledged that staffing is only one of multiple measures to improve safety and decrease adverse events, Some studies have indicated that in considering the cost-benefit, staffing ratios produce significant cost savings and is less costly than many other basic safety interventions.[58] Further, there is no evidence that expenditure on nursing will result in decreased use of other safety measures, such as poorer infection control practices.

The total cost of the proposed Regulations is $**9,016,297.** Table 5.6 considers the 10-year cost of the proposed Regulations as **$80,775,936.**

Table 5.7 Estimated total costs of proposed Regulations 2012–13 to 2022–23

Year	Cost $	Discounted Cost
2013-14	9,016,297	8,711,398
2014-15	9,174,082	8,564,104
2015-16	9,334,629	8,419,301
2016-17	9,497,985	8,276,945
2017-18	9,664,199	8,136,996
2018-19	9,833,323	7,999,415
2019-20	10,005,406	7,864,159
2020-21	10,180,501	7,731,190
2021-22	10,358,659	7,600,469

[55] Stanton MW, 2004, *Hospital Nurse Staffing and Quality of Care*, Agency for Healthcare Research and Quality, http://www.ahrq.gov/research/findings/factsheets/services/nursestaffing/nursestaff.pdf, accessed April 2013

[56] Australian Institute of Health and Welfare, 2013, *Australian Hospital Statistics 2011-12*, http://www.aihw.gov.au/publication-detail/?id=60129543133

[57] Australian Nursing Federation, 2009, *Issues Paper: Ensuring quality, safety and positive patient outcomes — Why investing in nursing makes $ense*, http://anf.org.au/documents/reports/Issues_Ensuring_quality.pdf

[58] National Nurses United, March 2013, *RN-to-Patient Ratios — A Cost-Effective Solution for Hospitals*, http://nurses.3cdn.net/e73fe5c9828a8b42b1_nrm6bzj4h.pdf

2022-23	10,539,936	7,471,959
TOTAL	**97,605,017.**	**80,775,936**

Multi-criteria analysis scores

Option A was scored for the MCA against the same criteria set down in Section 4. The benefit criteria considers the use of effective levels to provide safety and quality, as well as practicality of implementation.

The proposed Regulations were scored:

- +8 for the safety and quality criteria. A high score was ascribed in recognition that the proposed Regulations prescribe a minimum staff ratio and skill mix and there is a large evidence base referred to earlier that the proportion of registered nurses to patients and skill mix strongly correlates with improved patient outcomes and a reduction in adverse events, in some studies up to 30 per cent.
- +8 for the implementation criterion. Because this represents a continuation of what is now in place, implementation issues would be negligible.
- -4 for the cost criterion. The total incremental cost per year is equal to $**9,016,297**, and this will be borne by a small percentage of the sector. They are not insignificant amounts, but averaged across the number of beds or patient separations it is believed justifiable in ensuring patient safety.

Table 5.8 MCA scores for Option A: the proposed Regulations

Criterion	Weighting	Score	Weighted score
Protecting users through effective levels of safety and quality	25%	+8	+2
Practicality of implementation	25%	+8	+2
Cost	50%	-4	-2
TOTAL	**100%**		**+2**

5.5.3 Option B: the alternative regulatory option — principle based

The alternative regulatory option (Option B) also requires that the nursing staff are experienced and educated in the health area they are working in, and that there are sufficient numbers of nurses and other staff to provide patient care. Option B does not offer any definition or guidance about what constitutes ‘sufficient’ in what circumstances.

This approach is similar to the one taken in some jurisdictions and represents a high-level principle-based approach. The benefit of this approach is that it offers greater flexibility to proprietors in allocating staff, while still allowing regulators to intervene under the regulation if they become aware of issues regarding staffing numbers. The risk with this approach is that, by not prescribing what the regulator finds sufficient, some proprietors may bow to commercial pressures and not meet the regulator’s or the community’s expectations in the way they allocate staff.

Given the high-level, principle-based approach, it is difficult to know how proprietors will respond and therefore how to calculate the incremental costs of this alternative option.

In order to quantify this approach for comparison, it is assumed that Option B would provide for higher levels of RNs compared with the base case, but lower than the prescribed regulatory Option A.

Therefore, under the base case, 80 per cent compliance is assumed; under Option A, 100 per cent compliance is assumed; and Option B represents a midpoint average of 90 per cent compliance.

This midpoint is assumed to deliver 50 per cent of the incremental benefits. As per Table 5.9 below, this equates to just over 50 per cent of the cost.

Table 5.9 Additional costs attributable to alternative regulatory option (Option B)

Requirement	Annual cost $
Ensure that each nurse is professionally competent through education or experience to provide nursing care for the health service being provided	**1,329,894**
Ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of appropriately educated or experienced nursing and other health professional staff is on duty to provide care	1,550,911 + 59,814 = 1,610,725
TOTAL	**2,940,619**

Multi-criteria analysis scores

As per the above, Option B has been scored relative to the base case and the proposed Regulation. It is considered that they will be approximately 50 per cent less effective in protecting users, and therefore has been given 50 per cent of Option A's score for this criterion.

The cost for Option B is $2,940,619, compared with Options A's $**9,016,297**, or 33 per cent of Option A. As such, it has been scored -1.1 (33 per cent of Option A's score for this criterion).

Option B was scored +5 for the implementation criterion. As a principle-based approach it is thought transition costs would be minimal, but there would still be some education and support required compared with maintaining the current approach.

Table 5.10 MCA scores for Option B: the alternative regulatory option

Criterion	Weighting	Score	Weighted score
Protecting users through effective levels of safety and quality	25%	+4	+1
Practicality of Implementation	25%	+5	+1.25
Cost	50%	-1.3	- 0.66
TOTAL	**100%**		**+1.59**

5.5.4 Option C: the alternative regulatory option — class based

Option C specifies specific classes of services and prescribes staffing requirements for each. The classes of services are based on those that are characterised with particular or specific risks, and include: anaesthesia class; rapid opioid detoxification class, emergency class private health facilities; intensive care (Level 1 or 2) class private health facility; paediatric class private health; facilities; rehabilitation class private health facilities; maternity class (Level 1 or 2) private health facility; and mental health class. Under the NSW model, these are eight of the total of 18 classes of facilities. These have been identified for particular types of risk attributable to that class. However, it does not include specific requirements for other types of services, including cardiac catheterisation, cardiac surgery, chemotherapy, general medical, neonatal, radiotherapy, renal dialysis and general surgical. While data is not available in the Victorian context, these eight classes prescribed for would not equate to the majority

of service types performed, and therefore, it is the department's view that there is a residual risk associated with this approach.

Option C has also been scored relative to the base case, the proposed Regulation (Option A) and the principle-based approach (Option B). Option C uses a risk-based approach to providing for safety, but does not define sufficient staffing across all settings, Therefore, the remaining services, with lower risks, while not targeted by the ratios may, in the department's view, result in residual risk. Therefore, it was scored +6 for this criterion, which is lower relative to Option A, but higher than Option B.

Option C would be the least practical form of implementation at this point in time. The department is currently reviewing the Act and is considering options to better classify service types in order to apply targeted requirements. The department is of the view that the Act needs to be reviewed and potentially restructured in this way before any changes to staffing requirements in accordance with classes is considered. In addition, this option would require transition arrangements and education for the health services establishments. As such it was scored +4 for this criterion.

The cost of this approach is difficult to quantify. There is no information available on this (for example, from NSW cost-benefit assessments). For the purposes of the analysis it was scored -2, on the basis that it would be more expensive than Option B, but less expensive than Option A.

Table 5.11 MCA scores for Option C alternative

Criterion	Weighting	Score	Weighted score
Protecting users through effective levels of safety and quality	25%	+6	+1.5
Practicality of Implementation	25%	+4	+1.0
Cost	50%	-2	-1.0
TOTAL	**100%**		**+1.5**

5.6 The preferred approach

As per the table below, the scores for each option are very close. However, based on this analysis, the department considers that, at this time, the proposed Regulations are preferable to the alternative option assessed.

Table 5.12 Summary of MCA scores for options

Option	MCA score
Option A: the proposed Regulations	+2
Option B: the alternative regulatory option — principle based	+1.59
Option C: the alternative regulatory option — class based	+1.5
Base case	0

6 Information provided to patients on services and fees

6.1 The nature and extent of the problem to be addressed

As described in Section 2 of this RIS, 'information asymmetry' forms part of the rationale for government to regulate the private health establishments. Regulation is intended to address the problem of patients receiving insufficient or inadequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services or other matters they might reasonably expect from their health services.

These kinds of imbalances of information are thought to undermine markets functioning effectively. As such, government generally addresses asymmetries of information by requiring the sellers of services to provide more information, or by providing the information itself.

Data from complaints to the Health Services Commissioner (HSC) indicate that consumers of health services continue to have problems, or differences of opinion, with providers about the costs of their treatment. In the financial year ending 30 June 2012, five per cent of the enquiries received by the HSC, and 10 per cent of the complaints closed, related to fees for health services (both public and private).[59] A further nine per cent of complaints received related to communication and six per cent to patient rights. Further analysis by the HSC found that, when considering the component issues identified for all complaints, 27 per cent contained issues around communication.

The HSC has also previously observed:

> [t]here is a general lack of understanding in the community about the relationships that exist between private specialists and private hospitals and the fact that many smaller private hospitals do not employ their own doctors as staff.[60]

This is an issue that may undermine consumers' ability to make informed choices about which medical practitioners to consult and at which premises. In the event that problems arise, it may also be unclear to a consumer who carries responsibility for aspects of their treatment and care.

The Private Health Insurance Ombudsman (PHIO) is an independent body that resolves complaints about private health insurance, and acts as the umpire in dispute resolution at all levels within the private health industry. They can receive complaints about private health insurers, brokers and health care providers. In 2012 the PHIO found that complaints about private hospitals usually occur when patients experience unexpected funding gaps for a hospital admission.[61]

Contemporary health care continues to focus on rights-based or 'patient-centred' care, where patients are informed and involved in decisions about their health. This was recognised by the National Health and Hospital Reform Commission, whose 2009 report *A Healthier Future for All Australians*[62] detailed the importance of consumer voice and empowerment in creating an agile and self-improving health system.

Health professionals have a pivotal role in promoting health within a rights framework and ensuring that patients have access to information. The majority of health practitioners would ensure this as part of their 'business-as-usual approach' driven by professional standards. However, it has been acknowledged that

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[59] Health Services Commissioner, 2012, Annual report for the year ending 30 June 2012.

[60] Health Services Commissioner, 2010, Annual report for the year ending 30 June 2010.

[61] Private Health Insurance Ombudsman, 2012, Annual Report 2011-12.

[62] National Health and Hospitals Reform Commission, 2009*, A healthier future for all Australians* — Final Report June 2009, http://www.health.gov.au/internet/nhhrc/publishing.nsf/content/nhhrc-report, accessed 10 April 2013.

despite the introduction of frameworks for patient rights, these 'run the risk of becoming mere window dressing unless it becomes legislated and is supported by some form of accountability'.[63]

6.2 Objectives

The primary objective of the Regulations is to provide for the safety and quality of care to patients.

This objective of the Regulation relating to the provision of information to patients is to ensure patients receive adequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services.

6.3 Interstate arrangements

Table 6.1 shows the requirements in place in other Australian states that apply to the provision of information to patients in private hospitals and/or day procedure centres.

Table 6.1 Arrangements in other Australian jurisdictions

Jurisdiction	Legislation / Regulations	Requirements
New South Wales	Private Health Facilities Act 2007 Private Health Facilities Regulation 2010	The privacy of the patients of the facility must be considered and respected by all staff of the private health facility. A private health facility must have a written complaints policy outlining the procedure to be followed in managing and responding to complaints. The licensee of a private health facility must ensure that patients, relatives of patients and other carers are provided with information about the procedure for making complaints, and the process for managing and responding to any complaints. The licensee of a private health facility must ensure that the complaints policy is complied with.
Queensland	Private Health Facilities Act 1999 Private Health Facilities (Standards) Notice 2000	Patients have access to a document that explains their rights and responsibilities. Patients give informed consent to their treatment. Patients are informed in a culturally appropriate manner about: their condition; any necessary clinical investigations relevant to their condition; any treatment proposed; and the likely outcomes and risk of complications. Patients are informed about the role of the Health Quality and Complaints Commission as an independent complaint body.

6.4 Identification of options

Section 158 of the Act notes that the governor-in-council may make regulations with respect to prescribing:

[63] Human Rights Council, 2007, *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (fourth Session, Item 2).

- requirements to be complied with for the welfare of persons accommodated in or receiving health care or other services from health service establishments, including but not limited to matters of privacy and respectful treatment
- requirements for the provision of and the display of information and documents in health service establishments.

Two options to meet the objectives of the Regulations are described below.

Table 6.2 Regulatory options

Option A: the proposed Regulations	The proprietor of a private hospital or day procedure centre must ensure that on or before admission each patient of the hospital or centre is given: 1. a statement containing information in relation to the health care services provided 2. information about fees to be charged by the hospital or centre and any likely out-of-pocket expenses which may be incurred by the patient 3. a clear explanation of the treatment and services to be provided to the patient. A statement referred to must contain information about the following matters: • the quality or standard of health care and services provided • courteous treatment of patients • consideration of a patient's beliefs and ethnic, cultural and religious practices • consideration of a patient's special dietary needs, if any • a patient's privacy • that a patient may request the names and roles of the key health workers involved in the patient's care • a patient's entitlement to ask for a referral if they want to seek another medical opinion • that any personal information or identifying material about a patient is dealt with in a confidential manner except: (i) where necessary to enable another health care worker to assist in the patient's care; or (ii) when authorised by or under a law • a patient's consent to treatment • that a patient may refuse the presence of health workers not directly involved in the patient's care • that a patient may discharge themselves at any time despite the advice of the attending health care practitioner or staff of the hospital or centre • that a patient may comment on or complain about the treatment or the quality of the health services or care being provided, including details of to whom any complaint should be made.
Option B: the alternative regulatory option	The proprietor of a private hospital or day procedure centre must ensure that on or before admission each patient of the hospital or centre: 1. has access to a document which explains their rights and responsibilities 2. is given information about fees to be charged by the hospital or centre and any likely out-of-pocket expenses which may be incurred by the patient.

6.5 Assessing the options

A multi-criteria analysis was used to assess the costs and benefits of the identified options. The criteria, and their weightings, are shown in Table 6.3 below.

Table 6.3 Multi-criteria analysis criteria and weightings

Criterion	Weighting
Ensure patients receive adequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services	50%
Cost	50%

6.5.1 The base case

In the absence of regulation in this area, there are a number of other factors that address information to be provided to, and engagement with, patients and consumers.

Standard 2 of the National Standards is the Partnering with Consumers Standard. It requires:

> Leaders of a health service organisation implement systems to support partnering with patients, carers and other consumers to improve the safety and quality of care. Patients, carers, consumers, clinicians and other members of the workforce use the systems for partnering with consumers.[64]

To meet this standard, organisations must demonstrate consumer partnership in service planning, in designing care and in service measurement and evaluation.

Patient rights and engagement is also addressed in Standard 1 — Governance for Safety and Quality in Health Service Organisations. Specifically, this is to be achieved by implementing, through organisational policies and practices, a patient charter of rights that is consistent with the current national charter of health care rights.[65]

Informed financial consent (IFC) occurs when a patient, undergoing treatment as a private patient, receives relevant cost information about their treatment prior to the treatment taking place.[66] Providing this detail can sometimes be complicated by short lead-in times to treatment, multiple providers and complex health insurance policies. The PHIO found that, while in most cases there are adequate processes in place in private hospitals to ensure the provision of IFC, lack of information about costs represents the largest group of complaints.[67] In response, the PHIO provides a range of support materials online for patients to assist them in asking questions of their health providers.

The Australian Medical Association policy also states that:

> the medical practitioner should give the patient sufficient information regarding their likely fees and the associated rebates so that the patient is able to make an informed financial decision prior to the provision of medical services.[68]

A patient has a range of other rights under other legislation or regulations and under contract or common law. General consumer guarantees under the *Competition and Consumer Act 2010* (Commonwealth) that apply to services will, for example, generally apply to health services.

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[64] The Australian Commission on Safety and Quality in Health Care, 2012, *National Safety and Quality Health Service Standards*, http://www.safetyandquality.gov.au/publications/national-safety-and-quality-health-service-standards/

[65] Australian Commission on Safety and Quality in Health Care, 2008, *Australian Charter for Health Care Rights*, Sydney: ACSQHC.

[66] Productivity Commission, 2009, *Research report: Public and Private Hospitals*, http://www.pc.gov.au/projects/study/hospitals/report

[67] Australian Government, 2012, *Private Health Insurance Ombudsman Annual Report 2011–12*, http://www.phio.org.au/publications/publications/annual-reports.aspx, accessed 9 April 2013.

[68] Australian Medical Association, 2006, *Informed Financial Consent Policy*, https://ama.com.au/node/5091, accessed 11 April 2013.

Consent to medical treatment and the concept of provision of advice prior to treatment (sometimes referred to as informed consent) are dealt with in common law. There is a substantial amount of case law in the area of consent to medical treatment. As part of the duty of care, medical practitioners are obliged to provide such information as is necessary for the patient to give informed consent to treatment, including information on all 'material risks' of the proposed treatment.

In addition, he *Victorian Charter of Human Rights* requires that consent for medical treatment is free, full and informed and states:

> …consent must be voluntary and the person concerned must have been given sufficient information for an informed decision to be made. This would include information such as the nature of the person's condition and the treatment options available, including explanations of possible risks, side effects and benefits of the treatment.

Despite the range of drivers above, it is the view of the department that benefit comes from having a requirement for provision of information to patients in Victorian regulations. It is considered essential to enable government to act in cases where a registered health service establishment is not meeting these requirements and community expectations.

6.5.2 Option A: the proposed Regulations

The proposed Regulation is a continuation of the previous approach in that there is a requirement for patients to be provided with information about fees and a statement containing information in relation to the health care services provided. The Regulations clearly specify what form this information should include, for example, matters relating to privacy, confidentiality, consent and cultural considerations.

While arguably a more prescriptive approach, feedback from a number of private health establishment stakeholders indicate that these requirements are well aligned to best practice in the area and ensuring adequate provision of information.

The incremental costs of the proposed requirements for Option A are shown in Table 6.4 below.

Table 6.4 Additional costs attributable to proposed Regulations

Requirement	Annual Cost $	Average $ per patient episode
Preparation and distribution of a statement containing information in relation to the health care services provided at the hospital or centre	2,044,065	1.91
Provision of information about fees to be charged by the hospital or centre and any likely out of pocket expenses which may be incurred by the patient	3,609,438	3.36
Explanation of the treatment and services to be provided to the patient at the hospital or centre	4,634,824	$4.32
TOTAL	**10,288,327**	**9.59**

Full calculations are provided at Appendix A (iii).

Calculating the cost of the preparation and distribution of a statement containing information in relation to the health care services considered: the staff time involved (on average) and potential printing costs.

The time involved in developing the statement is estimated to be minimal. A range of materials have been developed by government and are available for private hospitals and day procedure centres to use. The Commonwealth Department of Health and Ageing has developed a *Private Patients' Hospital Charter,* a two-page document with an overview of the rights and responsibilities as a private patient in a public or private hospital.[69] The content meets the requirements of the Regulations and is available for download in 19 languages. This information is also available in expanded format in the brochure *Know your rights and responsibilities as a private patient in hospital.*[70] A number of materials on health care rights are also available in multiple languages from the department's website.[71]

These materials are used by many private health care providers, either by linking to these materials through their websites, or printing off copies for patients. Some larger private health care groups have developed their own, branded written advice to patients.

Estimations and assumptions used in calculating the cost:

- Average time spent developing and providing a patient with an information statement is five minutes.
- At an average hourly rate of $70.21, the five minutes equates to $5.85.
- Total number of patient separations per year is 1,073,000.
- Cost of printing is estimated at 10 cents per page; average five pages of materials provided (based on website search April 2013).

Based on the above, the cost of providing the information statement is approximately $6,813,550. However, the department estimates that given the other drivers for providing this information (as

[69] Department of health and Ageing, undated, *Private health insurance private patients' hospital charter*, http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-consumers-charter-index.htm, accessed 11 April 2013.

[70] Department of Health and Ageing, undated, *Know your rights and responsibilities as a private patient in hospital*, http://www.phio.org.au/downloads/file/PublicationItems/PrivatePatientsHospitalCharter.pdf, accessed 11 April 2013.

[71] Department of Health, 2011, *Australian Charter of Healthcare Rights in Australia*, http://www.health.vic.gov.au/patientcharter/, accessed 11 April 2013.

described in the base case) only 30 per cent of these costs are attributable to the Regulations. Therefore, the cost is $2,044,065 per year, or $1.91 per patient separation.

Staff time is also the major cost factor in calculating the cost of providing patients with fee information and any likely out-of-pocket expenses which may be incurred by the patient. The following are taken into consideration in estimating these costs:

- Private Hospitals and Day Procedure Centres will have mechanisms to calculate fees and costs, in order to bill insurers for payment.
- In approximately 85 per cent of cases there is no 'gap' payment or out-of-pocket expenses for patients.[72]
- In response to information campaigns, for example, by the PHIO and AMA, rates of IFC are growing.[73]

The department estimates that, on average, it would take five minutes to provide basic fee information to patients, and 10 minutes in cases where out-of-pocket expenses are identified and where further information or explanations may be required. The cost of this requirement is estimated at $7,218,875 per year. Again, given the Regulations are not the only reason why this information is provided to patients, only 50 per cent of this cost is attributed to the Regulations. Therefore, the incremental cost of this aspect of the Regulations is $3,609,438, or $3.36 on average per separation.

The final component of the proposed Regulation is the explanation of the treatment and services to be provided to the patient at the hospital or centre. Quantifying the time spent with patients for this purpose is difficult. There are a number of factors to consider, such as the complexity of the treatment to be provided, the information the patient has sought out independently, the patient's 'health literacy' and the extent to which they may have concerns and ask questions. It is expected that information would be provided by a range of health professionals, including nursing and medical practitioners.

A scan of research in this area assisted the department in estimating the average time health professionals spend with patients for this purpose. A range of studies found that:

- the average time a physician spent on face-to-face patient care was 13.3 minutes[74]
- the median consultation time for new patients at a surgical clinic was 4.3 minutes[75]
- average appointment time for a preadmission (surgery) clinic was less than 30 minutes[76]
- a typical patient–physician encounter takes 15–20 minutes[77]
- the amount of time patients spend with their doctors is about 19 minutes.[78]

For the purposes of quantifying costs of this part of the proposed Regulations, it is estimated that the average time spent by health practitioners providing this information to patients is 15 minutes. This

[72] Productivity Commission, 2009, *Research report: public and private hospitals*, http://www.pc.gov.au/projects/study/hospitals/report

[73] Ibid.

[74] Gottschalk A, Flocke SA, 2005, 'Time Spent in Face-to-Face Patient Care and Work Outside the Examination Room' *Ann Fam Med* vol. 3(6) pp. 488–493.

[75] Waghorn A, McKee M, Jun 1999, 'Surgical outpatient clinics: are we allowing enough time?' Int J Qual Health Care vol. 11(3) pp. 215-9.

[76] Pearson A, Richardson M, Peels S, Cairns M, 2004, 'The preadmission care of patients undergoing day surgery: a systematic review' Health Care Reports vol. 2(1) pp. 1–20.

[77] Weigl M, Muller M, Zupanc A, Angerer P, 2009, 'Participant observation of time allocation, direct patient contact and simultaneous activities in hospital physicians' BMC Health Services Research vol. 9(110) pp. 1–11.

[78] Taylor H, Leitman, R, 2001, 'Online consumers want more than most physicians want to provide — but that may change' *Harris Interactive Health Care News* vol. 1(1) pp. 1–3.

estimation is informed by the research noted above and feedback from clinicians and private health establishments.

On this basis, the cost of providing this information to patients is approximately $23,174,118. Given providing this information and seeking consent is also required from a range of other frameworks (health professional standards, common law, Human Rights Charter), only 20 per cent of these costs is attributed to the proposed Regulations. Therefore, incremental cost to the sector is **$4,634,824**, or on average, $4.32 per separation.

The total cost of these component parts of the proposed Regulation results in an incremental cost of $10,288,327 per year, or an average of $9.59 per patient separation.

Table 6.5 considers the 10-year cost of the proposed Regulations as $92,171,901.

Table 6.5 Estimated total costs 2012–13 to 2022–23

Year	Cost $	Discounted Cost
2013-14	10,288,327	9,940,413
2014-15	10,468,373	9,772,338
2015-16	10,651,569	9,607,105
2016-17	10,837,972	9,444,666
2017-18	11,027,636	9,284,974
2018-19	11,220,620	9,127,982
2019-20	11,416,981	8,973,644
2020-21	11,616,778	8,821,915
2021-22	11,820,071	8,672,752
2022-23	12,026,923	8,526,112
TOTAL	**111,375,249.47**	**92,171,901**

Multi-criteria analysis scores

Table 6.6 provides the score of the proposed Regulations against the determined criteria.

The proposed Regulations clearly articulate what information needs to be provided to patients in relation to services, fees and treatment and expands on this, providing 12 points that must be provided in that information statement. This additional detail is considered beneficial to provide clarity on what is considered ‘adequate information’, and better enables this to be given to patients. On this basis it was scored relatively highly at +7 for ‘ensuring information criteria’.

The proposed Regulations are estimated to cost **$10,288,327** per year, or an average of $9.59 per patient separation. In determining an appropriate score for the cost criteria it was considered that less than $10 per admission is a reasonable cost to ensure that patients are adequately informed. While acknowledging this does impose a cost on the sector, it is not considered significant on a per separation basis. On this basis it was scored +4 for the cost criterion.

This results in an overall score of +1.5 based on the MCA.

Table 6.6 MCA scores for Option A: the proposed Regulations

Criterion	Weighting	Score	Weighted score
Ensure patients receive adequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services	50%	+7	+3.5
Cost	50%	-4	-2
TOTAL	**100%**		**+1.5**

6.5.3 Option B: the alternative regulatory option

Option B, the alternative regulatory option, is a less-prescriptive, high-level principle approach. It maintains the core requirements of patients having access to information about their rights and fees, but does not specify the detail required.

Having less-prescriptive requirements is likely to decrease the incremental costs to the private sector, but may also decrease the effectiveness of the Regulation meeting its objective.

Given the broad description, it is difficult to estimate how the Option B Regulation may be interpreted and applied by the sector and therefore costed.

It is assumed that while the many proprietors would maintain high levels of information provision and engagement with clients, others would provide less detailed information. For the purposes of comparison, it is estimated that the cost of this option is equivalent to the first two components of Option A ($2.044 million and $3.61 million), and as this represents approximately 55 per cent of the costs of Option A, this is reflected in its score of -2.2 for the cost criterion. In scoring Option B, it was considered that a broader requirement would result in lower-quality information provision by some proprietors and, based on the department's observations with the sector, this was estimated at being approximately 30 per cent less effective than a more detailed provision, and therefore scored 30 per cent less against this creation than Option A. It is noted that this assumption has not been tested with stakeholders, and as noted previously, it is difficult to survey for compliance in the absence of regulations.

Accordingly, Option B has been scored as detailed in Table 6.7.

Multi-criteria analysis scores

Table 6.7 MCA scores for Option B: the alternative regulatory option

Criterion	Weighting	Score	Weighted score
Ensure patients receive adequate information about the services provided, the likely cost of the services, their ongoing health needs and their rights in relation to the services	50%	+5	+2.5
Cost	50%	-2.2	-1.1
TOTAL	**100%**		**+1.4**

6.6 The preferred approach

As shown in Table 6.8, the relative values of Option A and B are very close. However, given the proposed Regulations have scored slightly higher, and will offer continuity in the Regulation of the sector

for the interim period the Regulations are expected to be in place, the department considers that the proposed Regulations are preferable to the alternative option assessed.

Table 6.8 Summary of MCA scores for options

Option	MCA score
Option A: the proposed Regulations	+1.5
Option B: the alternative regulatory option	+1.4
Base case	0

7 Fees

7.1 The nature and extent of the problem to be addressed

The secondary objective of the Regulations is to 'prescribe fees forms and other matters required to be prescribed under the Health Services Act 1988 in relation to such health establishments'.

Regulations 8(b), 9(b), 10(b), 11(b), 12(b) and 13 prescribe fees for applying for:

- approval-in-principle for the purposes of Section 70(2) of the Act
- variation or transfer of certificate of approval-in-principle for the purposes of Section 74 of the Act
- registration for the purposes of Section 82(2) of the Act
- renewal of registration for the purposes of Section 88 of the Act
- variation of registration for the purposes of Section 92(2) of the Act
- an annual fee for the purposes of Section 87 of the Act.

Policy issues related to these functions are legislative matters that cannot be addressed by regulations and so are not set out in this discussion paper.

However, the value of the fees is set down in the proposed Regulations, and therefore, options are considered in the RIS.

7.2 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 government across the registered health service establishments.

7.3 Interstate arrangements

Table 7.1 shows the requirements in place in other Australian states that apply to the staffing or senior management of private hospitals and/or day procedure centres.

Table 7.1 Arrangements in other Australian jurisdictions

	Queensland $	Western Australia $	Tasmania $	New South Wales $	South Aust. $
Approval-in-principle (AIP)	1,300–3,900	1,500–5,000	1,584	6,020	207
Variation or transfer of AIP	195–389	NA	1,584	3,070	207
Registration fee	1,300–6,502	1,100	2,160–3,312	5,365–13,190	207
Registration renewal	195–3,119	200–1500	2,160–3,312	5,365–13,190	207
Variation of registration	195–779 / 1,300–6,502 Variation/ transfer	NA	1,584	3,535.	30

7.4 Identification of options

The *Cost Recovery Guidelines*[79] set out 10 steps to consider when setting fees. These are set out in Appendix B, together with a summary of the department's consideration of each step in accordance with the guidelines.

As noted above, the objective is to recover an appropriate amount of the costs of providing regulatory services, having regard to equity, efficiency and effectiveness.

Regulatory fees and user charges should generally be set on a full cost recovery basis; however, if it is determined that full cost recovery is not consistent with other policy objectives, then it may not be appropriate to introduce a full cost recovery regime. The *Cost Recovery Guidelines* note that 'efficiency and equity considerations may need to be balanced against each other in determining the appropriate form of cost recovery'.

Consideration may be given to a regime of partial cost recovery (if it can be demonstrated that a lower than full cost recovery does not jeopardise other objectives) and/or to rely on other funding sources (for example, general taxation) to finance the government activity.

Accordingly, where social policy or equity considerations are considered to outweigh the efficiency objectives associated with full cost recovery, and/or where full cost recovery might adversely affect the achievement of other government policy objectives, partial or zero cost recovery is to be considered. Therefore, proposed feasible fees options were considered:

Table 7.2 Regulatory options

Option A: full cost recovery	Relevant fee based on 100% of the average costs, both direct and indirect)
Option B: partial cost recovery	Assessed at 40% cost recovery
Option C: zero cost recovery	Effectively the 'base case', because if the proposed fee regulations are not remade then no fees would be prescribed

The partial cost recovery option (Option B) represents the proposed fees.

7.5 Assessing the options

A multi-criteria analysis was used to assess the costs and benefits of the identified options reflecting the *Cost Recovery Guidelines*.[80] The criteria used were:

- efficiency — fees set at a level to promote the efficient allocation of resources
- effectiveness — fees set at a level to achieve the government's policy objective
- equity — fees set at a level to promote the sharing of costs and benefits across society.

Accordingly, the 'efficiency', 'effectiveness' and 'equity' criteria were each assigned a weighting of 33 per cent, reflecting their overall importance in achieving the government's policy objectives in relation to fee setting. The criteria, and their weightings, are shown in Table 7.3 below.

[79] Department of Treasury and Finance (DTF), 2010, *Cost Recovery Guidelines*, Melbourne.

Table 7.3 Multi-criteria analysis criteria and weightings

Criterion	Weighting
Efficiency	33%
Effectiveness	33%
Equity	33%

7.5.1 The cost base

The cost base for the purposes of assessing recovery is based on the incremental costs associated with the department administering the Act as it relates to AIP and registration applications and associated tasks. An activity-based costing method was used to determine the fee for each individual activity (see Appendix B for breakdown of these calculations).

These tasks were examined along with the cost of staff time (incorporating on-costs and overheads) in undertaking these tasks. The amounts in Table 7.4 below show the costs to government associated with each application.

Table 7.4 Costs to government per application

Activity	Cost to government per year	Average number completed per year	Projected revenue from full cost recovery / year
Approval In Principle (AIP)	$3,521	42	$147,882
Variation or transfer of AIP	$947	1	$1,894
Registration fee (initial)	$2,120	2	$4,240
Registration renewal (Average)	$2,491	82	$204,262
Variation of registration	$672	19	$12,768
Transfer of Registration	$1,311	1	$1,311
TOTAL			**$372,357**

Once a health service establishment is registered, it is required to pay an application fee for registration renewal every two years, which is linked to an inspection by the senior nurse advisors to ensure compliance with the Regulations.

As well as fees for applications, proprietors of private hospitals and day procedure centres registered in Victoria are required by Section 87 of the Act to pay 'the prescribed annual fee' to the secretary.

Annual fees are intended to generate sufficient revenue to offset the costs of the support services provided to the industry not otherwise recovered from application fees. These include the cost of the department's monitoring and inspection services, enforcement, policy development, service planning and the enhancement of information systems. The annual fee is variable, determined by the number of beds operated by an establishment. The greater the number of beds, the higher the annual fee.

On analysis, there is no evidence that larger health service establishments impose a higher administrative cost on the department than smaller ones. While inspections of larger faculties will take longer and there can be more information to review, they are also more likely to have sophisticated business or quality systems, and therefore be less reliant on advice or guidance by the department and tend to have fewer follow-up inquiries. This tends to balance out the cost in assessing different types of applications.

However, the fee base is structured this way in order to achieve vertical equity. This is to ensure those with greater means contribute proportionally more than those with lesser means.[81]

The renewal and annual fees represent the total registration cost to private hospitals and day procedures, as well as representing the majority of 'regulation' revenue to the department. These components were combined for the purposes of the activity-based assessment of fees. The bulk of activities undertaken by the department are attributed to the activities associated with maintaining and renewing 164 registered health service establishments over a two-year cycle.

The second biggest area of work is the approval-in-principle (AIP) activity, where the department receives information regarding new private hospital or day procedures centre builds or renovations, assesses and provides advice on compliance with the Act.

Implications of the review

As detailed previously, Part 4 of the Act is under review, and as a result, these Regulations will be repealed following the commencement of the new Act and its accompanying revised Regulations.

A number of factors are being considered in the review of the Act, and it is possible the structure of the regulatory approach, and therefore the activities undertaken by the department in accordance with it, may change substantially.

The department is proposing to maintain the current fee structure and level to provide continuity during the review process. Changing the fees at this stage, for a period of less than two years, before being required to alter them again, is not considered an effective process. It would also not be equitable if only half the registered health service establishments (those in that part of the two-year renewal cycle) make a payment during this interim period.

7.5.2 Option A: full cost recovery

The *Cost Recovery Guidelines* state that the general government policy is that regulatory fees and user charges should usually be set on a full cost-recovery basis. In this case, full costs represent the value of all the resources used or consumed in the provision of registration, and the associated monitoring and compliance arrangements.

A departure from full cost recovery would result in the taxpayers providing a subsidy to the private health care sector. Moving to full cost recovery would increase fees from 86–294 per cent. Table 7.4 above lists the costs to government for each activity.

Given that full cost recovery is the most economically efficient option for fee levels and fully achieves the government's objective on efficiency grounds, a maximum score of 10 is assigned to this criterion.

A score of 7 is assigned to the equity criterion because the fees will be in place for less than two years, and this will result in half the registered health service establishments paying an increased fee, prior to transitioning to regulation under a different Act.

In terms of 'effectiveness', it is not believed that the full cost recovery fees would result in higher rates of noncompliance, or act as a barrier to entry to new health service establishments. However, it is expected that a change in fees for two years will lead to implementation challenges and consistency concerns; therefore, it has only been scored 5 for this criteria.

This results in a net score of +2.65. Table 7.5 summarises the scoring.

[81] Department of Treasury and Finance (DTF), 2010, *Cost Recovery Guidelines*, Melbourne.

Table 7.5 MCA full cost recovery

Criterion	Weighting	Score	Weighted score
Efficiency	33%	+10	+3.3
Equity	33%	-7	-2.3
Effectiveness	33%	+5	+1.65
TOTAL	**100%**		**+2.65**

7.5.3 Option B: partial cost recovery

The proposed regulations represent partial cost recovery. The proposed fees and percentage recovery for each is noted below in Table 7.6

Table 7.6 proposed fees and percentage recovery

Activity	Cost to government per year	Proposed Fee	% recovery
Approval In Principle (AIP)	$3,521	$801.90	25
Variation or transfer of AIP	$947	$201.70	25
Registration fee (initial)	$2,120	$691.70	33
Registration renewal (average including annual fee*)	$2,491	$1,337	54
Variation of registration	$672	$201.70	34
Transfer of Registration	$1,311	$598.90	46

** Fees are linked to government fee units which are updated annually. For 2012–13 the applications for registration renewal fee is $679.10. The figure in Table 7.6 is based on the average amount paid by establishment per year incorporating the annual fee.*

The percentage recovery of the proposed fees varies from 25 per cent (for AIP activities) to 54 per cent (for registration renewal activities). If the proposed partial cost recovery fees are applied, the total revenue for the department would total $149,532 (see calculations below in Table 7.7).

Table 7.7 Average revenue per year from proposed fees

Activity	Proposed Fee	Average number completed per year	Projected revenue from full cost recovery / year
Approval In Principle (AIP)	$801.90	42	$33,680
Variation or transfer of AIP	$201.70	1	$403
Registration fee (initial)	$691.70	2	$1,383
Registration renewal (Average)	$1,337	82	$109,634
Variation of registration	$201.70	19	$3,832
Transfer of Registration	$598.90	1	$599
TOTAL			**$149,532**

Projected over ten years, this equates to **$1,339,639** (see Appendix B, Table C8).

Because the projected revenue under a full cost recovery approach is $372,357, and from the proposed Regulations is $149,532, the proposed Regulations represent approximately 40 per cent cost recovery.

Partial cost recovery seeks to balance the efficiency objective against the equity objective, while ensuring that the government's overall policy objectives are not jeopardised.

The efficiency criterion is positive because proprietors would still make a contribution towards funding the regulation of the industry. Given that the proposed Regulations will result in 60 per cent less revenue, a score of 60 per cent less for this criteria has been given +4.

The effectiveness and equity criteria received a higher score (+7 and -2) than the full cost-recovery option because maintaining the current fee levels will prevent transition costs for a short-term change and prevent inequities in payments over the interim period.

This results in an MCA score of +2.9, as noted in Table 7.8.

Table 7.8 MCA scores for Option B: partial cost recovery

Criterion	Weighting	Score	Weighted Score
Efficiency	33%	+4	+ 1.3
Equity	33%	- 2	-0.66
Effectiveness	33%	+ 7	+ 2.3
TOTAL	**100%**		**+ 2.9**

7.6 The preferred approach

Table 7.9 Summary of MCA scores for options

Option	MCA score
Option A – full cost recovery	+ 2.65
Option B – partial cost recovery	+ 2.9
Base Case	0

As per the scores noted above in Table 7.9, the partial cost recovery for fess is the preferred option.

8 Other regulations

The analysis in this RIS has focused on those Regulations that result in an incremental cost to health service establishments. There are a number of proposed Regulations that have not been analysed for alternative options. The reasons why they have not been considered for further analysis include:

- the regulation gives practical effect to the Act
- the cost of the requirement is more accurately attributed to the Act
- the cost of the regulation or requirement is of low impact to the sector because it represents 'business as usual'
- the cost of the requirement is more accurately attributed to other frameworks

This section details these Regulations and provides a rationale for their inclusion and seeks to quantify the cost (if any).

8.1 Regulations that give practical effect to the Act

Regulations 8–13 prescribe the various forms of application which can be made under the Act and fees payable to the department. The fees component is discussed in Section 7. The forms are currently one-page documents that include up to ten fields for the provision of contact details and basic information (see Appendix F). It is not possible to streamline these forms further. While some of the forms require further documentation to be attached, this is in accordance with the criteria detailed in the Act, not the Regulations.

Regulation 48 prescribes the form of the notice of seizure for the purposes of the Act. This form needs to be completed by the department's authorised officer and provided to the proprietor in the event any items are seized in accordance with Section 147 of the Act during an inspection of a health service establishment. The form poses no burden on the sector.

8.2 Regulations with cost attributed to the Act

Regulations 6 and 7 prescribe 'health services of a prescribed kind or kinds' for the purposes of the definitions of 'private hospital' and 'day procedure centre' in Section 3 of the Act. These definitions provide the further detail on what is considered a prescribed health service required to be registered under the Act. The scope of who the Regulation applies to is attributable to the Act and therefore not analysed as part of the RIS.

Regulations 35 and 36 set down requirements for the patient admission and discharge register, and the staff register, in accordance with the Act. These registers are required by Section 109 of the Act; therefore, a cost associated with this requirement is attributable to the Act.

8.3 Low-impact regulations

The following Regulations have not been included for analysis of this RIS because they represent 'business as usual' for the administration and management of private hospitals and day procedure centres. In addition, the sector meets these requirements in accordance with their responsibilities under the Private Health Insurance Act 2007 (Commonwealth) for a provider to be accredited in order to be declared a hospital, and therefore have access funding via the private health insurance system. The Regulations are in place to allow the government to act in the event that these requirements are not met; however, it is considered that the Regulations themselves do not impose an additional burden on the sector.

Regulation 19 requires that a unit record numbers is allocated to patients.

Regulations 23–24 deal with the identification of patients and neonates.

Regulation 23 requires the proprietor of a health service establishment to ensure that patients are identified by means of an identity band or photograph attached to their clinical record. Regulation 24 imposes more stringent requirements in relation to infants born at, or admitted to, the hospital or day procedure centre. The current regulations impose identity bands as a basic minimum standard, and this is a reflection of 'business as usual' for all hospitals. There are, however, more sophisticated means of identifying patients and their intended treatment; for example, matching patients with their records, including treatment and medication through the use of electronic barcodes.

These requirements are intended to prevent adverse events that occur because of mistakes in identifying patients or correlating their information with the intended clinical intervention. This can lead to procedures on the wrong site or person, as well as medication, transfusion or other errors.

Data suggests these problems continue to occur. A trend analysis on Victorian sentinel event data from public health services spanning from 2002 to 2009 recorded procedures involving the wrong patient or body part ranging from 14 to 37 per cent per year, until the definition of this sentinel event was amended to specify only events 'resulting in death or major permanent injury', since which time there have not been any reported events.[82]

One of the ten national standards relates to 'patient identification and procedure matching'. Included in this standard is the requirement to develop, implement and review a patient identification system, including associated policies, procedures and/or protocols.

The use of unique record numbers is a way of namelessly identifying patients and is normal practice in health care. It enables information and data to be managed. For example, data about the admission and discharge of patients, their diagnosis and the type of care can be collected without breaching patient confidentiality.

Regulations 21–22 require the creation of a clinical record for each patient.

Regulation 21 imposes a requirement to maintain separate clinical records for each patient as soon as practicable after the admission of the patient and to maintain that record for the duration of the patient's stay. Regulation 22 sets out the information that a proprietor must take reasonable steps to ensure is in each clinical record, including, for example, relevant clinical details that must be recorded in relation to the patient or their treatment. The use of clinical patient records and files is part of core business in health care.

The Victorian *Health Records Act 2001* covers standards, called Health Privacy Principles, for how health information is handled by private and public health service providers (such as doctors and other health services) and patients' rights to access their health records in the private sector.

Maintaining clinical records is also a feature of health care professions' codes of conduct and practice guidelines. For example, *Good Medical Practice: A Code of Conduct for Doctors in Australia,* states that 'maintaining clear and accurate medical records is essential for the continuing good care of patients'.[83]

The national standards state 'using an integrated patient clinical record that identifies all aspects of the patient's care' is a core standard and requires that 'accurate, integrated and readily accessible patient clinical records are available to the clinical workforce at the point of care'.

Regulations 25 and 28 require that patients are treated with dignity and respect, are entitled to privacy, with their needs met promptly and effectively.

As described in Section 7, there are a number of frameworks under which patient's rights are prescribed. In addition, the national standards set down requirements for patient rights and engagement to ensure **'**patient rights are respected and their engagement in their care is supported'.

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[82] Department of Health, 2010, *Building foundations to support patient safety, Sentinel event program annual report 2009-10*.

[83] Australian Medical Council, 2009, *Good Medical Practice: A Code of Conduct for Doctors in Australia*.

Regulations 29–32 require proprietors to establish a mechanism for dealing with complaints made by, or on behalf of, patients.

National standards also require the implementation of a 'complaints management system that includes partnership with patients and carers'. A complaints management policy is considered 'business as usual' for the sector.

Regulations 33–34 provide for the transfer and discharge of patients from a private hospital or day procedure centre.

Regulation 33 requires private hospitals and day procedure centres to ensure that when a patient is transferred, all information and documents relating to the patient's medical condition and treatment that are necessary for the subsequent health service to provide appropriate ongoing treatment or care are sent with the patient.

Regulations 37 and 38 provide requirements for an operation theatre register and birth register.

The recording of this information is routine for private hospitals and day procedure centres. In addition, all health services are required to submit information about births in Victoria to the Victorian Perinatal Data Collection (VPDC). The VPDC is established by the *Public Health and Wellbeing Act 2008* under the functions of the Consultative Council on Obstetric and Paediatric Mortality and Morbidity. The VPDC was established as a population-based surveillance system to collect and analyse information on, and in relation to, the health of mothers and babies in order to contribute to improvements in their health.

Regulations 39–43 impose a range of requirements in relation to the suitability and maintenance of private health premises and equipment.

The overarching requirements for premises and equipment are those imposed by Regulations 42 and 43, which include that:

- the premises must be clean and hygienic, kept in a proper state of repair and free from hazards or accumulation of materials that may become injurious to health or likely to facilitate fire.
- all facilities, equipment, furnishings and fittings must be suitable for the kinds of health care being provided, kept in a proper state of repair and maintained in good working order.

More specific requirements about the suitability of premises for the provision of health services are imposed by Regulations 39–41, which require:

- rooms to be identified with a number/letter and the number of associated beds.
- an effective electronic communication system that enables patients and staff to summon assistance
- systems or mechanisms installed to control the outlet temperature of hot water to every bath, shower or hand basin used by patients which avoid the risk of scalding.

These requirements are focused on clinical, occupational health and fire safety. These requirements are considered standard practice in health care for ensuring the safety of patients and staff. This aligns with other requirements on the sector, such as the Occupational Health and Safety Act 2004, which sets out the key principles, duties and rights in relation to occupational health and safety.

In addition, the national standards require:

- collaboration with occupational health and safety programs to decrease the risk of infection or injury to health care workers
- providing or facilitating access to equipment and devices to implement effective prevention strategies and best practice management plans
- using risk management principles to implement systems that maintain a clean and hygienic environment for patients and health care workers.

Regulation 45 requires an infection control management plan.

This regulation requires proprietors of health service establishments to develop and implement an infection control management plan that provides for the surveillance, prevention and control of infection at the hospital or centre. The effective prevention, monitoring and control of infections are an integral part of the quality and safety and clinical risk management operations of any health service, and are considered core business for the sector.

Similarly, National Standard 3 is 'Preventing and Controlling Healthcare Associated Infections', which requires that:

- effective governance and management systems for health care-associated infections are implemented and maintained
- strategies for the prevention and control of health care-associated infection are developed and implemented
- safe and appropriate antimicrobial prescribing be a strategic goal of the clinical governance system
- health care facilities and the associated environment are clean and hygienic, and that reprocessing of equipment and instrumentation meets current best practice guidelines.

The National Health and Medical Research Council has also issued the *Australian Guidelines for the Prevention and Control of Infection in Healthcare*,[84] which outline the critical aspects of infection prevention and control. These guidelines are endorsed by the Royal College of Nursing Australia.

In addition, registered health professional groups also set guidelines in relation to infection control.

Regulation 46 requires the certificate of registration (or a copy), the names of senior staff, and the name of the complaints liaison officer to be displayed.

The cost of displaying this information on the premises does not impose a material cost on health service establishments.

8.4 Regulations attributed to other frameworks

Regulation 47 requires proprietors of health service establishments to provide statistical returns to the secretary containing specified particulars in relation to patient admissions.

These returns have been required to meet the secretary's obligations under Section 17 of the Public Health and Wellbeing Act 2008, as well as Victoria's reporting obligations under the National Health Information Agreement and the Australian Health Care Agreement. Section 17 of the Public Health and Wellbeing Act requires the secretary to establish and maintain a comprehensive information system which includes information about the:

- health status of persons and classes of persons in Victoria, including information about the extent and effects of disease, illness, injury, disability or premature death
- determinants of individual health and public health and wellbeing

and

- effectiveness of health interventions to improve public health in Victoria.

The returns generally form the Victorian Admitted Episodes Dataset (VAED). The VAED comprises morbidity data on all admitted patients from Victorian public and private acute hospitals and rehabilitation centres, extended care facilities and day procedure centres. Among other things, VAED data is used for

[84] National Health and Medical Research Council, 2010, *Australian Guidelines for the Prevention and Control of Infection in Healthcare*, http://www.nhmrc.gov.au/node/30290, accessed April 2013.

health services' planning, policy formulation, case-mix funding (for public facilities) and epidemiological research.

Similar data sets are required under commonwealth arrangements. Both the Hospital Casemix Protocol (HCP) data and Private Hospital Data Bureau (PHDB) data is mandated through the Private Health Insurance Act 2007 and its associated rules. The HCP collection includes clinical, demographic and financial information for privately insured, admitted patient services. Private hospitals are required to provide HCP data to health insurers. Health insurers, in turn, are required to provide the HCP data, supplemented with additional data fields specific to their role as insurers, to the Department of Health and Ageing (DoHA). The PHDB comprise episode data for all admitted patients and is submitted by private hospitals direct to DoHA.

There is an additional burden on the sector under the proposed regulations to provide the statistical information on a monthly basis, in the format required by the department. VAED is an electronic data collection and is designed, as far as possible, to be a by-product of the day-to-day data collection by a health service establishment for its own purposes. However, if a hospital or centre does not have the capacity to extract the information required, the department provides, free of charge, a basic system — the Admitted Patient Entry and Transmission (APET) system, to allow sites simply to transmit to VAED. Because health service establishments rely on the quality of their data for payment by insurance companies, most have IT systems and arrangements (whether internal or outsourced) to manage their data. It is assumed this is the reason why there are only around 12 private hospitals (inclusive of public and private) that utilise APET.

It is difficult to isolate the data management costs that are attributable to VAED data, because the same resources would be used to manage the hospital data required for their own purposes, invoicing and the Commonwealth data reporting. It is assumed that the incremental tasks associated with the VAED data would include:

- having a module in the software aligned to VAED requirements and modifying this as per department updates on an annual basis
- creating an extract file on a monthly basis and correcting any errors as required
- maintaining relevant data reference sets.

In an attempt to quantify the costs of submitting VAED data it was assumed that it requires on average:

- three hours of staff per month time for medium to large private hospitals (those greater than 50 beds).
- six hours of staff time per month for smaller health service establishments.

On this basis, the cost across the sector for staff time in completing VAED submissions is $59,608 per month or **$715,300** per year (see Appendix C for calculations).

It is equally difficult to quantify the costs of the information technology used in health service establishments that should be attributed to the proposed Regulations.

It has been reported that information technology costs account for approximately for 2.5–3.0 per cent of operating budgets in health.[85] Given the annual average expenditure for private hospitals in Victoria is $2,201,191,000, this would equate to approximately $66,035,730 spent on IT. Given this expenditure accounts for all IT costs for all purposes, the percentage attributable to the Regulations is estimated to be less than 10 per cent, or **$6,603,573** per year.

[85] Greenwalt D, Riney S, 2007, 'Measuring IT benefits: let us count the ways' Healthcare Financial Management vol. 61(2) pp. 86-92.

Combining the annual costs of VAED data ($715,300) and percentage of IT ($6,603,573) provides a total cost of $7,318,873. Total discounted cost over 10 years is equal to $**65,568,915** (see Appendix C for calculations)**.**

9 Impacts on competition

The analysis in this RIS has concluded that, based on the information available to the department, the proposed Regulations meet the objectives better than the base case and the assessed alternative approaches.

9.1 Groups affected

Groups affected by the proposed Regulations, or their alternatives, include private hospital proprietors, their staff and their patients.

9.2 Impact on small business

The *Victorian Guide to Regulation* provides a definitive guide to developing regulations in Victoria within the context of the government's vision of well-targeted, effective and appropriate regulations. In particular, it is important to examine the impact on small business, because the compliance burden of regulation often falls disproportionately on that sector of the economy.

There are a number of smaller registered health service establishments in Victoria: 58 per cent have fewer than 27 beds, and 41 per cent have fewer than 10 beds.

The impact of the proposed Regulations falls on proprietors of private hospitals. The majority of the measures contained in the proposed Regulations are scalable to the number of patients, and are therefore proportionate to establishment size. It is noted that some requirements are not based on establishment size, such as the need to have an infection control management plan and a complaints management processes in place, which theoretically impose a disproportional cost on smaller establishments. As discussed previously, these types of requirements are also considered 'business as usual' in health care, and part of the national standards for accreditation of health services.

Given that the proposed Regulations represent a continuation of the Regulations that have been in place for over 10 years, the department does not expect that the proposed Regulations will raise any implementation issues or cause unintended consequences for smaller health service establishments. The review of the Act may enable a different regulatory approach, and allow for regulations to be tiered, depending on the type of services being delivered or risk profile of a service.

Also, under the current regulatory approach, the department provides significant guidance and education to smaller establishments to support them to have required policies and procedures in place.

9.3 Assessment of impact on competition

The guiding principle in assessing competition impacts is that the Regulations should not restrict competition unless it can be demonstrated that the benefits of the restriction to the community as a whole outweighs the costs, and that the objectives of the Regulations can only be achieved by restricting competition. The National Competition Policy (NCP) 'competition test' was used to assess the proposed Regulations against any possible restrictions on competition. The test asks the following questions relating to the proposed Regulations:

- Is the proposed measure likely to affect the market structure of the affected sector(s)?
- Will it be more difficult for new firms or individuals to enter the industry after the imposition of the proposed measure?
- Will the costs/benefits associated with the proposed measure affect some firms or individuals substantially more than others (for example, small firms, part-time participants in occupations, etc.)?

- Will the proposed measure restrict the ability of businesses to choose the price, quality, range or location of their products?
- Will the proposed measure lead to higher ongoing costs for new entrants that existing firms do not have to meet?
- Is the ability or incentive to innovate or develop new products or services likely to be affected by the proposed measure?

Assessed against this test, the proposed Regulations impose restrictions on firms entering or exiting a market by requiring their registration. However, in this context, it is noted that the restrictions are imposed by the Act, with the proposed Regulations providing some detail to the regulatory requirements and giving practical effect to the Act. The cost of complying with the proposed Regulations is considered to be justified by the benefits achieved by the Regulations, and not materially greater than the costs associated with the base case (in which case the department would need to request information from proprietors in order to make a decision regarding registration, if not provided with the application).

The proposed Regulations are unlikely to make it more difficult for new proprietors to enter the market, because they represent minimum requirements for patient safety, and for services to receive funding under the private insurance arrangements they would need to demonstrate compliance with national standards that have considerable overlap with the Regulations. In this regard, they could be interpreted as restricting business ability to choose the quality of the service being offered, but the benefit of this to the community is considered to outweigh the costs.

Taking into account differences in the types of services provided and the level of acuity of patient across the range of registered establishments, the proposed Regulations are not considered to affect a relative competitive disadvantage or advantage.

It is acknowledged that private health care establishments are primarily in competition with each other for patients' business, rather than in competition with the public hospital system. This results in the different profile of services, risk and acuity in the private and public sectors. In addition, there are different drivers for choosing a private health service; for example, no waiting times for elective surgery and the ability to choose your specialist.

The proposed Regulations apply equally to all businesses and consumers and do not impose dissimilar requirements compared with other jurisdictions. Therefore, the proposed Regulations are considered to meet the NCP 'competition test' as set out in the *Victorian Guide to Regulation*.

9.4 Implementation and enforcement issues

The proposed Regulations are intended to commence on 10 September 2013. This will enable a continuation of the current regulatory framework, during which the review of the Act will be completed.

To assist stakeholders to understand the timing of the Regulations and the review of the Act, the department is planning a range of communication and implementation activities. Information on these will be provided closer to the time through the department's website and via direct correspondence.

Under the proposed Regulations, the department will continue to be responsible for the regulation of health service establishments, and undertake a range of monitoring and enforcement activities to ensure proprietors meet their obligations under the Act and Regulations.

The current scheme contains a range of enforcement measures, such as placing conditions on establishments' registration, infringement notices, revocation of registration or prosecution. In the current legislation, there are a number of prosecutable offences, but these are mainly taken as a last resort.

These measures offer a fair and proportionate range of compliance measures, which aim to educate proprietors and support them in making positive changes to their business and services offered to patients.

The senior nurse advisors, as authorised officers, monitor and enforce compliance with the Act, the Regulations and conditions of registration, by:

- inspections of establishments: assessing policy, procedures and practices in clinical care, as part of the application for renewal of registration or pre-registration
- prompt and thorough complaint investigation involving site visits that may, depending on risk analysis, lead to a full site inspection
- requiring action plans from proprietors to rectify issues of noncompliance where identified and conduct follow-up inspections
- power to impose sanctions in cases of continued noncompliance, including refusal of an application for renewal of registration, revocation of registration and prosecution for breaches of the Act or Regulations.

The authorised officer role has a strong educative focus and enables the meaningful exchange of information between the department and the private sector. Authorised officers can assist proprietors to understand and implement changes to procedures, practices and documents to ensure compliance with the legislation. This occurs both during inspections and as part of their ongoing relationship with the sector. In addition, authorised officers provide education through specific projects to assist proprietors in either complying with the legislation, or developing better practices.

If the minister is satisfied that the proprietor has failed to carry on the health service establishment in accordance with the Act, the Regulations or any condition of registration, the minister may revoke the registration of the establishment in accordance with the Act.

In the majority of cases, the department works with proprietors to resolve any problems.

9.5 Evaluation strategy

The Subordinate Legislation Act 1994 revokes statutory rules following 10 years of operation. This allows the government to examine whether there is still a problem that requires government intervention, and to take account of any changes or developments since the regulation was implemented. When regulations are remade, the government assesses whether the objectives of the regulation are being met, whether practical experience suggests ways in which they can be improved, or whether a different regulatory approach is warranted. Final development of the Regulations is informed by public input through the RIS process.

The proposed Regulations will be a temporary measure, while the review of Part 4 of the Health Services Act is conducted. As part of the process of developing the new Act, accompanying Regulations will be developed, and they will commence at the same time.

As noted in Section 9.4, the authorised officers will continue to visit registered health service establishments. These inspections provide compliance data that is used by the department as a proxy for the safety and quality performance in these facilities.

In addition, the department intends to analyse noncompliance data from inspections of private hospitals (for example, nurse ratios, mix, infection control) and compare to VAED data on health complications during admissions, as a proxy for adverse events at the hospital. This will assist them to assess whether there is a relationship between hospitals that are systematically noncompliant with regulations requirements and a higher rate of adverse events.

To date, while this data has been collected and assessed at an individual hospital level at the time of inspection and informs recommendations, systematic collation and analysis of data for themes has been broken down to whether or not a Regulation has been complied with — rather than the type of noncompliance.

In developing the supporting Regulations to the new Act, the department intends to review individual hospital inspection reports to ascertain more detail on the nature of any noncompliances.

In future, it is intended to move to a process of nationwide consistent indicators across health sectors, public and private.

In November 2009 health ministers endorsed Australian Commission on Safety and Quality in Health Care's recommendation that hospitals routinely monitor and review a succinct set of indicators. This is to be achieved by the establishment of the National Health Performance Authority (the authority); and the Performance and Accountability Framework (the framework).

The authority established under Commonwealth legislation began operations on 21 October 2011. They released a draft framework in May 2012 for consultation.

In part, the framework establishes the **conceptual basis** for the authority to fulfil its role in developing and producing reports on the performance of hospitals and health care services, including private hospital. The proposed core, hospital-based outcome indicators recommended for local generation and review are:

1. hospital standardised mortality ratio (HSMR)
2. death in low-mortality diagnosis related groups (DRGs)
3. in-hospital mortality for: a) acute myocardial infarction (AMI) b) stroke c) fractured neck of femur, and d) pneumonia
4. unplanned/unexpected hospital readmission of patients discharged following management of: acute myocardial infarction (AMI) / b) knee replacements c) hip replacements d) paediatric tonsillectomy and adenoidectomy
5. health care associated *Staphylococcus aureus* bacteraemia (SAB)
6. *Clostridium difficile* infection (CDI).

It is **currently not mandatory for private hospitals to provide this information**. Moving towards this has been contentious with private hospitals raising issues of commercial sensitivity. It is not clear at this stage when the framework will be fully realised.

10 Stakeholder consultation

Between November 2012 and March 2013 the department undertook a number of targeted consultations by contacting representatives of key stakeholders, to discuss the review of the regulatory framework applied to private hospitals and day procedure centres, and the development of a new Act for this purpose.

The majority of issues raised relate to the structure of the current Act. The key themes from the feedback related to:

- that regulation may need to be applied differently to different types of facilities or services
- how the national standards and accreditation processes can be used as evidence as meeting requirements under the regulations
- opportunities to streamline registration requirements to prevent duplication.

An overview of stakeholders views is provided below in Table 10.1

Table 10.1 Summary of stakeholder's views.

Stakeholder	Summary of view
Australian Nursing Federation	Regulation of private hospitals and day procedure centres is required to manage the risk to patients and staff. It is the view of the Australian Nursing Federation (Victorian Branch) that the integration of the National Standards and Accreditation Scheme for high-risk health services can be incorporated within Part 4 of the Act, and specified in the Regulations. We believe that the requirement to have arrangements for management and staff must be retained in the revised Act and Regulations. The current Regulations ensure that there are minimum processes in place to support key nursing and midwifery positions, such as the appointment of a director of nursing/midwifery (however titled). We believe the Regulations ensure that private hospitals implement strategies that assist in workforce development planning through minimum rostering and skills mix arrangements and provides for a nursing and midwifery workforce that are selected to make sure that there are staff available to work with the appropriate skills and are made up of the required professional group mix.
Cabrini Hospital Group	Recognised fee recovery object of government. Noted a tiered system with larger players subsidising smaller players may be reasonable. Minimum standards for staffing could be clearer for high-risk areas using a tiered system under the revised Act, for example, particular requirements for ICU.
Australasian College for Emergency Medicine	ACEM considers appropriate onsite medical staffing in EDs in private hospital setting is essential to ensuring high levels of patient safety and maintenance of quality care. Various factors must be considered when planning an emergency medicine medical workforce, including direct patient care requirements, supervision of junior medical staff, administrative requirements and teaching and training needs. Evidence shows that adequate senior staffing (and access to senior staff) are important in high patient safety levels, reduced length of stay, as well as improved decision making.
Australasian College for Infection	The national standards are designed to manage the quality of health services being provided by a facility, and accreditation should be accepted to demonstrate this requirement has been met.

Prevention and Control	The National Standards require facilities to be accredited. It is sufficient once a facility has been registered and accredited that there is a reporting mechanism in place within the Act that allows provision for the accrediting agencies to report matters only of serious risk to the department.
Australian Commission on Safety and Quality in Health Care	Regulatory framework should be focused on safety and quality and reducing risk to patients. The Act should include accreditation to the to capture 5% of facilities not currently accredited. Requirements that duplicate with National Standards and accreditation assessment process should be removed. Management and support of staff important but covered well in NSQHS Standards.
Epworth	A regulatory risk framework should be part of the government's approach to regulating and quality assuring Australia's large, diverse and complex private health care sector. By applying a risk-based approach, the Department of Health, as regulator, may adjust the content, frequency and intensity of regulatory review and quality assurance activities based on its risk assessment of a health service provider. The requirement to have suitable arrangements for management and staff should not be retained as a matter to be assessed by the Department of Health prior to approving a registration. This requirement serves no useful purpose, because great care is taken to ensuring the staff of a facility are appropriately qualified and experienced in relation to the services offered, and Epworth is self-regulating in this regard.
Ramsay Health Care	Support ongoing regulation, but seeks to decrease burden and duplication. Regulation should be based on service type and risk rather than premises — tiered system. Accreditation should be sufficient to demonstrate compliance with Regulations. Government could retain registering functions, investigation and enforcement powers, but effectively delegate the monitoring to accreditation requirements. Staffing: staff requirements, skill mix and ratios are addressed by national standards and should not be further regulated. If they are regulated, flexibility is required, particularly in rural areas. If there is a question of compliance, a review process should be available to consider the circumstances of the facility. Increased fees will increase the cost of private health care to the consumer.
St John of God Healthcare	The Act should continue to provide for Regulations that require a private hospital to ensure suitably qualified staff are engaged, retained and trained satisfactorily, and for training and competence to be maintained on an ongoing basis. However, because there is extensive contemplation of staffing adequacy and suitability under the NSQHS Standards through accreditation processes, ascertainment of these matters could be deferred to accreditation agencies. Private hospitals should be able to provide a safe and efficacious skill mix model that is based on acuity of the patients. The current regulation restricts flexibility and denies and expanded role of enrolled nurses in the private hospital sector. SJoG does not support full cost recovery.
Vic Parade Day Surgery Centre	Act should seek guidance from nurse colleges about appropriate level of qualification and experience for appointment to DoN position. Full cost recovery not warranted. Other compliance costs have increased 200–300% due to NSQHS accreditation. Unfair playing field for tax purposes compared to not-for-profits.
Health Services Commissioner	Minimum standards to act as a quality lever to ensure minimum standards of care. Include a requirement to provide a comprehensive complaints resolution mechanism.

In discussions, stakeholders expressed a preference for maintaining the current Regulations while the Act was reviewed and a new Act and accompanying new regulations were developed and implemented.

This enables business continuity and prevents additional transition costs in moving to a different set of Regulations, prior to the review of the Act, and then needing to make transitions again once the new Act is implemented.

It is likely that under a revised and modernised Act there will be increased ability to streamline the regulatory approach and decrease the administrative burden on the sector.

The next stage of consultation is to invite responses to this RIS. The Subordinate Legislation Act 1994 requires that the public be given at least 28 days to provide comments or submissions regarding the proposed Regulations. Because the proposed Regulations are substantively the same as the 2002 Regulations, the department considers that 28 days is adequate.

10.1 Consultation points

In developing this RIS, there has been ongoing consultation with stakeholders. In particular, the views of proprietors have been sought on key changes to the Regulations. Stakeholder views and concerns are summarised in Section 10.

While this feedback has been helpful in identifying requirements that parallel 'business as usual' activities, the quantification of additional costs of the proposed Regulations is largely based on departmental assumptions where stakeholders have not been able to quantify the cost impacts.

A primary function of the RIS process is to inform members of the public and seek comment on the proposed Regulations before they are finalised. While comments on any aspect of the proposed Regulations are welcome, stakeholders may wish to comment on the following consultation points:

- The proposed Regulations aim to clarify what proprietors are expected to do to meet the requirements under the Act. Do the proposed Regulations give sufficient clarity to proprietors? If not, in relation to which part of the Act or Regulations would greater clarity be useful?
- The department considers that the improvements in the Regulations related to adequate staffing, accommodation standards, effective complaints management, records and storage of medications will result in prevention of at least 10 serious incidents per year (compared with an absence of regulations). Is this realistic?
- Overall, are there any practical difficulties in meeting any of the requirements set out in the regulations?
- Overall, are there any transitional or implementation issues associated with the proposed Regulations?
- The proposed Regulations aim to ensure a suitably qualified person is appointed as the director of nursing, as defined as having nursing management experience and a registered nurse — does this provide sufficient clarity to proprietors about what is 'suitably qualified'?
- The proposed Regulations require proprietors to send notification to the department of senior appointments. Is this a reasonable expectation to assist in implementing the requirements of the Act? Are the estimated time costs to provide this information realistic?
- The proposed Regulations place requirements on proprietors regarding the sufficient number of appropriately educated or experienced nursing staff. Does this provide sufficient clarity to proprietors? Are there circumstances where a Regulation does not offer sufficient flexibility to proprietors? If so, what is the additional cost of this? Are there alternative staffing options, either in regard to ratios or skill mix, that should be explored? Are the assumptions made in calculating the incremental costs of these requirements reasonable?
- The proposed Regulations place requirements on proprietors regarding the provision of information to patients. Staff time is also the major cost factor in calculating the cost of providing patients with fee information — were the assumptions sued to calculate these costs reasonable?

- Some Regulations were not analysed in this RIS as they are considered ‘business as usual’ for the sector (see Section 8) is this a reasonable assumption? Are their further incremental costs attributable to these Regulations not addressed?
- Do the proposed Regulations have any impacts on competition not identified in RIS?

Written submissions are required by **5.00 pm Monday 12 August 2013.**

11 Appendices

Appendix A: Cost assumptions and calculations

Approach to assessing the regulatory options

In order to assess the options put forward in this RIS, an assessment is required of each option's costs and benefits. The *Victorian Guide to Regulation* advises of the following principles in regards to conducting cost-benefit assessment:

- Before a particular regulatory proposal can be implemented, it needs to be demonstrated that the net benefits associated with the proposal are greater than the other approaches available to address the problem.
- Where possible, a dollar figure should be assigned to costs and benefits.
- Analysis should include an assessment of less tangible impacts (such as health and safety outcomes).
- Cost-benefit analyses should also contain an assessment of risk to enable regulation to be in proportion to the risks involved.

The key objective in regulating health service establishments is to provide for the safety and quality of the services provided, and therefore protect the public that use them. For a range of reasons detailed in the RIS, health care is a not a 'typical market' and therefore, government intervention in the form of regulation is warranted.

Due to the number of variables involved in the provision of health care, it is challenging to quantify the costs and benefits of regulation in this area. There is no baseline data available to measure intervention against. Registration and regulation of private hospitals has been in place in Victoria for over 100 years. All Australian jurisdictions have a regulatory framework applied to private hospitals.

The less tangible, social impacts of the proposed Regulations include:

- improved quality of life associated to the extent that Regulations lead to better health care
- greater transparency around safety and quality requirements
- benefits of providing better quality information to patients.

Non-quantifiable costs associated with the base case of no regulation include those associated with:

- a reduced confidence in the private system by patients
- decreased satisfaction by patients and health care professionals
- increased physical and psychological discomfort for patients
- decreased quality of life for patients.

As discussed in Section 2.3 of the RIS, there is a range of research that points to the high cost of adverse events, many of which are found to be avoidable. This data can be used as a potential benefit measure of the proposed Regulations if avoidance is achieved. However, quantifying the scale of avoidable harm that could be attributed to the proposed Regulations cannot be done in any robust way.

To assist in assessing the costs and benefits of the viable regulatory options, this RIS utilises the multi-criteria analysis (MCA) assessment tool. This is the preferred assessment approach where it is not possible to quantify and assign monetary values to all impacts of an option.

MCA involves identifying assessment criteria relevant to the intervention objectives, weighting these criteria and scoring alternative options against these criteria. An overall score is derived by multiplying the score assigned to each measure by its weighting and calculating the total. This provides a qualitative score for each option, and the option with the highest score represents the preferred approach.

The criteria weightings consider the relative importance each criterion in achieving the Regulations' objectives. These values are necessarily subjective and informed by consultation with stakeholders and government policy.

The proposed Regulations and identified alternative approaches are scored relative to the base case. A scale of plus 10 (+10) to minus 10 (-10) was used, where 1 indicates a minimal positive impact and 10 indicates a high and material impact. This approach allows elements of the regulatory options to be differentiated in assessment. For example, if one option incurred costs of $2 million per year, and another option $4 million, then the former option might receive a rating of -5, while the latter would score 10.

General assumptions

Costs associated with complying with the Regulations will vary depending on the specific circumstances of each health service establishment.

The Regulations are not the only legislative framework or set of standards that require actions relating to patient safety and health care quality. As a result, a large proportion of health service establishments are likely already in compliance with the Regulations; therefore, there will be minimal costs attributed to them.

Factors that may determine the extent of costs compliance include: the resources of the establishment, the sophistication of the quality systems and level of staffing and management support around this.

Compliance costs for each category were estimated by:

- identifying additional (incremental) compliance tasks from the base case
- identifying key activities required to complete compliance tasks

and

- valuing those activities based on staff time and/or cost of inputs.

Valuing staff time

As a proxy for valuing an hour of a person's time in the private health care sector the general formula referenced in the *Victorian Guide to Regulation* was used.

The formula states: **HRx = (AEx × OOx)/(AWx × AHx),** where:

AEx = average weekly earnings (trend full-time, adult, total earnings in Victoria) multiplied by 52 weeks

AWx = number of weeks worked per annum (44 weeks)

AHx = average weekly hours for full-time workers (41 hours)

OOx = multiplier for on-costs and overhead costs (1.75).

Using data from November 2012 in ABS *Cat 6302.0 — Average Weekly Earnings, Australia,*[86] (full-time, adult, total earnings in Victoria of $1,392 per week) in the above formula gives an hourly rate of $70.21. See calculations below.

HRx = ([52 × 1,392] × 1.75) / (44 × 41)

= ($72,384 × 1.75) / (44 × 41)

= 126,672 / 1804

= $70.21

[86] Australian Bureau of Statistics, *Average Weekly Earnings, Australia, Nov 2012*, cat no. 6302.0 (Canberra: ABS, 2013).

This general formula was used, rather than analysing specific data for health care professionals, because the incremental costs of Regulations will involve tasks completed by a range of workers, from medical practitioners and nurses, management, administration and finance.

Discount rate

In order to consider the cost of the Regulations over their potential life (10 years), the future costs are assessed using a 'discount rate'. Applying a discount rate to future impacts allows them to be valued in today's dollars (which, in turn, can be used to compare the costs and benefits of different options on a consistent basis). These amounts are known as the present values of future streams of benefits and costs.

The present value calculation is: **PV = Σ Bt/(1+r)t** where:

Bt is the benefit (or cost) at time period t

r is the discount rate

t refers to the year in which the benefit/cost impact occurs.

The department's calculations:

- used a discount rate of 3.5 per cent as recommended by the *Victorian Guide to Regulation*
- assumed the number of private hospital and day procedure centres in Victoria to grow by 1.75 per cent per year. This figure is based on the growth in registrations between 2001 and 2012.

(i) Calculations and assumptions for options to regulate senior appointments — Chapter 4

In calculating the incremental costs the following data and assumptions were used:

- An estimated 20 per cent of facilities would not appoint a suitable DoN (or an acting DoN) in the absence of Regulations.
- Within this 20 per cent it is expected that half would have some form of management structure in place, whether it be a junior nurse or non-clinical manager; therefore, the appointment of a DoN in these cases does not equate to the employment of an additional staff member, but employment of a DoN at a higher rate of pay.
- According to MyCareer Victorian employment data, the average salary of a DoN is equal to $91,131 ($159,479 inclusive of on-costs and overheads) and the average salary a registered nurse (RN) is $80,492 (($140,861 inclusive of on-costs and overheads). Therefore, the price difference between these positions is equal to $18,618.
- The department receives an average number of 52 notifications of senior appointments per year.
- The average time for facilities to complete a one-page notification form and attach appointee's CV is 30 minutes.
- There are 164 registered health service establishments in Victoria to which the Regulations will apply.

Incremental cost of employing a suitably qualified DoN

- Incremental cost attributed to 20 per cent of 164 facilities = to 32.8 facilities.
- Half or 16.4 of these facilities will be required to employ a full-time DoN in addition to current staffing complement. 16.4 multiplied by $159,479 = $2,615,455.
- Half or 16.4 of these facilities will be required to employ a full-time DoN in addition to current staffing complement. 16.4 multiplied by $18,618 = $30,533.
- Total = $2,615,455 + $30,533 = **$2,920,790** or **$89,048** per impacted establishment per year.
- As per the table below, the total 10-year cost per impacted establishment is equal to **$797,772**.

Table A.1

Year	Cost $	Discounted Cost
2013-14	89,048	86,037
2014-15	90,606	84,582
2015-16	92,192	83,152
2016-17	93,805	81,746
2017-18	95,447	80,364
2018-19	97,117	79,005
2019-20	98,817	77,669
2020-21	100,546	76,356
2021-22	102,306	75,065
2022-23	104,096	73,796
TOTAL	**963,980**	**797,772**

Incremental cost of appointing acting DoN

- Incremental cost attributed to 20 per cent of 164 facilities = 32.8 facilities.
- Assumes the average period per year requiring an acting DoN is six weeks or 0.12 of a year.
- Half, or 16.4, of these facilities will be required to put an acting DoN in place. 16.4 facilities × $159,479 wages × 0.12 year = $313,855.
- Half, or 16.4, of these facilities will be required to put a more qualified acting DoN in place. 16.4 facilities × $ 18,618 wage increase × 0.12 year = $36,640.
- Total = $313,855 + $36,640 = **$350,495** or $**10,658** per impacted establishment per year.
- As per the table below, the total 10-year cost per impacted establishment is equal to $**95,484**.

Table A.2

Year	Cost $	Discounted Cost
2013-14	10,658	10,297.58
2014-15	10,845	10,123.92
2015-16	11,034	9,952.04
2016-17	11,227	9,783.68
2017-18	11,424	9,618.70
2018-19	11,624	9,456.13
2019-20	11,827	9,295.92
2020-21	12,034	9,138.76
2021-22	12,245	8,984.54
2022-23	12,459	8,832.42
TOTAL	**115,377**	**95,484**

Incremental cost of notifying the secretary of the senior appointment

- Equal to = (average notifications/year) × (time to prepare notification and send) × (average cost per hour).
- 52 notification × 0.5 hour × $70.21/hour = **$1,825** or $11.13 per registered establishment.
- As per the table below, the total 10-year cost per registered establishment is equal to $99.70.

Table A.3

Year	Cost $	Discounted Cost
2013-14	11.13	10.75
2014-15	11.32	10.57
2015-16	11.52	10.39
2016-17	11.72	10.21
2017-18	11.93	10.04
2018-19	12.14	9.88
2019-20	12.35	9.71
2020-21	12.57	9.55
2021-22	12.79	9.38
2022-23	13.01	9.22
TOTAL	**120.49**	**99.70**

Total incremental cost

- The total incremental cost is equal to: $ 2,920,790 + $350,495 + $1,825 = $**3,273,110**.
- As per the table below, the total 10 year cost is $**29,323,149**.

TableA.4

Year	Cost $	Discounted Cost
2013-14	3,273,110	3,162,425
2014-15	3,330,389	3,108,954
2015-16	3,388,389	3,056,133
2016-17	3,447,973	3,004,709
2017-18	3,508,313	2,953,905
2018-19	3,569,708	2,903,960
2019-20	3,632,178	2,854,859
2020-21	3,695,741	2,806,588
2021-22	3,760,416	2,759,134
2022-23	3,826,224	2,712,482
TOTAL	**35,432,441**	**29,323,149**

(ii) Calculations and assumptions for options to regulate staffing — Chapter 5

In calculating the incremental costs the following data and estimations were used:

- Estimated that under the base case 90 per cent of proprietors employing staff who are professionally competent. Therefore, 10 per cent of the cost of the sector meeting this requirement is attributable to the Regulations.
- Estimated that under the base case 80 per cent of proprietors employing sufficient number of nursing staff is on duty. Therefore, 20 per cent of the cost of the sector meeting this requirement is attributable to the Regulations.
- There are 82 registered day procedures centres (DPC) in Victoria, with a total of 731 beds, and 198,000 separations (completed episodes of patient care) per year.[87]
- There are 82 registered private hospitals (PH) in Victoria, with a total of 7,108 beds, and 875,000 separations per year.[88]
- The total nursing workforce in private hospitals or day procedure centres is 8,620.[89]
- DPCs usually operate one shift per day, while it is assumed that PH operating with full time employees rostered over three, eight hour shifts: morning, afternoon and evening.
- Average Victoria general nursing salary according to MyCareer.com is $79,516. Factoring in 44 weeks worked per annum, at average 41 hours per week, and using the 1.75 multiplier for on-costs and overhead costs, this equates to an hourly rate of $77.14.
- The benchmark for continuing professional development set by the NMBA is 20 hours per year.[90]

Incremental costs of ensuring each nurse is professionally competent

[87] Australian Institute of Health and Welfare, 2012, *Australia's Hospitals 2010-11 at a glance*, http://www.aihw.gov.au/publication-detail/?id=10737421715, accessed March 2013.

[88] Ibid.

[89] Ibid.

[90] Nursing and Midwifery Board of Australia, 2010, *Nursing and Midwifery Continuing Professional Development Registration Standard*, http://www.nursingmidwiferyboard.gov.au/Registration-Standards.aspx, accessed April 2013.

Total cost of nurse education = (no. of nurses) × (hourly rate) × (no. of hours professional education).

= 8620 × $77.14 × 20 hours

= $13,298,936.

Incremental cost of Regulations = 10% of total cost

= 10% of $13,298,936

= **$1,329,894**.

Incremental costs of employing sufficient number of nursing staff

- 'Sufficient' is defined in the proposed Regulations as one RN per 10 patients — day & evening shifts and one RN per 15 patients — night shift.
- Because it is estimated that 80 per cent of proprietors would meet this requirement under the base case, the incremental cost calculating the cost attributable to the 20 per cent who would need further staffing under the Regulations.
- It is assumed that under the base case the 20 per cent would seek to have fewer registered nurses (RNs) and more enrolled nurses (ENs), rather than the absence of staff altogether. The average of 50 per cent fewer RNs (1:20 instead of 1:10) is used for the purposes of estimating costs.
- The average salary difference between RN and EN = $16,365 per year (MyCareer.com).
- Incremental cost Regulations DPC:

  DPC capacity 731 beds, assuming full capacity.

  100% compliance @1:10 ratio = 73.1 RNs.

  80% compliance @1:10 ratio = 58.48 RNs.

  Assuming the remaining 20% operating at 1:20 = 7.31.

  Total RN (58.48 + 7.31) = 65.79.

  Incremental cost would be an additional 7.31 RNs per day.

  Assuming they have EN in place and the average wage difference of $16,365.

  7.31 × $16,365 = **$119,628** per year.
- Cost borne by the 20% DPCs = to approximately 16.47 DPCs, 146.2 beds, 39,600 separations.
- Averaged over these DPC this equates to ~ $7,924 per establishment, $818 per bed or $3.02 per separation.
- Incremental cost Regulations PH:

  PH capacity 7,108 beds, assuming full capacity.

  100% compliance @1:10 ratio = 710.8 RNs.

  80% compliance @1:10 ratio = 568.64 RNs.

  Assuming the remaining 20% operating at 1: 20 = 71.08 RNs.

  Total RN (568.64 + 71.08) = 639.72.

  100% compliance @ 1:15 ratio = 473.86 RNs.

  80% compliance @ 1:15 ratio = 379.09 RNs.

  Assuming the remaining 20% operating at 1: 30 = 47.3.

  Total RN 379.09 + 47.3 = 426.48.

Incremental cost would be an — additional 71.08 RNs per am shift

— additional 71.08 RNs per pm shift

— additional 47.38 RNs per night shift.

Incremental cost would be an additional 189.54 RNs per day.

Assuming they have EN in place and the average wage difference of $16,365.

189.54 × $16,365 = **$3,101,822**.

- Cost borne by the 20% PHs = to approx. 16.4 facilities,1421 beds and 175,000 separations/year.
- Averaged over these PH this equates to ~ $189,085 per establishment, $211 per bed or $17 per separation.

Incremental costs of employing sufficient skill mix

- 'Appropriate skill mix of nursing staff' requires that, if three or more nurses are on duty at a health service establishment during a shift, one-third may be enrolled nurses.
- The total nursing workforce in private hospitals or day procedure centres is 8,620.
- Total bed capacity at any given time in private health establishments is 7,839 beds: 7,108 in private hospitals and 731 in day procedure centres.
- The average salary difference between RN and EN = $16,365 per year.
- The skill mix component has been calculated relative to the regulated staff ratios because it is the department's view that these components of the Regulation are strongly related and need to be considered together.

To cost this requirement:

- Assuming the beds are at full capacity and applying the 1:10 RN: patient ratio, that would require the following number of RNs:

  PH: 1:10 applied to 7108 beds = 710.8 RNs per shift.

  Multiplied by three shifts = 2132.4 RNs.

  DPC: 1:10 applied to 731 beds = 73.1 RNs.

  Total RNs = 2132.4 + 73.1 = 2206 RNs.

- 2206 RNs of the 8,620 total nursing workface = approximately 25.6% RNS and assumed 74.4% ENs.
- In order to calculate the cost of providing that one-third (or 33%) can be EN and 66% RNs the number of additional RNs required needs to be estimated. This represents the gap between the 66% of total nursing workforce (5747) and the number of RNs required in accordance with the 1:10 requirement (2206).

  Therefore: 5747 - 2206 = 3541 Additional RNs.

  Cost = additional RNs × increased wage cost

  = 3541x $16,365

  = $57,948,465.

- Because 10% of this cost is attributable to the Regulations, the cost of this component

  = 10% × $57,948,465or **$5,794,847.**

B (iii) Calculations and assumptions for options to provide information to patients — Chapter 6

- In approximately 85 per cent of cases there is no 'gap' payment or out-of-pocket expenses for patients.[91]
- As discussed in the body of the RIS, the estimated average time spent by health practitioners providing this information to patients is 30 minutes.

Incremental costs of preparation and distribution of a statement

In calculating the incremental costs the following data and estimations were used:

- Estimated average time spent developing and providing a patient with information statement = 5 minutes or 0.083 hour.
- Estimated average hourly rate of $70.21.
- Total number of patient separations in private hospitals and day procedure centres per year is 1,073,000.
- Estimated average cost of printing estimated at 10 cents per page, average five pages of materials provided = $0.50 (based on website search April 2013).
- The percentage cost of providing this information attributable the Regulations is estimated at 30 per cent.
- Therefore, the total cost is equal to:

  (time spent × average hourly rate) + printing costs × no. of separations per year

  = (0.083 × $70.21) +$ 0.50 × 1,073,000

  = $5.85 + $0.50 × 1,073,000

  = $6.35 × 1,073,000

  = $6,813,550.
- 30 per cent is attributable the Regulations; therefore, 30 per cent of $6,813,550 = **$2,044,065**.

Incremental costs of provision of information about fees

Further assumptions in calculating this competent included:

- In approximately 85 per cent of cases there is no 'gap' payment or out-of-pocket expenses for patients.[92]
- Estimated five minutes or 0.083 hour to provide basic fee information to patients, and 10 minutes or 0.167 hour in cases where out-of-pocket expenses are identified.
- The percentage cost of providing this information attributable the Regulations is estimated at 50%.

  Basic fee calculations = (time spent × hourly rate) × (85% of separations per year)

  = (0.083 × 70.21) × (0.85 of 1,073,000)

  = 5.85 × 912,050

  = $5,335,492.

  'Gap' fee calculations = (Time spent × hourly rate) × (15% of separations per year)

  = (0.167 × 70.21) × (0.15 × 1,073,000)

[91] Productivity Commission, 2009, *Research report: public and private hospitals*, http://www.pc.gov.au/projects/study/hospitals/report.
[92] Ibid.

= $1,887,150.

- Total = basic fee cost + gap fee cost

  = $5,335,492 + $1,887,150

  = $7,222,642.

- 50% is attributable the Regulations; therefore, 50% of $7,222,642 = **$3,611,321**.

Incremental costs of explanation of the treatment and services

Further assumptions in calculating this competent included:

- estimated average time spent by health practitioners providing this information is 15 minutes
- estimated that 20 per cent of costs to provide this information attributable the Regulations
- average Victoria Medical and Healthcare Salary according to MyCareer.com is $89,051.[93] Factoring in 44 weeks worked per annum, at average 41 hours per week, and using the 1.75 multiplier for on-costs and overhead costs, this equates to an hourly rate of $86.39
- Cost = time spent × hourly rate × no. of patients per year

= 0.25 hour × $86.39 × 1,073,000

= $23,174,118.

- 20 per cent is attributable the Regulations; therefore, 20% of $23,174,118. = **$4,634,824**.

[93] My Career.com http://content.mycareer.com.au/salary-centre/healthcare/-/vic, accessed 11 June 2013.

Appendix B: Cost recovery and fee calculations

Table B.1

Step	Issues to be addressed	Departmental consideration
Appropriateness of cost recovery		
1	Is provision of the output or level of regulation appropriate?	The Regulations are the minimum necessary to provide for the safety and quality for patient care and achieve the government's objectives.
2	What is the nature of the output or regulation?	The Regulation is to ensure that private hospitals and day procedure centres are registered with the department and that they meet a range of standards in relation to patient safety and quality of care.
3	Who could be charged?	Potential parties to be charged are the proprietors of the health service establishments or their patients. Because the costs to government are directly linked to the registering of the facilities operated by the proprietors, the department considers it appropriate that fees be levied on proprietors rather than patients. Further, the Act provides only that fees may be prescribed to charge on proprietors.
4	Is charging feasible, practical and legal?	Charging of fees is feasible and practical because it can be administered as part of the application processes. This also minimises transaction costs. The Act provides that fees may be prescribed. The fees are relatively low, and as such, noncompliance with registration requirements is expected to be minimal.
5	Is full cost recovery appropriate?	Not at this time — see Section 7 for discussion.
Cost structures and nature of charges		
6	Which costs should be recovered?	The cost base for the purposes of assessing recovery is based on the costs associated with the department administering the Act as it relates to processing registration and other applications provided by proprietors. An activity-based costing method was used to determine the fee for each individual activity.
7	How should charges be structured?	The fees consist of fixed fees for applications and an annual fee that is variable, dependent on the number of beds in the registered establishment. This is considered the most equitable approach.
8	Are cost-recovery charges based on efficient costs?	The proposed fees are based on a partial cost-recovery basis at approximately 40%. This is considered the most appropriate approach in light of the current review of the Act. Ongoing costs to the department will ensure continued incentive to keep costs efficient.

Implementation features		
9	What is the importance of consultation?	Consultation of fees is occurring via this RIS process.
10	How should cost-recovery arrangements be monitored and reviewed?	Requirements about the review of existing cost recovery arrangements are stipulated in the Standing Directions of the Minister for Finance under the *Financial Management Act 1994.* These directions require the chief financial and accounting officer of the department to document, approve and annually review the level of charges levied by the department for the goods and services it provides. The department is recommending maintaining the fees at the same rate as the previous regulation to ensure continuity while the Act is being reviewed.

Calculation of fees

The fully distributed cost method was adopted for determining the fee levels outlined in this RIS. It is recommended that this methodology should be used where cost recovery activities account for a large proportion of an agency's activities.[94] While regulation activities are not a large proportion of the department's activities, it is the major activity of the Policy Instrument Compliance Unit. On this basis, the fully distributed cost method was adopted.

Cost types

According to the *Cost Recovery Guidelines*, direct costs are those 'that can be readily and unequivocally traced to a product or activity because they are incurred exclusively for that particular product/service'. On the other hand, indirect costs are not incurred exclusively for a particular product or activity. Fixed costs are unaffected by product or service delivery levels. Variable costs are directly related to the levels of production and service delivery.

For the purpose of determining the full costs incurred by the department in administering the regulatory scheme, costs have been categorised as follows:

- variable direct costs — these costs represent the salary costs (including on costs) associated with processing a particular type of application
- fixed direct costs (salary and operating) — these costs represent the ongoing costs of the program functions in the unit administering the regulatory scheme, such as compliance and education and policy costs; these costs are considered fixed
- indirect costs — these costs represent the corporate services costs, such as cost of operating database system.

The following hourly rates were used for the salary costs

- VPS Grade 4 $77.74
- VPS Grade 5 $92.86
- VPS Grade 6 $120.51
- EO 3 $177.10.

[94] Department of Treasury and Finance (DTF), 2010, *Cost Recovery Guidelines*, Melbourne.

The hourly rates were calculated as follows.

Table B.2

Position Level	Mid-point salary	Incl. On-cost & overheads (x1.75)	Cost per week (44 weeks)	Cost per day	Cost per hour
VPS 4	$74,272	$129,976	$2,954	$591	$77.74
VPS 5	$88,721	$155,262	$3,529	$706	$92.86
VPS 6	$115,140	$201,495	$4,579	$916	$120.51
EO 3	$169,210	$296,118	$6,730	$1,346	$177.10

The table was completed using the following assumptions:

- multiplier for on-costs and overhead costs is 1.75
- 44 week working year to account for public holidays, annual and sick leave
- 7.6 hours per business day.

An activity-based costing method was used to determine the variable cost for each individual activity.

This involved a step-by-step identification of the tasks undertaken by the department to process an application for which a fee is proposed to be set is required. Under this analysis, each task is assigned a time in minutes, a VPS salary grade of the person(s) undertaking the task and the resulting cost of each task. These costs are totalled, giving an overall variable direct cost of processing one application.

The estimates of time are based on the department's expectation of performance and have been informed by current practices.

The fixed costs have been attributed to the registration renewal activity, because the majority of the department's regulatory activity in this area revolves around this requirement, and it, combined with the annual fee, represents the greatest revenue for the department.

Approval-in-principle

The Act includes provision (via Section 70) for a person to apply to the secretary for an 'approval-in-principle' (AIP) prior to registration or variation of registration, This is designed to provide a level of assurance to enable a person to know, prior to the commitment of resources and time, whether an application to register or vary registration is likely to be successful. The process involves assessment of the design of the establishment. The department engages a health architect to assess the works once they are completed and the department's senior nurse advisors are also involved in the process. On average the department receives 40 AIP applications per year, mostly for renovations or extensions of premises. Approximately two of these per year are new builds and become new registered premises.

Table B.3

Tasks – Approval in Principle	Staff tariff	Time (per hour)	Cost
VARIABLE COSTS			
Telephone / email queries	$92.86	1	92.86
Pre-AIP meeting with proprietor.	$92.86	1	92.86
Receive application, stamp, file and enter into database	$92.86	0.5	46.43
Scan and record documents	$92.86	0.25	23.22
Check for completeness and assess against checklist	$92.86	1	92.86
Follow up applicant by phone/email if required	$92.86	0.5	46.43
Processing fee including invoice request and approval	$92.86	0.75	69.65
Full application assessment	$92.86	1	92.86
Liaison with Senior Nurse Advisors	$92.86	1	92.86
Preparation of brief and certificate for assessment	$92.86	1	92.86
Application package to be approved by manager	$120.51	0.25	$30.13
Once signed, approval letter generated	$92.86	0.4	37.14
Certificate and correspondence finalised and sent registered post	$92.86	0.4	37.14
Email of certificate and approval letter to applicant	$92.86	0.25	23.22
Update all files (hardcopy, internal drives and database)	$92.86	0.5	46.43
Contact applicant to arrange AIP site inspection	$92.86	0.5	46.43
Email applicant with information required prior to site inspection	$92.86	0.5	46.43
Arrange inspection (includes consultant architect documents	$92.86	0.75	69.65
AIP Inspection by authorised officer and consultant architect	$1,000	1	1,000.00
SNA site visit and advice	92.86	3	278.58
Review consultant architect inspection report	$92.86	1	92.86
Prepare correspondence to establishment	$92.86	1	92.86
Receive proof of outstanding items and document	$92.86	0.3	27.86
Send a follow up email/phone call to establishment if required	$92.86	0.3	27.86
Finalise the AIP by updating the database and hard copy file	$92.86	0.25	23.22
Fixed Costs			
Policy and Guidance Material development	$18,520		
Contract management, compliance and enforcement	$18,520		
Fixed cost over average 40 AIPs			$926
TOTAL			**$3,521**

Variation or transfer of approval-in-principle

Under Section 74 of the Act, the person who holds the original AIP certificate can apply to have this varied (for example, if there are changes in the planned design), or to transfer the certificate to another person (in cases where there is a change of proprietor). This process is less involved than the original AIP process and does not require an onsite visit. Variations and transfers aren't common; on average the department receives one per year.

Table B.4

Tasks - Variation or transfer of Approval in Principle	Staff tariff	Time (per hour)	Cost
Telephone / email queries	$92.86	0.5	46.43
Receive application, stamp, file and enter into database	$92.86	0.2	18.57
Scan and record documents	$92.86	0.2	18.57
Check for completeness and assess against checklist	$92.86	0.5	46.43
Follow up applicant by phone/email if required	$92.86	0.25	23.22
Processing fee including invoice request and approval	$92.86	0.25	23.22
Full application assessment	$92.86	0.75	69.65
Liaison with Senior Nurse Advisors	$92.86	0.45	41.79
Preparation of brief and certificate for assessment	$92.86	1	92.86
Application package to be approved by manager	$120.51	0.3	36.15
Once signed, approval letter generated	$92.86	0.3	27.86
Certificate and correspondence finalised and sent registered post	$92.86	0.4	37.14
Email of certificate and approval letter to applicant	$92.86	0.5	46.43
Update all files (hardcopy, internal drives and database)	92.86	0.5	46.43
Senior Nurse advice	$92.86	4	371.44
TOTAL			**$947**

Initial registration fee

Sections 82–85 of the Act provide for the registration of private hospitals and day procedure centres.

Under the Act, the applicant must provide evidence that they meet the criteria for registration. The activity base for the initial registration fee includes the tasks involved, including a site visit by the senior nurse advisors. On average, the department receives applications from two new premises per year. The activity base costing for an initial registration is less than the costing for a registration renewal (per year). This is because the fixed program costs have been attributed to the registration renewal activity base, as this can be applied equitably across all registered premises.

Table B.5

Tasks - Initial Registration Fee	Staff tariff	Time (per hour)	Cost
Telephone / email queries	$77.74	0.08	$6.22
Provision of information via email	$77.74	0.24	$29.15
Arrange establishment visit and provide advice documents	$92.86	0.5	$46.43
Pre visit preparation	$92.86	1.75	$162.51
Revise and reschedule (15 % av.)	$92.86	0.34	$31.57
Inspection and report	$92.86	11.3	$1,049.32
Letter of outcomes issued	$92.86	4	$371.44
Receipt of action plan	$92.86	0.425	$39.47
2nd visit if required	$92.86	1.14	$105.86
Receive application, stamp, file and enter into database	$77.74	0.25	$19.44
Check for completeness and assess against checklist	$77.74	0.16	$12.44
Follow up applicant by phone/email if required	$77.74	0.08	$6.22
Discussion with Mgr PICU	$77.74	0.08	$6.22
Preparation of brief with reference to inspection outcomes	$77.74	1	$77.74
Processing payment of fee	$77.74	0.16	$12.44
Prepare certificate for applicant	$77.74	0.08	$6.22
Application package to be approved by manager PICU	$120.51	0.25	$30.13
Application package to be approved by Director	$177.10	0.25	$44.28
Generate invoice and sign off	$77.74	0.25	$19.44
Update all files (hardcopy, internal drives and database)	$77.74	0.25	$19.44
Certificate and correspondence finalised and sent registered post	$77.74	0.25	$19.44
Advice sent to VAED and DOHA	$77.74	0.08	$6.22
TOTAL			**$2,121.60**

Registration renewal (over two-year cycle)

Section 88 of the Act provides for registration renewal. As the renewal applies for two years, the activity based costing below covers the two-year cycle of activities plus the fixed program costs. ***Table B.6.***

Tasks - Registration Renewal	Staff tariff	Time (hr)	Cost
VARIABLE COSTS			
Telephone / email queries	$77.74	0.75	$58.31
Generation of reminder letters and invoice	$77.74	0.50	$38.87
Determining renewal visit schedule	$92.86	0.18	$16.71
Arrange establishment visit and provide advice documents	$92.86	0.50	$46.43
Pre visit preparation	$92.86	1.75	$162.51
Revise and reschedule (15 % av.)	$92.86	0.34	$31.57
Inspection and report	$92.86	11.30	$1,049.32
Letter of Outcomes issued	$92.86	4.00	$371.44
Receipt of action plan	$92.86	0.43	$39.47
2nd visit if required	$92.86	1.14	$105.86
Receive application, stamp, file and enter into database	$77.74	0.50	$38.87
Check for completeness and assess against checklist	$77.74	1.50	$116.61
Follow up applicant by phone/email if required	$77.74	0.75	$58.31
Discussion with Mgr PICU	$77.74	0.25	$19.44
Preparation of brief with reference to inspection outcomes	$77.74	1.00	$77.74
Processing payment of fee	$77.74	0.50	$38.87
Prepare certificate for applicant	$77.74	0.25	$19.44
Application package to be approved by manager PICU	$120.51	0.25	$30.13
Application package to be approved by Director	$177.10	0.25	$44.28
Generate new invoice and sign off	$77.74	0.25	$19.44
Update all files (hardcopy, internal drives and database)	$77.74	0.25	$19.44
Certificate and correspondence finalised and sent registered post	$77.74	0.25	$19.44
Advice sent to VAED and DOHA	$77.74	0.25	$19.44
Issuing of annual fee, processing and documentation	$77.74	0.75	$58.31
FIXED PROGRAM COSTS (averaged over renewals)			
Development of policy and guidance materials	$60,916		$371.44
Education and support to registrants	$76,145		$464.30
Complaints and incident review and management	$60,916		$371.44
Website and information management	$50,997		$310.96
Management of issues identified	$158,109		$964.08
TOTAL			**$4,982.41**

Variation of registration

Section 92 of the Act provides for variation of a registration. This occurs, for example, when the number of beds in the establishment changes, or they types of services offered is expanded. To some extent this process is linked to the AIP process, because the premises would have likely been altered in order to accommodate these changes. A site visit is associated with this, but has been accounted for in the AIP process and therefore, the activities listed below are only those associated with processing the variation of the registration.

Table B.7

Tasks - **Variation of registration**	Staff tariff	Time (per hour)	Cost
Telephone / email queries	$92.86	0.16	$14.86
Generation of reminder letters and invoice	$92.86	0.08	$7.43
Receive application, stamp, file and enter into database	$92.86	0.5	$46.43
Check for completeness and assess against checklist	$92.86	1.5	$139.29
Follow up applicant by phone/email if required	$92.86	0.75	$69.65
Discussion with Mgr PICU	$92.86	0.25	$23.22
Preparation of brief with reference to inspection outcomes	$92.86	1	$92.86
Processing payment of fee	$92.86	0.5	$46.43
Prepare certificate for applicant	$92.86	0.25	$23.22
Application package to be approved by manager PICU	$120.51	0.25	$23.22
Application package to be approved by Director	$92.86	0.25	$23.22
Generate new invoice and sign off	$92.86	0.25	$23.22
Update all files (hardcopy, internal drives and database)	$92.86	0.25	$23.22
Certificate and correspondence finalised and sent registered post	$92.86	0.25	$23.22
Advice sent to VAED and DOHA	$92.86	0.25	$23.22
Issuing processing and documentation	$92.86	0.75	$69.65
TOTAL			**$672.31**

Table B.8 Projected fees for proposed Regulations over ten years

Year	Cost $	Discounted cost $
2013–14	149,532	144,475
2014–15	152,149	142,033
2015–16	154,811	139,631
2016–17	157,521	137,270
2017–18	160,277	134,949
2018–19	163,082	132,667
2019–20	165,936	130,424
2020–21	168,840	128,219
2021–22	171,795	126,051
2022–23	174,801	123,920
TOTAL	**1,618,743.63**	**1,339,639**

Transfer of registration

Section 92 of the Act also provides for variation of a registration in cases where the proprietor has changed hands. This is a more involved process, because the management change triggers additional communication and a visit with the new proprietor and staff to ensure they are aware of their obligations under the regulatory framework and to ensure there will be a continuation of appropriate safety and quality measures.

Table B.9

Tasks — transfer of registration	Staff tariff	Time (per hour)	Cost
Telephone/email queries	$77.74	0.16	$12.44
Generation of reminder letters and invoice	$77.74	0.08	$6.22
Arrange establishment visit and provide advice documents	$92.86	0.5	$46.43
Pre-visit preparation	$92.86	1.75	$162.51
Inspection and report	$92.86	3	$278.58
Letter of outcomes issued	$92.86	1	$92.86
Receipt of action plan	$92.86	0.425	$39.47
Second visit if required	$92.86	1	$92.86
Receive application, stamp, file and enter into database	$77.74	0.5	$38.87
Check for completeness and assess against checklist	$77.74	1.5	$116.61
Follow-up applicant by phone/email if required	$77.74	0.75	$58.31
Discussion with manager of PICU	$77.74	0.25	$19.44
Preparation of brief with reference to inspection outcomes	$77.74	1	$77.74
Processing payment of fee	$77.74	0.5	$38.87
Prepare certificate for applicant	$77.74	0.25	$19.44
Application package to be approved by manager PICU	$120.51	0.25	$30.13
Application package to be approved by Director	$177.10	0.25	$44.28
Generate new invoice and sign off	$77.74	0.25	$19.44
Update all files (hard copy, internal drives and database)	$77.74	0.25	$19.44
Certificate and correspondence finalised and sent registered post	$77.74	0.25	$19.44
Advice sent to VAED and DOHA	$77.74	0.25	$19.44
Issuing of annual fee, processing and documentation	$77.74	0.75	$58.31
TOTAL			**$1,311.07**

Appendix C: Calculation of costs to submit VAED data

In an attempt to quantify the costs of submitting monthly VAED data it was assumed that:

- three hours per month combined staff time for medium to large private hospitals (those greater than 50 beds)
- six hours per month combined staff time for smaller private hospitals and day procedure centres.

In Victoria there are 47 facilities with more than 50 beds and 118 with fewer than 50.

Therefore, to calculate the cost to large/medium facilities:

= no. of facilities × hours month staff time × average hourly rate

= 47 × 3 × $70.21

= $9,899.61.

To calculate the cost to large/medium facilities:

= no. of facilities × hours month staff time × average hourly rate

= 118 × 6 × $70.21

= $49,708.68.

Therefore, the total cost per month is:

= $9,899.61 + $49,708.68

= **$59,608.29**.

Total cost per year:

= $59,608.29 × 12

= $715,300.

Combining the annual costs of VAED data ($715,300) and percentage of IT ($6,603,573) provides a total cost of **$7,318,873.**

Estimated total costs 2012–13 to 2022–23

Year	Cost $	Discounted Cost
2013-14	7,318,873	7,071,375
2014-15	7,446,953	6,951,810
2015-16	7,577,275	6,834,268
2016-17	7,709,877	6,718,712
2017-18	7,844,800	6,605,111
2018-19	7,982,084	6,493,430
2019-20	8,121,771	6,383,639
2020-21	8,263,902	6,275,703
2021-22	8,408,520	6,169,592
2022-23	8,555,669	6,065,275
TOTAL	**79,229,724**	**65,568,915**

Total discounted cost over 10 years is equal to **$65,568,915.**

Appendix D: Regulations and Accreditation

The National Safety and Quality Health Service (NSQHS) Standards (the national standards) seek to drive the implementation and use of safety and quality systems and improve the quality of health service provision in Australia. The national standards apply to a wide variety of health service organisations. Because of the variable size, structure and complexity of Australian health care organisations, a degree of flexibility is required in the application of the Standards.

Core actions are critical for safety and quality. All core actions must be met before a health service organisation can be accredited to the NSQHS Standards. Developmental actions do not need to be fully met in order to achieve accreditation, although health service organisations need to demonstrate activity in these areas. Developmental actions are in areas where health service organisations should focus their future efforts and resources to improve patient safety and quality.

The 10 standards, and the number of core and developmental actions for each, is listed in the table below, for both hospitals and day procedure services.

Standards	Hospitals	Day procedure centre
Governance for Safety and Quality in Health Service Organisations	44 core 9 developmental	44 core 9 developmental
Partnering with Consumers	4 core 11 developmental	4 core 11 developmental
Preventing and Controlling Healthcare Associated Infections	39 core 2 developmental	38 core 3 developmental
Medication Safety	31 core 6 developmental	31 core 6 developmental
Patient Identification and Procedure Matching	9 core 0 developmental	9 core 0 developmental
Clinical Handover	9 core 2 developmental	9 core 2 developmental
Blood and Blood Products	20 core 3 developmental	20 core 3 developmental
Preventing and Managing Pressure Injuries	20 core 4 developmental	20 core 4 developmental
Recognising and Responding to Clinical Deterioration in Acute Health Care	15 core 8 developmental	15 core 8 developmental
Preventing Falls and Harm from Falls	18 core 2 developmental	18 core 2 developmental
TOTAL	**209 core** **47 developmental**	**208 core** **48 developmental**

The table below notes the extent to which the national standards address the parts of the proposed Regulations.

Proposed Regulations	Extent to which addressed by national standards
Part 1 Preliminary R1–5	DOES NOT MEET
Part 2 Prescribed Health Services R6–7	DOES NOT MEET
Part 3 Forms of Application and Fees R 8–13	DOES NOT MEET
Part 4 Senior Appointments R14–18	PARTIALLY MEETS
Part 5 Admission of Patients R19–24	PARTIALLY MEETS
Part 6 Care of Patients R25–28	PARTIALLY MEETS
Part 7 Complaints R 29–32	PARTIALLY MEETS
Part 8 Transfer and Discharge of Patients R33–34	MEETS
Part 9 Registers and Records R35–38	DOES NOT MEET
Part 10 Premises and Equipment R39–43	PARTIALLY MEETS
Part 11 Infection Control R45	MEETS
Part 12 Display of Information R46	DOES NOT MEET
Part 13 Statistical Returns R47	DOES NOT MEET
Part 14 Enforcement R48	DOES NOT MEET

Appendix E: Acts that appear in this document

Building Act 1993

Competition and Consumer Act 2010 (Commonwealth)

Copyright Act 1968

Drugs, Poisons and Controlled Substances Act 1981

Financial Management Act 1994

Health Care Act 2008 (SA)

Health Practitioner Regulation National Law Act 2009 (Victoria)

Health Records Act 2001

Health Services (Conciliation and Review) Act 1987

Health Services Act 1988

Hospitals and Health Services Act (WA)

NT Private Hospitals Act

Occupational Health and Safety Act 2004

Planning and Environment Act 1987

Private Health Facilities Act (NSW)

Private Health Facilities Act 1999 (QLD)

Private Health Insurance Act 2007

Public Health and Wellbeing Act 2008

Subordinate Legislation Act 1994

Appendix F: Proposed Regulations

Health Services (Private Hospitals and Day Procedure Centres) Regulations

Exposure Draft

TABLE OF PROPOSALS

Victoria

Health Services (Private Hospitals and Day Procedure Centres) Regulations

Exposure Draft

PART 1—PRELIMINARY

1 Objectives

The objectives of these Regulations are—

(a) to provide for the safety and quality of care of patients receiving health services in private hospitals and day procedure centres by prescribing—

(i) requirements for staffing; and

(ii) procedures for the handling of complaints; and

(iii) records to be kept; and

(iv) other requirements to ensure the welfare of patients; and

(b) to prescribe fees, forms and other matters required or permitted to be prescribed or necessary to be prescribed under the **Health Services Act 1988** in relation to private hospitals and day procedure centres.

2 Authorising provision

These Regulations are made under section 158 of the **Health Services Act 1988**.

3 Commencement

These Regulations come into operation on 8 September 2013.

4 Revocation

The Regulations listed in Schedule 1 are **revoked**.

5 Definitions

In these Regulations—

artificial insemination has the same meaning as in the **Assisted Reproductive Treatment Act 2008**;

assisted reproductive treatment has the same meaning as in the **Assisted Reproductive Treatment Act 2008**;

enrolled nurse means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the nursing and midwifery profession as a nurse (other than as a midwife or as a student); and

(b) whose name appears in the Division of Enrolled nurses (Division 2) of the Register of Nurses;

medical health services means health services provided to a patient by a registered medical practitioner that—

(a) involve diagnosis and non-operative treatment; and

(b) require nursing supervision or care;

National Agency means the Australian Health Practitioner Regulation Agency established under section 23 of the Health Practitioner Regulation National Law.

Register of Nurses means the Register of Nurses kept by the Nursing and Midwifery Board of Australia in accordance with section 222 of the Health Practitioner Regulation National Law;

registered dental specialist means a person registered under the Health Practitioner Regulation National Law—

(a) to practise a health profession (other than as a student); and

(b) whose name appears on the register kept by the Dental Board of Australia in conjunction with the National Agency in accordance with section 223(a) of the Health Practitioner Regulation National Law;

registered dentist means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the dental profession as a dentist (other than as a student); and

(b) whose name appears in the Dentists Division of the Register of Dental Practitioners;

registered health practitioner means a person registered under the Health Practitioner Regulation National Law to practise a health profession (other than as a student);

registered nurse means a person registered under the Health Practitioner Regulation National Law—

(a) to practise in the nursing and midwifery profession as a nurse (other than as a midwife or as a student); and

(b) whose name appears in the Division of Registered nurses (Division 1) of the Register of Nurses;

registered podiatric surgeon means a person registered under the Health Practitioner Regulation National Law—

(a) to practise a health profession (other than as a student); and

(b) whose name appears on the register kept by the Podiatry Board of Australia in conjunction with the National Agency in accordance with section 223(a) of the Health Practitioner Regulation National Law;

speciality health services means health services that are ordinarily undertaken only by, or under the supervision (whether direct or indirect) of, a specialist registered medical practitioner that require—

(a) the admission of the patient; and

(b) the use of specialist equipment; and

(c) the area in which the services are provided to be fitted out specifically for those kinds of services;

surgical health services means health services provided by a registered medical practitioner, registered podiatric surgeon, registered dental specialist or a registered dentist that—

(a) involve the use of—

(i) surgical instruments; and

(ii) an operating theatre, procedure room or treatment room; and

(b) require either—

(i) the attendance of one or more other registered health practitioners; or

(ii) post operative observation of the patient by nursing staff;

surgical instrument includes—

(a) a laser device that disrupts the integrity of epithelial tissue or stroma; and

(b) cannulae used to penetrate subcutaneous tissue for the purpose of removing either tissue or fluid or both tissue and fluid containing body fat;

the Act means the **Health Services Act 1988**;

unit record number means an identifying number unique to a patient that is allocated under regulation 19.

———————

PART 2—PRESCRIBED HEALTH SERVICES

6 Day procedure centres

For the purposes of paragraph (a) of the definition of ***day procedure centre*** in section 3(1) of the Act, the following are health services of a prescribed kind or kinds—

(a) medical health services;

(b) surgical health services;

(c) speciality health services for the provision of—

(i) artificial insemination; or

(ii) assisted reproductive treatment; or

(iii) cardiac services; or

(iv) emergency medicine; or

(v) endoscopy; or

(vi) mental health services; or

(vii) obstetrics; or

(viii) oncology (chemotherapy); or

(ix) oncology (radiation therapy); or

(x) renal dialysis; or

(xi) specialist rehabilitation services.

7 Private hospitals

For the purposes of the definition of ***private hospital*** in section 3(1) of the Act, the following are health services of a prescribed kind or kinds—

(a) medical health services;

(b) surgical health services;

(c) speciality health services for the provision of—

(i) artificial insemination; or

(ii) assisted reproductive treatment; or

(iii) cardiac services; or

(iv) emergency medicine; or

(v) endoscopy; or

(vi) intensive care; or

(vii) mental health services; or

(viii) neonatal services; or

(ix) obstetrics; or

(x) oncology (chemotherapy); or

(xi) oncology (radiation therapy); or

(xii) renal dialysis; or

(xiii) specialist rehabilitation services.

PART 3—FORMS OF APPLICATION AND FEES

8 Application for approval in principle

(1) For the purposes of section 70(2)(a) of the Act, the prescribed form is the form in Schedule 2.

(2) For the purposes of section 70(2)(b) of the Act, the prescribed fee is 64 fee units.

9 Application for transfer or variation of certificate of approval in principle

For the purposes of section 74(2) of the Act—

(a) the prescribed form is the form in Schedule 3; and

(b) the prescribed fee is 16·1 fee units.

10 Application for registration

(1) For the purposes of section 82(2)(a) of the Act, the prescribed form is the form in Schedule 4.

(2) For the purposes of section 82(2)(b) of the Act, the prescribed fee is 55·2 fee units.

11 Annual fees

For the purposes of section 87 of the Act, the prescribed annual fee for a private hospital or day procedure centre registered for the number of beds specified in column 1 of the Table below is the fee specified in column 2 of that Table opposite the relevant number of beds for that hospital or centre.

TABLE

Column 1 *Number of beds for which the private hospital or day procedure centre is registered*	*Column 2* *Fee*
1–26	63·5 fee units
27–50	73·2 fee units
51–75	83·0 fee units
76–100	92·8 fee units
101–150	107·4 fee units
151–200	127·0 fee units
201–300	146·5 fee units
301–400	175·9 fee units
401–500	214·9 fee units
501 or more	263·8 fee units

12 Application for renewal of registration

(1) For the purposes of section 88(2)(a) of the Act, the prescribed form is the form in Schedule 5.

(2) For the purposes of section 88(2)(b) of the Act, the prescribed fee is 54·2 fee units.

13 Application for variation of registration

(1) For the purposes of section 92(2)(a) of the Act, the prescribed form is the form in Schedule 6.

(2) For the purposes of section 92(2)(b) of the Act, the prescribed fee—

(a) in the case of an application for the transfer of the certificate to another person who intends to become the proprietor is 47·8 fee units; and

(b) in any other case is 16·1 fee units.

PART 4—SENIOR APPOINTMENTS

Division 1—Director of Nursing

14 Director of Nursing must be appointed

(1) The proprietor of a private hospital or day procedure centre must appoint a suitably qualified person as the Director of Nursing.

Penalty: 50 penalty units.

(2) For the purposes of subregulation (1), a person is suitably qualified if he or she has a qualification or practical experience in nursing management and is a registered nurse.

15 Acting Director of Nursing

If the Director of Nursing is absent or incapacitated, or the position is vacant, the proprietor of a private hospital or day procedure centre must appoint a person to act as the Director of Nursing during the period of the absence, incapacity or vacancy.

Penalty: 50 penalty units.

16 Secretary must be notified of appointment

The proprietor of a private hospital or day procedure centre must notify the Secretary in writing of the name, qualifications and experience of any person appointed by the proprietor—

(a) as the Director of Nursing; or

(b) to act as the Director of Nursing for a period of more than 28 days—

within 28 days after making the appointment.

Penalty: 20 penalty units.

Division 2—Other appointments

17 Chief Executive Officer and Medical Director

If the proprietor of a private hospital or day procedure centre appoints a Chief Executive Officer or Medical Director (however titled), the proprietor must notify the Secretary in writing of the name, qualifications and experience of the person appointed within 28 days of the appointment.

Penalty: 20 penalty units.

18 Secretary to be notified of termination or vacancy

If the proprietor of a private hospital or day procedure centre terminates the appointment of a Chief Executive Officer or Medical Director (however titled), or the position otherwise becomes vacant, the proprietor must notify the Secretary in writing within 28 days of the termination or vacancy.

Penalty: 20 penalty units.

PART 5—ADMISSION OF PATIENTS

Division 1—Unit record number

19 Unit record number must be allocated

The proprietor of a private hospital or day procedure centre must ensure that a unit record number is allocated to a patient on or as soon as practicable after the admission of the patient to the hospital or centre.

Penalty: 30 penalty units.

Division 2—Information to be given to patients

20 Information about fees and services

(1) The proprietor of a private hospital or day procedure centre must ensure that on or before admission each patient of the hospital or centre is given—

(a) a statement containing information in relation to the health care services provided at the hospital or centre that complies with subregulation (2); and

(b) information about fees to be charged by the hospital or centre and any likely out of pocket expenses which may be incurred by the patient; and

(c) a clear explanation of the treatment and services to be provided to the patient at the hospital or centre.

Penalty: 50 penalty units.

(2) A statement referred to in subregulation (1) must contain information about the following matters—

(a) the quality or standard of health care and services provided in the private hospital or day procedure centre;

(b) courteous treatment of patients;

(c) consideration of a patient's beliefs and ethnic, cultural and religious practices;

(d) consideration of a patient's special dietary needs (if any);

(e) a patient's privacy;

(f) that a patient may request the names and roles of the key health workers involved in the patient's care;

(g) a patient's entitlement to ask for a referral if he or she wants to seek another medical opinion;

(h) that any personal information or identifying material about a patient is dealt with in a confidential manner except—

(i) if necessary to enable another health care worker to assist in the patient's care; or

(ii) if authorised by or under a law;

(i) a patient's consent to treatment;

(j) that a patient may refuse the presence of health workers not directly involved in the patient's care;

(k) that a patient may discharge himself or herself at any time despite the advice of the attending registered health practitioner or staff of the hospital or centre;

(l) that a patient may comment on or complain about the treatment or the quality of the health services or care being provided, including to whom any complaint should be made.

Division 3—Clinical records

21 Clinical record must be created

The proprietor of a private hospital or day procedure centre must ensure that a separate clinical record for each patient is—

(a) created on or as soon as practicable after the admission of the patient to the hospital or centre; and

(b) maintained whenever patients are receiving health services from the hospital or centre.

Penalty: 30 penalty units.

22 Information to be included in clinical record

The proprietor of a private hospital or day procedure centre must take reasonable steps to ensure that each clinical record contains the following information—

(a) the patient's unit record number;

(b) the patient's name, address, date of birth and sex;

(c) the name and contact details of a relative or friend nominated by the patient;

(d) relevant clinical details of the patient including—

(i) clinical history on admission;

(ii) progress notes whenever patients are receiving health services from the hospital or centre;

(iii) any medication ordered or given;

(iv) known allergies and drug sensitivities;

(v) current medication;

(vi) pre-procedure assessment;

(vii) results of any relevant diagnostic tests;

(e) if a procedure is carried out on a patient—

(i) the consent form for the procedure and anaesthesia;

(ii) the date of the procedure;

(iii) the names and signatures of the registered health practitioners carrying out the procedure;

(iv) the type of procedure carried out;

(v) the pre-procedure check list by the attending practitioner or by the assisting nurse;

(vi) administered drugs and dosages;

(vii) a record of any monitoring undertaken;

(viii) a record of any intravenous fluids administered;

(ix) a procedure room report including any procedure findings;

(x) the final diagnosis of the patient on discharge.

Penalty: 30 penalty units.

Note

The **Health Records Act 2001** contains provisions relating to the retention of records. See HPP 4 of the Health Privacy Principles in that Act.

Division 4—Identification of patients

23 Means of identifying patients

The proprietor of a private hospital or day procedure centre must ensure that a patient can be readily identified at all times when the patient is receiving health care or other services at the hospital or centre by—

(a) an identity band or other suitable device attached to the patient; or

(b) a photograph, a copy of which must be attached to the clinical record of the patient.

Penalty: 40 penalty units.

24 Identification of infants

(1) The proprietor of a private hospital or day procedure centre must ensure that if an infant is born at the hospital or centre, at least 2 identity bands or other suitable devices which contain the birth information are attached to that infant—

(a) as soon as practicable after the birth and before leaving the delivery room; and

(b) while the infant remains in the hospital or centre.

Penalty: 30 penalty units.

(2) If, immediately after giving birth to an infant, a mother is admitted as a patient of a private hospital or day procedure centre for—

(a) the receipt of medical services in connection with the birth; or

(b) the provision of nursing services by a suitably qualified nurse that are directly related to the birth—

the proprietor of the hospital or centre must ensure that at least 2 identity bands or other suitable devices which contain the birth information are attached to the infant for as long as the infant remains in the hospital or centre.

Penalty: 30 penalty units.

(3) For the purposes of subregulations (1) and (2), the birth information is—

(a) the surname of the infant;

(b) the full name of the mother;

(c) the unit record number of the mother.

PART 6—CARE OF PATIENTS

Division 1—Management of patient care

25 Respect, dignity and privacy

The proprietor of a private hospital or day procedure centre must ensure that a patient—

(a) is treated with dignity and respect, and with due regard to his or her religious beliefs and ethnic and cultural practices; and

(b) is given privacy; and

(c) is not subjected to unusual routines, particularly with respect to the timing of meals and hygiene procedures, unless the routines are for the benefit of the patient.

Examples

1 Facilities are provided to allow patients to undertake personal activities, including bathing, toileting and dressing in private.

2 Facilities are designed to ensure auditory and visual privacy for patients whenever patients are receiving health services from the hospital or centre.

3 Where facilities are shared, provision is made to ensure patient privacy.

4 Patients are provided with meals in accordance with their religious beliefs and ethnic and cultural practices.

Division 2—Nursing and professional care

26 Nurses must be registered and competent

The proprietor of a private hospital or day procedure centre must ensure that each nurse at the hospital or centre—

(a) is registered in the Register of Nurses; and

(b) is professionally competent through education or experience to provide nursing care at the hospital or centre having regard to the kind or kinds of health services being provided.

Penalty: 50 penalty units.

27 Sufficient nursing staff must be on duty

(1) The proprietor of a private hospital or day procedure centre must ensure that whenever patients are receiving health services from the hospital or centre, a sufficient number of nursing staff are on duty to provide care for those patients.

Penalty: 50 penalty units.

(2) For the purposes of subregulation (1), a sufficient number of nursing staff is—

(a) in the case of a private hospital—

(i) at least one registered nurse for every 10 patients or fraction of that number during day and evening shifts; and

(ii) at least one registered nurse for every 15 patients or fraction of that number during night shifts; or

(b) in the case of a day procedure centre, at least one registered nurse for every 10 patients or fraction of that number.

(3) Despite subregulation (2), in determining the number of nurses on duty, if 3 or more nurses are on duty at a private hospital or a day procedure centre during a shift, up to one-third may be enrolled nurses.

28 Needs of patients must be met

The proprietor of a private hospital or day procedure centre must take reasonable steps to ensure that the needs of patients are met promptly and effectively by nursing staff and other professionally competent registered health practitioners.

Penalty: 50 penalty units.

PART 7—COMPLAINTS

29 Nomination of complaints officer

(1) The proprietor of a private hospital or day procedure centre must nominate a person to receive and deal with any complaints that may be made by, or on behalf of, a patient of the hospital or centre.

Penalty: 50 penalty units.

(2) The proprietor of a private hospital or day procedure centre must take reasonable steps to ensure that every patient and member of the staff of the hospital or centre is informed of the name of the person nominated by the proprietor to receive and deal with complaints.

Penalty: 50 penalty units.

30 Dealing with a complaint

(1) The proprietor of a private hospital or day procedure centre must ensure that a complaint is responded to as soon as practicable after the complaint has been made.

Penalty: 40 penalty units.

(2) The proprietor of a private hospital or day procedure centre must ensure that a complaint is dealt with as discreetly as possible in the particular circumstances.

Penalty: 40 penalty units.

(3) The proprietor of a private hospital or day procedure centre must ensure that the person who made the complaint is informed of the action taken in respect of the complaint.

Penalty: 40 penalty units.

31 Record of complaint

(1) The proprietor of a private hospital or day procedure centre must ensure that a written record is kept of every complaint made by, or on behalf of, a patient of the hospital or centre.

Penalty: 30 penalty units.

(2) For the purposes of subregulation (1), the written record must contain the following information—

(a) the nature of the complaint;

(b) the date of the complaint;

(c) the action taken in respect of that complaint.

(3) The proprietor of a private hospital or day procedure centre must ensure that the written record is kept in a secure place for a period of 7 years after the complaint has been made.

Penalty: 30 penalty units.

32 Person making complaint must not be adversely affected

The proprietor of a private hospital or day procedure centre must take reasonable steps to ensure that a patient of the hospital or centre or a person making a complaint on behalf of the patient is not adversely affected because the complaint has been made.

Penalty: 60 penalty units.

PART 8—TRANSFER AND DISCHARGE OF PATIENTS

33 Transfer of patients

If a patient is transferred from a private hospital or day procedure centre to another health service establishment or health care agency, the proprietor of the hospital or centre must ensure that all information and copies of any documents relating to the patient's medical condition and treatment necessary for the establishment or agency to provide appropriate ongoing treatment or care are sent with the patient.

Penalty: 40 penalty units.

34 Discharge of patients

(1) The proprietor of a private hospital or day procedure centre must take reasonable steps to ensure that a patient being discharged from the hospital or centre is given a clear explanation of any recommendations or arrangements which have been made with respect to the future health care needs of the patient.

Penalty: 60 penalty units.

(2) An explanation referred to in subregulation (1) may be given orally or in writing.

PART 9—REGISTERS AND RECORDS

Division 1—Patient Register

35 Patient Admission and Discharge Register

For the purposes of section 109(1) of the Act, with respect to persons who receive care in the private hospital or day procedure centre—

(a) the prescribed manner is in writing; and

(b) the prescribed period is 7 years; and

(c) the prescribed particulars are—

(i) the unit record number of the patient;

(ii) the full name of the patient;

(iii) the sex of the patient;

(iv) the address and telephone number of the patient;

(v) the patient's date of birth;

(vi) the date of the patient's admission and discharge;

(vii) a description of care received and the status of the patient at discharge;

(viii) if the 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.

Division 2—Staff Register and records

36 Staff Register

For the purposes of section 109(1) of the Act, with respect to staff employed in the private hospital or day procedure centre—

(a) the prescribed manner is in writing; and

(b) the prescribed period is 2 years; and

(c) the prescribed particulars are—

(i) the full name of every member of the nursing staff and other registered health practitioners;

(ii) the date of birth of every member;

(iii) the designation of every member;

(iv) the qualifications of every member;

(v) if applicable, the registration number or code of every member.

Division 3—Other Registers

37 Operation Theatre Register

(1) The proprietor of a private hospital or day procedure centre at which surgical health services or speciality health services for the provision of endoscopy may be carried on must ensure that an Operation Theatre Register is kept at the hospital or centre.

Penalty: 30 penalty units.

(2) For the purposes of subregulation (1), an Operation Theatre Register must be in writing and contain the following information with respect to each procedure performed at the hospital or centre—

(a) the date and time of the procedure;

(b) the unit record number of the patient;

(c) the full name of the patient, his or her sex and date of birth;

(d) the nature of the procedure;

(e) the name of the registered health practitioner undertaking the procedure and assistant (if any);

(f) the name of the anaesthetist and assistant (if any);

(g) the names of attending theatre staff;

(h) any remarks concerning the outcome of the procedure;

(i) the anaesthetic administered;

(j) any anaesthetic or procedural complications encountered.

Note

The **Health Records Act 2001** contains provisions relating to the retention of records. See HPP 4 of the Health Privacy Principles in that Act.

38 Birth Register

(1) The proprietor of a private hospital or day procedure centre in which speciality health services for the provision of obstetrics may be carried on must ensure that a Birth Register is kept at the hospital or centre.

Penalty: 30 penalty units.

(2) For the purposes of subregulation (1), a Birth Register must be in writing and contain the following information with respect to each birth at the hospital or centre—

(a) the date and time of the birth;

(b) the full name of the mother;

(c) the unit record number of the mother;

(d) the sex of the infant;

(e) the names of all health care personnel in attendance at the birth.

(3) The proprietor of a private hospital or day procedure centre must retain a Birth Register for at least 25 years after the date of the last entry.

Penalty: 30 penalty units.

PART 10—PREMISES AND EQUIPMENT

39 Identification of rooms

The proprietor of a private hospital or day procedure centre must ensure that each room in which beds or recovery chairs are provided for the accommodation of patients is clearly identified at the entrance to that room by a sign stating—

(a) the letter or number of that room; and

(b) the number of beds and recovery chairs ordinarily in that room.

Penalty: 10 penalty units.

40 Communications

(1) The proprietor of a private hospital or day procedure centre must ensure that an effective electronic communication system is provided and kept operational at the hospital or centre.

Penalty: 60 penalty units.

(2) For the purposes of subregulation (1), an electronic communication system must—

(a) enable patients and staff to summon assistance; and

(b) enable calls to be made from—

(i) each bed;

(ii) any recovery chair in a recovery room;

(iii) each toilet, shower or bath or other facility used for the bathing of patients;

(iv) any common room, recreational or rest area or other place where patient care is provided.

41 Prevention of scalding

The proprietor of a private hospital or day procedure centre 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.

Penalty: 50 penalty units.

42 Repair and cleanliness of premises

The proprietor of a private hospital or day procedure centre must ensure that the premises are kept—

(a) in a clean and hygienic condition; and

(b) in a proper state of repair; and

(c) free of hazards or the accumulation of materials which may become offensive, injurious to health or likely to facilitate the outbreak of fire.

Penalty: 80 penalty units.

43 Suitability and cleanliness of facilities, equipment, furnishings and fittings

(1) The proprietor of a private hospital or day procedure centre must ensure that facilities, equipment, furnishings and fittings at the hospital or centre are suitable for the kind or kinds of health services being provided by the hospital or centre.

(2) The proprietor of a private hospital or day procedure centre must ensure that facilities, equipment, furnishings and fittings at the hospital or centre are—

(a) kept in a proper state of repair and maintained in good working order; and

(b) kept in a clean and hygienic condition.

Penalty: 80 penalty units.

PART 11—INFECTION CONTROL

44 Infection Control Management Plan

(1) The proprietor of a private hospital or day procedure centre must implement and maintain an Infection Control Management Plan.

Penalty: 80 penalty units.

(2) For the purposes of subregulation (1), an Infection Control Management Plan must provide for the surveillance, prevention and control of infection at the hospital or centre.

(3) Without limiting subregulation (2), an Infection Control Management Plan must—

(a) state its objectives;

(b) identify and assess all the infection risks specific to the hospital or centre which the proprietor knows, or can reasonably be expected to know, exists or may exist, and state how these risks are to be minimised;

(c) provide for an ongoing infection control education program for the staff of the hospital or centre;

(d) state the particulars of training for persons who provide services at the hospital or centre that involve infection control risks;

(e) set out how the proprietor will monitor and review the implementation and effectiveness of the plan.

PART 12—DISPLAY OF INFORMATION

45 Information to be prominently displayed

The proprietor of a private hospital or day procedure centre must display in a prominent position at the entrance foyer or reception area of the hospital or centre the following information—

(a) the certificate of registration of the premises as a private hospital or day procedure centre or a full size copy of the certificate;

(b) the name of the Director of Nursing and, if a Chief Executive Officer or Medical Director (however titled) has been appointed, the name of the Chief Executive Officer or Medical Director;

(c) the name and contact telephone number of the person nominated under regulation 29 to receive and deal with complaints.

Penalty: 20 penalty units.

PART 13—STATISTICAL RETURNS

46 Returns to be made to the Secretary

(1) The proprietor of a private hospital or day procedure centre must prepare a return for each month containing the following information relating to each patient—

(a) unit record number;

(b) campus code;

(c) admission date, time and type of admission;

(d) admission source;

(e) date of birth and country of birth;

(f) indigenous status;

(g) postcode and locality;

(h) marital status and sex;

(i) type of care received and procedures carried out;

(j) health fund and level of insurance;

(k) Medicare number;

(l) account classification;

(m) separation date, time and type;

(n) transfer source;

(o) date of discharge or death;

(p) discharge destination;

(q) final diagnoses on discharge.

Penalty: 40 penalty units.

(2) The proprietor of a private hospital or day procedure centre must prepare a return for each month containing the following information relating to occupancy rates—

(a) the number of separations;

(b) the number of same day separations;

(c) the number of bed days;

(d) the average number of available beds.

Penalty: 40 penalty units.

(3) A proprietor must ensure that a return prepared under this regulation does not include the name or address of a patient.

Penalty: 40 penalty units.

(4) A proprietor must ensure that a return prepared under this regulation is forwarded to the Secretary—

(a) within 17 days after the end of the month to which the return relates; or

(b) if the Secretary has determined a time being not less than 14 days after the end of the month to which the return relates, and has notified a proprietor in writing of that time, within that time.

Penalty: 40 penalty units.

PART 14—ENFORCEMENT

47 Form of notice of seizure

For the purposes of section 147(2)(a) of the Act, the prescribed form is the form in Schedule 7.

SCHEDULES

SCHEDULE 1

Regulation 4

REVOCATIONS

S.R. No.	*Name*
79/2002	Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002
113/2005	Health Services (Private Hospitals and Day Procedure Centres) (Fees) Regulations 2005
176/2009	Health Services (Private Hospitals and Day Procedure Centres) Amendment Regulations 2009
88/2010	Health Services (Private Hospitals and Day Procedure Centres) Amendment Regulations 2010

SCHEDULE 2

Regulation 8(1)

APPLICATION FOR APPROVAL IN PRINCIPLE OF A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

SECTION A

1. Full name of applicant:
2. Postal address of applicant:
3. The name, telephone and facsimile numbers and email address of a contact person for the purposes of the application:
4. If the applicant is a body corporate, the name and address of a director or officer of the body corporate who may exercise control over the private hospital or day procedure centre:

SECTION B

1. The kind of health service establishment to which the application relates is:

   *a private hospital

   *a day procedure centre

2. The name (or proposed name) of the private hospital or day procedure centre, its street address and the municipal district in which the hospital or centre is, or is to be, located:
3. This application is for an approval in principle for:

   *the use of particular land or premises as a private hospital or a day procedure centre;

   *premises proposed to be constructed for use as a private hospital or day procedure centre;

   *alterations or extensions to premises used, or proposed to be used, as a private hospital or day procedure centre;

   *a variation of the registration of a private hospital or day procedure centre to alter the number of beds to which the registration relates;

   *a variation of the registration of a private hospital or day procedure centre to vary the kinds of prescribed health services that may be carried on on the premises;

*a variation of the registration of a private hospital or day procedure centre to vary the number of beds that may be used for the specified kinds of prescribed health services.

SECTION C

In accordance with section 70(3) of the **Health Services Act 1988**, I have given notice in writing of this application to any other person who has an interest in the land as owner or lessee.

Signature of applicant:

Name of each signatory (in BLOCK LETTERS):

Date:

*(Strike out whichever does not apply)

SCHEDULE 3

Regulation 9(a)

APPLICATION FOR TRANSFER OR VARIATION OF CERTIFICATE OF APPROVAL IN PRINCIPLE OF A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

SECTION A

1. Full name of applicant:
2. Postal address of applicant:
3. The name, telephone and facsimile numbers and email address of a contact person for the purposes of the application:

SECTION B

1. The kind of health service establishment to which the application relates is:

   *a private hospital

   *a day procedure centre
2. The name (or proposed name) of the private hospital or day procedure centre, its street address and the municipal district in which the hospital or centre is, or is to be, located:
3. This application is for approval in principle for:

   *variation of the certificate of approval in principle or any condition to which it is subject;

   *transfer of the certificate of approval in principle to another person.
4. Reason for the proposed variation:
5. If the application relates to the transfer of the certificate to another person—

   (a) the name of that person; and

   (b) the postal address of that person; and

   (c) that person's telephone and facsimile numbers and email address.
6. If the transferee is a body corporate, the name and address of any director or officer of the body corporate who may exercise control over the private hospital or day procedure centre:

SECTION C

In accordance with section 70(3) of the **Health Services Act 1988**, I have given notice in writing of this application to any other person who has an interest in the land as owner or lessee.

Signature of applicant:

Name of each signatory (in BLOCK LETTERS):

Date:

*(Strike out whichever does not apply)

SCHEDULE 4

Regulation 10(1)

APPLICATION FOR THE REGISTRATION OF A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

SECTION A

1. Full name of applicant:
2. Postal address of applicant:
3. The name, telephone and facsimile numbers and email address of a contact person for the purposes of the application:
4. If the applicant is a body corporate, the name and address of any director or officer of the body corporate who may exercise control over the private hospital or day procedure centre:

SECTION B

1. The kind of health service establishment for which registration is sought:

   *a private hospital

   *a day procedure centre

2. The proposed name of the private hospital or day procedure centre, its street address and the municipal district in which the hospital or centre is located:
3. The proposed number of beds:
4. The kind or kinds of health service for which registration is being sought:

   *Medical health services

   *Surgical health services

   *Speciality health services for the provision of—

      *Artificial insemination

      *Assisted reproductive treatment

      *Cardiac Services

      *Emergency Medicine

      *Endoscopy

      *Intensive Care

*Mental Health Services

*Neonatal Services

*Obstetrics

*Oncology (Chemotherapy)

*Oncology (Radiation Therapy)

*Renal Dialysis

*Specialist Rehabilitation Services

5. Is the applicant the owner or tenant of the premises?

6. If the applicant is not the owner, please state the name and address of the owner:

Signature of applicant:

Name of each signatory (in BLOCK LETTERS):

Date:

*(Strike out whichever does not apply)

SCHEDULE 5

Regulation 12(1)

APPLICATION FOR THE RENEWAL OF REGISTRATION OF A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

SECTION A

1. Full name of applicant:
2. Postal address of applicant:
3. The name, telephone and facsimile numbers and email address of a contact person for the purposes of the application:
4. If the applicant is a body corporate, the name and address of any director or officer of the body corporate who may exercise control over the private hospital or day procedure centre:

SECTION B

1. The name of the private hospital or day procedure centre and its street address:
2. Date of expiry of current registration:

SECTION C

In accordance with section 88(3) of the **Health Services Act 1988**, I have given notice in writing of this application to any other person who has an interest in the land as owner or lessee.

Signature of applicant:

Name of each signatory (in BLOCK LETTERS):

Date:

SCHEDULE 6

Regulation 13(1)

APPLICATION FOR THE VARIATION OF THE REGISTRATION OF A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

SECTION A

1. Full name of applicant:
2. Postal address of applicant:
3. The name, telephone and facsimile numbers and email address of a contact person for the purposes of the application:

SECTION B

1. The nature of the variation sought:

   *change of the kind of establishment to which the registration applies

   *transfer of the certificate of registration to another person who intends to become the proprietor of the establishment

   *variation of any condition to which the registration is subject

   *an alteration in the number of beds to which the registration relates

   *variation of the kinds of prescribed health services that may be carried on on the premises

   *variation of the number of beds that may be used for specified kinds of prescribed health services
2. Details of the variation sought:
3. If the application relates to the transfer of the certificate of registration to another person, the name, postal address, telephone and facsimile numbers and email address of the proposed transferee.

SECTION C

In accordance with section 92(3) of the **Health Services Act 1988**, I have given notice in writing of this application to any other person who has an interest in the land as owner or lessee.

Signature of applicant:

Name of each signatory (in BLOCK LETTERS):

Date:

*(Strike out whichever does not apply)

SCHEDULE 7

Regulation 47

Health Services (Private Hospitals and Day Procedure Centres)
Regulations 2013

NOTICE OF SEIZURE OF DOCUMENT OR THING FROM A PRIVATE HOSPITAL OR DAY PROCEDURE CENTRE

Name of private hospital or day procedure centre:

Address of private hospital or day procedure centre:

I, (print full name), being an authorised officer of the Department, am seizing under section 147 of the **Health Services Act 1988** the document or thing listed below.

The seized document or thing will be returned to the place of seizure within 48 hours from the time of seizure.

DOCUMENT OR THING SEIZED

1.

2.

3.

Signed: Date: Time:
(Authorised Officer)

Signed: Date: Time:
(Proprietor/staff member)

DOCUMENT OR THING RETURNED

Signed: Date: Time:
(Authorised Officer)

Signed: Date: Time:
(Proprietor/staff member)

ENDNOTES

Fee Units

These Regulations provide for fees by reference to fee units within the meaning of the **Monetary Units Act 2004**.

The amount of the fee is to be calculated, in accordance with section 7 of that Act, by multiplying the number of fee units applicable by the value of a fee unit.

The value of a fee unit for the financial year commencing 1 July 2013 is $12.84. The amount of the calculated fee may be rounded to the nearest 10 cents.

The value of a fee unit for future financial years is to be fixed by the Treasurer under section 5 of the **Monetary Units Act 2004**. The value of a fee unit for a financial year must be published in the Government Gazette and a Victorian newspaper before 1 June in the preceding financial year.

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Penalty Units

These Regulations provide for penalties by reference to penalty units within the meaning of section 110 of the **Sentencing Act 1991**. The amount of the penalty is to be calculated, in accordance with section 7 of the **Monetary Units Act 2004**, by multiplying the number of penalty units applicable by the value of a penalty unit.

The value of a penalty unit for the financial year commencing 1 July 2013 is $144.36.

The amount of the calculated penalty may be rounded to the nearest dollar.

The value of a penalty unit for future financial years is to be fixed by the Treasurer under section 5 of the **Monetary Units Act 2004**. The value of a penalty unit for a financial year must be published in the Government Gazette and a Victorian newspaper before 1 June in the preceding financial year.