ACIL ALLEN CONSULTING

REPORT TO
NEW SOUTH WALES MINISTRY OF HEALTH

15 MAY 2017

PRIVATE HEALTH FACILITIES REGULATION 2017

REGULATORY IMPACT STATEMENT

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ACIL ALLEN CONSULTING 2017, *REGULATORY IMPACT STATEMENT FOR THE PRIVATE HEALTH FACILITIES REGULATION 2017, MAY.*

CONTENTS

EXECUTIVE SUMMARY

The *Private Health Facilities Act 2007* (the Act) and the *Private Health Facilities Regulation 2010* (the Regulation) set out the requirements for licensing and the minimum standards for the provision of safe, appropriate and quality health care for patients in private health facilities in New South Wales (NSW).

The Regulation supports the purpose of the Act by:

- requiring private health facilities to meet minimum standards relating to the safety and quality of services
- prescribing minimum qualifications for certain staff at a private health facility
- requiring private health facilities to display their licence in a prominent place in the entry foyer of the facility
- making provisions for, or with respect to:
  - the particulars that are required to be entered in the register of patients
  - the membership of the facility's medical advisory committee
  - permitting a member of a root cause analysis team to make information available to certain committees in connection with any research or investigation the committee is authorised to conduct
  - the disclosure of certain pecuniary interests
  - the provision of information to the Secretary of the Ministry of Health.

Under the provisions of the *Subordinate Legislation Act 1989*, the *Private Health Facilities Regulation 2010* is due for staged repeal on 1 September 2017. The NSW Ministry of Health (the Ministry) is proposing to remake the 2010 Regulation subject to a number of amendments set out in the *Private Health Facilities Regulation 2017* (the Draft Regulation).

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation (Parliamentary Counsel's Office, 2014).

Objectives sought to be achieved by the Draft Regulation

Potentially preventable incidents arising from health care management continue to occur across both public and private sectors. The problem has been reported in studies conducted nearly a decade apart, indicating persistence despite systemic government responses. Given the significance of the problem overall, and the potentially catastrophic consequences of worst-case incidents, the issues of safety and quality in private health facilities continues to warrant the attention of the NSW Government.

The problems relating to safety and quality of care arise from information asymmetries between health care practitioners and patients, and costs imposed on third partiers from failures to meet adequate

standards. Further, regulation of private health facilities serves an important equity objective in ensuring that all patients, irrespective of location, have access to quality and safe healthcare services. Non-legislative means such as self-regulation, quasi-regulation or provision of information are not sufficient to address the problem.

The Act and the Draft Regulation are intended to protect patients by maintaining appropriate and consistent standards of health care and professional practice in private health facilities and providing a framework for adequate governance, oversight and accountability of private health facilities in NSW.

Options considered

The Ministry has identified the following options to be considered in this RIS.

- **Base Case** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).
- **Option 1** — this option entails remaking the existing Regulation without any changes (the *status quo* option).
- **Option 2** — this option entails making the Draft Regulation, which would entail remaking the existing Regulation with several proposed amendments. Generally, the amendments fall within one or more of the following areas.
    a) Minor rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of private health facilities.
    b) Updated licensing fees.
    c) Updated references to current or more relevant professional standards/guidelines.
    d) Removal of transitional provisions, requirements and standards that are no longer relevant or needed.
    e) Inclusion in the Draft Regulation of requirements that were previously included in the conditions of the licence for certain private health facilities (leaving the obligations of the facilities unchanged).
    f) Changes to definitions in the Draft Regulation.
    g) Changes to the required qualifications for director of nursing (DoN) of a private health facility.
    h) New requirements for private health facilities.

    Most of the amendments proposed under the areas above leave the obligations of private health facilities largely unchanged, except for amendments under areas f) to h) which impose new and/or different requirements (further details of the proposed changes under these areas are provided in Table ES 1). Additional details of the proposed changes under all of the above areas are provided in Chapter 5.

TABLE ES 1 SUMMARY OF SELECTED AMENDMENTS PROPOSED FOR THE REGULATION

Area of change	Proposed change (all clauses refer to the Draft Regulation)
f) Changes to definitions in the Regulation	**Definition Classes of Private Health Facilities (Part 2, Division 1, Clause 6)** The definition of Medical Class has been amended to exclude facilities for the diagnosis or treatment of conditions relating to sleep. **Definition of adverse event (Schedule 1, Division 3, Clause 21(4))** *Adverse event* means an incident or event resulting in: a) a patient suffering a major permanent loss of function (being sensory, motor, physiological or psychological) that is unrelated to the natural course of the illness for which the patient is receiving treatment and differs from the expected outcome of the patient's management, or that necessitates any of the following: i) lengthening the patient's stay at the facility, ii) surgical intervention, or b) a patient suffering significant disfigurement, or c) a risk of serious and imminent harm to a patient due to the patient's absence from the facility contrary to medical advice, or d) a patient being physically or verbally assaulted, or threatened with such assault, causing the facility to request external or police intervention.
g) Changes to the required qualifications for director of nursing of a facility.	**Qualifications for director of nursing of facility (Part 3, Clause 14)** Minimum necessary qualifications for a registered nurse to be appointed as director of nursing have been changed to 5 years post basic or post graduate nursing experience *and* 1 year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital.
h) New requirements	**Schedule 2, Part 4 Chemotherapy class private health facilities** The following new standards have been added to the Draft Regulation. – A chemotherapy class private health facility must have written policies and procedures for: a) the provision of information and counselling to patients and their relatives, and b) the admission and discharge of patients, including continuing care and review, and c) the management of side effects, and d) access to relevant specialists for consultation. – A chemotherapy class private health facility must ensure that the clinical record for each patient who receives a cytotoxic drug includes: a) a written treatment plan based on the assessment of the patient, and b) a signed record of the patient's consent to the treatment. – The medical advisory committee of a chemotherapy class private health facility must include a specialist oncologist or a consultant physician trained in oncology when matters relating to cytotoxic agents are discussed. – A chemotherapy class private health facility must ensure that treatment plans outside the scope of normal clinical practices are regularly and independently reviewed and audited.

SOURCE: MINISTRY OF HEALTH AND ACIL ALLEN CONSULTING.

Assessment of options

The following sections summarise the assessment of impacts of the regulatory options outlined above. The first section assesses the expected impacts of the Base Case (i.e. of letting the Regulation sunset) and the second section assesses the impacts of the proposed Draft Regulation (Option 2) against the status quo, i.e. the current Regulation (Option 1).

The benefits and costs associated with the alternative options are not amenable to quantification due to the unfeasibility of measuring the scale of avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way, and the relatively marginal impact of the possible changes. As such, these impacts are discussed qualitatively. In addition, in preparing this RIS, selected stakeholder consultations were conducted with a number of organisations. Where relevant, key comments made by stakeholders have been included in the discussion. These views need to be

further tested during the public consultation period before a decision is made about the remaking of the Regulation.

Impacts of letting the Regulation sunset (the Base Case)

The likely general implications of letting the Regulation sunset are that:

- the Act would be unable to fully operate in the absence of legislative detail
- private health facilities would still be required to be licensed under the Act, but there would be no minimum standards that they would have to meet in relation to the safety and quality of services
- a private health facility's licence could not be cancelled for non-compliance with the standards (as there would be none)
- private health facilities would be self-regulated and governed by voluntary accreditation standards.

Broadly, the benefits of discontinuing the Regulation would include:

- elimination/reduction of compliance and administrative costs for private health facilities
- reduced regulatory costs for the NSW Government in administering the licensing regime, including administrative, monitoring and enforcement costs
- a potential increase in:
  - the number of private health facilities in NSW and the range of treatments offered by those facilities
  - competition in the industry, and associated impacts on the pricing of services.

The costs associated with eliminating minimum standards and relying on industry self-regulation include:

- provision of health services in facilities that may not be adequately equipped and resourced to safely provide those services, which could result on:
  - a potential decreased in the quality of care for patients
  - increased risks to the safety and quality of services
- increased information asymmetries due to lack of information regarding performance/safety of private health facilities
- having a licensing regime which is in effect unable to operate.

Overall, letting the Regulation sunset is not considered appropriate as the risks and costs associated with eliminating minimum standards and relying on industry self-regulation are considered to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

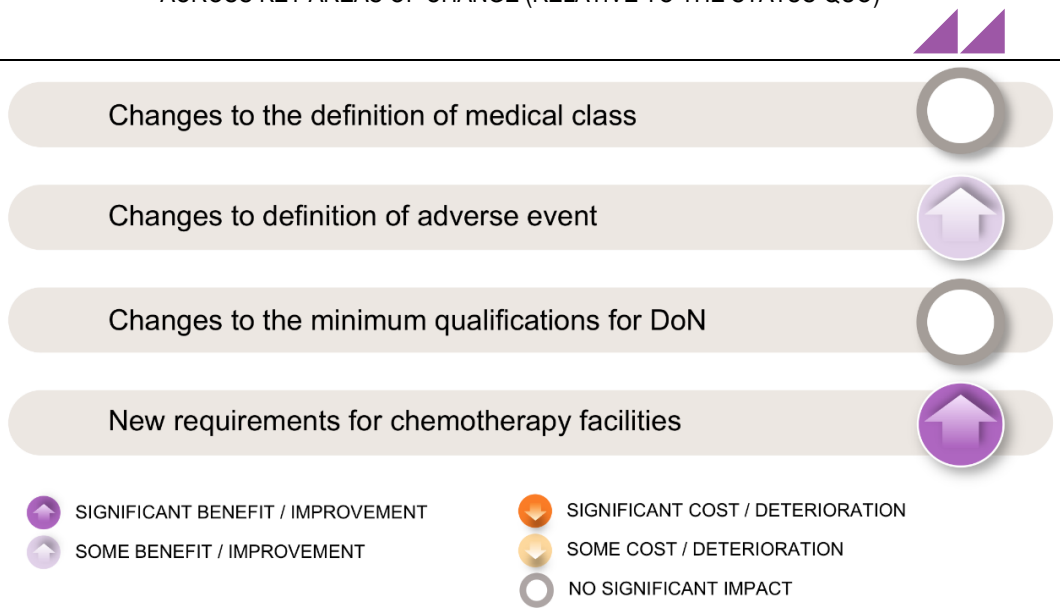
Impacts of the proposed Regulation (Option 1 and Option 2)

As noted before, most of the amendments proposed for the Regulation under Option 2 leave the obligations of private health facilities largely unchanged, except for amendments under areas f) to h) in Table ES 1. In light of this, the analysis of the impacts of the Draft Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1) has been structured around the following four areas, rather than around each of the options.

1. Changes to the definition of medical class.
2. Changes to the definition of adverse event.
3. Changes to the required qualifications for director of nursing of a private health facility.
4. New requirements for chemotherapy private health facilities.

As discussed before, the benefits and costs associated with the alternative options are not amenable to quantification. However, Figure ES 1 provides a summary of the relative nature of the benefits and costs of the changes proposed under Option 2 across the four areas outlined above, with respect to Option 1 (i.e. the *status quo*).

FIGURE ES 1 SUMMARY OF POTENTIAL RELATIVE IMPACTS OF THE PROPOSED REGULATION ACROSS KEY AREAS OF CHANGE (RELATIVE TO THE STATUS QUO)



SOURCE: ACIL ALLEN CONSULTING.

Changes to the definition of medical class

Excluding facilities for the diagnosis or treatment of conditions relating to sleep from the definition of medical class in the Draft Regulation would result in reduced costs for:

- the three current licensed private health facilities purely dedicated to the diagnosis or treatment of conditions relating to sleep which would no longer need a license to operate, and any future facilities of this type
- any facilities that offer a range of services but which only have a medical class license for the purpose of sleep studies which would no longer need a medical class license (facilities that would still be required to be licensed as medical class for other services they offer would not experience any cost savings)
- the Ministry in administering and monitoring current (and future) licenses for the above type of facilities.

It is unclear that excluding facilities dedicated to the diagnosis or treatment of conditions relating to sleep from the requirement to obtain a medical class license would result in increased risks to patient's safety because:

- the services provided at sleep facilities are considered to be relatively low risk, with diagnosis carried out through non-invasive tests and more complex/riskier treatments (e.g. surgery) carried out at appropriate licensed facilities
- there are several unlicensed facilities lawfully providing diagnosis and treatment of sleep conditions across NSW. Sleep clinics are only currently required to be licensed if they provide services to admitted patients
- the Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities. In the absence of a licensing requirement, facilities would still be expected to meet safety and quality standards based on:
  - accreditation imperatives — for instance, the Australasian Sleep Association (ASA) / National Association of Testing Authorities (NATA) Sleep Disorders Services Accreditation Program, which sets out minimum standards for sleep disorders services
  - insurance requirements
  - liability and reputational concerns
  - professional standards and obligations of registered health practitioners.

Changes to the definition of adverse event

The aims of the proposed changes to the definition of adverse event and incident are to:

- tighten the current definition (which is very broad) so that there is increased clarity for facilities about the type of events for which their incident management systems should include policies/procedures
- align with public health facilities' requirements for "Major Clinical Consequences" (as per the Ministry of Health Policy Directive PD2014_004 Incident Management Policy, MoH 2014).

In this respect, the intent of the proposed changes is not to increase reporting or incident management obligations, but rather to clarify them.

The changes proposed to the definition of adverse event in the Draft Regulation would not change the number of incidents that have to be reported to the Ministry (these incidents are determined by the definition of reportable incident, which would remain unchanged). However, under the proposed changes to the Regulation, some events identified as adverse would also be reportable incidents (i.e. all reportable incidents under the current Regulation would also be considered adverse events under the proposed Regulation but not all adverse events under the Draft Regulation will be considered reportable incidents – these would remain unchanged under both scenarios).

A tightened definition of adverse event would help to ensure that incident management systems in private health facilities include policies/procedures for all relevant major adverse events and incidents. Broadly, this could result in:

- increased accountability of private health facilities
- improved organisational learning from incidents, including near-miss events and system failures, to mitigate future risk
- a potential reduction of risks of unsafe or inappropriate practices, incidents and events
- improved dissemination of information on patient care and quality.

The proposed changes to the definition of adverse event in the Draft Regulation may result in additional administrative/compliance costs for facilities due to potential revisions to their policies and guidelines and incident management systems. However, the Ministry does not expect the proposed changes to the definition of adverse event to result in an increase in the number of events identified, reported and investigated by private health facilities as adverse.

Changes to the required qualifications for director of nursing of a private health facility

The proposed reduction in the minimum qualifications required for a DoN would increase the pool of people who are eligible for the position, making it easier to recruit and decreasing facilities' staff search costs. However, the changes are unlikely to result in meaningful reductions of staff costs as staff in these positions are generally payed in accordance with their grading/title, which will remain as director of nursing.

It is likely that larger facilities may continue to employ a DoN with extensive clinical nursing and administrative management experience (equivalent to, or above the current minimum requirements in the Regulation) to minimise risks given the scope of the role. However, smaller and/or regional facilities (who may have a reduced pool of skilled people available for the role) are more likely to employ directors of nursing with lower qualifications and/or experience as allowed by the decreased minimum requirements in the Draft Regulation.

It is unclear whether the changes proposed to the minimum qualifications required for a DoN would lead to any increased risks on patients' safety (in some circumstances, a slightly less experienced DoN would be more appropriate for smaller facilities providing less complex/risky services, but this may not be the case for all facilities under all circumstances). However, it is worth noting that:

- the proposed changes are relatively small, leaving the requirements of post basic/post graduate nursing experience unchanged, but reducing the required administrative experience by one year[1]

[1] It is noted that this proposed change is different to the change on which feedback was sought during the consultations undertaken with selected stakeholders for this RIS. The change on which views were gathered from stakeholder was to change the qualifications of DoN to five years post basic or post graduate nursing experience, *or one* year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital. This was subsequently changed by the Ministry.

- as mentioned before, it is likely that larger/riskier facilities will continue to employ a DoN with extensive clinical nursing and administrative management experience and it is possible that a less experienced DoN is more appropriate for smaller facilities providing less complex/risky services
- as noted previously, the Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities.

New requirements for chemotherapy private health facilities

The proposed new standards for chemotherapy class private health facilities are likely to result in:

- improved governance of chemotherapy treatments in private health facilities
- improved dissemination of information to patients about their care and treatment
- improved transparency of chemotherapy class private health facility policies and procedures
- reduced risks of unsafe or inappropriate practices.

Ultimately, these effects are considered likely to improve the quality of health care provided by private chemotherapy facilities in NSW.

The new standards are likely to result in additional minor administrative/compliance costs for facilities. While many large and/or specialised chemotherapy facilities already have in place best practice policies and procedures similar to the new requirements in the Draft Regulation (and hence would not incur any additional compliances costs), the impact could be different for smaller facilities where there is a greater variation in meeting best practice standards.

The Ministry does not expect the proposed additional requirements to result in increased monitoring activities or increased costs of administering the Draft Regulation.

Conclusion

The Act and the Draft Regulation are intended to protect patients by maintaining appropriate and consistent standards of health care and professional practice in private health facilities in NSW.

Letting the Regulation sunset is not considered appropriate as discontinuing the Regulation would mean that the Act would be unable to fully operate, resulting in a licensing regime which is in effect inoperable. This would increase the risks to the safety and quality of services provided and information asymmetries due to lack of information regarding performance/safety of private health facilities. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to government and industry related to reduced compliance and administrative costs.

In relation to the four key changes proposed for the Draft Regulation, the following is concluded.

- Overall, it is considered unlikely that excluding facilities dedicated to the diagnosis or treatment of conditions relating to sleep from the requirement to obtain a medical class license would significantly increase risks to patient's safety because:
  - the services provided at sleep facilities are considered to be relatively low risk, with diagnosis carried out through non-invasive tests and more complex/riskier treatments (e.g. surgery) carried out at appropriate licensed facilities
  - there are several unlicensed facilities lawfully providing diagnosis and treatment of sleep conditions across NSW
  - there are a range of other mechanisms to help ensure patient safety and quality in clinics providing services relating to the diagnosis and treatment of sleep conditions.

  To the extent that excluding sleep facilities from the definition of medical class in the Draft Regulation does not increase risks to patients' safety, then the proposed change would result in minor compliance and administrative cost savings (both for industry and government), as there is only a small number of currently licensed facilities that would no longer need to be licensed.
- Provided that the proposed changes to the definition of adverse event and incident reduce the level of interpretation of the requirements currently required by facilities, and increase clarity about the type of events for which private health facilities should have policies and procedures in place, the change is expected to be overall beneficial.

— If the proposed changes to the necessary qualifications for a registered nurse to be appointed as DoN of a private health facility achieve the right balance of minimum consistent qualification requirements for all facilities without increasing the overall risks to patients, then the change would be beneficial for those facilities which have difficulties fulfilling the DoN role due to low number of applicants with the current required minimum qualifications. These benefits are unlikely to be major as the proposed changes only decrease the required administrative experience by one year.

  Overall, it is considered unlikely that the proposed changes to the DoN qualifications would lead to a significant increase in risk to patients' safety because:

  – the proposed changes are relatively small, leaving the requirements of post basic/post graduate nursing experience unchanged, but reducing the required administrative experience by one year
  – it is likely that larger/riskier facilities will continue to employ a DoN with extensive clinical nursing and administrative management experience and it is possible that a less experienced DoN is more appropriate for some facilities providing less complex/risky services (but this may not be the case for all facilities under all circumstances)
  – as noted previously, the Draft Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities.

— The benefits from reduced risks and improved patient outcomes stemming from the proposed new requirements for chemotherapy private health facilities are likely to outweigh the additional administrative/compliance costs related to the proposed changes.

  However, the Ministry would like to hear submission on whether the proposed changes in the Draft Regulation are appropriate before a final decision is made regarding pursuing the proposed changes.

Next steps

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft Regulation and respond accordingly. Key issues on which stakeholder views are sought include the following:

— Is it appropriate to exclude facilities that provide services relating to the diagnosis or treatment of conditions relating to sleep from the definition of medical class in the Draft Regulation?

— Is the new proposed definition of adverse event appropriate?

— Should the necessary qualifications for a registered nurse to be appointed as DoN of a private health facility be changed to five years post basic or post graduate nursing experience, and *one* year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital? Does this change achieve the right balance between the needs of different facilities?

— Are the proposed new standards for chemotherapy private health facilities appropriate?

— Are there any costs and benefits of the Draft Regulation that have not yet been considered, and how material are these impacts?

— Are there any risks of the Draft Regulation that have not yet been considered?

In addition to feedback on the proposed Draft Regulation, the Ministry would also like to hear stakeholder views on a number of other issues. These issues are outlined in Box ES 1 and Box ES 2.

Consistent with the *Subordinate Legislation Act 1998*, the RIS and Draft Regulation will be open for public consultation until **30 June 2017**. Submissions received as part of the consultation process will be considered in finalising the Draft Regulation.

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au.

Individuals and organisations should be aware that generally any submissions received will be publically available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry of Health, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

BOX ES 1 ADDITIONAL AREA FOR CONSIDERATION BY STAKEHOLDERS: STANDARDS FOR RADIOTHERAPY AND CHEMOTHERAPY CLASS PRIVATE HEALTH FACILITIES

Standards for radiotherapy and chemotherapy class private health facilities

The Ministry would like to hear submissions as to whether additional standards should apply to radiotherapy and chemotherapy class of private health facilities in relation to providing a multidisciplinary model of care and, in relation to radiotherapy, requiring facilities to have a system for independent dosimetry auditing of linear accelerators (linacs) and their associated treatment planning systems.

The radiotherapy and chemotherapy class do not have any standards relating to the provision of treatment in the context of a multidisciplinary approach. This can be contrasted, for example, with the standards for the rehabilitation class, which contain requirements relating to a multidisciplinary approach to treatment.

The Ministry considers that radiotherapy and chemotherapy is best delivered through an integrated and multidisciplinary model as part of a quality comprehensive cancer service. This includes clear linkages to a number of sub-speciality disciplines such as medical oncology, surgical oncology, clinical haematology, palliative care and rehabilitation. In addition, radiotherapy and chemotherapy services need to have an appropriate level of clinical support services, such as diagnostic imaging, nuclear medicine, pathology, intensive care unit and pharmacy services to support the delivery of quality services, and the skilled workforce necessary to provide a quality sustainable service. On-site or networked services in supportive care, psychosocial assistance and pharmacy services are also required. This comprehensive service model is provided by a range of health professionals including medical, technical, nursing and allied health professionals. Services need to have an appropriately skilled specialist workforce and support staff to provide a safe and quality service for patients.

In addition, in relation to radiotherapy class, to safeguard the quality and safety of a radiation oncology service, equipment should be well maintained, in good working order and linacs should be subject to dosimetry auditing to ensure the delivery of radiation dose is accurate and consistent.

The Ministry is therefore considering amendments to the standards applicable to radiotherapy and chemotherapy class private health facilities to include requirements relating to a multidisciplinary approach to treatment and, in relation to radiotherapy class, dosimetry auditing. These standards would be along the lines of requiring facilities to:

- have a written policy on the provision on radiotherapy/ chemotherapy services including:
  - consultation and referral pathways to sub-specialities disciplines
  - access to clinical support services
- have specialists for consultation
- have sufficient appropriate practitioners for the services provided, including radiation therapists, radiation oncologists and medical physicists or, in relation to chemotherapy, medical oncologists.

In relation to radiotherapy class, this would also require facilities to ensure that their equipment is maintained in good working order, including having a system for independent dosimetry auditing of linacs.

Including a requirement in relation to the above standards would be expected to result in only minimal additional costs for facilities as most facilities would be likely to already be complying. The cost of dosimetric auditing would on average be $15,000 per year for a service with two linear accelerators, with additional costs of approximately $22,500 for an audit of a linac prior to its commissioning. The terms and conditions of funding for the Commonwealth Government's Radiation Oncology Health Program Grants (ROHPG) Scheme will require that radiation oncology facilities must undergo mandatory ongoing independent dosimetry auditing, prior to submitting an application for ROHPG funding. The Ministry would expect that most, if not all, radiotherapy class facilities are likely to apply for ROHPG funding and will be subject to this condition of funding. Therefore, the proposal would not be imposing additional costs for this dosimetry auditing requirement where a facility is subject to the funding conditions under the ROHPG Scheme.

Question for consideration

Should the Private Health Facilities Regulation be amended to include specific standards for radiotherapy and chemotherapy class private health facilities relating to a multidisciplinary approach to treatment and, in respect of radiotherapy class, dosimetry auditing?

SOURCE: NSW MINISTRY OF HEALTH.

BOX ES 2 ADDITIONAL AREA FOR CONSIDERATION BY STAKEHOLDERS: EXCLUSION OF DENTAL SERVICES FROM ANAESTHESIA AND SURGICAL CLASS

Exclusion of dental services from anaesthesia and surgical class

The Ministry would like to hear submissions on whether the current exclusion of certain dental services from the anaesthesia and surgical class private health facilities remain appropriate.

Clause 6 of the Draft Regulation sets out the types of classes of private health facilities and relevantly provides:

> *anaesthesia (being a facility licensed for the treatment of patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include sedation provided in connection with dental procedures),*
>
> *surgical (being a facility licensed for surgical procedures performed on patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include a surgical procedure carried out by a dentist).*

The definition above is relevantly the same as is the case under the current Regulation.

The definition of these classes mean that facilities providing dental procedures are only required to be licensed if the procedure is carried out using general, epidural or major regional anaesthetic. On the other hand, if the facility only uses more than conscious sedation, the facility is not required to be licensed.

The exclusion of facilities that carry out dental practices using more than conscious sedation from private health facility licensing is in part a reflection of historical practices whereby dental practitioners have carried out dental surgery using more than conscious sedation in dental surgery, with dental regulators (currently the Dental Board of Australia) setting standards relating to the use of sedation. Further, there are other public protections in place to protect patients. The Health Practitioner Regulation National Law (NSW)[2] also sets limits on how sedation is used in dental practices and prohibits a dentist from administering more than simple sedation by the intravenous route unless the dentist:

- has been endorsed by the Dental Board of Australia to administer sedation; and
- is assisted by another person who is either:
  - a registered nurse who has received training in intensive care or anaesthesia; or
  - a dentist, appropriately trained in the observation and monitoring of sedated patients and in resuscitation, whose sole responsibility in assisting is to monitor the level of consciousness and cardio-respiratory function of the patient and to administer resuscitation if necessary.

In addition, the current exclusion is also reflective of the nature of dental surgery, particularly involving children. Dental surgery involving children may often be carried out using sedation. However, as sedation is a continuum it can be difficult to determine in advance whether conscious sedation or more than conscious sedation will be occur in practice. Requiring dental practices that use more than conscious sedation to be licensed could therefore inadvertently require all dental practices that carry out dental surgery to be licensed. This could result in an increase in costs, which would be passed onto patients, and could result in patients (particularly children) from disadvantaged socio-economic groups being unable to obtain treatment.

The Draft Regulation retains the exclusion of the requirement of licensing for facilities that carry out dental surgery using more than conscious sedation. However, the Ministry would like to hear submission on whether it remains appropriate to retain the current exclusion.

Question for consideration

Should facilities carrying out dental surgery or practices using more than conscious sedation continue to be excluded from the requirement to obtain a private health facility license?

SOURCE: NSW MINISTRY OF HEALTH.

[2] Section 121A of the Health Practitioner Regulation National Law (NSW).

1 INTRODUCTION

The *Private Health Facilities Act 2007* (the Act) and the *Private Health Facilities Regulation 2010* (the Regulation) set out the requirements for licensing and the minimum standards for the provision of safe, appropriate and quality health care for patients in private health facilities in New South Wales (NSW).

The Regulation supports the purpose of the Act by:

- requiring private health facilities to meet minimum standards relating to the safety and quality of services
- prescribing minimum qualifications for certain staff at a private health facility
- requiring private health facilities to display their licence in a prominent place in the entry foyer of the facility
- making provisions for, or with respect to:
  - the particulars that are required to be entered in the register of patients
  - the membership of the facility's medical advisory committee
  - permitting a member of a root cause analysis team to make information available to certain committees in connection with any research or investigation the committee is authorised to conduct
  - the disclosure of certain pecuniary interests
  - the provision of information to the Secretary of the Ministry of Health.

Since 2010 there have been minor changes to the Regulation including (amongst other) to include provisions and standards for facilities that perform cosmetic surgery, to increase the licencing fees and to set out the type of incidents that are reportable.

Under the provisions of the *Subordinate Legislation Act 1989*, the *Private Health Facilities Regulation 2010* is due for staged repeal on 1 September 2017. The NSW Ministry of Health (the Ministry) is proposing to remake the Regulation subject to a number of amendments. The proposed remake of the Regulation is set out in the Draft Private Health Facilities Regulation 2017 (Draft Regulation).

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a Regulatory Impact Statement (RIS) and a period of public consultation (Parliamentary Counsel's Office, 2014). The primary purpose of a RIS is to ensure that the costs and benefits of regulatory proposals are fully examined so that affected stakeholders can be satisfied that the benefits of the regulation exceed the costs. To achieve these ends, the *Subordinate Legislation Act 1989* requires a RIS to contain certain information including:

- an analysis of the nature and extent of the problem sought to be addressed by the regulation and establishing the need for regulation
- a statement of the objectives sought to be achieved by the regulation
- the identification of the alternative options by which those objectives can be achieved

- an assessment of the costs and benefits of the impacts of the alternative options
- an assessment as to which of the alternative options involves the greatest net benefit or the least net cost to the community
- a statement of the consultation program to be undertaken.

In addition to the *Subordinate Legislation Act 1989*, the introduction of regulations in NSW is also governed by Better Regulation Principles. The principles (Box 1.1), introduced in 2008, are intended to be a best practice guide for policy development and regulatory design process and must be followed in the development of every regulatory proposal.

In light of this, the chapters in this report are structured around the RIS content requirements and the application of the Better Regulation Principles.

BOX 1.1 THE BETTER REGULATION PRINCIPLES

- **Principle 1:** The need for government action should be established
- **Principle 2:** The objective of government action should be clear
- **Principle 3**: The impact of government action should be properly understood by considering the costs and benefits of a range of options, including non-regulatory options
- **Principle 4:** Government action should be effective and proportional
- **Principle 5**: Consultation with business and the community should inform regulatory development
- **Principle 6:** The simplification, repeal, reform or consolidation of existing regulation should be considered
- **Principle 7:** Regulation should be periodically reviewed, and if necessary reformed to ensure its continued efficiency and effectiveness

SOURCE: HTTP://WWW.DPC.NSW.GOV.AU/PROGRAMS_AND_SERVICES/BETTER_REGULATION/REGULATORY_IMPACT_ASSESSMENT

2 NATURE AND EXTENT OF THE PROBLEM

When conducting a review of a Regulation due to be repealed, it is important to clearly demonstrate that the Regulation is still relevant. This consists of two steps. First, it is necessary to identify that a problem exists. Second, the RIS should demonstrate that the problem is amenable to a government intervention and that a regulatory response is appropriate.

This chapter addresses the first requirement through outlining the nature and extent of the problem that the Regulation intends to address. Chapter 3 will assess the case for government intervention.

2.1 Safety and quality in private health facilities

The Regulation and Draft Regulation aim to support the objectives of the Act in maintaining appropriate and consistent standards of healthcare and professional practice in private health facilities, along with comprehensive, balanced and coordinated health services throughout NSW. Essentially, this can be understood as ensuring that private health facilities provide safe and quality care to patients and that this standard is consistent across the state.

The Australian Safety and Quality Framework for Health Care, endorsed by the Australian Health Ministers in 2010, defines three core principles for safe and high-quality care. These are that care is (ACSQHC, 2010):

- consumer centred, meaning that:
  - it is easy for patients to get care when they need it
  - healthcare staff respect and respond to patient choices, needs and values
  - there are partnerships between patients, their family, carers and healthcare providers
- driven by information, meaning that:
  - up-to-date knowledge and evidence is used to guide decisions about care
  - safety and quality data are collected, analysed and fed back for improvement
  - action is taken to improve patients' experiences
- organised for safety, meaning that:
  - safety is a central feature of how healthcare facilities are run, how staff work and how funding is organised.

An analysis of adverse events in NSW and South Australian hospitals (including both private and public facilities) classified the main causes of adverse events (Harrison et al. 1999) as:

- the technical performance of a procedure or operation
- failure to use and act upon available information
- failure to request or arrange an investigation, procedure or consultation
- a lack of care and attention to the patient.

The study identified several prevention strategies, including new, better, or better implemented policies or protocols, more or better formal quality monitoring or assurance processes, better education and training, and more consultation with other specialists or peers (Harrison et al. 1999).

The consequences of a failure in safety and quality are diverse, ranging from relatively minor to catastrophic. These include:

- inconvenience to patients and their families
- loss of earnings for patients and carers
- cost of investigations, complaints handling and inquiries
- costs arising from legal action and claims
- resources required to remedy adverse or unexpected events
- extended or additional treatment, rehabilitation or care
- decreased quality of life
- loss of life.

2.2 Extent of the problem

This section discusses the frequency at which poor safety and quality outcomes in healthcare occur in Australia and NSW and examines the likely economic costs of adverse events and incidents. Given that regulations in relation to healthcare have existed at both Commonwealth and state/territory levels for several decades, the analysis is limited to failures of safety and quality and the associated costs occurring even when regulation is in place. The likely outcomes without regulation are discussed in Chapters 5 and 6.

Overall, there is a relative paucity of information in relation to the quality of private healthcare in NSW. Therefore, in assessing the presence and prevalence of the problem, this section draws on a range of Australian sources, highlighting data specific to private health facilities in NSW where possible.

The 1995 Quality in Australian Health Care Study (QAHC) is the seminal research on adverse events among hospitalised patients. Covering 28 public and private hospitals in NSW and South Australia, the study found that 16.6 per cent of patient admissions were associated with an adverse event caused by health care management. Half of the incidents were considered preventable. The consequences ranged from temporary disability resolved within 12 months in 77.1 per cent of incidents, to permanent disability in 13.7 per cent of cases and patient death in 4.9 per cent of incidents. On average, adverse events resulted in 7.1 additional days in hospital (Wilson et al. 1995).

A repeat of the study would be costly (Hamilton et al. 2014). However, in the two decades since the study was published, a range of data sources on safety and quality of healthcare in Australia have been developed, largely as part of a government response to the QAHC study.

The Australian Institute of Health and Welfare (AIHW) reports that around 30 per cent of adverse events were recorded in private hospitals in Australia in 2014-15, equating to a rate of 4.1 incidents per 100 separations. The incidents include a broad category of events, such as infections, falls resulting in injuries, and problems with medication and medical devices. Some of the adverse events may be preventable (AIHW, 2016).

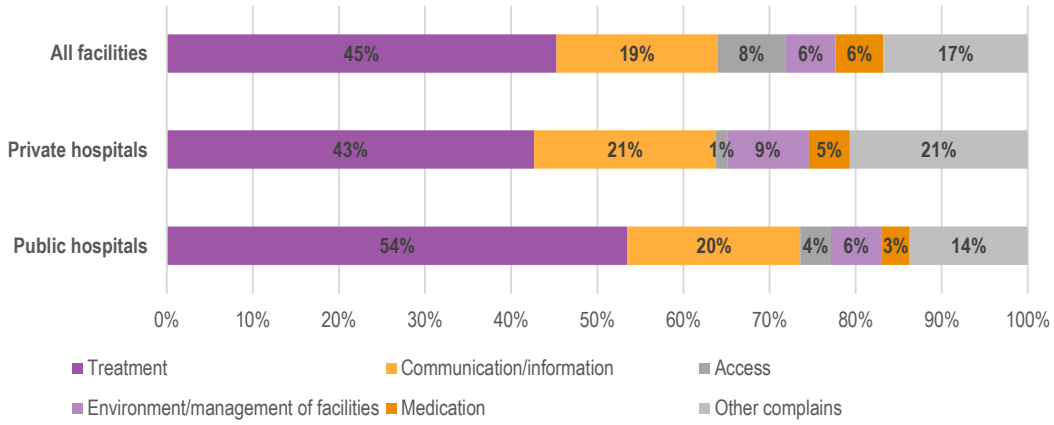
The Australian and New Zealand Audit of Surgical Mortality collects data from surgical mortality audits, but does not report on public and private providers separately. Further, only 47 per cent of NSW private hospitals participated in 2015, in contrast to other states and territories where all eligible facilities participated in the survey. Nonetheless, while not fully representative of NSW private hospitals, the findings show that the quality and safety of clinical management remains an important consideration in Australia. The audit found that there was significant criticism of clinical management in 12.4 per cent of cases, and that clinical management caused or contributed to death in nearly 20 per cent of cases (RACS, 2016).

The NSW Health Care Complaints Commission (HCCC) captures an important facet in safety and quality of healthcare through monitoring and resolving patient complaints. In 2015-16, the HCCC

received 113 complaints about private hospitals, accounting for 5.2 per cent of the total complaints against health organisations.

Figure 2.1 shows the most common issues raised by complainants. The types of complaints made in relation to private hospitals differ somewhat from those made about public hospitals. Overall, fewer complaints about private hospitals relate to the treatment, while a slightly large proportion are about the environment and management of facilities. Cost of care is raised in 9.5 per cent of complaints about private hospitals, but is unsurprisingly almost absent in relation to public facilities.

FIGURE 2.1 MOST COMMON ISSUES RAISED IN COMPLAINTS ABOUT HEALTH ORGANISATIONS 2015-16



SOURCE: NSW HEALTH CARE COMPLAINTS COMMISSION ANNUAL REPORT 2015-16.

2.2.1 The cost of poor safety and quality

A number of studies have attempted to measure the economic costs resulting from poor safety and quality in healthcare in Australia. While these studies do not directly relate to NSW private health facilities, they provide a useful insight into preventable incidents arising from health care management in both the public and private health care sectors. [3]

Drawing on the Quality in Australian Health Care study, discussed in the section above, a further investigation of the 12 most common adverse event types found that the total average cost of treating the resulting injuries amounted to nearly $1 million per 10,000 hospital discharges, equating to 2-3 per cent of the annual budget of a typical Australian community hospital with 120 beds (Rigby and Litt, 2000).

A study on adverse events in Victorian hospitals, covering 86.4 per cent of inpatient activity weighted based on complexity, found that admissions with an adverse event lasted on average 10 days longer and were associated with a seven-fold increase in the risk of in-hospital death. This translated to an annual cost of $460 million in the Victoria dataset alone. Assuming that half of the incidents would have been preventable, this translates to a cost nationally of around $1 billion (Ehsani, Jackson and Duckett, 2006).

Lastly, a study on potentially preventable adverse events in Australian acute care hospitals found that the direct medical costs exceeded $2 billion per year and that the total life-time costs may be twice as much (Runciman and Moller, 2001).

[3] The studies quantifying the cost of shortfalls in safety and quality in Australia discussed in this section are the most up to date studies identified in the literature. Sources consulted by ACIL Allen during the literature search included, amongst other, the Australian Commission on Quality and Safety in Health Care and the NSW Clinical Excellence Commission. Studies discovered but not discussed in this section given their limited application to the problem addressed by the Draft Regulation include Roughead and Semple (2009) investigating the cost of medication related safety in acute care and Kondalsamy-Chennakesavan et al. (2011) examining the hospital cost associated with adverse events in gynecological oncology.

3 THE CASE FOR GOVERNMENT INTERVENTION

Establishing that a problem exists is not sufficient to justify government intervention. Rather, the case for action must be established on the basis of market failure, regulatory failure, or in order to achieve societal or environmental outcomes that would not be delivered by the market alone. Further, in building the case for government action, it is important to demonstrate that the problem could not be solved by the market itself or through alternative quasi or non-regulatory responses (NSW Department of Finance, Services and Innovation, 2016).

The remainder of this chapter explores the various types of market failure that are related to quality and safety of healthcare and whether there are non-legislative means for addressing them.

3.1 Market failure

Generally, a competitive market is the most efficient means of allocating resources across a society, ensuring that the goods and services demanded by consumers are produced efficiently and promoting innovation as well as consumer choice. A situation when a market fails to perform these functions is commonly known as market failure.

The presence of market failure implies that there is a potential for the government to improve outcomes for consumers, businesses, the economy and society as a whole. However, government action is not always warranted, and poorly designed regulations may create further inefficiencies or impose administrative and compliance burdens for businesses, consumers and government.

The four main types of market failure accepted by governments and regulators are public goods, externalities, information asymmetries and natural monopolies. These are described further in Box 3.1.

In the context of regulation of private health facilities, the economic and policy rationale for government intervention is most likely to be justified on the grounds of information asymmetries and externalities. These are discussed in the following sections.

BOX 3.1 EXAMPLES OF MARKET FAILURE

Information asymmetries

In some markets it can be difficult for consumers to be certain about the quality of a good or service before they consume it (NSW Department of Finance, Services and Innovation, 2016). This can disadvantage suppliers of better quality products because they will find it difficult to convince customers to pay the higher prices, which are necessary to cover any additional costs the producers have incurred.

Another way in which information asymmetry may manifest is when consumers purchase/consume a good or service without fully being aware of the consequences of their decisions/actions. High sugar diets and obesity-related health issues are good example, where the quantity of unhealthy food consumed by an individual may be more than they otherwise would if they were aware of the illnesses such diets are known to cause.

Externalities

Externalities exist when the welfare of some agent, or group of agents, is affected by the actions of another and this is not reflected in market prices. When the effects of one economic agent on another are not taken into account, market prices will not reflect the true marginal cost/benefit of the good or service traded. A common example is pollution, where unless a producer is required to compensate society for the pollution they generate (by internalising the cost of mitigating/remediating in their production cost), they would produce more of that good than at the socially optimum level.

Public goods

Examples of public goods include, roads, public parks, national security, public schools and other intangible goods such as clean air and waterways. These goods are unique in that they are both non-excludable and non-rivalrous. Unlike private goods where non-paying consumers can be prevented from accessing it, both paying and non-paying consumers can access a public good. The non-rivalrous nature of public goods also means that use/consumption of the good by one agent (typically) does not reduce the ability for others to use/consume it. As a result, an unregulated market will lead to an undersupply of public goods at the detriment of social welfare, and thus, require governments to intervene in their provision.

Natural monopolies

Natural monopolies exist in industries that are more efficient when only one (or few) firm(s) produces a good rather than multiple firms. This typically occurs where there are large initial costs associated with setting up the infrastructure needed for production and delivery; for example, water and energy networks. Where there is a single monopoly firm, governments may also choose to regulate market power more directly – for example, through ex-ante price controls.

SOURCE: ACIL ALLEN CONSULTING.

3.1.1 Information asymmetry

It has been well-established that information asymmetries in healthcare exists. Medical knowledge is complex, and as a result the physician is likely to possess greater information in relation to treatment possibilities and consequences than the patient (Arrow, 1963).

The consequences of information asymmetry in healthcare are two-fold. Firstly, it is possible that medical practitioners may be able to advise more treatment that would be necessary when following standard treatment protocols. This leads to a phenomenon known as supplier-induced demand, causing the patient to opt for more healthcare treatment than they would have, had the information asymmetry not have existed.

Supplier-induced demand results in inefficient allocation of resources societally (more healthcare is consumed than would have otherwise been the case). In addition, supplier-induced demand unnecessarily increases risk to patients. Probabilities compound over time, so that even if the likelihood of a negative outcome associated with any given medical procedure is small, the risk increases the more treatment is prescribed.

A second aspect of information asymmetry arises if a patient receives less treatment than they would have chosen if given complete information about their care.

3.1.2 Externalities

As discussed before, externalities are costs and benefits arising from a transaction incurred by third parties. In relation to quality and safety of private healthcare, failures to meet adequate standards can impose burdens on other patients and/or the public health system.

Resources required to manage adverse events and poor patient outcomes may increase waiting times for other patients, particularly in remote and rural areas where patients have access to fewer alternative providers. Further, the public health system incurs an additional burden in the form of increased costs and waiting times if cases are unnecessarily transferred back to the public health system for resolution.

3.1.3 Equality of access

In addition to market failure, government action may be justified on the basis of achieving particular social and equity outcomes that would not be achieved by the market alone.

Remote or rural areas may often only have one single private provider of critical healthcare services, mainly due to the small size of the local market. Consumer choice in these areas is highly restricted. A regulated minimum standard therefore serves an important equity objective in ensuring that all patients, irrespective of location, have access to quality and safe healthcare services.

3.2 Can the problem be addressed by non-legislative means?

Having established a justification for government action arising from market failure and the presence of an equity outcome likely not delivered by the market alone, it is necessary to consider whether there are non-regulatory or quasi-regulatory responses the government could pursue, or whether the market may self-correct through its normal functioning.

3.2.1 Is there scope for self-regulation, quasi-regulation or market self-correction?

According to the *Australian Government Best Practice Regulation Handbook,* self-regulation is typically characterised by the industry formulating rules and codes of conduct, with industry itself being solely responsible for monitoring and enforcing them (Commonwealth of Australia, 2007).

Quasi-regulation includes a wide range of rules and/or arrangements where governments influence businesses/industry to comply, but which do not form part of explicit government regulation (Commonwealth of Australia, 2007). Examples of quasi-regulation include accreditation schemes and codes of conduct/practice developed with government involvement. Box 3.2 outlines the circumstances in which self or quasi-regulation may be appropriate.

Self-regulation is appropriate when the health and safety concerns are relatively low or when the problem has low impact or significance. Further, self-regulation may be feasible if the market is capable of stepping in to develop a solution, for instance in order to ensure industry survival or where there is a particular market advantage to a proactive response. Self-regulation is likely to be successful where a sufficient proportion of the industry participates, the industry is cohesive and there is evidence that a voluntary approach can work.

Quasi-regulation is likely to be successful when government is not convinced of the need to develop or mandate a code for the whole industry, flexible, tailor-made solutions and less formal mechanisms bring cost advantages, and the industry is capable of engaging in a cohesive response.

BOX 3.2 CHECKLISTS FOR ASSESSMENT OF SELF AND QUASI-REGULATION

Self-regulation should be considered where:

- there is no strong public interest concern, in particular, no major public health and safety concern
- the problem is a low-risk event, of low impact or significance
- the problem can be fixed by the market itself.

Quasi-regulation should be considered where:

- there is a public interest in some government involvement in addressing a community concern and the issue is unlikely to be addressed by self-regulation
- there is a need for an urgent, interim response to a problem in the short term, while a long-term regulatory solution is being developed
- government is not convinced of the need to develop or mandate a code for the whole industry
- there are cost advantages from flexible, tailor-made solutions and less formal mechanisms
- there are advantages in the government engaging in a collaborative approach with industry, with industry having substantial ownership of the scheme. For this to be successful, there needs to be:
  - a specific industry solution rather than regulation of general application
  - a cohesive industry with like-minded participants, motivated to achieve the goals
  - a viable industry association with the resources necessary to develop and/or enforce the scheme
  - effective sanctions or incentives to achieve the required level of compliance, with low scope for benefits being shared by non-participants
  - effective external pressure from industry itself (survival factors), or threat of consumer or government action.

As in the case of self-regulation, proposed approaches should not restrict competition.

SOURCE: BEST PRACTICE REGULATION HANDBOOK (COMMONWEALTH OF AUSTRALIA, 2007).

Accreditation in the Australian and NSW health care systems

Following the establishment of a safety and quality framework (discussed in Section 2.1), the Australian Commission for Safety and Quality in Health Care (ACSQHC) developed a national accreditation scheme and standards to operationalise the framework. The National Safety and Quality Health Service (NSQHS) standards were endorsed by the Australia Health Ministers in 2011 (ACSQHC, 2012).

By June 2016, 98 per cent of all hospitals and day procedures services in Australia had been accredited (ACSQHC, 2016). Furthermore, according to the latest statistics by the AIHW, the majority of private hospitals in NSW are accredited against the NSQHS Standards (AIHW 2016).

Public hospitals in NSW are required to be accredited under the NSQHS standards since January 2013. Accreditation for private hospitals is not mandatory; however, according to the Ministry, private health facilities are required to 'engage' with the NSQHS as a condition of the licence (MoH, 2017). As a result, the NSQHS standards are, in effect, a form of quasi-regulation for private health facilities in NSW, covering many of the requirement mandated under the Draft Regulation.

The NSW regulatory system strongly encourages the uptake of accreditation in private health facilities through:

- including comparable requirements in regulation and licensing standards, so that the national standards are covered by the NSW regulatory system
- requiring licensed private health facility to 'engage' with the national accreditation scheme
- receiving information on shortfalls (requirements 'not met' or if 'significant risk' is identified) from accrediting agencies.

Where a facility does not address shortfalls identified as part of the accreditation survey, the Ministry may impose additional/changed licence conditions, as well as restrict, suspend, or cancel a licence.

Despite the substantial overlap between accreditation standards and the Draft Regulation, some important differences between the two remain.

— The NSQHS standards are designed to apply across a wide range of health organisations, setting a uniform standard of quality and safety (ACQSHC, 2012). In contrast, the Draft Regulation sets both general requirements for private health facilities as well as specific conditions for each licence class.
— NSQHS standards not included in the Draft Regulation include safe prescription of medications and prevention of falls. In contrast, the Draft Regulation includes specific requirements for building standards and staff qualifications not covered by the accreditation.
— Non-compliance with accreditation standards does not mean that a facility cannot operate — a licensing regime grounded in regulation is necessary for compelling non-compliant service providers to either gain compliance or cease operations.

In addition to quasi-regulation, the market could address the problem independently of government action. This could happen either through the normal operating of the market or through self-regulation.

Firstly, it is possible that the market would address the problem and ensure sufficient safety and quality of care. Possible mechanism for market correction include registered health practitioners' professional obligations, reputational considerations or requirements from insurers (professional indemnity insurance for practitioners as well as private health funds). Secondly, the market could self-regulate through developing its own, self-enforced codes of conduct or voluntarily adopting the NSQHS accreditation standards.

The Ministry estimates that in the absence of a regulatory response, non-legislative drivers would lead to an 80-90 per cent rate of compliance with safe standards among the currently licensed private health facilities. However, not all facilities would meet the same consistent standards, potentially leading to increased safety risk as well as loss of confidence among the public. Further, it is possible that 'rogue' operators not adhering to adequate safety and quality standards would emerge — however, in the absence of a licensing regime, the NSW Government would not have the means to take action if a facility is causing a risk to the public.

It is clear that the conditions for relying in market self-correction, quasi-regulation or self-regulation do not exist among licensed private health facilities in NSW. There is a strong public interest in the quality and safety of health facilities as an adverse event can, in the worst case scenario, result in loss of life.

The Draft Regulation covers quality and safety standards not included in the current accreditation standards. The risk of 'rogue' providers emerging means that government needs to have the ability to restrict the operations of these facilities prior to severe incidents occurring, which can only be achieved through a licensing regime. The relatively disparate nature of the sector as well as the information asymmetries, externalities and the regional dimensions of healthcare discussed in Section 3.1 mean that an industry-owned scheme would be unlikely to deliver the desired public safety objectives. Finally, analysis of the NSQHS accreditation reform highlights the importance of government's regulatory powers in enforcing safe standards (Greenfield et al., 2014).

Therefore, due to the risks arising from inadequate safety and quality standards among currently licensed private health facilities, these non-regulatory responses are not considered to be sufficient.

3.2.2 Provision of information

A possible non-regulatory response by government to problems arising from information asymmetry is to provide more information to consumers in an attempt to ensure they are fully informed. However, this is unlikely to be effective in relation to private health facilities. In the context of healthcare where the knowledge is highly complex and medical practitioners often possess more information about the treatment and various options, provision by government of standardised information is unlikely to substantially improve patient outcomes. Therefore, while requiring the disclosure of information to patients about their treatment may form an important part of a regulatory response, information provision by government on its own is not sufficient to address the problem.

4 OBJECTIVES OF THE PROPOSED REGULATION

An important goal of a regulatory impact statement is to identify clearly the objective of the regulatory intervention.

The current and Draft Regulation have been designed to give effect to particular provisions of the Act that seek to ensure that private health facilities meet minimum standards relating to the safety and quality of private health facilities.

The objectives of the Draft Regulation remain the same as the *Private Health Facilities Regulation 2010*. These are to make provisions with respect to:

a) licensing standards for private health facilities
b) fees for an application for a private health facility licence and for other purposes
c) the minimum necessary qualifications for a director of nursing at a private health facility
d) the particulars that are required to be entered in the register of patients
e) the membership of the medical advisory committee for a public health facility
f) permitting a member of a root cause analysis team to make information available to certain committees in connection with any research or investigation the committee is authorised to conduct
g) the disclosure of certain pecuniary interests
h) requiring a licensee to display the licence for a private health facility in a prominent place in the entry foyer of the facility
i) requiring a licensee to notify the Secretary of the Ministry of Health if certain orders are made under the *Local Government Act 1993* or the *Environmental Planning and Assessment Act 1979*.

Overall, the key objectives of the Draft Regulation can be seen as to provide:

— legislative support and administrative detail for the operation of the Act
— clear minimum standards for private health facilities relating to the safety and quality of the services provided to patients
— a framework for adequate governance, oversight and accountability of private health facilities.

5 OPTIONS CONSIDERED

A RIS should identify and assess the policy options that could achieve the objectives of government action outlined in Chapter 4. The options that have been identified by the Ministry are the following.

- ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).
- ***Option 1*** — this option entails remaking the existing Regulation without any changes (the *status quo* option).
- ***Option 2*** — this option entails making the Draft Regulation, which would entail remaking the existing Regulation with several proposed amendments.

Each of these options are discussed in more detail in the sections below.

5.1 Base case: letting the Regulation sunset

This option entails letting the Regulation sunset, which means that the Regulation would be repealed and not replaced.

In considering this option it is useful to outline a view of the likely general implications of such a regulatory change, as this will provide a basis for assessing the range of potential costs and benefits under this scenario.

If the Regulation were discontinued, the *Private Health Facilities Act 2007* would be unable to fully operate in the absence of legislative detail, as the Regulation is required to specify some parts of how the Act operates. Under this scenario, private health facilities would still be required to be licensed under the Act, but there would be no minimum standards that facilities would have to meet in relation to the safety and quality of services. This includes no prescriptive requirements regarding:

- clinical standards and quality assurance
- staffing qualifications and experience
- equipment
- design and construction of private health facilities.

In the absence of the Regulation, and of standards to be met by facilities, the Ministry would have no ability to cancel a facility's licence for non-compliance with the standards (as there would be none), resulting on a licensing regime unable to operate properly.

Under this scenario, private health facilities would be self-regulated and governed by voluntary accreditation standards.[4] Facilities may seek to differentiate on the basis of quality, cost, specialisation

[4] According to the latest statistics by the Australian Institute of Health and Welfare Currently, the majority of private hospitals in NSW are accredited against the National Safety and Quality Health Service (NSQHS) Standards (AIHW 2016). This widespread accreditation of

or competitive advantage. While these drivers, as well as liability and insurance concerns and professional obligations of registered health practitioners, may promote safety and quality of private health facilities, there is no power for the NSW Government to act or intervene in circumstances where a facility is causing a risk to the public or is not meeting the voluntary standards.

5.2 Option 1: remaking the existing Regulation without changes (status quo)

This option entails remaking the existing Regulation without any changes, which means that the obligations of private health facilities would remain unchanged.

5.3 Option 2: remaking the existing Regulation with changes

Option 2 entails remaking the Regulation with several amendments contained in the *Private Health Facilities Regulation 2017* (Draft Regulation). Generally, the amendments proposed in the Draft Regulation fall within one or more of the following areas.

1. Minor rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of private health facilities.
2. Updated licensing fees.
3. Updated references to current or more relevant professional standards/guidelines.
4. Removal of transitional provisions, requirements and standards that are no longer relevant or needed.
5. Inclusion in the Draft Regulation of requirements that were previously included in the conditions of the licence for certain private health facilities (leaving the obligations of the facilities unchanged).
6. Changes to definitions in the Draft Regulation.
7. Changes to the required qualifications for director of nursing of a private health facility.
8. New requirements for private health facilities.

Additional details about the proposed changes under each of these areas are provided in Table 5.1 below.

Most of the amendments proposed under the areas above leave the obligations of private health facilities largely unchanged, except for amendments under areas 6) to 8) which impose new and/or different requirements. The impacts of these changes is explored in more detail in the following chapter.

TABLE 5.1 SUMMARY OF AMENDMENTS PROPOSED FOR THE REGULATION

Area of change	Proposed change (all clauses refer to the Draft Regulation)
1. Minor rewording, renumbering, restructuring and clarifications	Minor changes to the following clauses. – Part 3, Clause 15 – Part 6, Clause 20 (1) (d) – Part 7, Clause 21 – Clauses under Schedule 1 have been restructured and reworded, including Clause 3, Clause 5, Clause 12, Clause 16, Clause 17, Clause 21, Clause 23 – Schedule 2, Clause 74, Clause 78 (2), Clause 80
2. Updated licensing fees	Part 2, Division 2 — Licensing fees updated in line with most recent fee provisions.

facilities is encouraged by insurers requiring hospitals to be accredited and private facilities being unable to join industry groups such as the Australian Private Hospital Association unless accredited.

Area of change	Proposed change (all clauses refer to the Draft Regulation)
3. Updated references to current or more relevant professional standards/guidelines	Professional standards/guidelines in the following clauses have been updated. – Schedule 1, Clauses 4 and 13 – Schedule 2, Part 7, Clause 25 — the requirement for gastrointestinal endoscopy class facilities to also be licenced as an anaesthesia class private health facility was replaced with a requirement for compliance with the Australian and New Zealand College of Anaesthetist (ANZCA) guideline *PS09 (2014) - Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures.* – Schedule 2, Part 6, Clause 27
4. Removal of transitional provisions, requirements and standards that are no longer relevant or needed	– Part 7 — transitional arrangements for rapid opioid detoxification facilities and existing facilities have been removed – Schedule 1, Clause 5 — the requirement to have an electronic communication system in each staff station has been removed – Part 14 — the reference to bedding requirements for patients under two has been removed as the *AS/NZ 2130:1998, Cots for day nursery, hospital and institutional use—Safety requ*irements is no longer valid.
5. Inclusion of requirements that were previously included in the conditions of a facility's licence	– Part 5, Clause 17 Reportable incident — a new subclause has been added requiring the private facility to notify the Secretary of all reportable incidents within 2 working days of the incident's occurrence – Schedule 1, Division 2 — a new clause has been added requiring the Medical Advisory Committee to approve admission policies and procedures – Schedule 2, Part 6, Clause 19 — a new subclause has been included to clarify an emergency class private health facility must be open to receive patients at all times – Part 5, Clause 17 Reportable incident — a new requirement has been added requiring a Root Cause Analysis team (appointed under s44 of the Act) to provide its report to the licensee and chair of the Medical Advisory Committee within 70 calendar days of the occurrence of the reportable incident.
6. Changes to definitions in the Regulation	**Definition Classes of Private Health Facilities (Part 2, Division 1, Clause 6)** – The definition of Medical Class has been amended to exclude facilities for the diagnosis or treatment of conditions relating to sleep. – Minor amendments to the definitions of the following classes: anaesthesia, chemotherapy, maternity, mental health, rehabilitation class. **Definition of adverse event (Schedule 1, Division 3, Clause 21(4))** *Adverse event* means an incident or event resulting in: a) a patient suffering a major permanent loss of function (being sensory, motor, physiological or psychological) that is unrelated to the natural course of the illness for which the patient is receiving treatment and differs from the expected outcome of the patient's management, or that necessitates any of the following: i) lengthening the patient's stay at the facility, ii) surgical intervention, or b) a patient suffering significant disfigurement, or c) a risk of serious and imminent harm to a patient due to the patient's absence from the facility contrary to medical advice, or d) a patient being physically or verbally assaulted, or threatened with such assault, causing the facility to request external or police intervention.
7. Changes to the required qualifications for director of nursing of a facility	**Qualifications for director of nursing of facility (Part 3, Clause 14)** Minimum necessary qualifications for a registered nurse to be appointed as director of nursing have been decreased to 5 years post basic or post graduate nursing experience and *1 year* administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital.

Area of change	Proposed change (all clauses refer to the Draft Regulation)
8. New requirements	**Schedule 2, Part 4 Chemotherapy class private health facilities** The following new standards have been added to the Regulation. – A chemotherapy class private health facility must have written policies and procedures for: a) the provision of information and counselling to patients and their relatives, and b) the admission and discharge of patients, including continuing care and review, and c) the management of side effects, and d) access to relevant specialists for consultation. – A chemotherapy class private health facility must ensure that the clinical record for each patient who receives a cytotoxic drug includes: a) a written treatment plan based on the assessment of the patient, and b) a signed record of the patient's consent to the treatment. – The medical advisory committee of a chemotherapy class private health facility must include a specialist oncologist or a consultant physician trained in oncology when matters relating to cytotoxic agents are discussed. – A chemotherapy class private health facility must ensure that treatment plans outside the scope of normal clinical practices are regularly and independently reviewed and audited.

SOURCE: ACIL ALLEN CONSULTING BASED ON THE DRAFT PRIVATE HEALTH FACILITIES REGULATION 2017.

6 IMPACT ANALYSIS

This chapter assesses the impacts of the regulatory options outlined in Chapter 5. It first assesses the expected impacts of the Base Case (i.e. of letting the Regulation sunset) and then assesses the impacts of the proposed Draft Regulation (Option 2) against the *status quo*, i.e. the current Regulation (Option 1).

Notably, the benefits and costs associated with the alternative options are not amenable to quantification due to the unfeasibility of measuring the scale of avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way, and the relatively marginal impact of the proposed changes. As such, these impacts are discussed qualitatively.

Further, in preparing this RIS, selected stakeholder consultations were conducted with a number of organisations. Where relevant, key comments made by stakeholders have been included in the discussion. Further information about the stakeholder consulted can be found in Appendix A.

6.1 Impacts of letting the Regulation sunset (the Base Case)

As noted in Section 5.1, the likely general implications of letting the Regulation sunset are that:

- the Act would be unable to fully operate in the absence of legislative detail
- private health facilities would still be required to be licensed under the Act, but there would be no minimum standards that they would have to meet in relation to the safety and quality of services
- a private health facility's licence could not be cancelled for non-compliance with the standards (as there would be none)
- private health facilities would be self-regulated and governed by voluntary accreditation standards. Facilities would meet safety and quality standards based on accreditation imperatives, insurance and liability and reputational concerns and professional obligations of registered health practitioners.

Benefits

Broadly, the benefits of discontinuing the Regulation would include:

- elimination/reduction of compliance and administrative costs for private health facilities
- reduced regulatory costs for the NSW Government in administering the licensing regime, including administrative, monitoring and enforcement costs
- a potential increase in:
  - the number of private health facilities in NSW and the range of treatments offered by those facilities
  - competition in the industry, and associated impacts on the pricing of services.

Costs

The costs associated with eliminating minimum standards and relying on industry self-regulation include:

- provision of health services in facilities that may not be adequately equipped and resourced to safely provide those services, which could result on:
  - a potential decreased in the quality of care for patients
  - increased risks to the safety and quality of services to patients
- increased information asymmetries due to lack of information regarding performance/safety of private health facilities
- having a licensing regime which is in effect unable to operate
- inconsistent standards applying across facilities.

Conclusion

Overall, letting the Regulation sunset is not considered appropriate as the risks and costs associated with eliminating minimum standards in relation to the safety and quality of services and relying on industry self-regulation are considered to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

As noted by PWC (2009, p. 21), 'The Government requires the visibility to detect poor quality outcomes and the certainty provided by legal sanctions to meet its broader social welfare responsibilities to the current and future generations.'

It is noted that all stakeholders consulted for the RIS agreed that letting the Regulation sunset is not an appropriate option as the Regulation is central to maintaining adequate standards for patient safety.

6.2 Impacts of the proposed Regulation (Option 1 and Option 2)

As noted before, most of the amendments proposed for the Regulation under Option 2 leave the obligations of private health facilities largely unchanged, except for amendments under areas 6 to 8 in Table 5.1, which relate to:

- changes to definitions in the Regulation, particularly with regards to the definition of:
  - medical class
  - adverse event
- changes to the required qualifications for director of nursing of a private health facility
- new requirements for private health facilities.

Given this, the analysis of the impacts of the Draft Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1) has been structured around the above areas, rather than around each of the options.

6.2.1 Changes to definition of medical class in the Regulation

Part 2, Division 1, Clause 6 of the Draft Regulation defines the classes of private facilities which are required to be licensed under the Act. Under Option 2 it is proposed that the definition of medical class be amended to exclude facilities for the diagnosis or treatment of conditions relating to sleep.

This change would mean that facilities dedicated to the diagnosis or treatment of conditions relating to sleep which admit patients overnight would no longer have to be licensed under the Draft Regulation.[5] These include:

- facilities *purely* dedicated to the diagnosis or treatment of conditions relating to sleep which admit patients overnight — these facilities would no longer need a license to operate (according to data from the Ministry, there are currently only three licensed facilities of this type in NSW)

[5] Facilities providing in-home sleep studies and treatment or not admitting patients (even if these patients stay in the facility overnight), are not required to be licensed under the current Act and Regulation.

— large facilities that offer a multiple services (including the diagnosis or treatment of conditions relating to sleep) and are licensed in the medical and/or other classes — these facilities would still need to hold the required licenses for the range of services they offer according to the classes of health services in the Draft Regulation.

The Draft Regulation sets out the following specific standards for medical class facilities (in addition to the general licensing standards for all private health facilities)[6]:

— minimum accommodation requirements — a medical class private health facility must provide for the accommodation of patients who are admitted for more than 24 hours

— accommodation standards — a medical class private health facility must comply with the overnight accommodation standards.

Benefits

The main benefits from excluding facilities for the diagnosis or treatment of conditions relating to sleep from the definition of medical class in the Draft Regulation would be:

— the elimination/reduction of compliance and administrative costs related to obtaining the medical licence for:
  - the three current licensed private health facilities *purely* dedicated to the diagnosis or treatment of conditions relating to sleep
  - any facilities that offer a range of services but which only have a medical class license for the purpose of sleep studies (facilities that would still be required to be licensed as medical class for other services they offer would not experience any cost savings)
  - any future facilities that would have fallen in the above areas

— reduced regulatory costs for the Ministry in administering and monitoring current (and future) licenses for the above type of facilities.

Costs

While sleep disorders are serious conditions that often require complex treatments, particularly in patients with additional health conditions[7] (Institute of Medicine Committee on Sleep Medicine and Research, 2006), the services offered at facilities dedicated to the diagnosis or treatment of conditions relating to sleep are considered to be relatively low risk.

It is unclear that excluding facilities dedicated to the diagnosis or treatment of conditions relating to sleep from the requirement to obtain a medical class license would result in increased risks to patient's safety because:

— the services provided at sleep facilities are considered to be relatively low risk, with diagnosis carried out through non-invasive tests and more complex/riskier treatments (e.g. surgery) carried out at appropriate licensed facilities

— there are several unlicensed facilities lawfully providing diagnosis and treatment of sleep conditions across NSW. Sleep clinics are only currently required to be licensed if they provide services to *admitted* patients

— the Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities. Even if facilities providing sleep studies to admitted patients were not required to be licensed, facilities would be expected to meet safety and quality standards based on:
  - accreditation imperatives — for instance, the Australasian Sleep Association (ASA) / National Association of Testing Authorities (NATA) Sleep Disorders Services Accreditation Program, which sets out minimum standards to support the delivery of high quality sleep disorders services in both the public and private sectors

[6] The general licensing requirements for all private health facilities set out standards in relation to: the facilities' environment (e.g. the design, construction and maintenance of buildings, facilities and equipment, fire and emergency responses, disaster planning, waste and hazardous substances, etc.); clinical care (e.g. a requirement to have sufficient number of qualified and experienced staff – however, the Regulation does not specifically prescribe the number of staff and/or their particular qualifications by each facility type –, requirements about clinical records and patient information, infection control, dispensaries, admission policies, identification and transfer of patients and separation requirements); and quality improvement (e.g. management of adverse events, complaints, quality and outcome audits and risk assessment and safety inspections).

[7] For instance, those with cardiovascular disease, hypertension, diabetes and obesity.

- insurance requirements
- liability and reputational concerns
- professional standards and obligations of registered health practitioners
- general business requirements.

Some stakeholders consulted for the RIS argued that explicitly excluding sleep studies from the definition of medical class in the Draft Regulation could affect the payments that facilities receive for privately insured patients from some health funds. While from a facility's point of view a reduction in the benefits received for privately insured patients from some health funds would represent a cost, there is an equal and opposite reaction for health funds who will experience a benefit from reduced payments to these facilities. Further, excluding sleep studies from the definition of medical class is likely to reduce start-up costs for the establishment of new facilities and could bring greater competition.

Conclusion

To the extent that excluding facilities for the diagnosis or treatment of conditions relating to sleep from the definition of medical class in the Draft Regulation does not increase risks to patients' safety, then the proposed change would result in minor compliance and administrative cost savings (both for industry and government), as there is only a small number of currently licensed facilities that would no longer need to be licensed.

However, the Ministry would like to hear submissions on the issue of whether facilities that provide services relating to the diagnosis and treatment of sleep conditions should be excluded from the definition of medical class.

6.2.2 Changes to definition of adverse event in the Regulation

Currently, the Act and Regulation establish requirements for the management and response of adverse events and reportable incidents. These are outlined below.

Adverse event

The current Regulation requires private health facilities to have a written incident management system outlining the procedures to be followed in the case of an incident or adverse event. This incident management system must provide for the following:

- identification of incidents and adverse events
- notifying the Ministry about adverse events
- investigation of incidents and adverse events
- management of the outcomes of any such investigation.

The current Regulation defines an adverse event and an incident as follows.

- *adverse event* means an unintended injury to a patient, or a complication caused by the health care management of a patient, that results in disability, death of the patient or a prolonged hospital stay by the patient
- *incident* means any unplanned event resulting in, or that is likely to cause, injury or damage to a patient at a private health facility.

The following amendments are proposed in relation to adverse events in the Draft Regulation.

- References to 'incidents' to be removed so instead the relevant clauses just refer to 'adverse events'.
- Adverse event to be defined as an incident or event resulting in:
  a) a patient suffering a major permanent loss of function (being sensory, motor, physiological or psychological) that is unrelated to the natural course of the illness for which the patient is receiving treatment and differs from the expected outcome of the patient's management, or that necessitates any of the following:
     i) lengthening the patient's stay at the facility,
     ii) surgical intervention, or
  b) a patient suffering significant disfigurement, or

c) a risk of serious and imminent harm to a patient due to the patient's absence from the facility contrary to medical advice, or

d) a patient being physically or verbally assaulted, or threatened with such assault, causing the facility to request external or police intervention.

The aims of the proposed changes to the definition of adverse event and incident are to:

— tighten the current definition (which is currently very broad) so that there is increased clarity for facilities about the type of events for which their incident management systems should include policies/procedures

— align with public health facilities requirements for "Major Clinical Consequences" – as per the Ministry of Health Policy Directive PD2014_004 Incident Management Policy (MoH 2014).

In this respect, the intent of the proposed changes is not to increase reporting or incident management obligations, but rather to clarify them.

Reportable incidents

The Act and current Regulation requires that, when a reportable incident involving a private health facility is reported to the licensee of the facility, the licensee is to appoint a root cause analysis team in relation to the reportable incident. That is, while in the case of adverse events the main regulatory requirement is to have a written incident management system outlining the procedures to be followed when an adverse event occurs, when a reportable incident occurs a private health facility needs to report it to the Ministry and appoint a root cause analysis team to investigate the incident.

The Draft Regulation adopts the definition of reportable incident outlined in the Ministry of Health Policy Directive PD2014_004 Incident Management Policy (Appendix D) (see Box 6.1).

The following amendments are proposed in relation to reportable incidents in the Draft Regulation (Part 5, Clause 17).

— A new subclause has been added requiring the private facility to notify the Secretary of all reportable incidents within two working days of the incident's occurrence.

— A new requirement has been added requiring a Root Cause Analysis team (appointed under s44 of the Act) to provide its report to the licensee and chair of the Medical Advisory Committee within 70 calendar days of the occurrence of the reportable incident.

The requirements above were previously included in the conditions of a facility's licence, hence the obligations of the facilities under the proposed amendments remain unchanged.

Notably, the changes proposed to the definition of adverse event in the Draft Regulation would not change the number of incidents that have to be reported to the Ministry (these incidents are determined by the definition of reportable incident, which would remain unchanged).

BOX 6.1 REPORTABLE INCIDENT DEFINITION

The Ministry of Health Policy Directive PD2014_004 Incident Management Policy (MoH 2014) defines a reportable incident as follows.

1) The incident must have had "serious clinical consequences" (as defined below) and the probability of recurrence must fall into one of categories (i) to (iv) listed below; OR
2) The incident must have had "major clinical consequences" (as defined below) and the probability of recurrence must fall into one of categories (i) to (ii) listed below.

Serious Clinical Consequence

An incident with "serious clinical consequence" is one that involves:

- the death of a patient unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management
- suspected suicide of a person (including an inpatient or community patient) who has received care or treatment for a mental illness from the relevant Health Services organisation where the death occurs within 7 days of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- suspected homicide committed by a person who has received care or treatment for mental illness from the relevant Health Services organisation within six months of the person's last contact with the organisation or where there are reasonable clinical grounds to suspect a connection between the death and the care or treatment provided by the organisation
- unexpected intra-partum stillbirth

OR

- The Sentinel Events, those being:
  - procedures involving the wrong patient or body part resulting in death or major permanent loss of function
  - suspected suicide of a patient in an inpatient unit
  - retained instruments or other material after surgery requiring re-operation or further surgical procedure
  - medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
  - intravascular gas embolism resulting in death or neurological damage
  - haemolytic blood transfusion reaction resulting from ABO (blood group) incompatibility
  - maternal death or serious morbidity associated with labour or delivery
  - infant discharged to wrong family.

Major Clinical Consequences

An incident with "major clinical consequences" is one which involves a patient:

- suffering a major permanent loss of function (sensory, motor, physiologic or psychological) unrelated to the natural course of the illness and differing from the expected outcome of patient management
- suffering significant disfigurement as a result of the incident
- at significant risk due to being absent against medical advice/absconding
- subjected to threatened or actual physical or verbal assault requiring external or police intervention.

Probability of Recurrence

i) Frequent - expectation that the incident will recur immediately or within weeks or months
ii) Likely - probability incident will recur more than once within 12 months
iii) Possible - possibility incident may recur at some time every 1 to 2 years
iv) Unlikely - possibility incident may recur at some time in 2 to 5 years.

SOURCE: MINISTRY OF HEALTH 2014.

Benefits

A tightened definition of adverse event would help to ensure that incident management systems in private health facilities include policies/procedures for all relevant major adverse events and incidents. Broadly, the potential benefits of this include:

- increased accountability of private health facilities

- improved organisational learning from incidents, including near-miss events and system failures, to mitigate future risk
- a potential reduction of risks of unsafe or inappropriate practices, incidents and events
- improved dissemination of information on patient care and quality
- consistency in the approach to adverse event management across NSW public and private health facilities.

Costs

The proposed changes to the definition of adverse event in the Draft Regulation may result in additional administrative/compliance costs for facilities due to potential revisions to their policies and guidelines and incident management systems.

Notably, the Ministry does not expect the proposed changes to the definition of adverse event to result in an increase in the number of events identified, reported and investigated by private health facilities as adverse.

Conclusion

To the extent that the proposed changes to the definition of adverse event and incident reduce the level of interpretation of the requirements currently required by facilities, and increase clarity about the type of events for which private health facilities should have policies and procedures in place, the change is expected to be overall beneficial.

6.2.3 Changes to the required qualifications for Director of Nursing of a private health facility

The Regulation establishes the minimum necessary qualifications for a registered nurse to be appointed as a Director of Nursing (DoN) at a private health facility. Currently the minimum requirements are to have:

- five years post basic or post graduate nursing experience, and
- *two* years administrative experience in a position *of*, or more senior than that of, nursing unit manager in a hospital.

The changes proposed in the Draft Regulation under Option 2 would slightly decrease the minimum necessary qualifications for a registered nurse to be appointed as DoN to:[8]

- five years post basic or post graduate nursing experience, and
- *one* year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital.

The objective of the proposed changes is to try to achieve the right balance between:

- setting minimum qualifications for a DoN that are sufficient for patient care and safety
- setting minimum qualification requirements that are appropriate for all facilities, while recognising that different types of facilities have different levels of risks (e.g. a small day procedure centre only providing low risk services has a lower overall risk than a large hospital that is licensed in multiple classes to provide a wide range of services) and hence different requirements for a DoN in terms of experience and qualifications
- being too prescriptive and 'setting the bar too high', making it harder (and more costly) for some facilities to find a DoN that meets the minimum requirements.

Benefits

The proposed reduction in the minimum qualifications required for a DoN is likely to increase the pool of people who are eligible for the position, making it easier to recruit and decreasing facilities' staff

[8] It is noted that this proposed change is different to the change on which feedback was sought during the consultations undertaken with selected stakeholders for this RIS. The change on which views were gathered from stakeholder was to change the qualifications of DoN to five years post basic or post graduate nursing experience, *or one* year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital. This was subsequently changed by the Ministry.

search costs. This benefit would be particularly important for those small and/or regional facilities which have difficulties fulfilling the DoN role due to low number of applicants with the current required minimum qualifications.

The proposed changes are unlikely to result in staff costs savings as staff these positions are generally payed in accordance with their grading/title, which will remain as director of nursing.

Costs

Appropriate clinical governance and management arrangements in private health facilities are important factors in achieving safety and quality of services. Commonly, these roles are fulfilled by the DoN. Indeed, while the scope of the DoN role may differ between a large and small facilities, a DoN is central in providing appropriate clinical governance and management of the facility and administrative leadership of nursing services.

Under the proposed changes in the Draft Regulation it is likely that larger facilities may continue to employ a DoN with extensive clinical nursing and administrative management experience (equivalent to, or above the current minimum requirements in the Regulation) to minimise risks given the scope of the role. However, smaller and/or regional facilities (who may have a reduced pool of skilled people available for the role) are more likely to employ directors of nursing with lower qualifications and/or experience as allowed by the decreased minimum requirements in the Draft Regulation.

It is unclear whether the changes proposed to the minimum qualifications required for a DoN would lead to any increased risks on patients' safety (for instance, in some circumstances, a slightly less experienced DoN would be more appropriate for smaller facilities providing less complex/risky services, but this may not be the case for all facilities under all circumstances). However, it is worth noting that:

- the proposed changes are relatively small, leaving the requirements of post basic/post graduate nursing experience unchanged, but reducing the required administrative experience by one year
- as mentioned before, it is likely that larger/riskier facilities will continue to employ a DoN with extensive clinical nursing and administrative management experience and it is possible that a less experienced DoN is more appropriate for smaller facilities providing less complex/risky services
- as noted previously, the Draft Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities. In addition to the minimum standards required by the Draft Regulation, facilities meet safety and quality standards based on accreditation imperatives, insurance requirements, liability and reputational concerns and professional standards and obligations of registered health practitioners.

Conclusion

If the proposed changes achieve the right balance of minimum qualification requirements for all facilities without increasing the overall risks to patients, then the change would be beneficial for those facilities which have difficulties fulfilling the DoN role due to low number of applicants with the current required minimum qualifications.

The Ministry would like to hear submissions on whether the proposed changes to the minimum qualifications for a DoN are appropriate.

6.2.4 New requirements for chemotherapy private health facilities

As discussed before, the Draft Regulation under Option 2 imposes the following new standards for chemotherapy class private health facilities in Schedule 2, Part 4.

- A chemotherapy class private health facility must have written policies and procedures for:
  a) the provision of information and counselling to patients and their relatives, and
  b) the admission and discharge of patients, including continuing care and review, and
  c) the management of side effects, and
  d) access to relevant specialists for consultation.

— A chemotherapy class private health facility must ensure that the clinical record for each patient who receives a cytotoxic drug includes:
  a) a written treatment plan based on the assessment of the patient, and
  b) a signed record of the patient's consent to the treatment.
— The medical advisory committee of a chemotherapy class private health facility must include a specialist oncologist or a consultant physician trained in oncology when matters relating to cytotoxic agents are discussed.
— A chemotherapy class private health facility must ensure that treatment plans outside the scope of normal clinical practices are regularly and independently reviewed and audited.

Benefits

The proposed new standards for chemotherapy class private health facilities are likely to result in the following benefits:

— improved governance and oversight of chemotherapy treatments in private health facilities
— improved dissemination of information to patients about their care and treatment
— improved transparency of chemotherapy class private health facility policies and procedures
— reduced risks of unsafe or inappropriate practices.

Ultimately, the above effects would assist in improving the quality of health care provided by private chemotherapy facilities in NSW.

Costs

The new standards proposed for chemotherapy class private health facilities are likely to result in additional administrative/compliance costs for facilities (e.g. due to increased reporting and potential revisions to the facilities' policies and guidelines). While many large and/or specialised chemotherapy facilities already have in place best practice policies and procedures similar to the new requirements in the Draft Regulation (and hence would not incur any additional compliances costs[9]), the impact could be different for smaller facilities where there may be a greater variation in practices.

The Ministry notes that the proposed additional chemotherapy requirements are unlikely to result in increased monitoring activities or increased costs of administering the Draft Regulation.

Conclusion

Overall, it is considered that the benefits from reduced risks and improved patient outcomes stemming from the increased requirements for chemotherapy class private health facilities are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.

Notably, all stakeholders consulted for the RIS supported the proposed changes as a way to improve the governance and oversight of chemotherapy treatments in NSW.

[9] Notably, this was the view of two 'standalone' chemotherapy facilities consulted for the RIS who noted that the proposed changes would not impose a meaningful additional compliance burden for them.

7 CONCLUSION

The NSW Ministry of health has identified the following options to be considered in this RIS.

- ***Base Case*** — best practice regulatory impact analysis suggests that a RIS should use as the base case the option whereby there is 'no Regulation'. As such, the Base Case for this RIS is to let the existing Regulation sunset (i.e. discontinue).
- ***Option 1*** — this option entails remaking the existing Regulation without any changes (the *status quo* option).
- ***Option 2*** — this option entails making the Draft Regulation, which would entail remaking the existing Regulation with several proposed amendments.

The Base Case option is not considered appropriate as discontinuing the Regulation:

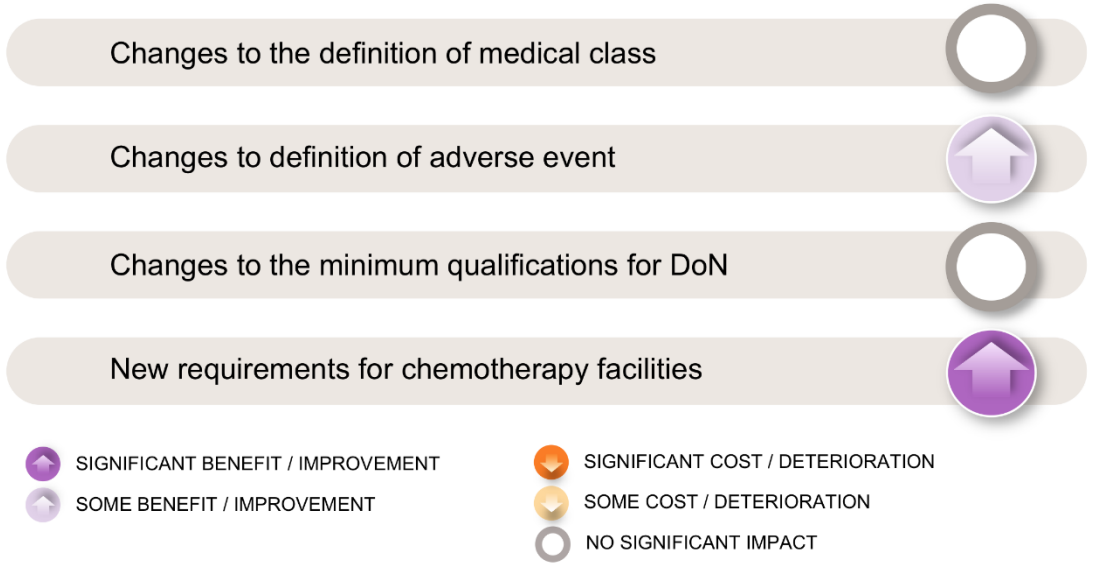
- would mean that the Act would be unable to fully operate in the absence of legislative detail, resulting in a licensing regime which is in effect inoperable
- would increase the risks to the safety and quality of care for patients and information asymmetries due to lack of information regarding performance/safety of private health facilities. The costs associated with these increased risks are likely to significantly outweigh any potential benefits to Government and industry related to reduced compliance and administrative costs.

The analysis of the impacts of the proposed amendments to the Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1) has been structured around the following four areas, rather than around each of the options.

1. Changes to the definition of medical class.
2. Changes to the definition of adverse event.
3. Changes to the required qualifications for Director of Nursing of a private health facility.
4. New requirements for chemotherapy private health facilities.

As discussed before, the benefits and costs associated with the alternative options are not amenable to quantification due to the unfeasibility of measuring the scale of avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way, and the relatively marginal impact of the proposed changes. However, Figure 7.1 provides a summary of the relative nature of the benefits and costs of the changes proposed under Option 2 across the four areas outlined above, with respect to Option 1 (i.e. the *status quo*).

FIGURE 7.1 SUMMARY OF POTENTIAL RELATIVE IMPACTS OF THE PROPOSED REGULATION ACROSS KEY AREAS OF CHANGE (RELATIVE TO THE STATUS QUO)



SOURCE: ACIL ALLEN CONSULTING.

In summary, in relation to the four key changes proposed for the Regulation:

- Overall, it is considered unlikely that excluding facilities dedicated to the diagnosis or treatment of conditions relating to sleep from the requirement to obtain a medical class license would significantly increase risks to patient's safety because:
  - the services provided at sleep facilities are considered to be relatively low risk, with diagnosis carried out through non-invasive tests and more complex/riskier treatments (e.g. surgery) carried out at appropriate licensed facilities
  - there are several unlicensed facilities lawfully providing diagnosis and treatment of sleep conditions across NSW
  - the Draft Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities. In the absence of licensing requirements, facilities would be expected to meet safety and quality standards based on accreditation imperatives, insurance requirements, liability and reputational concerns and professional standards and obligations of registered health practitioners.

  To the extent that excluding sleep facilities from the definition of medical class in the Draft Regulation does not increase risks to patients' safety, then the proposed change would result in minor compliance and administrative cost savings (both for industry and government), as there is only a small number of currently licensed facilities that would no longer need to be licensed.

  However, further feedback on the proposed changes and their potential impacts is sought from stakeholders to assist the Ministry in making a decision about the proposed changes.
- Provided that the proposed changes to the definition of adverse event and incident reduce the level of interpretation of the requirements currently required by facilities, and increase clarity about the type of events for which private health facilities should have policies and procedures in place, the change is expected to be overall beneficial.
- If the proposed changes to the necessary qualifications for a registered nurse to be appointed as DoN of a private health facility achieve the right balance of minimum consistent qualification requirements for all facilities without increasing the overall risks to patients, then the change would be beneficial for those facilities which have difficulties fulfilling the DoN role due to low number of applicants with the current required minimum qualifications. These benefits are unlikely to be major as the proposed changes only decrease the required administrative experience by one year.

Overall, it is considered unlikely that the proposed changes would lead to a significant increase in risk to patients' safety because:

- the proposed changes are relatively small, leaving the requirements of post basic/post graduate nursing experience unchanged, but reducing the required administrative experience by one year
- it is likely that larger/riskier facilities will continue to employ a DoN with extensive clinical nursing and administrative management experience and it is possible that a less experienced DoN is more appropriate for some facilities providing less complex/risky services (but this may not be the case for all facilities under all circumstances)
- as noted previously, the Draft Regulation is only one of a range of mechanisms to help ensure patient safety and quality in private health facilities.

However, further feedback on the proposed changes and their potential impacts is sought from stakeholders to assist the Ministry in making a decision about the proposed changes.

— The benefits from reduced risks and improved patient outcomes stemming from the proposed new requirements for chemotherapy private health facilities are likely to outweigh the additional administrative/compliance costs related to the proposed changes.

8 CONSULTATION

The *Subordinate Legalisation Act 1989* states that the remaking of a statutory rule (even if it is to be remade without changes) requires the preparation of a RIS and a period of public consultation.

Consistent with the *Subordinate Legislation Act 1998*, the Draft Regulation and RIS will be open for public consultation until **30 June 2017**.

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au.

Individuals and organisations should be aware that generally any submissions received will be publically available under the *Government Information (Public Access) Act 2009* and may be published. The Ministry of Health, in considering the submissions received may also circulate submissions for further comment to other interested parties or publish all, or parts, of the submissions. If you wish your submission (or any part of it) to remain confidential (subject to the Government Information (Public Access) Act), this should be clearly stated on the submission.

Interested stakeholders are encouraged to consider aspects of the assessment contained within this RIS and the Draft Regulation. Key issues on which stakeholder views are sought include the following:

- Is it appropriate to exclude facilities that provide services relating to the diagnosis or treatment of conditions relating to sleep from the definition of medical class in the Draft Regulation?
- Is the new proposed definition of adverse event appropriate?
- Should the necessary qualifications for a registered nurse to be appointed as DoN of a private health facility be changed to five years post basic or post graduate nursing experience, and *one* year administrative experience in a position *equivalent to*, or more senior than, nursing unit manager in a private health facility or a public hospital? Does this change achieve the right balance between the needs of different facilities?
- Are the proposed new standards for chemotherapy private health facilities appropriate?
- Are there any costs and benefits of the Draft Regulation that have not yet been considered, and how material are these impacts?
- Are there any risks of the Draft Regulation that have not yet been considered?

In addition to feedback on the proposed Draft Regulation, the Ministry would also like to hear stakeholder views on a number of other issues. These issues are outlined in Box 8.1 and Box 8.2.

BOX 8.1 ADDITIONAL AREA FOR CONSIDERATION BY STAKEHOLDERS: STANDARDS FOR RADIOTHERAPY AND CHEMOTHERAPY CLASS PRIVATE HEALTH FACILITIES

Standards for radiotherapy and chemotherapy class private health facilities

The Ministry would like to hear submissions as to whether additional standards should apply to radiotherapy and chemotherapy class of private health facilities in relation to providing a multidisciplinary model of care and, in relation to radiotherapy, requiring facilities to have a system for independent dosimetry auditing of linear accelerators (linacs) and their associated treatment planning systems.

The radiotherapy and chemotherapy class do not have any standards relating to the provision of treatment in the context of a multidisciplinary approach. This can be contrasted, for example, with the standards for the rehabilitation class, which contain requirements relating to a multidisciplinary approach to treatment.

The Ministry considers that radiotherapy and chemotherapy is best delivered through an integrated and multidisciplinary model as part of a quality comprehensive cancer service. This includes clear linkages to a number of sub-speciality disciplines such as medical oncology, surgical oncology, clinical haematology, palliative care and rehabilitation. In addition, radiotherapy and chemotherapy services need to have an appropriate level of clinical support services, such as diagnostic imaging, nuclear medicine, pathology, intensive care unit and pharmacy services to support the delivery of quality services, and the skilled workforce necessary to provide a quality sustainable service. On-site or networked services in supportive care, psychosocial assistance and pharmacy services are also required. This comprehensive service model is provided by a range of health professionals including medical, technical, nursing and allied health professionals. Services need to have an appropriately skilled specialist workforce and support staff to provide a safe and quality service for patients.

In addition, in relation to radiotherapy class, to safeguard the quality and safety of a radiation oncology service, equipment should be well maintained, in good working order and linacs should be subject to dosimetry auditing to ensure the delivery of radiation dose is accurate and consistent.

The Ministry is therefore considering amendments to the standards applicable to radiotherapy and chemotherapy class private health facilities to include requirements relating to a multidisciplinary approach to treatment and, in relation to radiotherapy class, dosimetry auditing. These standards would be along the lines of requiring facilities to:

- have a written policy on the provision on radiotherapy/ chemotherapy services including:
  - consultation and referral pathways to sub-specialities disciplines
  - access to clinical support services
- have specialists for consultation
- have sufficient appropriate practitioners for the services provided, including radiation therapists, radiation oncologists and medical physicists or, in relation to chemotherapy, medical oncologists.

In relation to radiotherapy class, this would also require facilities to ensure that their equipment is maintained in good working order, including having a system for independent dosimetry auditing of linacs.

Including a requirement in relation to the above standards would be expected to result in only minimal additional costs for facilities as most facilities would be likely to already be complying. The cost of dosimetric auditing would on average be $15,000 per year for a service with two linear accelerators, with additional costs of approximately $22,500 for an audit of a linac prior to its commissioning. The terms and conditions of funding for the Commonwealth Government's Radiation Oncology Health Program Grants (ROHPG) Scheme will require that radiation oncology facilities must undergo mandatory ongoing independent dosimetry auditing, prior to submitting an application for ROHPG funding. The Ministry would expect that most, if not all, radiotherapy class facilities are likely to apply for ROHPG funding and will be subject to this condition of funding. Therefore, the proposal would not be imposing additional costs for this dosimetry auditing requirement where a facility is subject to the funding conditions under the ROHPG Scheme.

Question for consideration

Should the Private Health Facilities Regulation be amended to include specific standards for radiotherapy and chemotherapy class private health facilities relating to a multidisciplinary approach to treatment and, in respect of radiotherapy class, dosimetry auditing?

SOURCE: NSW MINISTRY OF HEALTH.

BOX 8.2 ADDITIONAL AREA FOR CONSIDERATION BY STAKEHOLDERS: EXCLUSION OF DENTAL SERVICES FROM ANAESTHESIA AND SURGICAL CLASS

Exclusion of dental services from anaesthesia and surgical class

The Ministry would like to hear submissions on whether the current exclusion of certain dental services from the anaesthesia and surgical class private health facilities remain appropriate.

Clause 6 of the Draft Regulation sets out the types of classes of private health facilities and relevantly provides:

> *anaesthesia (being a facility licensed for the treatment of patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include sedation provided in connection with dental procedures),*
>
> *surgical (being a facility licensed for surgical procedures performed on patients who are administered general, epidural or major regional anaesthetic or sedation resulting in deeper than conscious sedation, but does not include a surgical procedure carried out by a dentist).*

The definition above is relevantly the same as is the case under the current Regulation.

The definition of these classes mean that facilities providing dental procedures are only required to be licensed if the procedure is carried out using general, epidural or major regional anaesthetic. On the other hand, if the facility only uses more than conscious sedation, the facility is not required to be licensed.

The exclusion of facilities that carry out dental practices using more than conscious sedation from private health facility licensing is in part a reflection of historical practices whereby dental practitioners have carried out dental surgery using more than conscious sedation in dental surgery, with dental regulators (currently the Dental Board of Australia) setting standards relating to the use of sedation. Further, there are other public protections in place to protect patients. The Health Practitioner Regulation National Law (NSW)[10] also sets limits on how sedation is used in dental practices and prohibits a dentist from administering more than simple sedation by the intravenous route unless the dentist:

- has been endorsed by the Dental Board of Australia to administer sedation; and
- is assisted by another person who is either:
  - a registered nurse who has received training in intensive care or anaesthesia; or
  - a dentist, appropriately trained in the observation and monitoring of sedated patients and in resuscitation, whose sole responsibility in assisting is to monitor the level of consciousness and cardio-respiratory function of the patient and to administer resuscitation if necessary.

In addition, the current exclusion is also reflective of the nature of dental surgery, particularly involving children. Dental surgery involving children may often be carried out using sedation. However, as sedation is a continuum it can be difficult to determine in advance whether conscious sedation or more than conscious sedation will be occur in practice. Requiring dental practices that use more than conscious sedation to be licensed could therefore inadvertently require all dental practices that carry out dental surgery to be licensed. This could result in an increase in costs, which would be passed onto patients, and could result in patients (particularly children) from disadvantaged socio-economic groups being unable to obtain treatment.

The Draft Regulation retains the exclusion of the requirement of licensing for facilities that carry out dental surgery using more than conscious sedation. However, the Ministry would like to hear submission on whether it remains appropriate to retain the current exclusion.

Question for consideration

Should facilities carrying out dental surgery or practices using more than conscious sedation continue to be excluded from the requirement to obtain a private health facility license?

SOURCE: NSW MINISTRY OF HEALTH.

[10] Section 121A of the Health Practitioner Regulation National Law (NSW).

9 REFERENCES

Arrow, K. J. 1963, Uncertainty and the Welfare Economics of Medical Care, *American Economic Review*, 53(5), pp. 941-973.

Australian Commission on Safety and Quality in Health Care (ACSQHC) 2010, *Australian Safety and Quality Framework for Health Care*, https://www.safetyandquality.gov.au/wp-content/uploads/2012/04/Australian-SandQ-Framework1.pdf, Accessed 8 March 2017.

ACSQHC (2012), *National Safety and Quality Health Service Standards, https://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf, Accessed 31 March 2017.*

Australian Institute of Health and Welfare (AIHW) 2016, *Hospital resources 2014–15: Australian hospital statistics*, Health services series no. 71. Cat. no. HSE 176. Canberra: AIHW

Bureau of Health Information (BHI) 2017, http://www.bhi.nsw.gov.au/, Accessed 8 March 2017.

Clinical Excellence Commission (CEC) 2017, About the CEC, http://www.cec.health.nsw.gov.au/about/about-cec, Accessed 8 March 2017.

Commonwealth of Australia 2007, *Best Practice Regulation Handbook*.

Deloitte Access Economics (DAE) 2011, Re-awakening Australia: the economic cost of sleep disorders in Australia, 2010, report for the Sleep Health Foundation, October.

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

Greenfield, D, Hinchcliff, R, Banks, M, Mumford, V, Hogden, A, Debono, D, Pawsey, M, Westbrook, J and Braithwaite, J, 2015, 'Analysing 'big picture' policy reform mechanisms: the Australian health service safety and quality accreditation scheme' *Health Expectations*, 18(6), pp. 3110–3122.

Harrison, B.T., Gibberd, R.W., Hamilton, J.D. and Wilson, R.M., 1999, 'An analysis of the causes of adverse events from the Quality in Australian Health Care Study', *Medical Journal of Australia*, 170(9), pp.411-415.

Hamilton, J.D., Gibberd, R.W. and Harrison, B.T., 2014, 'After the Quality in Australian Health Care Study, what happened?' *Medical Journal of Australia*, 201(1), pp.17-20.

Health Care Complaints Commission 2016, *Annual Report 2015-16*, Sydney.

Institute of Medicine (US) Committee on Sleep Medicine and Research; Colten HR, Altevogt BM, editors. *Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem*. Washington (DC): National Academies Press (US); 2006. 3, Extent and Health Consequences of Chronic Sleep Loss and Sleep Disorders. Available from: https://www.ncbi.nlm.nih.gov/books/NBK19961/ (Accessed 23 March 2017)

NSW Department of Finance, Services and Innovation 2016, *NSW Guide to Better Regulation*.

NSW Ministry of Health (MoH) 2014, *Incident Management Policy*, Policy Directive PD2014_004, February.

Moh 2017, *Licensing of Private Health Facilities,* http://www.health.nsw.gov.au/Hospitals/privatehealth/Pages/licensing-of-private-health-facilities.aspx, last accessed 31 March 2017.

Parliamentary Counsel's Office 2014, *Information Sheet on the Staged Repeal of Statutory* Rules, Parliament of New South Wales. Sydney.
From http://www.pco.nsw.gov.au/corporate/SR_IS.pdf accessed 13 March 2017.

PricewaterhouseCoopers (PwC) 2009, *Regulatory Impact Statement for the Private Health Facilities Regulation 2009*, prepared for NSW Health, June.

Rigby, K.D. and Litt, J.C.B., 2000, 'Errors in health care management: what do they cost?' *Quality in Health Care*, 9(4), pp.216-221.

Royal Australasian College of Surgeons (RACS) 2016, *Australian and New Zealand Audit of Surgical Mortality National Report 2015,* http://www.surgeons.org/media/24853564/2016-11-22_rpt_anzasm_national_report_2015.pdf, Accessed 8 March 2017.

Runciman W, Moller J, 2001, *Latrogenic 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.

Wilson R, Runciman W, Gibberd RW, Harrison BT, Newby L, Hamilton JD, 1995, 'The Quality in Australian Health Care Study' *Medical Journal of Australia*, 163(9), pp. 458–471.

A STAKEHOLDER CONSULTATIONS

As part of the development of this RIS, ACIL Allen undertook informal consultations during March 2017 with a limited number of stakeholders. The stakeholders consulted are outlined in Table A.1 below.

TABLE A.1 STAKEHOLDER CONSULTATIONS

Organisation consulted	Date
Cancer Care Associates	6 March 2017
Chris O'Brien Lifehouse	7 March 2017
Evolution Healthcare	13 March 2017
Ramsay Health Care	22 March 2017

Stakeholders who were asked to participate in the consultations, but were not available to participate include:

— Australian Medical Association (NSW).

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