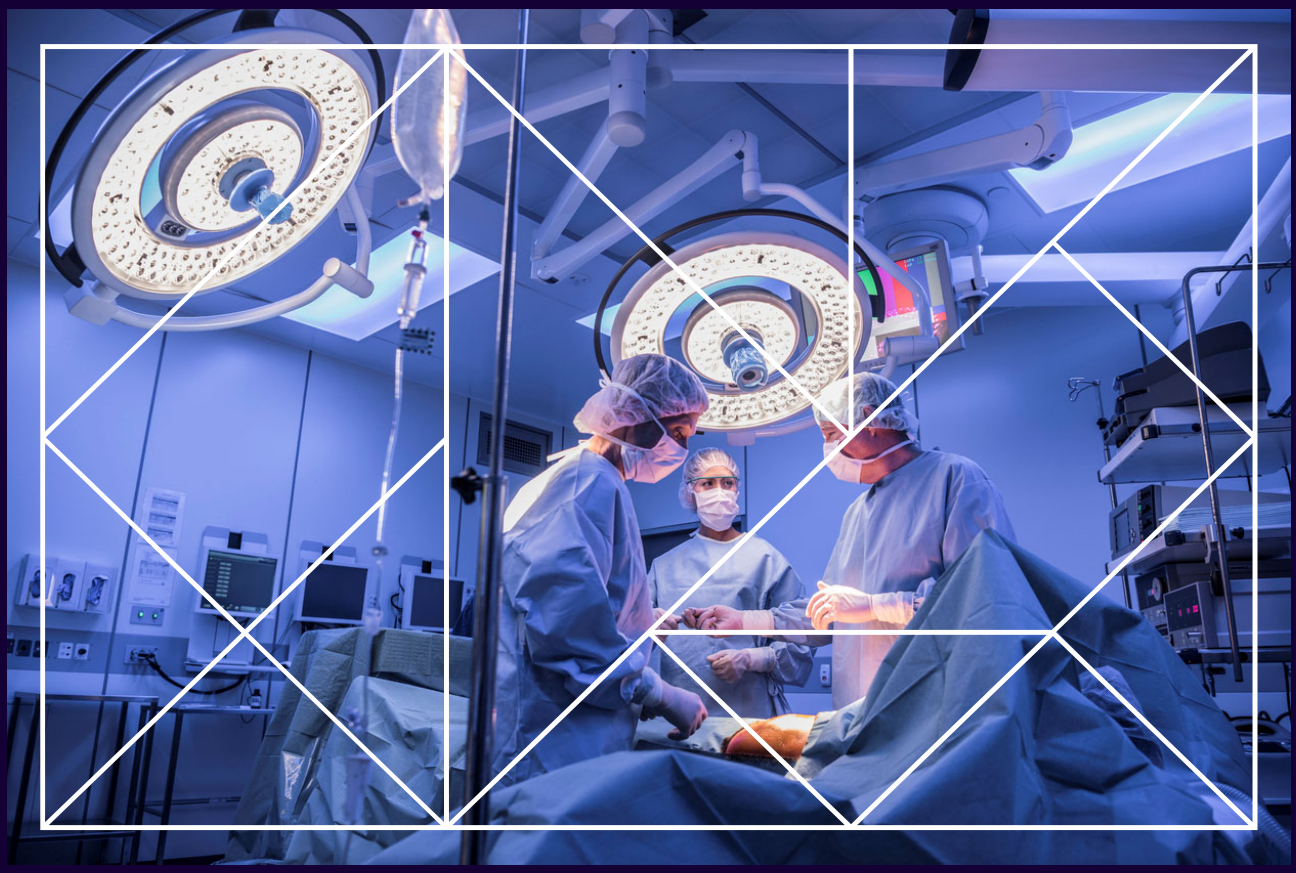
ACIL ALLEN

February 2024

Report to NSW Ministry of Health

Private Health Facilities Regulation 2024

Regulatory Impact Statement



About ACIL Allen

ACIL Allen is a leading independent economics, policy and strategy advisory firm, dedicated to helping clients solve complex issues.

Our purpose is to help clients make informed decisions about complex economic and public policy issues.

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Contents

Executive summary

The *Private Health Facilities Act 2007* (the Act) and the *Private Health Facilities Regulation 2017* (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 NSW. The Act and the Regulation protect the health of NSW residents by requiring that certain medical procedures are only undertaken in appropriate private health facilities (or a public hospital).

The Regulation supports the purpose of the Act by:

- prescribing the requirements for private health facilities to meet minimum standards relating to the safety, care and quality of life of patients
- 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 type of incidents that are reportable
  - the membership of the facility's medical advisory committee
  - permitting a member of an adverse event review (SAER) team[1] 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.

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 2024 (Draft Regulation). In addition, the RIS seeks feedback on whether additional changes are required in a number of areas.

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[2]. ACIL Allen has been engaged by the Ministry to prepare the RIS for the remake of the Regulation.

[1] Previously known as root cause analysis team.

[2] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 11 March 2022.

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 considered sufficient to address the problem (see Chapter 3 for additional details).

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 in private health facilities in NSW

— a framework for adequate governance, oversight and accountability of private health facilities.

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 proposed for the remaking of the Regulation fall within one or more of the following areas.[3]

  a) Minor rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of private health facilities.

  b) Removal of transitional provisions, requirements and standards that are no longer relevant or needed.

  c) Updated references to current or more relevant professional standards/guidelines.

  d) Reviewing the written policies and procedures required for mental health class facilities.

  e) Amending the standards relating to maternity class facilities. These changes will only allow a maternity level 2 class private health facility to admit a patient for a maternity class procedure before 34 weeks gestation (but not before 32 weeks gestation) if (in addition to existing requirements), the facility has a policy that addresses certain matters relating to clinical governance, competency and transfer that is developed having regard to the NSW Maternity and Neonatal Service Capability Guidelines (herein referred to as Maternity Guidelines)[4].

[3] All clauses refer to the current Regulation.

[4] NSW Ministry of Health 2022, *Maternity and Neonatal Service Capability Guidelines*, May, https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/GL2022_002.pdf, accessed 23 June 2022.

f) Extending the cosmetic surgery licence requirements to cover additional types of cosmetic surgery.

Most of the amendments proposed under the areas above leave the obligations of private health facilities largely unchanged, except for amendments under areas d) to f) which impose new and/or different requirements. Further details of the proposed changes under these areas are provided in the sections below.

Review of written policies and procedures required for mental health class facilities

This change entails:

- amending the requirement in Clause 67(a) of Schedule 3 of the Regulation so that the facility's philosophy of service is consistent with the principles in Section 68 of the *Mental Health Act 2007*
- requiring mental health private health facilities at which electro convulsive therapy (ECT) is administered to have procedures in place to ensure compliance with:
  - the *Mental Health Act 2007*, Chapter 4, Part 2, Division 3
  - *Electroconvulsive Therapy: ECT Minimum Standard of Practice in NSW* (ECT Standard) published by the Ministry of Health in January 2011.

Expand the standards relating to maternity class facilities

This change entails amending Clause 48 in Schedule 3 of the Regulation to require level 2 class private health facilities that seek to admit a patient between 32 and 34 weeks gestation to have a policy that addresses the following, and that has been developed having regard to the Maternity Guidelines published by the Ministry of Health on 22 May 2022:

- clinical governance, including competence and credentialling and quality and safety processes
- service requirements, including consultation, escalation and transfer and education.

The goal of this change is to ensure that maternity class facilities have the appropriate level of support services for the types of maternity services they are providing.

Extending the cosmetic surgery licence requirements

This change entails extending the cosmetic surgery licence requirements to cover additional types of cosmetic surgery. In particular, the following changes are proposed:

- Add the following procedures to the list of surgeries required to be undertaken in a licenced facility:
  - breast revision[5]
  - buttock revision[6]
  - breast or buttock augmentation or revision involving fat transfer
  - gynecomastia surgery
  - hymenoplasty[7].

[5] In particular, Clause 5 (2) (d) in Schedule 1 would be amended to read 'breast augmentation, revision or reduction, including by fat transfer or for gynecomastia'.

[6] In particular, Clause 5 (2) (e) in Schedule 1 would be amended to read 'buttock augmentation, revision or reduction, including by fat transfer'.

[7] In particular, Clause 5 (2) (p) in Schedule 1 would be amended to read 'vaginoplasty, labiaplasty or hymenoplasty'.

- Lowering the threshold at which liposuction and fat transfer must be carried out in licensed private health facilities:
  - From a maximum transfer of 2.5 litres of lipoaspirate when conducting a fat transfer procedure to a maximum of 500ml per day (i.e. fat transfer that involves the transfer of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).
  - From a maximum removal of 2.5 litres of lipoaspirate when conducting a liposuction procedure to a maximum of 500ml per day (i.e. liposuction that involves the removal of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).

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 have been analysed in this RIS qualitatively. This is because:

- the Ministry's advice that the RIS was to be prepared on a qualitative basis
- the benefits and costs associated with the alternative options are not amenable to easy quantification due to:
  - limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
  - the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

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. Facilities would meet safety and quality standards based on accreditation imperatives, insurance and liability and reputational concerns and professional obligations of registered health practitioners.

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 decrease 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.

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. 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.

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 that relate to mental health class facilities, maternity class facilities and cosmetic surgery. 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 these three areas, rather than around each of the options.

Mental health class facilities

Amending the standards for mental health private health facilities to ensure the facilities' philosophy of service is consistent with the principles in Section 68 of the *Mental Health Act 2007* and to require mental health class facilities that administer ECT to have procedures in place to ensure compliance with Chapter 4, Part 2, Division 3 of the *Mental Health Act 2007* and the NSW ECT Minimum Standards of Practice would have the following benefits:

- increased accountability of mental health class private health facilities
- a potential reduction of risks of:
  - unsafe practices when providing ECT
  - inappropriate practices when treating people with mental illness
- improved dissemination of information on best practice principles for patient care and quality
- consistency in the approach for caring for people with mental illness across NSW public and private health facilities.

While the proposed changes to the licensing requirements for private mental health facilities in the Regulation would not impose additional obligations from what is already required of facilities under the *Mental Health Act 2007* and in the ECT Standard, the changes may result in additional administrative/compliance costs for facilities due to potential revisions to their policies and guidelines.

Maternity class facilities

Expanding the standards for maternity class private health level 2 facilities that seek to admit a patient between 32 and 34 weeks gestation. Under the proposed changes, such a facility would only be able to admit a patient for maternity class procedures before 34 weeks completed gestation, if the facility has a policy that addresses the following, and that has been developed having regard to the Maternity Guidelines:

- clinical governance, including competence and credentialling and quality and safety processes
- service requirements, including consultation, escalation and transfer and education.

The potential benefits of this proposed change include:

- increased safety and quality of care for women and their newborns, particularly where the pregnancy has additional risks, by:
  - providing a shared and consistent understanding of the planned service capability of a facility at a particular level
  - improving decision making on admissions, escalation of care, transfers, and return transfers for maternity and neonatal services
  - providing a framework for assessing the planned service capability of a facility and assisting in maternity and neonatal service planning and risk management
  - requiring facilities to have clearly defined (and understood) pathways and processes for consultation, escalation of care and/or transfer and established links with networked maternity and neonatal services
- increased accountability of maternity class private health facilities, particularly with respect to the patients that are admitted given the facility's service capability
- decreased risk of private facilities admitting high risk patients who are likely to require a transfer to a higher care hospital
- improved dissemination of information on maternity patients' care and quality
- consistency in the approach for maternity services across NSW public and private health facilities.

The new standards proposed for maternity class private health facilities are likely to result in additional administrative/compliance costs for facilities (e.g. due to increased reporting, potential revisions to the facilities' policies and procedures and new educational processes for staff).

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

Cosmetic surgery

The aim of the proposed changes to cosmetic surgery licensing requirements is to protect patients' safety by requiring that higher risk cosmetic procedures are carried out at licensed health facilities which have to comply with wide ranging standards that relate to both the safety of the premises and clinical care, and which are better prepared to manage potential adverse events. Broadly, the proposed changes could result in:

- a potential reduction of some of the risks related to cosmetic surgery (particularly when there is an adverse event/unexpected complication that requires patients to be transferred to another facility with higher care)
- improved clinical care and patient safety
- a potential reduction in the costs of complications from cosmetic surgery to the Australian public health system

— the Ministry being able to monitor the safety and quality of care of procedures which would now be required to be undertaken in licensed facilities.

Importantly, while undertaking cosmetic procedures in a licensed facility instead of in a clinic setting would inherently improve patient safety and reduce the risks related to adverse events (due to the higher standards that these facilities need to have as a condition of their licence), it is important to note that there is currently no available evidence about the number and type of cosmetic procedures conducted in a clinic-based setting that result in unexpected complications and that need to be transfer to higher care facilities.

Broadly, the proposed changes to the Regulation of cosmetic surgery could result on practitioners currently undertaking the procedures subject to change in a clinic- or office-based setting:

— Cease performing these procedures – this would result in loss in income for these practitioners and could result in the closure of some cosmetic clinics (for instance, clinics for which most/all of its revenue comes from liposuctions[8]). However, it is important to note that the proposed changes to the Regulation do not restrict individual medical practitioners from performing the relevant cosmetic procedures, it requires them to ensure that the facilities where they practice are suitably equipped and staffed to deal with the level of risk involved with these procedures (i.e. that the facilities where they undertake these procedures are licensed).

— Moving these procedures to a licensed private health facility – this would result in additional costs for patients who would need to pay hospital fees in addition to the cost of surgery. These additional costs would be offset by the additional benefit of having the procedure done in a licensed facility which offers higher standards and a lower risk environment in case of complications during the procedure.

— Applying for their own licence – licensing requirements for facilities are extensive and impose a significant regulatory burden on businesses (one of the stakeholders consulted argued that the cost of becoming a licensed facility would be over $1 million), so this may not be an option for many cosmetic clinics. These additional costs could potentially be offset by additional revenue if licensing gives potential patients more confidence about the facility and the safety of the procedure (thereby increasing demand) or the facility can be used by other practitioners for other procedures. Additional investments in obtaining a licence would only be undertaken if they provide proprietors with a return greater than any of the other alternatives (e.g. greater than undertaking a procedure at an existing licensed facility).

— With respect to liposuction specifically, practitioners can remove the desired amount of fat through several procedures undertaken in different days, removing a maximum of 500 ml in each procedure (i.e. by undertaking several ‘mini liposuctions’). This is likely to result in additional costs for the overall procedure for patients.

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

[8] To provide a sense of magnitude about the number of potentially affected procedures, ACCSM data shows that the caseload for liposuction for 40 of their fellows in 2020 was 4,334 procedures and they expect the total caseload for 2021 to be approximately 5,000-5,500 cases (allowing for COVID shutdowns). While the caseload data is not broken down by volume of lipoaspirate removed, it is likely that a high proportion of these cases would need to be conducted in a licensed facility under the proposed changes to the Regulation.

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 three key areas of change proposed for the Draft Regulation, the following is concluded.

- To the extent that the proposed changes to the requirements for **mental health facilities** increase clarity and consistency about the standards of care and treatment of patients with mental illnesses, and potentially reduce the risk of inappropriate or unsafe practices when treating patients at marginal administrative/compliance costs, the change is expected to be overall beneficial.
- The benefits from reduced risks and improved patient safety stemming from the proposed new requirements for **maternity private health facilities** are likely to outweigh the additional administrative/compliance costs related to the proposed changes.
- While there is limited evidence about the number and type of **cosmetic procedures** conducted in a clinic-based setting that result in unexpected complications and result in patients needed to be transferred to higher care facilities (and so it is not possible to establish with certainty whether there is a net benefit associated with the proposed changes to the Regulation), overall, given the well-known risks posed by cosmetic surgery procedures, it is considered that the proposed changes to the licensing requirements to cosmetic surgery are appropriate based on the precautionary principle. Notably, it would be desirable that the proposed changes are accompanied by improvements in data collection regarding adverse events and complications related to cosmetic surgery, so that future policy decisions can be based on better information.

Next steps

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 require mental health class private facilities that their philosophy of service is made consistent with the principles in s68 of the *Mental Health Act 2007*? Would this change improve consistency with the *Mental Health Act 2007*?
- With regards to cosmetic surgery licencing requirements:
  - Should the volume of lipoaspirate that can be transferred or removed in an unlicensed facility be lowered? If so, what volume limit would be appropriate?
  - Should the following procedures be added to the list of surgeries required to be undertaken in a licenced facility:
    - breast revision
    - buttock revision
    - breast or buttock augmentation or revision involving fat transfer
    - hymenoplasty?
  - Are there any other cosmetic procedures that should be added to the list of surgeries required to be undertaken in a licenced facility?
  - Are there any cosmetic procedures that should be removed from to the list of surgeries required to be undertaken in a licenced facility?
  - Does the list of surgeries required to be undertaken in a licenced facility need any clarification?
- 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?
- Are there any additional amendments which could have a net positive impact on the proposed Regulation?
- Could the results of the proposed Regulation be achieved through any alternative options?
- If the proposed changes to the Regulation are made, would industry need time to adjust and comply with the new provisions?

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

Consistent with the *Subordinate Legislation Act 1998*, the Draft Regulation and RIS will be open for public consultation for a period of at least 21 days. Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
St Leonards NSW 1590

Submissions may also be made via email to NSWH-LegalMail@health.nsw.gov.au. Any submission should be made by **14 June 2024**.

Individuals and organisations should be aware that generally any submissions received will be publicly 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: changes to medical advisory committees

The Act requires the licensee of a private health facility to appoint a Medical Advisory Committee (MAC) consisting of a least 5 medical practitioners (each of whom holds general or specialist registration in the medical profession) and such other health practitioners as the licensee considers appropriate. Under the current regulation, at least one medical practitioner appointed to the MAC must not have a pecuniary interest in the private health facility.

Under the Act and Regulation, the MAC is responsible for a range of matters, including:

a) advising the licensee on the accreditation of practitioners to provide services at the facility and the delineation of their clinical responsibilities, and

b) advising the licensee on matters concerning clinical practice at the facility, and

c) advising the licensee on matters concerning patient care and safety at the facility, and

d) providing advice in relation to any admission policies and procedures for the facility

The MAC must also report to the Secretary any repeated failure by the licensee of the facility to act on the committee's advice on matters specified in subsection (2) where that failure is likely to adversely impact on the health or safety of patients.

The MAC is intended to operate as an important governance tool for a facility and provide advice in relation to credentialling, clinical practice and patient care. However, there are no specific requirements in the Act or Regulation about:

— How often the MAC should meet. This means that while a MAC must be established, there is no specific requirement about when the MAC actually meets.

— The qualifications for medical practitioners who sit on the MAC. For example, there is no requirement that if a private health facility is licensed in the surgical class, that a member of the MAC must be a specialist surgeon when issues relating to credentialling of practitioners or safety of patients during or following surgery are discussed.

Due to the important role the MAC is intended to play, the Ministry would like to hear submissions on whether the regulation should be amended to include:

— the minimum number of times that the MAC must meet and, if so, what the minimum number of meetings should be

— a requirement that when the MAC discusses issues relating to accreditation and credentialing of classes of practitioners, or issues relating to clinical practice, the MAC must have a member who is a specialist medical practitioner in the area that is being discussed. For example, if issues relating to credentialling of practitioners who perform surgical procedures are discussed, there must be a specialist surgeon on the MAC. Or if there are issues relating to the safety of maternity patients, there must be a specialist obstetrician and gynaecologist on the MAC

— a requirement that when the MAC discusses issues relating to admissions of particular classes of patients (e.g. surgical patients), the MAC must have a member who is a specialist medical practitioner relevant to that class of patients (e.g. a specialist surgeon).

Source: NSW Ministry of Health.

1 Introduction

1.1 Overview

The *Private Health Facilities Act 2007* (the Act) and the *Private Health Facilities Regulation 2017* (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 NSW. The Act and the Regulation protect the health of NSW residents by requiring that certain medical procedures are only undertaken in appropriate private health facilities (or a public hospital).

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- making provisions for, or with respect to:
  - the particulars that are required to be entered in the register of patients
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  - the membership of the facility's medical advisory committee
  - permitting a member of an adverse event review (SAER) team[9] 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.

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 2024 (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[10]. ACIL Allen has been engaged by the Ministry to prepare the RIS for the remake of the Regulation.

[9] Previously known as root cause analysis team.

[10] Parliamentary Counsel's Office 2018, *Information Sheet on the Staged Repeal of Statutory Rules*, https://www.pco.nsw.gov.au/corporate/Staged_repeal_of_statutory_rules_information.pdf, accessed 11 March 2022.

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 (outlined in Box 1.1) are 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. government action should only occur where it is in the public interest, that is, where the benefits outweigh the costs.
- **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 (using all available data) 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, modernisation 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: NSW Treasury 2019, NSW Government Guide to Better Regulation, tpp19-01.

1.2 Scope of the RIS

The evaluation of costs and benefits of the alternative options analysed in this RIS has been undertaken on a qualitative basis. This is because the benefits and costs associated with the alternative options are not amenable to easy quantification due to:

- limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
- the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

Nature and extent of the problem 2

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 assesses the case for government intervention.

2.1 Safety and quality in private health facilities

The Regulation aims 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[11]:

- 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.

A range of organisations act to improve safety and quality of health care. At a national level, the Australian Commission on Safety and Quality in Health Care (the Commission) leads and coordinate national improvements in the safety and quality of health care in Australia. The Commission (in collaboration with the Australian Government, state and territories, the private sector, clinical experts, consumers and carers) developed the National Safety and Quality Health

[11] 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 11 March 2022.

Service (NSQHS) Standards (see Box 2.1). All public and private hospitals, day procedure services and most public dental practices in Australia must be assessed against the NSQHS Standards, under the Australian Health Service Safety and Quality Accreditation (AHSSQA) Scheme.

The primary aims of the NSQHS Standards are to protect the public from harm and to improve the safety and quality of health care provision by describing the processes and structures that are needed in healthcare services to help keep people safe and improve the quality of health care they receive.

Box 2.1 National Safety and Quality Health Service (NSQHS) Standards

The NSQHS Standards were developed by the Australian Commission on Safety and Quality in Health Care in collaboration with the Australian Government, states and territories, private sector providers, clinical experts, patients and carers. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision. The eight NSQHS Standards provide a nationally consistent statement about the level of care consumers can expect from health services.

Standard 1: Clinical Governance — ensures there are processes to maintain and improve the reliability, safety and quality of health care.

Standard 2: Partnering with Consumers — ensures consumers are partners in the design, delivery and evaluation of healthcare systems and services, and they are supported to be partners in their own care.

Standard 3: Preventing and Controlling Infections — ensures processes are in place to prevent and control infection, and support antimicrobial stewardship, as well as the sustainable use of infection prevention and control resources.

Standard 4: Medication Safety — ensures clinicians safely prescribe, dispense and administer appropriate medicines, and monitor medicine use. It also ensures consumers are informed about medicines, and understand their own medicine needs and risks.

Standard 5: Comprehensive Care — ensures that consumers receive comprehensive health care that meets their individual needs. It considers the impact of their health issues on their life and wellbeing and it ensures risks to patients during health care are prevented and managed.

Standard 6: Communicating for Safety — ensures there is effective communication between patients, carers and families, multidisciplinary teams and clinicians, and across the health service organisation, to support continuous, coordinated and safe care for patients.

Standard 7: Blood Management — ensures patients' own blood is safely and appropriately managed, and that any blood and blood products that patients receive are safe and appropriate.

Standard 8: Recognising and Responding to Acute Deterioration — ensures acute deterioration in a patient's physical mental or cognitive condition is recognised promptly and appropriate action is taken.

Source: Australian Commission on Safety and Quality in Health Care 2022, Introduction to the National Safety and Quality Health Service Standards, https://www.safetyandquality.gov.au/publications-and-resources/resource-library/consumer-fact-sheet-1-introduction-national-safety-and-quality-health-service-standards, accessed 28 March 2022.

At the state level, the Clinical Excellence Commission (CEC) is responsible for leading safety and quality improvement in the NSW *public health system*. The CEC was established in 2004 to reduce adverse events in public hospitals, support improvements in transparency and review of these events in the health system and promote improved clinical care, safety and quality in health services across NSW.

For *private* health facilities in NSW, the Ministry is responsible for setting minimum standards for the provision of safe, appropriate and quality health care for patients.

The consequences of a failure in safety and quality in health care facilities 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 Australian Institute of Health and Welfare (AIHW) reports that around 27 per cent of adverse events were recorded in private hospitals in New South Wales in 2019-20, equating to a rate of 3.7 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. In NSW private hospitals, in incidents where a place of occurrence was recorded, 48 per cent of the 47,393 adverse events occurred outside the facility where that adverse event was treated. Similarly, 51 per cent of adverse events treated at a public health facility occurred at another facility. It is not known how many of these occurred out of the hospital system entirely[12].

Of these adverse events in private hospitals, 74 per cent were as a result of complications from procedures, while a further 6 per cent were caused by unintentional events during surgical and medical care (Table 2.1).

Table 2.1 Adverse events treated within NSW private hospitals by external cause

External cause of injury or poisoning	Number of cases	Share of cases (%)*
Adverse effects of drugs, medicaments and biological substances	8,108	18%
Unintentional events during surgical and medical care	2,569	6%
Procedures causing abnormal reactions/complications	32,786	74%
Other external causes of adverse events	818	2%

[12] Australian Institute of Health and Welfare (AIHW) 2021, *Admitted patient care 2019-20, Information related to the safety and quality of the health system.*. Canberra: AIHW

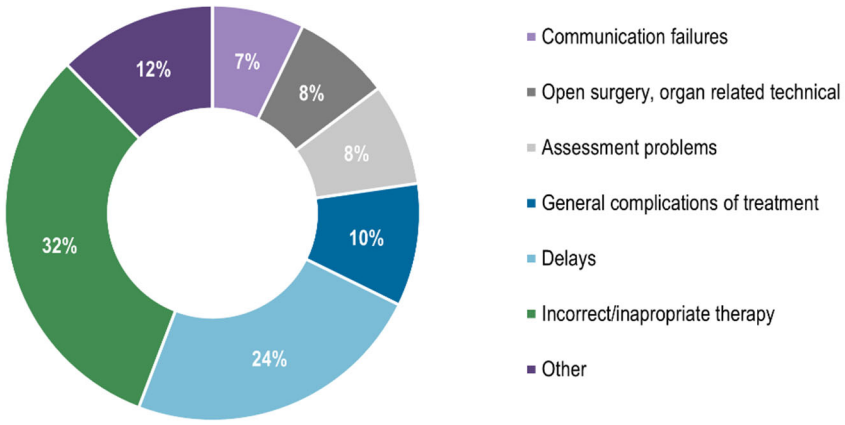
External cause of injury or poisoning	Number of cases	Share of cases (%)*

** refers to share of cases within NSW private hospitals*

Source: AIHW

The New South Wales Clinical Excellence Commission publishes the Collaborating Hospitals' Audit of Surgical Mortality (CHASM), which audits closed cases for surgical deaths. While participation shares are not published, there are over 1,900 surgeons registered as participants. In 2018, there were 1,322 closed cases assessed by surgeons, and of these 19 per cent had an area of consideration, concern or an adverse event identified. As shown in Figure 2.1, of the cases with an area of consideration, concern or adverse event, 32 per cent were identified to have incorrect/inappropriate therapy and 23.5 per cent under the category of delays (which includes delays to surgery or re-operation or earlier operation desirable, delays in diagnosis and delays in transfer to surgical unit, ICU, or tertiary hospital).[13]

Figure 2.1 Categories of deficiency of care - identified areas of consideration or concern, and adverse events for surgical deaths occurring in the 2018 calendar year



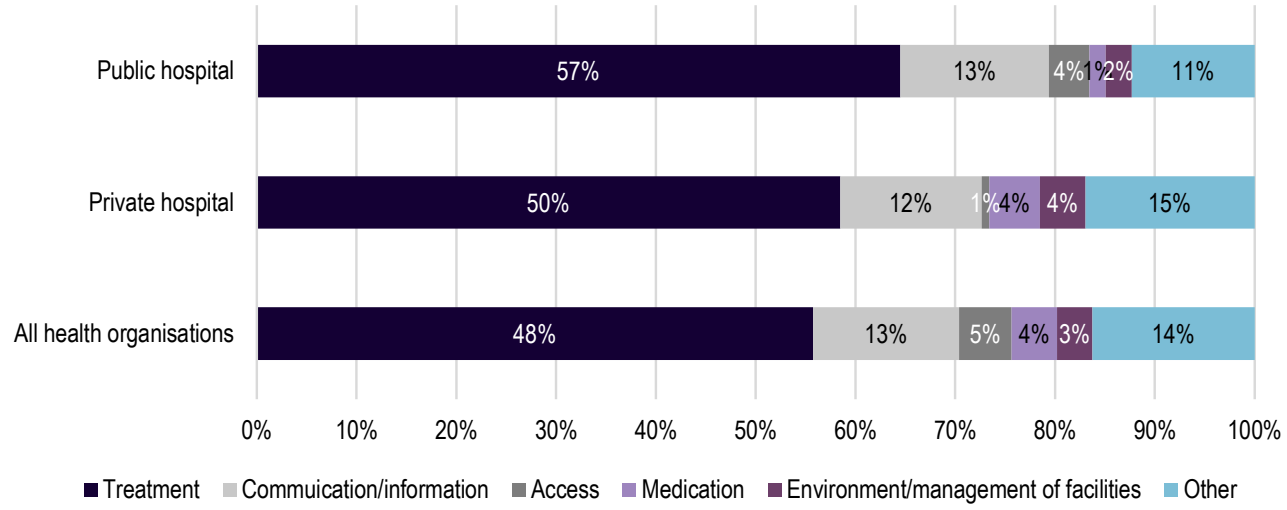
Source: New South Wales Clinical Excellence Commission 2018, CHASM Casebook 2018.

The NSW Health Care Complaints Commission (HCCC) captures an important facet in safety and quality of healthcare through monitoring and resolving patient complaints. In 2020-21, the HCCC received 462 complaints about private hospitals, accounting for 4.0 per cent of the total complaints against health organisations.

Figure 2.2 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 4.1 per cent of complaints about private hospitals, but is unsurprisingly almost absent in relation to public facilities.

[13] New South Wales Clinical Excellence Commission (2018), *CHASM Casebook 2018*, https://www.cec.health.nsw.gov.au/__data/assets/pdf_file/0017/643211/CHASM-Casebook-2018.pdf, accessed 13 April 2022.

Figure 2.2 Most common Issues raised in complaints about health organisations 2020-21



Source: NSW Health Care Complaints Commission Annual Report 2020-21.

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 the costs of preventable incidents arising from health care management in both the public and private health care sectors.

The Australian Government Independent Hospital Pricing Authority, in its 2021 'Pricing and funding for safety and quality' report uses three years of public hospital activity and cost data to model the incremental cost of hospital acquired complications. It finds that the average incremental cost increase in public hospitals across all hospital acquired complications (HACs) was 8.3 per cent relative to an admission without a HAC. Surgical complications that required an unplanned return to theatre have an incremental cost of 11.4 per cent.[14]

A 2018 report by the Grattan Institute also found that patients who suffer complications after a procedure extend their hospital stay by five days on average, and that there are approximately 900,000 complications a year.[15]

A report commissioned by the Australian Commission on Safety and Quality in Health Care found that in 2011-12 hospital acquired complications (HACs) extended the stay of patients by just over five days, and that costs were on average $9,200 higher per episode, and that these additional costs represented 12-16.5 per cent of hospital total costs.[16]

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

[14] Independent Hospital Pricing Authority, 2021, *Pricing and funding for safety and quality – Risk adjustment model for hospital acquired complications*

[15] Duckett, S. and Jorm, C. 2018, *All complications should count. Using our data to make hospitals safer*. Grattan Institute.

[16] Health Policy Analysis, 2013, *Analysis of hospital-acquired diagnoses and their effect on case complexity and resource use – Final report*, Australian Commission on Safety and Quality in Health Care, Sydney

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.[17]

A study on latrogenic injury in Australia potentially which examined preventable adverse events in 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.[18]

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[19].

Cosmetic surgery

The type, availability and popularity of cosmetic procedures has grown dramatically in NSW and Australia over recent years and cosmetic procedures are now frequently carried out by a range of medical practitioners (from specialist plastic surgeons to general practitioners) in a variety of health and office-based environments.

Australia ranks in the top 10 countries spending the most money in cosmetic surgery, and in 2017 it hit the billion-dollar mark on spending in these procedures.[20] The total number of cosmetic procedures in Australia in 2018 was 202,642 (102,404 were surgical cosmetic procedures and 100,238 non-surgical)[21]. According to statistics collected by the International Society of Plastic Surgery (ISAPS), while most people in Australia have cosmetic surgery carried out at a hospital (72.1 per cent), around a fifth of all procedures (20 per cent) are carried out at an office facility and 7.9 per cent in a free standing ambulatory surgical facility.[22]

As the number of cosmetic procedures has grown there have been increased concerns about its safety and regulation across Australia.

The incidence of complications and costs of poor safety and quality related to cosmetic surgery are not well understood in NSW (or Australia) due the lack of data and underreporting of safety issues in this sector. In the 2020-21 annual report for the HCCC, it was reported that there were only 21 complaints about cosmetic health facilities, or 0.7 per cent of all complaints about health organisations.[23] This is supported by the reporting of the NSW Committee on the Health Care Complains Commission, which reported that the HCCC only received 94 complaints in 2016-17 (or

[17] 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.

[18] 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.

[19] 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.

[20] Victorian Cosmetic Institute 2020, Cosmetic Surgery Statistics Australia & Around the World, https://www.thevictoriancosmeticinstitute.com.au/2020/01/cosmetic-surgery-statistics-australia-around-the-world/, accessed 28 March 2022.

[21] International Society of Plastic Surgery (ISAPS) 2018, *Cosmetic Procedures by Location*, ISAPS International Survey on Aesthetic/Cosmetic Procedures Performed in 2018, https://www.thevictoriancosmeticinstitute.com.au/2020/01/cosmetic-surgery-statistics-australia-around-the-world/, accessed 28 March 2022.

[22] Ibid.

[23] Health Care Complaints Commission, 2021, Annual report 2020-21

1.5 per cent of all complaints) regarding cosmetic surgery, which was said to be low for the number of surgeries.[24] Several reasons for this low complaints rate were offered, including:

— complaints are often directed to fair trading
— complaints being issued within day hospitals, and not identified as cosmetic surgery complaints
— patients are unaware that they can complain, or that complaining is not useful
— embarrassment.

Concerns by some industry participants and recent media reporting[25] about serious safety and quality issues in some cosmetic surgery practices (including serious hygiene breaches, patient safety issues, poor patient care, unsatisfactory surgical outcomes and aggressive and inappropriate marketing techniques – see case studies in Box 2.2) has led to the following recent reviews relating to cosmetic procedures:

— an independent review commissioned by the Australian Health Practitioner Regulation Agency (AHPRA) and the Medical Board of Australia (MBA) of the regulation of medical practitioners who perform cosmetic surgery (the final report from this review was published on 1 September 2022)
— a review agreed by all health ministers of the use of the title surgeon by medical practitioners (as part of this review a Consultation RIS was released in December 2021 explaining the current regulatory framework and the potential issues that may be arising from it and proposing potential reform options which may help to address these issues).

Previous reviews relating to cosmetic surgery include:

— A NSW Committee of Inquiry into Cosmetic Surgery in 1998 reviewing the adequacy of existing consumer safeguards and the quality and accessibility of sources of current consumer information on cosmetic procedures.
— A review of cosmetic medical and surgical procedures by the Australian Health Ministers' Advisory Council's (AHMAC) Inter-jurisdictional Cosmetic Surgery Working Group in 2010 which examined the adequacy of current consumer safeguards in relation to cosmetic surgery and assessed the need for a national approach to regulating cosmetic surgery.
— A 2013 review by the Queensland's Health Quality and Complaints Commission of complaints received about cosmetic surgical and medical procedures provided by registered health practitioners in Queensland.
— An inquiry into cosmetic health service complaints in NSW in 2018.

More recently, federal, state and territory Health Ministers Health Ministers tasked the Australian Commission on Safety and Quality in Health Care to lead a review of licensing standards and arrangement of facilities where cosmetic procedures are performed and to develop national standards for the safe delivery of high quality cosmetic procedures.[26] The Commission's report is now complete and that report supports continued regulation of cosmetic surgery.

[24] Committee on the Health Care Complaints Commission, 2018, 'Cosmetic Health Service Complaints in New South Wales'. Report 4/56

[25] Arising from investigations by the Sydney Morning Herald, The Age and the ABC's Four Corners program.

[26] Department of Health and Aged Care 2022, *Health Ministers Meeting (HMM): Statement*, 2 September 2022, https://www.health.gov.au/sites/default/files/documents/2022/09/hmm-statement-on-cosmetic-surgery-2-september-2022_0.pdf.

Box 2.2 Consumer harm case studies

Case study 1

The NSW Health Complaints Commission filed a complaint with the NSW Medical Professional Standards Committee against Dr Niroshan Sivathasan, a cosmetic surgeon who worked at the Cosmetic Institute. In 2015, while working at the Cosmetic Institute a patient in Dr Sivathasan's care went into cardiac arrest while undergoing breast augmentation as a result of an allergy to anaesthetic. After stabilising the patient, Dr Sivathasan recommenced the procedure before calling an ambulance. The Committee determined that this represented unsatisfactory professional conduct.

Case study 2

In the case of Health Care Complaints Commission v Blackstock [2020], the NSW Health Complaints Commission filed complaints against Blackstock in the NSW Civil and Administrative Tribunal that he conducted surgery in an unlicenced private health facility, among other incidences of misconduct. Blackstock's patients reported developing infections that lead to leaking breasts and in some cases required corrective surgery.

Case study 3

In this case, a medical practitioner was deemed not competent to perform laser lipolysis by the NSW Civil and Administrative Tribunal after a consumer suffered serious harm following the procedure. The practitioner was found to be 'inadequately trained in the procedure' and had administered inappropriate levels of morphine and failed to call an ambulance within a reasonable time after the patient became cyanosed. The tribunal ordered that the practitioner's registration be suspended for six months, and their registration be subject to conditions following reinstatement. These conditions prohibited the practitioner from performing both cosmetic procedures and surgical procedures, with minor exemptions. Before this order, the practitioner had general (i.e. not specialist) registration and had completed training to perform lipolysis procedures at the American Academy of Aesthetic Medicine in Thailand.

Case study 4

The Health Complaints Commission (NSW) filed complaints against a practitioner for failing to adequately conduct assessments prior to surgery of patients. These complaints were supported by expert evidence. The practitioner did not obtain informed consent from prospective consumers prior to performing various procedures and used a formulaic approach to obtaining consent to serious procedures.

The practitioner was also said to have woken and sat patients up during surgical procedures to enquire if patients were happy with the size and positioning of breast implants inserted or instead requested associates to enter the room to comment. Information provided about post-operative care was also deemed insufficient or not provided to patients at all.

Following breast augmentation procedures, patients reported being in extreme pain requiring medical intervention, developed fevers and infections, had wounds split open post-surgery and had stiches dissolve resulting in a streptococcus infection.

One patient alleged she arrived at the practitioner's surgery to undergo a breast augmentation and received no hospital gown or sedation and was in 'excruciating pain', stating:

> *He sewed me up and sent me out into another room. No observations were taken, and a staff member gave me Endone. I was told I could leave immediately after the procedure.*

The NSW Civil and Administrative Tribunal held that the practitioner 'engaged in a gross dereliction of his duty of care to' a particular patient upon twice removing and washing an infected implant and reinserting it into the patient. The tribunal held that the practitioner engaged in serious unprofessional conduct to the level that cancellation of his registration was required. The tribunal also held that the practitioner could not have his registration reinstated for a period of seven years.

Source: AustLii, NCAT Annual Report 2020-21, Use of the title 'surgeon' by medical practitioners in the Health Practitioner Regulation National Law, Consultation Regulation Impact Statement. Victorian Health Council

While cosmetic surgery is not funded by Medicare or private health insurance and procedures cannot be performed in a public hospital due to their purely elective nature[27], when there are complications or emergencies arising from cosmetic surgery, patients can be admitted to a public hospital for treatment and/or revision surgery. These places an extra burden on the public health system and additional costs to taxpayers.

There is some academic literature on the incidence and cost of complications from cosmetic surgery, including one study by Miller et. al.[28] This study estimates the total cost to the Australian public health system of the treatment of complications following cosmetic breast augmentation. The authors estimate that between 2000 and 2015 there were 15,251 re-operations to rectify complications out of a total 102,875 breast surgeries over the same period (a complication rate of 14.8 per cent). The cost of these complications was estimated at around $10.4 million. The study also projected an additional $50 million in costs to the Australian public health system over the subsequent fifteen years (2015 to 2030) if cosmetic breast augmentation rates were to increase at the 2000-2015 rate until 2030. Notably, this analysis:

— only shows surgeons' and surgical assistants' Medicare rebates and do not include complications arising from augmentations performed prior to 2000, or revision augmentations and cosmetic augmentations performed overseas. Indeed, the authors estimate that the total health spending on complications from breast surgery between 2000 and 2015 was almost $200 million

— only reflects the costs of treating complications for one type of cosmetic surgery.

Therefore, the results of this study are a significant understatement of the real cost to the public health system and wider economy of complications related to cosmetic surgery.

While the volume of issues with cosmetic surgery may be poorly understood, the type of risks are well documented. Particular risks include infection, faulty implants, hematoma, seroma and inappropriate anaesthetic dosage, leading to excess pain or local anaesthetic toxicity,

Currently, it is possible for cosmetic surgeons performing surgeries not listed in the Regulation to use a lower level of anaesthesia than would otherwise be appropriate in order to avoid the threshold for regulation. Misuse of anaesthetic has led to a number of cardiac arrests in NSW, including in two women who received surgery at The Cosmetic Institute.[29]

In one study by Livingston, the cost of complications arising from 'cosmetic tourism' at one public hospital over 12 months found the average cost of procedures to rectify complications was AUD $12,597.71.[30] A similar American review of the average cost of complications at one hospital found the cost per patient to be USD $26,657.19, most commonly resulting from infection.[31]

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[27] As noted by the Independent Review of the Regulation of Health Practitioners in Cosmetic Surgery, 'while cosmetic surgery is undertaken when there is no clinical need, it should be noted that some surgical procedures within this class may be medically indicated and thus eligible for a Medicare rebate, for example, breast reduction and functional rhinoplasty (septoplasty). It should also be noted that reconstructive surgery differs from cosmetic surgery as, while it incorporates aesthetic techniques, it restores form and function as well as normality of appearance. Surgery done only for reconstructive purposes is not considered cosmetic surgery.' (Australian Health Practitioner Regulation Agency and Medical Board of Australia 2022, *Independent review of the regulation of health practitioners in cosmetic surgery, Consultation Paper*, March).

[28] Miller, G. et al, 2018 'Cosmetic breast augmentation in Australia: a cost of complication study' *Australasian Journal of Plastic Surgery* 1(2):51–64

[29] Ibid

[30] Livingston R, et al. 2015 'The Real Cost of "Cosmetic Tourism" Cost Analysis Study of "Cosmetic Tourism" Complications Presenting to a Public Hospital'. *Eplasty*. 15:e34

[31] Venditto, C. et al. 2021 'Complications of Cosmetic Surgery Tourism: Case Series and Cost Analysis'. *Aesthetic Surgery Journal* 41(5):627-634.

The case for government intervention 3

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.[32]

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.[33] 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

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

[33] Ibid.

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. Another example are cosmetic surgeries (which are usually requested by consumers directly from the medical practitioner undertaking the procedure without a referral from a general practitioner) where consumers who request these procedures may have poor appreciation of the risks of some of these complex medical and surgical procedures.

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.

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.[34] In the case of cosmetic surgeries, the entirely elective nature of the procedure and the fact that these procedures are usually initiated and requested by consumers without a referral from a general practitioner can amplify the information asymmetry (as noted by the MBA[35], in this case, healthcare becomes a commercial activity where the relationship between the medical practitioner and the patient is blurred by the underlying roles of the medical practitioner as a commercial service provider (the 'seller') and the patient as a customer (the 'buyer')).

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 have not existed.

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

[35] Medical Board of Australia (MBA) 2015, *Public Consultation Paper and Regulation Impact Statement: Registered medical practitioners who provide cosmetic medical and surgical procedures*, March.

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 Equity 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*[36], 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.

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.[37] 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

[36] Commonwealth of Australia 2007, *Best Practice Regulation Handbook*.

[37] Ibid.

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: Commonwealth of Australia 2007, Best Practice Regulation Handbook.

Accreditation in the Australian and NSW health care systems

As discussed in Section 2.1, following the establishment of a safety and quality framework, the ACSQHC developed a national accreditation scheme and standards to operationalise the framework. The NSQHS standards were endorsed by the Australia Health Ministers in 2011[38].

All public and private hospitals, day procedure services and public dental practices are required to be accredited to the NSQHS Standards (with state and territory health departments determining which health service organisations must be assessed against the NSQHS Standards). Many other healthcare facilities also choose to be accredited in order to improve the safety and quality of health care provision.

[38] 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 29 March 2022.

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[39]. 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, which enables the Ministry to respond to emerging issues and oversee compliance.

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 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.[40] In contrast, the Regulation sets both general requirements for private health facilities as well as specific conditions for each licence class.
— NSQHS standards not included in the Regulation include safe prescription of medications and prevention of falls. In contrast, the 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). However, these mechanisms would only address the quality of care provided by individual practitioners, but would not address systemic failures of a facility where the operator is not a registered health practitioner. Secondly, the market could self-regulate through developing its own, self-enforced codes of conduct or voluntarily adopting the NSQHS accreditation standards.

In the absence of a regulatory response, it is likely that non-legislative drivers would lead to high 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

[39] Ministry Of Health 2017, Licensing of Private Health Facilities, https://www.health.nsw.gov.au/Hospitals/privatehealth/Pages/licensing-of-private-health-facilities.aspx, last accessed 29 March 2022.

[40] 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 29 March 2022.

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 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 before, means that an industry-owned scheme would be unlikely to deliver the desired public safety objectives.

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 by requiring that certain medical procedures are only undertaken in appropriate private health facilities (or a public hospital).

The objectives of the Draft Regulation remain the same as the *Private Health Facilities Regulation 2017.* 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 certain staff at a private health facility
d) the particulars that are required to be entered in the register of patients
e) the type of incidents that are reportable
f) the membership of the medical advisory committee for a private health facility
g) permitting a member of an adverse event review (SAER) team[41] to make information available to certain committees in connection with any research or investigation the committee is authorised to conduct
h) the disclosure of certain pecuniary interests
i) requiring a licensee to display the licence for a private health facility in a prominent place in the entry foyer of the facility
j) 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 in private health facilities in NSW
— a framework for adequate governance, oversight and accountability of private health facilities.

[41] Previously known as root cause analysis team.

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.[42] Facilities may seek to differentiate on the basis of quality, cost, specialisation 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 Draft Regulation. Generally, the amendments proposed for the remaking of the Regulation fall within one or more of the following areas. [43]

1. Minor rewording, renumbering, restructuring and clarifications that have no material effect on the obligations of private health facilities.
2. Removal of transitional provisions, requirements and standards that are no longer relevant or needed.
3. Updated references to current or more relevant professional standards/guidelines.
4. Reviewing the written policies and procedures required for mental health class facilities.
5. Amending the standards relating to maternity class facilities that seek to admit a patient between 32 and 34 weeks gestation. Under the proposed changes, such a facility can only admit a patient for maternity class procedures before 34 weeks completed gestation, if the facility has a policy that addresses the following, and that has been developed having regard to the Maternity Guidelines:
   - clinical governance, including competence and credentialling and quality and safety processes
   - service requirements, including consultation, escalation and transfer and education.
6. Extending the cosmetic surgery licence requirements to cover additional types of cosmetic surgery.

Additional details about the proposed changes under each of these areas are discussed in the sections below. The impacts of these changes are explored in more detail in the following chapter.

5.3.1 Rewording, renumbering, restructuring and clarifications

The Regulation has been fully re-structured and re-numbered. During this process some clauses have been re-worded, redundant text eliminated and some clarifications to the text have been made. These changes have no material effect on the obligations of industry.

[42] According to the ACSQHC, since January 2013, all hospitals and day procedure services in Australia (1,312 organisations) have been accredited at least once to the first edition of the NSQHS Standards, and 906 health service organisations have completed two assessment cycles. This widespread accreditation of 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.

[43] All clauses refer to the current Regulation.

5.3.2 Removal of transitional provisions, requirements and standards no longer relevant

Clause 23A has been removed from the regulation. This clause was a provision that set the repeal date for COVID related provisions in the Act. This occurred in March 2022, and as such, the clause is no longer required.

5.3.3 Updated references to current or more relevant professional standards/guidelines

A number of references to professional standards and guidelines have been updated in the Regulation. These changes only entail updating the standards'/guidelines' reference numbers or year of publication. No changes to which standards are referred to in the Regulation have been made.

The Draft Regulation refers to two new documents:

- the *Electroconvulsive Therapy: ECT Minimum Standard of Practice in NSW* (additional discussion about this change is provided in Section 5.3.4 below)
- the Maternity Guidelines (additional discussion about this change is provided in Section 5.3.5 below).

5.3.4 Review of written policies and procedures required for mental health class facilities

This change entails:

- amending the requirement in Clause 67(a) of Schedule 3 of the Regulation so that mental health facilities' philosophy of service is consistent with the principles in Section 68 of the *Mental Health Act 2007*
- requiring mental health class facilities at which ECT is administered to have procedures in place to ensure compliance with:
  - the *Mental Health Act 2007*, Chapter 4, Part 2, Division 3
  - *Electroconvulsive Therapy: ECT Minimum Standard of Practice in NSW* published by the Ministry of Health in January 2011.

5.3.5 Expand the standards relating to maternity class facilities

This change entails amending Clause 48 in Schedule 3 of the Regulation to require level 2 class private health facilities that seek to admit a patient between 32 and 34 weeks gestation to have a policy that addresses the following, and that has been developed having regard to the Maternity Guidelines published by the Ministry of Health on 22 May 2022:

- clinical governance, including competence and credentialling and quality and safety processes
- service requirements, including consultation, escalation and transfer and education.

The goal of this change is to ensure that maternity class facilities have the appropriate level of support services for the types of maternity services they are providing.

5.3.6 Extending the cosmetic surgery licence requirements

This change entails extending the cosmetic surgery licence requirements to cover additional types of cosmetic surgery. In particular, the following changes are proposed:

- Add the following procedures to the list of surgeries required to be undertaken in a licenced facility:

  - breast revision[44]
  - buttock revision[45]
  - breast or buttock augmentation or revision involving fat transfer
  - gynecomastia surgery
  - hymenoplasty[46].
- Lowering the threshold at which liposuction and fat transfer must be carried out in licensed private health facilities:
  - From a maximum transfer of 2.5 litres of lipoaspirate when conducting a fat transfer procedure to a maximum of 500ml per day (i.e. fat transfer that involves the transfer of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).
  - From a maximum removal of 2.5 litres of lipoaspirate when conducting a liposuction procedure to a maximum of 500ml per day (i.e. liposuction that involves the removal of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).

[44] In particular, Clause 5 (2) (d) in Schedule 1 would be amended to read 'breast augmentation, revision or reduction, including by fat transfer or for gynecomastia'.

[45] In particular, Clause 5 (2) (e) in Schedule 1 would be amended to read 'buttock augmentation, revision or reduction, including by fat transfer'.

[46] In particular, Clause 5 (2) (p) in Schedule 1 would be amended to read 'vaginoplasty, labiaplasty or hymenoplasty'.

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 have been analysed in this RIS qualitatively. This is because:

- the Ministry's advice that the RIS was to be prepared on a qualitative basis
- the benefits and costs associated with the alternative options are not amenable to easy quantification due to:
  - limited data available to comprehensively demonstrate the effectiveness of the existing Regulation
  - the impracticability of measuring the scale of *marginal* avoidable harm that could be attributed to the proposed changes to the Regulation in a robust way.

Further, in preparing this RIS, selected stakeholder consultations were conducted with several organisations.[47] Where relevant, comments by stakeholders have been included in the discussion. These views need to be further tested during the public consultation period before remaking of the Regulation. Comments received from stakeholders about areas of the Regulation for which changes are not being proposed are presented for future consideration by the Ministry in Appendix B.

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.

[47] Further information about the stakeholder consulted can be found in Appendix A.

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 decrease 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)

This section qualitatively assessed the impacts of the Draft Regulation (Option 2) against the *status quo* (i.e. the current Regulation, Option 1). This analysis has been structured around the impacts of each of the substantive changes proposed for the Regulation, namely changes that relate to:

- mental health class facilities
- maternity class facilities
- cosmetic surgery.

6.2.1 Mental health class facilities

Part 12 in Schedule 2 of the Regulation outlines the licensing standards that mental health facilities must meet in NSW. These include standards regarding:

- the design and construction of mental health class private health facilities
- the conduct of mental health class private health facilities
- visiting hours and telephone access
- accommodation of patients.

Under Option 2 it is proposed that the standards regarding the conduct of mental health class private health facilities are amended to:

- ensure that Clause 67(a) of Schedule 3 of the Regulation is consistent with the principles for care and treatment of patients in Section 68 of the *Mental Health Act 2007*
- require mental health class facilities that administer ECT to have procedures in place to ensure compliance with:
  - the *Mental Health Act 2007*, Chapter 4, Part 2, Division 3
  - *Electroconvulsive Therapy: ECT Minimum Standard of Practice in NSW* (ECT Standard) published by the Ministry of Health in January 2011.

Benefits

The proposed changes would tie in the Regulation with the requirements for private health facilities in the *Mental Health Act 2007* and in the ECT Standard. Broadly, the potential benefits of this include:

- increased accountability of private health facilities
- a potential reduction of risks of:
  - unsafe practices when providing electro convulsive therapy
  - inappropriate practices when treating people with mental illness
- improved dissemination of information on best practice principles for patient care and quality
- consistency in the approach for caring for people with mental illness across NSW public and private health facilities.

Costs

While the proposed changes to the licensing requirements for private mental health facilities in the Regulation would not impose additional obligations from what is already required of facilities under the *Mental Health Act 2007* and the minimum requirements in the delivery of ECT in NSW, the changes may result in additional administrative/compliance costs for facilities due to potential revisions to their policies and guidelines.

Conclusion

To the extent that the proposed changes to the requirements for mental health facilities increase clarity and consistency about the standards of care and treatment of patients with mental illnesses, and potentially reduce the risk of inappropriate or unsafe practices when treating patients, the change is expected to be overall beneficial.

6.2.2 Maternity class facilities

Part 10 in Schedule 3 of the Regulation outlines the licensing standards that maternity private health facilities must meet in NSW. These include standards regarding:

- the type of patients that level 1 and level 2 maternity class private health facilities can admit
- the support services, infrastructure and staff required to provide care for normal and moderate risk pregnancies
- accommodation of neonates
- patient transfer
- a birth register
- minimum accommodation requirements and standards.

Level 2 maternity class private health facilities can also only admit a patient for maternity class procedures before 34 weeks completed gestation, but not prior to 32 weeks completed gestation, if the licence for the facility is subject to a relevant condition and the facility is also licensed as a neonatal class private health facility. This relevant condition means a condition to the effect that the private health facility must have support services, infrastructure and staff with appropriate clinical expertise that, in the opinion of the Secretary, are appropriate for the provision of maternity class procedures to patients who have completed between 32 and 34 weeks gestation.

Under Option 2 it is proposed that the standards for maternity class private health facilities are expanded for maternity class private health level 2 facilities that seek to admit a patient between 32 and 34 weeks gestation. Under the proposed changes, such a facility would only be able to admit a patient for maternity class procedures before 34 weeks completed gestation, if the facility has a policy that addresses the following, and that has been developed having regard to the Maternity Guidelines:

- clinical governance, including competence and credentialling and quality and safety processes
- service requirements, including consultation, escalation and transfer and education.

The Maternity Guidelines are a NSW Health document that describes the planned activity and clinical complexity that a maternity and neonatal facility can safely provide. They aim to provide clear assessment and identification of the service capability of each NSW Health maternity and neonatal health facility. Requiring private health facilities to have regard to the Maternity Guidelines makes explicit the link that private facilities with maternity and neonatal services have with the public health system through tiered perinatal networking arrangements. It also recognises that, while private maternity and neonatal facilities provide high-level care, they cannot always provide complex care for pregnant women, mothers and babies with significant and complex co-morbidities and so care may need to be transferred to a public hospital.

The Maternity Guidelines support the provision of maternity and neonatal services at site specific levels by providing advice about the planned activity and clinical complexity that a facility is capable of safely providing. They provide guidance on admission, escalation and back transfer regarding both maternity and neonatal services and outline the essential elements required by maternity and neonatal services to function at each specific service capability level, including the service scope and requisite core clinical services.

Benefits

The proposed change to the standards for maternity class private health facilities would ensure that maternity class facilities have the appropriate level of support services for the types of maternity services they are providing. The potential benefits of this include:

- increased safety and quality of care for women and their newborns, particularly where the pregnancy has additional risks, by:
  - providing a shared and consistent understanding of the planned service capability of a facility at a particular level

  - improving decision making on admissions, escalation of care, transfers, and return transfers for maternity and neonatal services
  - providing a framework for assessing the planned service capability of a facility and assisting in maternity and neonatal service planning and risk management
  - requiring facilities to have clearly defined (and understood) pathways and processes for consultation, escalation of care and/or transfer and established links with networked maternity and neonatal services
- increased accountability of maternity class private health facilities, particularly with respect to the patients that are admitted given the facility's service capability
- decreased risk of private facilities admitting high risk patients who are likely to require a transfer to a higher care hospital
- improved dissemination of information on maternity patients' care and quality
- consistency in the approach for maternity services across NSW public and private health facilities.

Costs

The new standards proposed for maternity class private health facilities are likely to result in additional administrative/compliance costs for facilities (e.g. due to increased reporting, potential revisions to the facilities' policies and procedures and new educational processes for staff). While many large facilities may 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 compliance costs), the impact could be different for smaller facilities where there may be a greater variation in practices.

The Ministry notes that the proposed additional 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 safety stemming from the increased requirements for maternity class private health facilities are likely to outweigh the additional the administrative/compliance costs related to the proposed changes.

6.2.3 Cosmetic surgery

Currently, private health facilities require a cosmetic surgery class licence under the Act if they provide:

- any cosmetic surgical procedure that is intended to alter or modify a person's appearance or body and involves general, epidural or major regional anaesthetic or sedation resulting in more than conscious sedation (other than a dental procedure or in certain diagnostic imaging practices), or
- any of the surgical procedures in the following list (hereinafter referred to as 'the list'), however that surgery is described and regardless of the level of anaesthesia or sedation used:
  - abdominoplasty (tummy tuck)
  - belt lipectomy
  - brachioplasty (armlift)
  - breast augmentation or reduction
  - buttock augmentation, reduction or lift
  - calf implants

- facial implants that involve inserting an implant on the bone or surgical exposure to deep tissue
- fat transfer that involves the transfer of more than 2.5 litres of lipoaspirate
- liposuction that involves the removal of more than 2.5 litres of lipoaspirate
- mastopexy or mastopexy augmentation
- necklift
- pectoral implants
- penis augmentation
- rhinoplasty (other than revision rhinoplasty — see below)
- superficial musculoaponeurotic system facelift (SMAS facelift)
- vaginoplasty or labiaplasty.

Revision rhinoplasty means a rhinoplasty performed on a patient at least 12 months after an initial rhinoplasty is performed on the patient, and where each of the following circumstances applies:

a) the procedure requires only a local anaesthetic to be administered
b) the procedure does not involve any bony structures or turbinates
c) if a nasal airway is obstructed, it must only be a minor obstruction that can be corrected by the removal of mucous membrane or cartilage
d) the patient has an adequate amount of skin available to perform the procedure.

The requirement for a facility to be licensed if it provides cosmetic surgery involving major anaesthesia or sedation reflects the risks associated with:

- the types of procedures that are performed under such levels of anaesthesia or sedation, and
- the use of such levels of anaesthesia or sedation.

In contrast, the list in the Regulation is intended to capture cosmetic surgeries which pose a high risk to patients, regardless of the level of anaesthesia or sedation intended to be used. In particular, the risks associated with:

- the procedure itself (e.g. the risk of significant blood loss, the likelihood of the patient requiring transfer to higher care and the risk of patient being non-ambulatory if there was a need to evacuate in an emergency)
- the levels of anaesthesia or sedation that may be required to perform the procedure (so as not to cause undue discomfort or pain), particularly the risk that the level of anaesthesia or sedation may result in the patient inadvertently becoming unconscious and/or experiencing local anaesthesia toxicity. This includes the risk of local anaesthetic toxicity for patients undergoing procedures performed by solo proceduralists in an unlicensed clinic
- not including the procedure in the list in the Regulation, such as the possibility of persons attempting to perform the procedure with lower levels of anaesthesia or sedation than would usually be used (to circumvent the licensing requirement that would continue to apply if major anaesthesia or sedation was used).

As noted in the previous chapter, the following changes are proposed to the cosmetic surgery licence requirements:

- Add the following procedures to the list of surgeries required to be undertaken in a licenced facility:
  - breast revision
  - buttock revision
  - breast or buttock augmentation or revision involving fat transfer
  - gynecomastia surgery
  - hymenoplasty.

- Lowering the threshold at which liposuction and fat transfer must be carried out in licensed private health facilities:
  - From a maximum transfer of 2.5 litres of lipoaspirate when conducting a fat transfer procedure to a maximum of 500ml per day (i.e. fat transfer that involves the transfer of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).
  - From a maximum removal of 2.5 litres of lipoaspirate when conducting a liposuction procedure to a maximum of 500ml per day (i.e. liposuction that involves the removal of more than 500ml of lipoaspirate will need to be conducted at a licenced health facility).

Benefits

The aim of the proposed changes to cosmetic surgery licensing requirements is to protect patients' safety by requiring that higher risk cosmetic procedures are carried out at licensed health facilities which have to comply with wide ranging standards that relate to both the safety of the premises and clinical care, and which are better prepared to manage potential adverse events. Broadly, the proposed changes could result in:

- a potential reduction of some of the risks related to cosmetic surgery (particularly when there is an adverse event/unexpected complication that requires patients to be transferred to another facility with higher care)
- improved clinical care and patient safety
- a potential reduction in the costs of complications from cosmetic surgery to the Australian public health system
- the Ministry being able to monitor the safety and quality of care of procedures which would now be required to be undertaken in licensed facilities.

Importantly, while undertaking cosmetic procedures in a licensed facility instead of in a clinic setting would inherently improve patient safety and reduce the risks related to adverse events (due to the higher standards that these facilities need to have as a condition of their licence), it is important to note that there is currently no available evidence about the number and type of cosmetic procedures conducted in a clinic-based setting that result in unexpected complications and that need to be transfer to higher care facilities. However, the Australasian Society of Aesthetic Plastic Surgeons (ASAPS) noted during consultations that their members are 'frequently called upon to treat avoidable life-threatening complications and sub-standard aesthetic results following cosmetic surgery'[48].

Stakeholders consulted for the RIS had polarised views about the need and benefits of the proposed changes, with some arguing that the regulation of cosmetic procedures need to go even further than the proposed changes (see Appendix B) and others claiming that there have not been any adverse events related to clinic-based cosmetic surgery since the 2017 changes to the Regulation and hence that the proposed changes are unnecessary. Despite these differences in views, all the stakeholders consulted for this RIS supported most of the proposed changes to cosmetic surgery in the Draft Regulation, except for the proposed amendments to liposuction, which were opposed by the Australasian College of Cosmetic Surgery and Medicine (ACCSM). The ACCSM argues the changes to liposuction are not necessary given that[49]:

- over the last five years since the 2017 changes to the Regulation of cosmetic procedures, there were approximately 25,000 liposuctions performed by their fellows in a clinic-based setting without any (reported) significant adverse events

[48] ASAPS 2022, *Submission to ACIL Allen review into New South Wales Private Health Facilities Regulation 2017*, 22 April, p. 1.

[49] ACCSM 2022, *Briefing Document: Proposed changes to NSW Private Health Facilities Regulation (2017)*, 7 April.

— it is a requirement by most medical insurance providers that liposuction over 500ml should be performed in accredited facilities as per the NSQHS standards.

Costs

Broadly, the proposed changes to the Regulation of cosmetic surgery could result in practitioners who are currently performing these procedures in a clinic- or office-based setting:

— Cease performing these procedures – this would result in loss in income for these practitioners and could result in the closure of some cosmetic clinics (for instance, clinics for which most/all of its revenue comes from liposuctions[50]). However, it is important to note that the proposed changes to the Regulation do not restrict individual medical practitioners from performing the relevant cosmetic procedures, it requires them to ensure that the facilities where they practice are suitably equipped and staffed to deal with the level of risk involved with these procedures (i.e. that the facilities where they undertake these procedures are licensed).

— Moving these procedures to a licensed private health facility – this would result in additional costs for patients who would need to pay hospital fees in addition to the cost of surgery. These additional costs would be offset by the additional benefit of having the procedure done in a licensed facility which offers higher standards and a lower risk environment in case of complications during the procedure.

— Applying for their own licence – licensing requirements for facilities are extensive and impose a significant regulatory burden on businesses (one of the stakeholders consulted argued that the cost of becoming a licensed facility would be over $1 million), so this may not be an option for many cosmetic clinics. These additional costs could potentially be offset by additional revenue if licensing gives potential patients more confidence about the facility and the safety of the procedure (thereby increasing demand) or the facility can be used by other practitioners for other procedures. Additional investments in obtaining a licence would only be undertaken if they provide proprietors with a return greater than any of the other alternatives (e.g. greater than undertaking a procedure at an existing licensed facility).

— With respect to liposuction specifically, practitioners can remove the desired amount of fat through several procedures undertaken in different days, removing a maximum of 500 ml in each procedure (i.e. by undertaking several ‘mini liposuctions’). This is likely to result in additional costs for the overall procedure for patients.

Conclusion

While there is some evidence about the existence of externality costs related to safety and quality issues in some cosmetic surgery practices (see Section 2.2.1), there is limited evidence about the number and type of cosmetic procedures conducted in a clinic-based setting that result in unexpected complications and that require a patient to be transferred to higher care facilities. Therefore, it is not possible to establish with certainty whether there is a net benefit associated with the proposed changes to the Regulation.

However, the risks posed by cosmetic surgery procedures have been well documented. On this basis, and noting that the aim of the Regulation (and the Act) is to protect the health and safety of NSW residents (including by identifying and avoiding risks to patients), a precautionary approach to regulating cosmetic surgery is considered appropriate. It would be desirable that the proposed

[50] To provide a sense of magnitude about the number of potentially affected procedures, ACCSM data shows that the caseload for liposuction for 40 of their fellows in 2020 was 4,334 procedures and they expect the total caseload for 2021 to be approximately 5,000-5,500 cases (allowing for COVID shutdowns). While the caseload data is not broken down by volume of lipoaspirate removed, it is likely that a high proportion of these cases would need to be conducted in a licensed facility under the proposed changes to the Regulation.

changes are accompanied by improvements in data collection regarding adverse events and complications related to cosmetic surgery, so that future policy decisions can be based on better information.

The Ministry would like to hear submissions on whether the proposed changes to cosmetic surgery licencing requirements are appropriate and on their likely impacts.

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 impacts of each of the substantive changes proposed for the Regulation, namely changes that relate to:

— mental health class facilities

— maternity class facilities

— cosmetic surgery.

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.

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

— To the extent that the proposed changes to the requirements for mental health facilities increase clarity and consistency about the standards of care and treatment of patients with mental illnesses, and potentially reduce the risk of inappropriate or unsafe practices when treating patients at marginal administrative/compliance costs, the change is expected to be overall beneficial.

- The benefits from reduced risks and improved patient safety stemming from the proposed new requirements for maternity private health facilities are likely to outweigh the additional administrative/compliance costs related to the proposed changes.
- While there is limited evidence about the number and type of cosmetic procedures conducted in a clinic-based setting that result in unexpected complications and result in patients needed to be transferred to higher care facilities (and so it is not possible to establish with certainty whether there is a net benefit associated with the proposed changes to the Regulation), overall, given the well-known risks posed by cosmetic surgery procedures, it is considered that the proposed changes to the licensing requirements to cosmetic surgery are appropriate based on the precautionary principle. However, the Ministry would like to hear submissions on whether the proposed changes to cosmetic surgery licencing requirements are appropriate and on their likely impacts

  Notably, it would be desirable that the proposed changes are accompanied by improvements in data collection regarding adverse events and complications related to cosmetic surgery, so that future policy decisions can be based on better information.

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 for a period of at least 21 days.

Submissions about the Draft Regulation can be made to:

Legal and Regulatory Services
NSW Ministry of Health
Locked Bag 2030
ST LEONARDS NSW 1590

Submissions may also be made via email to NSWH-LegalMail@health.nsw.gov.au. Any submission should be made by **14 June 2024**.

Individuals and organisations should be aware that generally any submissions received will be publicly 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 require mental health class private facilities that their philosophy of service is made consistent with the principles in s68 of the *Mental Health Act 2007*? Would this change improve consistency with the *Mental Health Act 2007*?
- With regards to cosmetic surgery licencing requirements:
  - Should the volume of lipoaspirate that can be transferred or removed in an unlicensed facility be lowered? If so, what volume limit would be appropriate?
  - Should the following procedures be added to the list of surgeries required to be undertaken in a licenced facility:
    - breast revision
    - buttock revision
    - breast or buttock augmentation or revision involving fat transfer
    - hymenoplasty?
  - Are there any other cosmetic procedures that should be added to the list of surgeries required to be undertaken in a licenced facility?

  - Are there any cosmetic procedures that should be removed from to the list of surgeries required to be undertaken in a licenced facility?
  - Does the list of surgeries required to be undertaken in a licenced facility need any clarification?
- 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?
- Are there any additional amendments which could have a net positive impact on the proposed Regulation?
- Could the results of the proposed Regulation be achieved through any alternative options?
- If the proposed changes to the Regulation are made, would industry need time to adjust and comply with the new provisions?

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

Box 8.1 Additional area for consideration by stakeholders: changes to medical advisory committees

The Act requires the licensee of a private health facility to appoint a Medical Advisory Committee (MAC) consisting of a least 5 medical practitioners (each of whom holds general or specialist registration in the medical profession) and such other health practitioners as the licensee considers appropriate. Under the current regulation, at least one medical practitioner appointed to the MAC must not have a pecuniary interest in the private health facility.

Under the Act and Regulation, the MAC is responsible for a range of matters, including:

e) advising the licensee on the accreditation of practitioners to provide services at the facility and the delineation of their clinical responsibilities, and

f) advising the licensee on matters concerning clinical practice at the facility, and

g) advising the licensee on matters concerning patient care and safety at the facility, and

h) providing advice in relation to any admission policies and procedures for the facility

The MAC must also report to the Secretary any repeated failure by the licensee of the facility to act on the committee's advice on matters specified in subsection (2) where that failure is likely to adversely impact on the health or safety of patients.

The MAC is intended to operate as an important governance tool for a facility and provide advice in relation to credentialling, clinical practice and patient care. However, there are no specific requirements in the Act or Regulation about:

- How often the MAC should meet. This means that while a MAC must be established, there is no specific requirement about when the MAC actually meets.
- The qualifications for medical practitioners who sit on the MAC. For example, there is no requirement that if a private health facility is licensed in the surgical class, that a member of the MAC must be a specialist surgeon when issues relating to credentialling of practitioners or safety of patients during or following surgery are discussed.

Due to the important role the MAC is intended to play, the Ministry would like to hear submissions on whether the regulation should be amended to include:

- the minimum number of times that the MAC must meet and, if so, what the minimum number of meetings should be
- a requirement that when the MAC discusses issues relating to accreditation and credentialing of classes of practitioners, or issues relating to clinical practice, the MAC must have a member who is a specialist medical practitioner in the area that is being discussed. For example, if issues relating to credentialling of practitioners who perform surgical procedures are discussed, there must be a specialist surgeon on the MAC. Or if there are issues relating to the safety of maternity patients, there must be a specialist obstetrician and gynaecologist on the MAC
- a requirement that when the MAC discusses issues relating to admissions of particular classes of patients (e.g. surgical patients), the MAC must have a member who is a specialist medical practitioner relevant to that class of patients (e.g. a specialist surgeon).

Source: NSW Ministry of Health.

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Appendices

Stakeholder consultations A

As part of the development of this RIS, ACIL Allen undertook informal consultations during March-April 2022 with a limited number of stakeholders to gather stakeholder views about the impacts of potential amendments to the Regulation.

In addition to their views about potential amendments to the Regulation, through these consultations, stakeholders shared their views about a number of other issues related to the Regulation (noting that there will be no regulatory changes associated with these issues at this time). These issues are outlined for future consideration in Appendix B.

The stakeholders consulted through these workshops are outlined in the table below.

Table A.1 Stakeholders consulted during preparation of this RIS

Organisation	Date
Day Hospitals Australia	15 March 2022
Australian Society of Plastic Surgeons	21 March 2022
Australasian College of Cosmetic Surgery and Medicine	29 March 2022
Australasian Society of Aesthetic Plastic Surgeons	30 March 2022
Ramsay Health Care	1 April 2022
Healthe Care	1 April 2022
Macquarie Group	1 April 2022
Healthscope	1 April 2022

Source: ACIL Allen Consulting.

The Australian Private Hospitals Association was asked to participate in the consultations, but were not able to participate.

Issues raised by stakeholders for future consideration

B

Stakeholders consulted for this RIS suggested a number of other refinements to the overall regulatory framework around the areas dealt with by the Regulation. These are presented below for future consideration by the Ministry where feasible. It is important to note that some of these suggestions fall outside the remit of the Regulation and/or the Ministry.

- Some stakeholders provided the following feedback regarding the current list of cosmetic procedures that need to be undertaken in licensed facilities in the Regulation.
  - Regarding breast revision, it was suggested that the term needs to be more nuanced as some revisions (e.g. revision of scars) can be safely done in rooms and do not need to be done in a licensed facility. The following text was suggested 'breast augmentation, reduction or *revision involving removal, repositioning or replacement of implants*'
  - Regarding buttock revision, the following amendment was suggested 'buttock augmentation, reduction, lift or revision *(excluding minor scar revisions)*'.
  - Regarding penis augmentation, it was suggested that the Regulation should read: 'Penis augmentation *by any means*' to cover both prostheses and fat grafting.
  - It was suggested adding further explanation regarding superficial musculoaponeurotic system facelift (SMAS facelift). This additional explanation could read as 'Superficial musculoaponeurotic facelift (SMAS facelift). *This does not preclude a skin only facelift with limited undermining performed under local anaesthetic in a healthy (i.e. ASAI) patient*.'
  - Regarding abdominoplasty, it was suggested to add the following text: 'abdominoplasty (tummy tuck*/apronectomy in all forms*)'
  - It was suggested that blepharoplasties that breach the orbital septum to remove orbital fat, or alter the tarsal plate or levator musculature and blepharoplasties performed on the lower eyelid should be added to the list of procedures to be undertaken in a licensed facility. Blepharoplasties performed on the upper eyelid that do not breach the orbital septum may be undertaken in unregistered facilities.
- The Australasian Society of Aesthetic Plastic Surgeons (ASAPS) made the following recommendations regarding the overall regulatory framework for cosmetic surgeries in NSW:
  - Greater and more proactive enforcement of the existing regulation to give the community confidence that patient safety is being prioritised and upheld. In addition, ASAPS recommends that data around breaches of licensing conditions for cosmetic surgery class private health facilities are regularly published to further support reform of the sector.
  - Amend licensing conditions so that individuals or corporations applying for a license to operate a cosmetic surgery class private health facility must provide documentation proving that cosmetic procedures are undertaken by a registered specialist in surgery, registered through the Australian Health Practitioner Regulation Agency (AHPRA). A requirement to provide documentation of AHPRA registration status will help ensure that only medical practitioners with specialised surgical training and are conducting procedures in private facilities.

  - ASAPS recommends that the Regulation be amended to ensure only specialist anaesthetists registered though AHPRA are licenced to deliver anaesthesia for cosmetic surgery in NSW private health facilities.
  - Medical practitioners should be required to display their specialist surgical registration status in NSW private health facilities to help patients make informed choices based on factual information, and understanding of the practitioner's skills and qualifications and the associated risks.
- The Australasian College of Cosmetic Surgery and Medicine (ACCSM) suggested that all clinics performing liposuction between 500ml – 2,500ml of lipoaspirate should by accredited by the Australian NSQHS standards. The ACCSM believes that the NSQHS standards sufficiently capture all the necessary standards to ensure public safety whilst also maintaining equity of access for these procedures to the general public.
- The following comments were made with regards to the regulation of day facilities in NSW.
  - It was suggested that there should be a licencing category for facilities with stays of under 23 hours. The rationale for this change is that many hospitals that need the 23 hours coverage for recovery tend to go for an overnight hospital licence which tends to distort day hospital data (the issue relates to patients who stays overnight but less than 23 hours).
  - The Australian Standard AS 4187 is going to be combined with the office based standard and renamed AS 5369. This amalgamation will have significant cost implications for smaller facilities (and it was flagged that some facilities will have to close because they will not be able to meet this new standard).

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