AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

# National Safety and Quality Health Service Standards and their use in a Model National Accreditation Scheme

## Decision Regulatory Impact Statement

October 2010

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# 1. Introduction

The preparation of this Regulatory Impact Statement (RIS) is the final stage of an extensive consultation process undertaken by the Australian Commission on Safety and Quality in Health Care (the Commission) to develop a set of national safety and quality health service standards and their use in a model national accreditation scheme for safety and quality in health care. It includes information gathered from stakeholders on the consultation RIS. There are ten National Safety and Quality Health Service Standards (the Standards) and a model national accreditation scheme that proposes a revised process for accreditation of health services organisations and reporting of performance against the standards. Work over the last decade and extensive consultation with stakeholders over the past 4 years has been fundamental to the development of the Standards and model.

Where regulations are to be implemented at a State, Territory or Commonwealth level, a regulatory impact assessment is required. This involves a number of steps:

- Identifying the problem and the case for action
- Considering the feasible options for addressing the problem
- Consulting with key stakeholders throughout the analysis of the problem and development of options
- Recommending the option that is both proportional to the issue being addressed and generates the greatest net benefit for the community.

Regulation refers broadly to any legally enforceable requirement which becomes mandatory for businesses and the community, therefore is applicable in the private rather than public sector. This includes government voluntary codes and advice for which there is a reasonable expectation by governments that there will be widespread compliance. The Standards implemented for high risk health services via a national accreditation program are an example of where there is a reasonable expectation of compliance.

As part of the Council of Australian Governments (COAG) processes, Ministerial Councils follow an established process of undertaking consultation on proposals that have a potential regulatory impact. Governments have agreed that in order to establish and maintain effective regulatory arrangements and avoid unnecessary compliance costs and restriction on business a regulatory assessment must be undertaken prior to a decision on regulatory changes being made. An analysis of comments from stakeholders forms a RIS presented to governments to inform their decision making processes.

The Australian Health Ministers' Conference (AHMC) is the Ministerial Council which will decide on the adoption of the Standards and their implementation through the model national accreditation scheme.

# 2. Development of national safety and quality health service standards

## Context

Health services have progressively sought to improve the safety and quality of health care through external assessment against standards. This process is known as accreditation. These processes commenced in the mid 1970s and have progressively expanded in scope and coverage from acute care hospitals to cover public and private services, pathology, general practices, radiology services, community and ambulatory care and the aged care sector.

The development of this system has resulted in a number of organisations and businesses offering accreditation services to the market, assessing health services against a range of different safety and quality standards. In some cases accreditation processes overlap with State and Territory private health facilities licensing systems and contractual obligations required to access health insurance funding.

Accreditation is a necessary part of a comprehensive system to support safety and quality. Such a safety and quality system includes the resources, policies, processes and procedures of the health services that are organised, integrated, regulated and administered. The system:

- interfaces risk management, governance, operational processes and procedures, including education, training and orientation
- deploys an active implementation plan and feedback mechanisms
- has agreed protocols and guidelines, decision support and other resource material
- employs a range of incentives and sanctions to influence behaviours and encourage compliance with policy, protocol, regulation and procedures.

By itself accreditation against standards does not ensure the safety and quality of health care provided to patients. However, accreditation is effective as part of an improvement system because it can verify that actions are being taken, that system data and information are being used to inform the analysis of issues and program solutions, and that safety and quality improvement is being achieved.

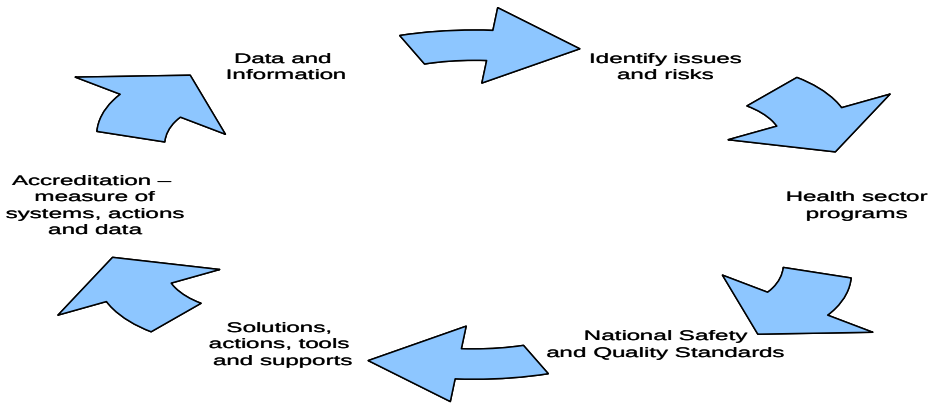


Figure 1: Australian Quality Improvement for Health Care Cycle

National approaches to safety and quality improvements, which include accreditation, have the potential to reduce the harm to patients and the cost to the health system of safety and quality lapses.

## Australian Health Minister's Considerations

For the past ten years, the AHMC has had an increasing focus on national strategies for improving the quality and safety of health care in the Australian system. For the period 2000 to 2005, this work was led by the former Australian Council for Safety and Quality in Health Care, and included a review of standards setting and accreditation in 2003. This involved a detailed literature review and significant stakeholder consultation that resulted in three publications:

- *Standards setting and accreditation literature review and report, July 2003 [1]*. This paper summarised the main systems of standards setting nationally and internationally, focusing on governance, standards content, assessment approaches, compliance issues and public reporting.
- *Standards settings and accreditation systems in health: Consultation paper, July 2003 [2]*. Individuals and organisations were invited to provide comment on the issues raised in the consultation document at workshops or interviews or in written submissions. The consultation document specifically sought comment on:
  - governance of accreditation systems
  - standard setting process
  - the process of external evaluation of compliance against standards
  - ensuring action on the outcome of accreditation evaluations, and
  - promoting continuous quality improvement.
- *Standards setting and accreditation system in health consultation: A marketing research report, 2003 [3].* This paper provided an overview of comments and issues about accreditation identified by stakeholders in their submissions and during consultation workshops and interviews.

In July 2004, AHMC established a *Review of Future Governance Arrangements for Safety and Quality in Health Care* (the Paterson Review) [4] which called, *inter alia*, for an alternative model of health service accreditation and proposed that "Ministers be provided with a plan to transform accreditation arrangements to enhance the role of accreditation in both quality improvement and in the implementation of agreed national standards". The recommendations of the Paterson Review were endorsed by Health Ministers in July 2005 and led to the establishment of the Commission in January 2006.

The Commission was established to lead and coordinate national improvement in safety and quality. In addition it was charged specifically with recommending nationally agreed standards for safety and quality improvement.

In June 2006, the Commission was tasked by AHMC to:

- Review accreditation in Australia: consider the current arrangements in light of international experiences and recommend a revised model for accreditation of both public and private health services across Australia
- Outline the strengths and weaknesses of the current system, the benefits that can be gained in a future system, and a process and timetable for recommending an alternative model for accreditation, including a national set of standards by which health services would be assessed.

In November 2006, AHMC agreed to the public release of the Commission Discussion Paper, *National Safety and Quality Accreditation Standards* for consultation [5].

In July 2007, AHMC agreed in principle to a model to reform the accreditation system developed following consultation with jurisdictions, health services, accrediting agencies and the health industry. Ministers recommended the model be the basis of further consultation with key stakeholders.

In April 2008, AHMC endorsed in principle a model of accreditation that had as its central tenets national coordination of safety and quality accreditation and the Standards. This model built on the strengths of the existing accreditation models to:

- Address the lack of coordination, fragmentation and duplication in the current accreditation system.
- Allow State, Territory and Commonwealth governments to provide input into the content of and direct involvement in, the development of safety and quality health service standards.
- Increase transparency by providing State, Territory and Commonwealth governments with access to information about health services accreditation outcomes and by giving greater access to information for consumers.
- Introduce a single set of uniform standards that apply across all health services and that set the minimum expected level of safe and quality care to be provided to patients.

In November 2009, AHMC received an update on the Commission's work program that noted significant progress that had been achieved through comprehensive consultation and collaboration with key public and private health sector stakeholders. This has resulted in:

- the development of the draft Standards
- the development of a new model national scheme of accreditation for health service organisations
- clarification of the recommended scope for national accreditation
- an approach to the approving of accrediting agencies to accredit against the Standards.

The Commission has now developed a set of National Safety and Quality Health Service Standards and a model national accreditation scheme for consideration by AHMC in November 2010.

In summary this development is the result of:

- over 100 meetings convened with stakeholder organisations
- 56 focus groups convened to discuss the model and standards with over 600 participants
- a national workshop of 140 participants representing all key stakeholders
- 12 reports
- 290 written submissions received and analysed
- over 70 presentations to health sector participants.

## National Health Reform

On 20 April 2010, COAG agreed (with the exception of Western Australia) to sign the National Health and Hospitals Network Agreement. This Agreement provides for the establishment of an independent permanent national safety and quality commission that has responsibility for the development of safety and quality standards [6]. A Bill to establish the Commission as a permanent independent Commonwealth Authority was tabled in Federal Parliament on 23 June 2010. The Bill was reintroduced into Parliament on 29 September for its first and second readings. It was referred to Senate Community Affairs Legislation Committee on 30 September and this Committee is due to report on 18 November 2010. It listed the functions of the proposed Commission including:

> Clause 9 (1)
>
> (e) to formulate, in writing, standards relating to health care safety and quality; and
>
> (j) to monitor the implementation and impact of:
>
> (i) standards formulated under paragraph (e)
>
> (l) to formulate model national schemes that:
>
> (i) provide for the accreditation of organisations that provide health care services: and
>
> (ii) relate to health care safety and quality matters.

# 3. National Safety and Quality Health Service Standards

The National Safety and Quality Health Service Standards (the Standards) are an explicit statement of the level of care consumers should be able to expect from health services. Standards also provide a mechanism to enable the systematic review of complex systems and a way of tracking changes in the safety and quality of patient care. Meeting standards achieves a range of purposes, including:

- Improving safety systems
- Standardising processes and products
- Implementing quality improvement practices
- Providing a quality basis on which funding can be made.

Critical to accreditation reform are ten National Safety and Quality Health Service Standards (the Standards). These Standards were selected because they address known safety and quality issues

- that impact on a large number of patients
- where there is known gap between the current situation and best practice outcomes, and
- in which improvement strategies exist that are evidence based and achievable.

The development of the ten Standards has occurred over the past 18 months and has involved extensive consultation, including:

- Reviewing evidence and advice from stakeholders on the content areas
- Drafting the standards in conjunction with technical experts and stakeholders
- Testing and validating the standards with Commission standing committees, working groups and jurisdictional representatives
- Calling for public submissions
- Convening focus groups with consumers
- Meeting with industry groups and accrediting agencies
- Piloting standards in health services.

This process has been completed for an initial set of five standards. The input from stakeholders, which is detailed in Section 9, was significant, with stakeholders seeking amendments to the structure, format and language of the standards. There was, however, broad stakeholder support for the content of the standards which has remained largely unchanged.

The five additional standards were released publicly for comment on the content of the Standards in August 2010. These incorporate the amendments to format, structure and language recommended by stakeholders on the national Standards. The current Standards consultation process is specifically seeking comment on the technical content, in contrast to this RIS process which is seeking advice on the impact of adopting the ten national Standards.

All of the Standards are available from the Commission's web site at: www.safetyandquality.gov.au. The ten Standards are:

1. *Governance for Safety and Quality in Health Service Organisations*, which provides the framework for Health Service Organisations as they implement safe systems
2. *Partnering for Consumer Engagement* describes a consumer-centred health system by including consumers in the design and delivery of quality health care
3. *Healthcare-Associated Infection*, describes the standard expected to prevent infection of patients within the healthcare system and to manage infections effectively when they occur, to minimise their consequences
4. *Medication Safety*, describes the standard expected to ensure clinicians prescribe, dispense and administer appropriate and safe medication to informed patients
5. *Patient Identification and Procedure Matching*, specifies the expected processes for identification of patients and correctly matching their identity with the correct treatment
6. *Clinical Handover*, describes the requirement for effective clinical communication whenever accountability and responsibility for a patient's care is transferred
7. *Blood and Blood-product Safety* sets the standard to ensure that the patients who receive blood and blood products are safe
8. *Prevention and Management of Pressure Ulcers* specifies the expected standard to prevent patients developing pressure ulcers and best practice management when pressure ulcers occur
9. *Recognising and Responding to Clinical Deterioration in Acute Health Care* describes the systems required by health services responding to patients when their clinical condition deteriorates
10. *Preventing Falls and Harm from Falls* describes the standards for reducing the incidence of patient falls in Health Service Organisations.

Standards 1, and 3-6 were released for public consultation in November 2009. Standards 2, and 7-10 were released for public consultation August 2010.

The Governance for Safety and Quality Standard and the Partnering for Consumer Engagement Standard provide the context for the implementation of each of the other standards. These ten Standards set the overarching requirements for effective implementation of the remaining eight standards which address clinically specific areas of patient care.

The Governance Standard provides the safety and quality framework by outlining the expected governance structures and processes of a safe organisation. It requires clear governance processes, routine risk management systems, monitoring of services and quality improvement programs to be in place throughout an organisation. In combination these elements constitute a safety system.

Increasingly the evidence suggests that engaging consumers leads to improved safety, quality and efficiency. However tools and guidance about the most effective methods of consumer engagement are only just becoming available. The Partnering for Consumer Engagement Standard requires the effective and meaningful engagement of consumers in organisational planning. This Standard provides the framework for a patient focused service culture by involving consumers in the review, design and implementation of services.

## Core and Developmental Measures

The Standards provide a nationally consistent and uniform set of measures of safety and quality across health services and so will be able to be applied across a wide variety of services where the complexity, size, service delivery model and structure vary. Not all issues present an equal safety and quality risk in all health services and neither are the Standards equally applicable across all health services. For example, dental practices and medical rooms are unlikely to use blood or blood products.

To apply the Standards in an effective and beneficial way requires a degree of flexibility in assessment. Each Standard contains a number of measures to be used in an assessment process. Most of these are core measures and satisfactory performance against these measures must be demonstrated to meet the Standards. A small number of measures are developmental measures, intended to provide aspirational targets. Developmental measures flag areas where focused quality improvement activities and/or investments are to be made by health services to improve patient safety and quality. Performance against these measures should not be included in determining the overall performance of a health service.

Where a health service is of the opinion that a particular Standard is not applicable to it, for example the Blood and Blood Product Standards in the case of a dental practice, then initially a common sense approach will apply to exempt assessment for that standard across similar health services. Further opportunity will then exist for exemption applications from individuals and sectors for other Standards.

## Rating

The model national scheme for accreditation uses a 'met/not met' scale. This is because it has the potential to enhance the inter-rater reliability across multiple accreditation bodies and service types and provide a clear outcome of the assessment against the standards.

# 4. 'The Problem' being addressed

In April 2008 and again in November 2009, Health Ministers supported the implementation of uniform national standards. Given this, the problem this RIS addresses is the formulation and systematic implementation of national standards that can most effectively:

1. Reduce the variation and costs associated with multiple sets of standards
2. Provide a clear separation of standards setting and assessment processes
3. Increase the transparency and access to standards
4. Reduce the limitations in the current application of standards

### 1. Reduce the variation and costs associated with multiple sets of standards

In Australia safety and quality standards have been developed by a range of bodies, including:

- Government agencies
- National bodies representing disease specific organisations, professional associations, or peak bodies
- Accreditation agencies that develop health specific and/or facility standards
- International and national standards setting bodies

In 2006 the Commission mapped the existing standards being used to assess safety and quality of health services. This process involved the documenting 17 sets of standards. The process showed that there is no one set of safety and quality standards that is applied across all health services. The sector in which the health service operates and the accrediting agency engaged by the health service largely determine the standards against which a service is assessed.

Hospitals can be accredited against either the standards developed by the Australian Council on Healthcare Standards (ACHS using the EQuIP standards) or the International Standards Organisation (ISO 9001) combined with the 'Core Standards for Safety and Quality in Health Care' developed by a committee of the Joint Accreditation Scheme of Australia and New Zealand (JAS-ANZ).

Professional practices largely use standards developed by their professional associations, while community and ambulatory health services use a range of standards developed by the Quality Improvement Council (for example drug and alcohol services), their professional organisations (for example general practitioners, physiotherapists), government agencies (for example Aboriginal controlled health services, National Pathology Accreditation Advisory Committee), ISO or ACHS standards.

The impact from the use of multiple sets of standards is that variations exist in the level of care assessed as acceptable. Infection control is one such example. The JASANZ Core Standard requires health services to comply with practice guidelines, although which guidelines are not specified, and while the national guidelines are currently being updated, health services are being assessed against guidelines last updated in 2004. The 3rd Edition Royal Australian College of General Practitioner's standard on infection control concerns sterilisation of equipment, occupational health and safety of staff, and managing cross infection. The ACHS 4th Edition requires that the infection control system supports safe practice and ensures a safe environment for consumers/patients and healthcare workers. While the criteria are mandatory and are supported by guidelines, they do not directly address antibiotic stewardship or governance issues.

### 2. Provide a clear separation of standards setting and assessment

The current accreditation system enables the accrediting agencies to both set safety and quality standards and undertake the assessment of a health service against those standards. Such agencies determine the number and the complexity of the standards, and the frequency, format and mechanisms by which the standards are measured and health service performance is reviewed. While safety and quality plays its part in these decisions, concerns exist that commercial considerations can also be an influence.

While accrediting agencies that both set and review health standards in Australia consult broadly in the development of their standards, the final decisions on the scope, content and measures of performance are made separately from those bodies that are held accountable for the performance of health services.

The separation between standards development and assessment is considered by the Commission and State and Territory Health Departments to be a key requirement of good governance.

### 3. Increase the transparency and access to standards

Under the current system of standards development and adoption, not all sets of safety and quality standards are available publicly. Many are accessible only to members of the standard setting body or at substantial cost. Further, where the standards are available, the interpretive documentation that underpins the standards are often proprietary products that remain unavailable to non-members.

For the public and health policy makers and managers the lack of access to this information means understanding and interpreting the intent of the standards and the level at which they will be assessed can be restricted. It also means that accreditation outcomes information about health services are not available for analysis to an agency, such as the Commission, to understand and report on trends in safety and quality.

### 4. Reduce the limitations of the current application of standards

A literature review and then broad consultation with industry and community stakeholders undertaken by the Commission between 2007 and 2010, identified the following limitations and issues with the current safety and quality standards [21]:

- the proliferation of standards with safety and quality components, particularly without a process to identify those which are essential to achieving safety and quality outcomes
- a lack of transparency in accreditation processes with no clear accountability or mechanisms for taking action if standards are not met
- the use of standards with a limited consumer focus, as a growing body of evidence suggests patient centred care improves the safety and quality of services
- an absence of nationally consistent safety standards across all settings of care, despite a high level of consumer expectation that such standards would exist
- Ministers are held accountable by the community for the safety of the health system, but have limited influence on the standards and the accreditation process that apply.

## Reasons for reforming accreditation

Australia has a mature accreditation system and in the hospital sector, stakeholders consider that the accreditation process has promoted positive change, improved decision making processes and resulted in more structured organisational processes. This is supported by the, albeit limited, literature in this field [7].

However, there are still substantial gains to be made in safety and quality, and these could be facilitated in part by a more effective national accreditation scheme which focuses on the development of national standards areas where there is evidence of both harm to patients and effective strategies to improve quality and safety.

The potential for improvements arises from:

- Reducing harm to patients and reducing the costs of care
- Improving system and consumer productivity, and
- Improving consumer trust in the healthcare system.

### *Reducing harm to patients and reducing the costs of care*

Where standards address key safety and quality issues and are systematically applied and assessed effectively patient harm can be reduced. In 2007/08 Australia spent $103.6 billion or 9.1% of its gross domestic product on health. Governments fund almost 70% of this expenditure. In Australia, health care is generally associated with good health outcomes. It is, however, known that patients are still harmed, care is not always coordinated and patients do not always access the information needed to make informed choices about their care. This harm occurs despite there being close to 100 percent accreditation coverage of hospitals and day procedure services and approximately 83% of general practices being accredited. Improving the effectiveness of testing safety and quality systems and driving quality improvement using accreditation is an essential part of reducing harm.

Table1: An recent analysis of published reports on the incidence of healthcare harm internationally has estimated the following [8]:

| The incidence of: | Ratio |
|---|---|
| Experiencing an adverse event in an intensive care unit [a] | 1 : 2 |
| Being injured if you fall in hospital [b] | 1 : 2 |
| An adverse event in ICU being serious enough to cause death or disability [c] | 1 : 10 |
| Experiencing an adverse event or near miss in hospital [d] | 1 : 10 |
| Experiencing a complication from a medication or drug [e] | 1 : 20 |
| Developing a hospital acquired infection [f] | 1 : 30 |
| Being harmed while in hospital [g] | 1 : 300 |
| Dying from a medication error in hospital (as an inpatient) [h] | 1 : 854 |
| Having a retained foreign body after surgery (intra-abdominal) [i] | 1 : 1,000 |
| Being subjected to wrong site surgery [j] | 1 : 112,999 |
| Dying as a result of anaesthesia [k] | 1 : 250,000 |
| Contracting HIV as a result of a screened blood transfusion [l] | 1 : 2,600,000 |

[a] Andrews et al, 1997; [b] Schwendimann et al, 2006; [c] Andrews et al, 1997; [d] CCGR data, average across studies in Australia, Canada, Denmark, New Zealand, UK and USA; [e] Andrews et al, 1997; [f] Pittet, 2005; [g] Multiple sources of data, averaged by CCGR across studies in Australia, Canada, Denmark, New Zealand, UK and USA; [h] Kohn et al, 1999; [i] Gawande et al, 2003; [j] Kwann et al, 2006; [k] JCAHO,1998; [l] Lackritz et al, 1995.

While not all of these studies have been reproduced using Australian data, because of the similarities in care delivered in healthcare systems it is reasonable to assume that the reported incidences reflect or at least are consistent with the occurrence of patient harm in Australia. Further, a study undertaken in the United States of America of the appropriateness of care delivered, found that patients only received 55% of the recommended clinical care and this was consistent across all socioeconomic groups studied [9].

While there is limited information on the overall cost of safety and quality lapses, recent reports illustrate the current monetary costs including:

- Overall hospital acquired illness and injury
  *"Health care-associated injury and ill health...add between 13 and 16 per cent to hospital costs alone; at least one dollar in every seven dollars spent on hospital care"* [10].

- Medication safety
  There are approximately 190,000 medicine related hospital admissions in Australia each year with an estimated cost of $660 million [11].

- Falls
  If nothing is done to prevent falls, the total estimated cost attributable to falls-related injury will increase almost threefold from $498.2million per year in 2001 to $1,375million per year in 2051 [12].

- Antimicrobial stewardship
  If there was optimal antimicrobial use and containment of antimicrobial resistance, $300 million of the Australian national healthcare budget could be redirected to more effective use every year [13].

- Medical indemnity in Australia
  The ultimate cost of claims grew from $159 million in 2004–05 to $203 million in 2007–08. [14]

- Overseas costs
  Multiple costs have been identified including:

  a. In the US, avoidable post-operative sepsis can cost up to $57,700 per patient; reopening of a surgical incision results in $40,300 per patient excess charges and 'selected infection due to medical care' $38,700 per patient

  b. In the US, the average cost of one hospital pressure ulcer was $37,288 in 1999 (nationally a cost of $2.2bn to $3.6bn)

  c. In the UK, one patient fall, causing a fractured neck of femur (hip), costs £11,452 [15].

A study released by the Society of Actuaries estimated that in 2008 medical errors cost the American economy at least $19.5 billion. Of that total, about $17 billion was due to increased medical costs, $1.1 billion to lost productivity from short-term disability claims, and $1.4 billion from increased mortality rates [14].

### *Improving system and consumer productivity*

Safer systems also have the potential to increase the capacity and productivity of the system. Accreditation is an industry accepted mechanism to test safety systems against standards and that these systems are being implemented effectively. Improved productivity may come with a reduction in patient harm, for example:

- Hospital-acquired illness and injury

  The costs of hospital acquired illnesses and injuries are substantial: they add between 15 and 20% to the costs of hospital care. The opportunity costs of these illnesses and injuries are also large: in one Australian state alone, they were found to add 393,000 bed days to patient stays over a 12 month period (equivalent to 76,000 additional admissions). Among the top four hospital acquired diagnosis were multi resistant infections and falls resulting in fractured hips. [10, 16].

- Healthcare associated infection

  Modeling has led to estimates of excess length of stay (LOS) attributed to surgical site infections (SSI) that ranged between 3.5 and 23 days, depending on the type of infection. The report estimated that the total national number of bed days lost to surgical site infections for a one year period was 206,527 [17].

- Falls

  Research across all settings shows that, in the face of an ageing population, if nothing is done by 2051 to prevent falls in hospitals, 886,000 additional bed days per year, or the equivalent of 2,500 additional beds, will be permanently allocated to treating falls-related injuries [12].'

While there are system productivity gains, there are also individual productivity gains as a reduction of disability or morbidity results in increased capacity to participate in economic and personal activities.

*Improving consumer trust in the healthcare system*

Trust is important in health care, in particular for the effective sharing of information and for agreement and compliance with care plans. This can impact on overall health outcomes. The uncertainty that is integral to healthcare provision, the consequences of failing to manage this uncertainty and the intimate nature of the services provided mean that trust must underlie the relationships between patients, providers and institutions [18-19].

Patient and community trust in the healthcare system is genuinely impacted when system failures occur in health services. In Australia there has been little research about trust in the health system. However, a 2007 population survey found that confidence in the health system was low and found that only 24% of respondents felt that the current healthcare system works well, 55% felt that fundamental changes were needed and 18% suggested a complete rebuild [20]. In a more recent survey that specifically asked about trust in the health system, healthcare providers and institutions reported high levels of consumer trust in doctors but moderate levels of trust in hospitals.

The model national accreditation scheme would provide greater access to information thereby increasing consumers' ability to trust in the healthcare system by providing consumers with publicly available information about the assessed performance of health services in relation to 10 critical safety and quality standards. As the accreditation system will become more consistent and reliable, patients will be able to use this information in their decision making. In addition, information from the accreditation process will provide the evidence of systems improvement that reduces risks of harm to patients.

# 5. Objectives

The objectives of implementing the National Safety and Quality Health Service Standards are to:

a. Maximise the effectiveness of accreditation to improve the quality of care delivered and reduce the harm to patients

b. Reduce the waste of health care resources associated with inadequate safety and quality in the health system.

c. Ensure that standards critical for safety and quality in health care are evidence based.

# 6. Options for implementing a national set of Safety and Quality Health Service Standards

Health Ministers are seeking to achieve improved safety and quality in health care through a model national accreditation scheme though the implementation of national safety and quality standards. As requested by Health Ministers, the Commission has developed a national set of safety and quality standards, for their consideration. The RIS consultation process has sought the views of stakeholders on a range of options for standards that could meet the Ministerial request.

### Option 1 – Release of the National Safety and Quality Health Service Standards, and modification of existing standards as required

This option involves the release of the Standards that are then mapped to existing sets of accreditation standards. This option retains, as much as possible, the current standards while still targeting uniformity. The content of the Standards would be aligned to existing accrediting agency requirements which would use their current assessment mechanisms, rating scale and reporting mechanisms. Any gaps that exist between the existing accreditation standards and the national Standards would need to be addressed by either amending the existing accreditation standards or adopting the national Standard.

Health services would not necessarily recognise the Standards as separate from the existing accreditation standards used in their normal assessment process. There would continue to be duplication as both the Standards and other sets of standards to which they have been mapped would need to be regularly reviewed and then remapped. The opportunities for misinterpretation and gaps to occur across the different sets of standards in the review process are significant.

Accrediting agencies would be responsible for extracting information relevant to the national Standards for the purpose of reporting to the regulators and regularly, but infrequently to the Commission to meet its obligations to report broadly on safety and quality across the system.

### Option 2 – Health Ministers require the adoption of National Safety and Quality Health Service Standards

This option involves the release of the Standards that can be applied consistently across all health services and accredited uniformly in high risk services, with a phased introduction of accreditation to all high risk health services. High risk services are defined as health services that undertake 'invasive' procedures into a body cavity or dissecting skin while using anaesthesia or sedation. Assessment against the Standards would be a requirement for the awarding of accreditation or be required as part of internal safety and quality assessment processes. All accrediting agencies would use the Standards. It would not be possible to modify the Standards to fit other processes, or map them against other safety and quality standards for assessment.

To maintain the Standards as contemporary and relevant there would be a process of review on a four yearly basis that would involve technical experts and all key stakeholders, to:

- Remove or amend standards that are no longer applicable or current best practice
- Review developmental and core elements
- Replace individual criteria or items within the Standards

This option allows for reporting against a single and consistent set of Standards that can be assessed across all high risk services. The data would be comparable thus enabling ongoing analysis and monitoring of accreditation outcomes and the ongoing monitoring of trends and appropriate evidence based revision of standards.

### An option not considered feasible – the adoption of an existing set of standards as the national standards

Retaining the status quo, with multiple sets of standards being developed by multiple standard setting bodies for use by accrediting agencies to assess health services is not a feasible option. This is due to the level of investment and commitment by Health Ministers and stakeholders to the development of the National Safety and Quality Health Service Standards and the high degree of stakeholder support for the Standards to date.

Adopting an existing set of standards for use nationally is not considered to be an acceptable option. The available alternative sets of standards are proprietary products. It is not recommended that Health Ministers mandate the use of a specific commercial product as the national safety and quality standards. This would have significant implications for competition policy. While other health standards are developed through consultative processes, none of these processes have the independence of decision making provided by the Commission or involve the level and extent of consultation that the national Standards have undergone. Nor have they been submitted to Health Ministers for their endorsement.

For these reasons, this option is not considered further in this paper.

### Additional options to be considered

The Consultation RIS asked respondents to identify any other options that could be more cost or clinically effective and still meet Health Ministers requirements for national safety and quality standards.

The 21 respondents to the RIS identified a number of additional clinical areas in which standards could be written for example credentialling and correct site surgery. However, they did not recommend a comprehensive alternative option that could be considered by Health Ministers.

The National Pathology Accreditation Advisory Council suggested an additional option for the pathology sector, that it be exempt from complying. As they do not meet the definition of high risk, pathology laboratories fall outside of the recommendations of this RIS.

# 7. Impact analysis

## Overview

No cost benefit studies have been undertaken in Australia to assess the impact of accreditation against standards, nor of the costs of introducing new sets of standards. This is in part because the introduction of new standards is usually an iterative process, with new standards building on the requirements of a previous version of a standard. Therefore, the status quo is the benchmark against which the identified options are being assessed.

Measuring performance against standards is the mechanism for ensuring that systems, policies, processes and reporting are in place. The existence of these systems, policies and processes is an essential part of operating a health service. The cost of implementing systems that ensure high quality and safety care (and thereby meet the standards), includes measurement, which is only one component of the process. It is therefore difficult to allocate costs between providing a service and meeting the standard.

An economic analysis of the cost of hospital care in Canada found that at least one in seven dollars is spent on hospital care resulting from hospital associated illness and injury [7]. While no analysis of the Australian data is available, the similarities between the Australian and Canadian systems would suggest that it is reasonable to assume the proportional costs are consistent. In 2007/08 recurrent hospital expenditure in Australia totalled $38,557 million [24]. Using the Canadian formula, this would mean that expenditure of approximately $5,500 million resulted from hospital associated illness and injury. If the Standards and their use in the model national accreditation scheme were to improve the system as little as 1% this would equate to $55 million per annum in avoided costs to the healthcare system.

It is also noted that provision of safety and quality systems is part of the duty of care of a health service to its patients. Costs of safety and quality systems cannot be attributed solely or even largely to meeting the requirements of meeting standards for the purpose of accreditation.

## Impacts identified from the Standards pilot

Twenty seven health services from most States and Territories participated in a pilot program to test the applicability of the initial five standards. In reporting these results the Commission is mindful that for some categories of health services, the number of respondents to the pilot evaluation was small and all services self selected, so there is likely to be a selection bias with high quality and safe focused health services participating. The level of sophistication and maturity of the safety and quality systems in a service will impact on costs incurred by a health service implementing the standards.

An estimate of the costs of assessing health services against the initial five Standards is included at Attachment 1.

Pilot sites identified a range of strategies that they would need to put in place to ensure they met all of the requirement of the five Standards. These are listed Table 2.

Table 2: Strategies needed to meet the Standards identified by pilot sites

| Accredited Health Services<br>Eg. Hospitals, Day Procedure Services | Unaccredited Health Services<br>Eg Dental Practices, Selected Medical Rooms |
|---|---|
| **Documenting policies, procedures and protocols** | |
| Documentation will require updating to meet the requirements and standards.<br><br>Day procedure services estimated this may take up to 2 days to complete. | Development of a large proportion of the documentation necessary for accreditation is likely to be required. Where template documentation is made available by the professional body the costs of producing these documents will be significantly reduced. |
| **Staff communication and education in relation to amended policies and procedures** | |
| Staff will need to be trained in the content of the new policies, procedures and protocols.<br><br>Day procedure services estimate this may take up to a week to complete. For hospitals the task may be more complex because of the number of staff, range of services, and potential number of campuses across which training would need to be provided. | Staff will need to be trained in the content of the new policies, procedures and protocols.<br><br>Procedures and protocols are likely to be in place in unaccredited health services, even if they are not documented. Staff will require some training in relation to changes to existing processes. |
| **Training of staff in the interpretation and use of standards for accreditation** | |
| Staff in these health services will have an understanding of the processes, intent, and requirements of accreditation. They will however require training in the content of the Standards.<br><br>One hospital indicated that training will need to be available in a flexible format and preferably electronic, to enable multi centre and remote centre access.<br><br>The costs of this would be significantly reduced if the training tools were developed centrally and made available to services, as proposed by the Commission. | Staff will require training in relation to the processes, intent and requirements of accreditation as well as the content of the Standards. |
| **Auditing and monitoring of clinical processes to support quality improvement and to evidence the standards are being meet.** | |
| Health services indicate auditing of safety and quality processes are currently underway, however additional audits will need to be scheduled to meet the requirements of the Standards.<br><br>Day procedure services indicated this will require approximately 3 days per audit to plan, audit then analyse the information. An additional 3 to 4 audits will need to be conducted each year.<br><br>Hospitals indicated an additional 2 to 3 audits would be required annually, which may require up to 2 full time staff, for 2 to 3 weeks per audit. | Health services indicated the current level of formal auditing is low and where it is undertaken is not well documented.<br><br>A range of audits will need to be implemented by unaccredited health services. This will be less resource intense where there are electronic systems that collect the information. Indications are that between 60 and 65% of dental practices routinely use electronic record and practice support systems. |
| **Implementing cultural change in health services to support safety and quality and meet the Standards** | |
| To increase the focus on safety and quality, one health service indicated they would need dedicated staff resources to support change management processes to improve safety and quality. | |
| **Interoperability of information systems, particularly electronic systems to support systems and monitor and report** | |
| To maximise the efficiency of the health services reporting, there may be a need to assess and improve the services reporting systems. The objective will be to maximise the interoperability of electronic data collection and reporting systems. | |
| **External expert support to implement safety and quality systems and to meet the Standards** | |
| | Health services indicated external support may be required initially to assess the safety and quality gaps and guide the services implementation of safety and quality systems. |

There will be an enormous variation in the scope and scale of action required to implement these strategies. Each health service will be commencing from a different base for teaching and training, currency and completeness of policy and procedure documentation, opportunity to share resources with other services or access them from a centralized or corporate office. The difference in size and location will also have a bearing. Hence it is not possible to generalise the cost of implementing the reforms from the information that is available.

It is of relevance that the health system currently lacks the capacity and an agreed methodology to accurately measure the avoided costs that may result from improved safety and better quality services.

### Indicative Costs of participating in accreditation

#### Health Services

In 2007/08 Australia had 762 public hospitals, 280 private hospitals and 272 private day procedure services [22]. The vast majority of these services are accredited.

It is estimated that there are 6,400 dental practices in Australia, and an unknown number of medical practices that are considered 'high risk services' and therefore would be included in the proposal to participate in accreditation. For these health services the impact of implementing the Standards will vary and depend on current practices and systems. These health services will need to establish systems and processes to meet the standards and will incur costs associated with participation in accreditation processes.

RIS submissions identified areas in which costs may be incurred by health services implementing the Standards, but did not provide any quantitative information on costs. Many of the costs identified reflect those identified in the pilot process and are applicable to both accredited and unaccredited services. Additional costs include:

- mapping the requirements of the standards to existing practices and systems
- implementing cultural change and change management strategies
- funding additional human resources to meet documentation and reporting requirements
- increasing the number and frequency of clinical audits to provide the evidence required by the Standards
- orientating and training staff in the standards and amended protocols associated with system changes
- establishing or realigning reporting systems
- meeting the requirements of the Standards
- responding to the requirements of surveyors following assessment of a health service.

Private health services, with a contract for services with a clinical pharmacist will be required to review and possibly amend the contract to ensure there is the capacity for comprehensive medication history, reconciliation of medicines, provision of information and risk management to patients, collating patient feedback and a reconciled medication list to be available to patients and practitioners on discharge.

In addition to the costs listed above, health services that have not previously been accredited may also incur new costs, including the cost of:

- external support and contractors to prepare for accreditation. In relation to dental services, the Australian Dental Association has indicated the national and state branches will provide that support.
- membership or fee for service to participate in an accreditation program

The costs for each health service will vary, depending on the maturity of the existing safety and quality systems, the culture, design, work practices and leadership of the service. None on the RIS respondents estimated the costs for implementing the reforms for health services.

### Accrediting Agencies

Accrediting agencies operating in the health sector will be directly affected by the implementation of the Standards. There are 13 organisations known to be accrediting health services at the present time, they are:

- Australian Council on Healthcare Standards (ACHS) – (also currently sets standards)
- Australian General Practice Accreditation Ltd /Quality in Practice Pty Ltd (subsidiary of AGPAL)
- Business Strategy International Management
- Global Mark Pty Ltd
- Institute of Health Communities
- International Standards Certification Health Division
- Health and Disability Auditing Australia Pty Ltd (HDAA)
- National Association of Testing Authorities (NATA)
- Pharmacy Guild of Australia
- Quality Improvement Council – (also currently sets standards)
- Quality Management Services
- SAI Global Certification Services Pty Ltd -
- Total Quality Certification Services International

Five accrediting bodies provided comment on the Consultation RIS, they were ACHS, AGPAL, HDAA, NATA and the Pharmacy Guild of Australia. They identified the costs for accrediting agencies to be:

- analysing the standards for each health service group, determining appropriate evidence and authority sources for that evidence which will be required to demonstrate a service has met the standards
- training lead assessors, accrediting agency staff and surveyors
- changes in infrastructure, including human resources and information technology systems to accommodate the processing and reporting on the Standards
- developing or adapting tools and templates being used by multiple accrediting agencies
- communicating changes in the Standards to their constituent health services
- cost of reporting to the regulators and the Commission
- participation costs to further develop and refine the accreditation processes in collaboration with the Commission

- the complexity of the Standards may result in additional survey time being required

A number of potential indirect costs to business were also identified. They include:

- the impact on the corporate branding of an accrediting agency as health services who find the standards irrelevant associate the standards with the accrediting agency
- potential existing client frustration and angst that impacts on accrediting agencies conducting business and the opportunity cost of staff time not available to undertake core business
- pressure on a limited surveyor workforce with expanded scope of accreditation
- dissatisfaction with the changes to the way surveys are undertaken and a resulting loss in the involvement of skilled surveyors from the (volunteer) workforce
- liaison costs associated with interacting with regulators, particularly where their health services do not meet the Standards or demonstrate areas of poor performance.

AGPAL/QIP indicated that for each health service type that commences in an accreditation program, such as dental practices or allied health practitioners, there would be an estimated cost of $300,000 for AGPAL/QIP to:

- develop, test and modify the information technology systems
- project plan the necessary changes, standards analysis and evidence resource development
- pilot systems and processes to accredit health services
- meet staffing requirements
- provide surveyor and staff training
- marketing the changes to and educating target health services
- contribution to the overheads of the accrediting agency

As no breakdown of these costs was provided it is unclear how these figures were derived. No estimate of the accrediting agencies additional income related to such a new services was provided.

### Estimate of additional costs for accrediting agencies

As accrediting agencies already have systems and process in place for surveyor training, costs to support the transition across to the national accreditation functions will arise in the following categories:

- Training of the existing surveyor workforce in the interpretation and scoring associated with the NSQHS Standards (1,000 surveyors/auditors)
- Training and support of additional surveyors/auditors required to meet the needs of the expanded health services requiring accreditation (estimated additional 120 new surveyors/auditors)
- Training systems based upon face-to-face and e-Learning systems (i.e. web-based IT training)
- Publication of training and guidelines material
- Additional administration expenses
- Data collection, including quality control, collection and reporting

An estimate of the one off and recurrent costs associated with the reforms and the assumptions used to estimate the costs prepared by the Commission is at Attachment 2.

In summary, total transition costs for all accrediting bodies to train surveyors/auditors and implement new assessment processes are estimated to be in the order of:

- One-off costs of $1.058 million incurred by all agencies over three years; and
- Recurrent maximum costs of approximately $60,000 per annum incurred by each agency depending on the use of e-Learning, the need to engage an additional staff member to assist with additional reporting requirements and the size and complexity of the agency involved.

Costs will be influenced by a range of factors, including the current business model of the accrediting agency, the sophistication and adaptability of the IT systems, the frequency of and level of training already provided to the surveyors/auditors, the support available from industry to develop resources, provide communication and support change.

- ACHS has indicated that the following additional information is required to fully assess the financial impact on accrediting agencies.
    - frequency of surveys
    - relationship of surveys to self assessment
    - duration of cycle (e.g. 3 or 4 year membership)
    - payment of surveyors that may be necessary to raise numbers to sufficient levels
    - number of surveyors; training needs of surveyors

The Commission has indicted that the cycle should be between 3 and 4 years, which is consistent with current industry practice. The Commission is recommending that an accreditation cycle include an external survey. Most accrediting agencies already undertaken external assessment on a yearly or biennial basis. Both volunteer and paid surveyors operate in the current market place. A shift towards more paid surveyors will have an impact on the cost of accreditation. However, a review of surveyor participation undertaken on behalf of the Commission in June 2009, indicated there are increasing difficulties accessing a volunteer workforce, and forecast the need for paid surveyors.

The Commission does not anticipate having a role in determining the business model adopted by any accrediting agency.

- ACHS has identified following issues with the model national accreditation scheme
    - turnaround time between survey and submission of a report to the Commission
    - customer service support for organisations preparing for survey
    - number of standards that are core - proportion that organisations will be held accountable for meeting to grant a ‘pass’
    - process for follow-up and regulatory response for organisations that fail to meet the standards
    - responsibilities of the accreditation body – scope of work (e.g. development of data analysis tools, development of database to track survey processes)

The Commission has flagged in one-on-one meetings and workshops with accrediting agencies that all of these issues will be worked out in collaboration with accrediting agencies, health services and regulators as part of the implementation of the Standards and model national accreditation scheme.

- ACHS has sought clarification on the date by which assessment should take place following launch of National Standards

The Commission is recommending that the program commence from July 2011, and if approved by Health Ministers health services would commence implementation of the Standards once their accreditation was next due to commence. For health services that are due to be accredited in the first year, they could choose to be accredited against their current standards or the national Standards. In this way all health services will be accredited against the standards over a 4 year period, but those health services with accreditation due in the first year would not be disadvantaged.

- ACHS have noted the competitive environment for surveying organisations – multiple approved accrediting agencies is problematic.

The health accreditation agency sector in Australia is currently competitive. The national standards will level the playing field and may allow other accrediting agencies into the market. This could have an impact on the market share and business model of all of the accrediting agencies currently operating, that may ultimately benefit of health services who will have greater choice and be able to choose from a range of different business options.

NATA noted that while there were potential additional costs for accrediting agencies, their client base primarily fell outside of the definition of a high risk service.

### Costs and benefits of implementing the National Safety and Quality Health Service Standards

The Standards have been designed to be sufficiently comprehensive to assess all key aspects of safety and quality in health care for high risk services. They focus on areas essential to improving safety and quality of care for patients where a substantial body of evidence about patient harm currently exists and where actions can be taken to effectively reduce harm to patients. They provide an explicit statement of the expected level of safety and quality of care to be provided to patients by health services, while providing a means of assessing performance. They are based on national and international research, and were developed in consultation with technical expert groups, consumers, stakeholders and the community.

The Standards however, do not cover all areas a health service or regulator may wish to have assessed during an accreditation process or all of the requirements of private health facilities licensing.

The cost and benefits listed in Table 3 are those that are considered to be additional to the cost or benefits associated with existing standards and accreditation programs. Where feedback was provided by RIS respondents it has been incorporated into the table.

Table 3: Summary of costs and benefits of implementing each individual national Standard

| Costs | Benefits |
|---|---|
| **1. Governance for Safety and Quality in Health Service Organisations (SQ)** | |
| • increased cost from integration of safety and quality into the organisations' risk management system and governance structure<br>• additional workforce education on quality and safety management<br>• costs associated with monitoring service processes and outcomes. | • integration of patient safety and quality in all management processes and decision making<br>• clearer statement of accountabilities and responsibilities for preventing and managing patient error<br>• focuses planning and implementation of patient centred care<br>• monitoring systems to increase the organisational responsiveness to patient safety risks |
| **2. Partnering for Consumer Engagement** | |
| • cost of training and supporting consumer participation in health service design, planning, measurement and evaluation<br>• education of the workforce on the value of consumer engagement<br>• complex and significant cost to implement for small health services. | • better patient experience of health care<br>• greater effectiveness of services from consumer participation<br>• safer systems of care<br>• greater consumer engagement in decisions, including resource allocation |
| **3. Healthcare Associated Infection** | |
| • cost of additional workforce training<br>• surveillance costs to monitor critical clinical processes and indicators, for example bacterial infection rates | • reduces risk of patient harm and death from infections<br>• clarifies roles, responsibilities and accountabilities for prevention and management of infections<br>• improves information about infection outbreaks and causes through surveillance<br>• identifies emerging issue of antimicrobial stewardship to address future efficacy of antibiotic use<br>• improves organisational governance that is more responsive to infection risks<br>• greater clarity of the requirements for tracking of invasive, reusable devices<br>• increases focus on specific evidence based strategies to reduce preventable infections, such as hand hygiene |
| **4. Medication Safety** | |
| • costs of establishing, using and maintaining medication reconciliation processes and systems<br>• cost of additional workforce training<br>• information systems for reporting internally and externally | • increases information available to patients about medications<br>• medication management becomes part of an integrated risk management system<br>• specifies requirements for medication reconciliation to reduce patient harm and death resulting from medication error occurring when patients are transferred between health services |
| **5. Patient Identification and Procedure Matching** | |
| • costs of implementing three consistent unique identifiers for all patients<br>• cost of additional workforce training<br>• change management costs of introducing new systems | • reduces the risk of patient harm and death from patient mis-identification<br>• clarifies roles, responsibilities and accountability for patient identification and procedure matching<br>• involves patients in their own care and improves their experience of health care |
| **6. Clinical Handover** | |
| • cost of implementing structured clinical handover, including change management and training the workforce<br>• monitoring and audit costs | • a new clinical standard based on new research in an area known to cause harm to patients<br>• reduces risk of patient harm and death from communication errors<br>• standardised structured systems applied consistently across health services |

| 7. Blood and Blood Product Safety | |
|---|---|
| • costs of meeting requirements of the safe ordering, storage, prescribing and administration of blood and blood products<br>• cost of training the workforce | • nationally standardised safety and quality requirement for a product that costs Australia approximately $1 billion annually<br>• integrates clinical and corporate governance system to maximise the efficient use of blood and blood products<br>• greater monitoring to reduce waste of a finite resource |
| **8. Prevention and Management of Pressure Ulcers** | |
| • costs of safety systems for screening, identification and management of pressure ulcers<br>• cost of equipment to prevent and manage pressure ulcers<br>• cost of workforce training | • comprehensive requirement for screening, identification and management of pressure ulcers to reduce the frequency and improve the clinical management of pressure ulcers<br>• reduces patient harm and death to patients and costs of health care from pressure ulcers |
| **9. Recognising and Responding to Clinical Deterioration in Acute Health Care** | |
| • cost of implementing response systems for detecting and managing patients whose clinical condition deteriorates<br>• cost of introducing standardised monitoring including observation charts<br>• cost of staffing response teams | • reduces patient harm and death from unrecognised clinical deterioration<br>• a new clinical standard based on new research in an area known to cause harm to patients<br>• the implementation of evidence based tools to trigger an early response to clinical deterioration |
| **10. Preventing Falls and Harm from Falls** | |
| • cost of training multidisciplinary teams<br>• cost of equipment to prevent and manage patient falls | • reduces risk of patient harm and death from falls<br>• increase productivity associated with shorter length of stay<br>• multidisciplinary approach to falls prevention to improve falls prevention and management strategies<br>• decreases burden on society from lost independence of individuals resulting from falls |

## Issues identified in implementing the Standards

None of the respondents commenting specifically on the Standards provided any quantitative advice on the cost of implementing the Standards. Table 4 lists the issues raised by respondents.

Table 4: Issues identified by respondents in response to the national Standards

| Issue identified by respondents | Comment |
|---|---|
| The Standards are evidence based and consumer focused. | The standards are based on the best available evidence and the input of technical experts. |
| Some of the processes in the consumer participation standard present difficulty to monitor and manage for decentalised health services, so will take greater staff and consumer training locally, and organisational cultural change. | The Commission has reviewed the literature, developed a consultation paper and identified cost effective tools and resources to support health services implement this Standard. In addition, a number of items and measures will be classified 'developmental' to allow health services time to develop systems and processes to meet the Standard. |
| Meeting the requirements of the HAI standard requires practices that are already in place. Any significant cost burden will result from complying with hand hygiene auditing, which has already been implemented in some services. | Hand hygiene is an integral component of an effective infection prevention program. Numerous programs to increase the rate of compliance with hand hygiene regimes have been ineffective. Auditing provides a mechanism for ongoing monitoring that is considered essential to the effective implementation of this Standard. |
| Implementation will require a review of the structures and resources by health services to ensure standards are met. | This is considered to be an integral part of the ongoing monitoring of a health service and consistent with processes put in place whenever new standards are introduced. |
| The Patient Identification and Procedure Matching standard may require staff training, changes to documentation and processes, clinical observation and audit processes to monitor implementation. | |
| The Clinical Handover and Blood and Blood Product Standards may require cultural and professional changes which will involve some considerable planning, identification to the barriers and strategies to implement change. Costs will be staff training and ongoing audit and feedback. | |
| While work is already in place to meet the requirements of the pressure ulcer standard, there may be considerable costs involved in meeting the requirements of this standard. | |
| The auditing requirements for recognising and responding to clinical deterioration can be integrated with other audit functions, so reducing the cost impact of meeting this standard. | |
| The cost of meeting the falls standard is associated with the additional detailed clinical audit required. | |
| Small health services will face significant costs and difficulty in implementing the Consumer Engagement standards. | |
| Not all Standards are applicable in all settings. | For some health services, it will be clear that some standards are not applicable. This will be declared as part of their introduction. In addition a process to allow applications for exemption from assessment against a standard or part of a standard will be established. |
| Concern that the level of detail is insufficient to ensure standards are properly implemented and outcomes monitored at present. | The Commission recognises the need for additional information for both health services and accrediting agencies. This work is underway, with accrediting agencies currently piloting the Standards and work on implementation documentation is being developed. |
| The scope of coverage overlapped with some other standards, such as NATA/RPCA, NPAAC | Where there is overlap in standards, it is anticipated that the national Standards will be applied. Health Services should not be subject to unnecessary duplication. |

| | |
|---|---|
| | Pathology laboratories are not included under the high risk definition. |
| For health services that contract to access pharmacy services there is the potential for a significant cost increase. Contracts will need to be reviewed to ensure the range of services provided is sufficiently comprehensive to meet the requirements of the Standards. | This will increase costs for some health services, however the number of services affected and the quantum of increase cost are not known and were not reported by respondents. In addition, all of these processes are consistent with the management of safe medications management and would be expected to be part of existing processes. |
| Introducing new standards could result in a disruption to the ACHS comparative data series, and they will no longer be able to provide retrospective comparative data or trends data to the system. | It should be noted that processes for reporting on performance at a hospital level and for primary health care organisations is part of the health reforms agreed to by States and Territories in April 2010 currently being introduced by the Federal Government. |
| Improvements in the quality of clinical processes and national healthcare outcomes will not be measurable. | There available evidence has shown that accreditation promotes change in health organisations, however the direct link between accreditation and improved health outcomes is yet to be established quantitatively. The University of NSW has a multi-variable study underway, which will research accreditation and evaluate the impact of the proposed reforms. |
| ACHS note that the EquIP standards, surveyor training and organisational processes are accredited by ISQua and state that the national Standards as they are currently drafted may not meet the requirements of this external assessment process. | Health Ministers can decide to externally accredit the national Standards. However, is should be noted that it is not usual to seek external confirmation of standards or regulatory requirements that are set by governments. The extensive consultation on the national Standards today would suggest the ISQua requirements for broad consultation have been met. |
| NSW, WA and Vic Health Departments have all identified potential costs for regulators required to manage the processes of receiving accreditation data, implementing process for escalating response to issues of performance and managing services that fail to meet the Standards. | Work with regulators on the detail of implementation is required before costs can be quantified. |
| A number of stakeholders, including ACHS, consumers and health services have identified the need for further work on measures of performance in the standards if improvements from implementation of the standards are to be quantified. | Work is underway on guides and implementation documents that will provide clarity in relation to measures. The Commission agrees with ACHS that a communication strategy to report on health system improvements will be necessary to gain consumer support. |

## Resource impact of the Options

Comment on a preliminary analysis of the costs and benefits of meeting the Standards for each option was sought in a consultation RIS. There were 21 responses to the RIS (see Attachment 3).

### Option 1 – Release of the National Safety and Quality Health Service Standards, and modification of existing standards as required

This option involved modifying existing standards and requiring accrediting agencies to map the national Standards to their existing standards, and extract outcome information relating to the national Standards from the accreditation outcome data. Respondents that commented on the tables included in the Consultation RIS, agreed the information accurately reflected the potential costs of implementing the reforms, some noted the benefits were optimistic and may not all be achievable. Feedback from respondents has been incorporated into the table.

Table 4: Costs and benefits for stakeholders from implementing Option 1

| Stakeholder | Costs | Benefits |
|---|---|---|
| Accrediting Agencies | • Cost of mapping standards and establishing reporting systems to extract data to meet reporting requirements.<br>• Cost of developing additional standards where there are gaps in the standards mapped from the national Standards. | • Expanded business opportunities from professional and industry groups commencing accreditation. |
| Health Services that are already accredited | • Cost of meeting the national Standards associated with implementing safety and quality systems | • The potential for improving health care would depend on extent to which the existing standards covered all of the requirements in the national Standards and the level at which they were assessed. |
| Health Services not yet accredited | • Cost of participating in accreditation<br>• Cost of training staff<br>• Cost of meeting the Standards associated with implementing safety and quality systems | • The potential for improving health care would depend on extent to which the existing standards covered all of the requirements in the national Standards and the level at which they were assessed. |
| Consumers | • Potential for some increase in service costs associated with newly accredited services passing on additional costs.<br>• As there will be differences in mapping of the existing standards to national Standards it will continue to be difficult for consumers to judge variation in risks between health services. | • Potential for reduced risk of harm<br>• Increased trust in health services known to be meeting standards that are nationally consistent |
| System | • Duplicated costs of developing and maintaining the both the current standards and the national Standards to which they are mapped.<br>• There is continued proliferation of standards, and ongoing variation in assessment outcomes, that are not comparable.<br>• Processes to address gaps in existing standards, including the development of new standards to ensure accrediting agencies cover all domains in the national Standards.<br>• Translation of existing standards to the national Standards may be too difficult (and therefore costly) because of the complexity of the Standards.<br>• Increased variability, complexity and errors. | • Potential for reduced costs from reduced harm to patients. |

Of the 21 respondents, three support the implementation of this option. They were the Pharmacy Guild of Australia (PGA), Medical Technology Association of Australia and the National Pathology Accreditation Advisory Council (NPAAC). The PGA's concern related to a number of standards not being relevant in its industry. The Commission has recognised that this will be an issue for some health services. Where relevant, exemptions from whole or part of a standard will be declared prior to the introduction of the model national accreditation scheme. In addition a process for applying to be exempt from assessment against a standard or part of a standard will be established.

The NPAAC interpretation of the model national accreditation scheme is that it will apply to all pathology services, and that this requirement will result in a duplication of processes (and costs) for pathologists and the potential application of less rigorous standards by this industry group. However, the Commission does not see pathology being included under the high risk definition and this being required to be accredited against the national Standards.

While supporting option 2, AGPAL/QIP provided comment on option 1. They noted that option 1 is attractive because it allows standards to remain relevant to a specific industry group, retaining the current standards, while achieving uniformity. However they also note that mapping may be difficult to the national Standards. The Standards however are designed to be of greatest benefit to health care consumers and the community, providing improved safety and quality of care and consequently improving the efficiency of health care delivery.

ACHS noted implementing option 1 presents challenges, because of the differences in assessment mechanisms, rating scales and reporting mechanisms. This is further complicated by the use of the Standards by multiple accreditation agencies.

### Option 2 – Health Ministers require the adoption of National Safety and Quality Health Service Standards

This option involves the promulgation of new national Standards that would be implemented by accrediting agencies across all high risk health services. This would involve a phased introduction of the Standards to high risk health services. Accrediting agencies would adapt their existing processes to meet the requirements of the Standards and national reporting on the outcomes of accreditation would be in place. Both the costs of implementing the Standards and the benefits will vary across health services.

Respondents generally supported the analysis of costs and benefits listed in the following table. Where feedback was provided by RIS respondents it has been incorporated into the table.

Table 5: Costs and benefits for stakeholders from implementing Option 2

| Stakeholder | Costs | Benefits |
|---|---|---|
| Accrediting Agencies | • Training of agency and surveyors in the use of the Standards<br>• Analysing the Standards for each health service group, determining appropriate evidence and authority source that will be required to demonstrate a service has met the standards<br>• Changes in infrastructure, including human resources and information technology systems to accommodate the processing and reporting on the Standards<br>• Communication strategy to constituent health services<br>• Reporting to the regulators and the Commission<br>• Additional surveyor time assessing against the national Standards<br>• Assessing against multiple sets of standards is more complex and prone to error, so will incur greater costs than assessing single set of standards | • Expanded business opportunities from professional and industry groups commencing accreditation. |
| Health Services that are already accredited | • Meeting the Standards associated with implementing safety and quality systems and change management processes, which will vary across health services depending on existing systems and processes.<br>• Training staff<br>• Increased audit and monitoring<br>• Establishment or realignment of reporting systems to meet the Standards requirements.<br>• Costs greatest in smaller health services. | • Increased capacity to improve safety of patient systems<br>• Costs lowered by providing safer care such as from reduced compensation, insurance and legal costs from fewer adverse events to patients.<br>• Avoided cost enables the provision of additional services |
| Health Services not yet accredited | • Participating in accreditation<br>• Staff training<br>• Meeting the Standards associated with implementing safety and quality systems which include one off costs to allow a health service to meet the Standards and recurrent costs to maintain a quality service. | • Increased capacity to improve safety of patient systems<br>• Costs lowered by providing safer care such as from reduced compensation, insurance and legal costs from fewer adverse events to patients. |
| Regulators | • Collection and analysis of data<br>• Implementing processes to escalate management of health services when accreditation issues identified. | • Consistent and uniform national system of safety and quality compliance<br>• Protection for consumers due to oversight and corrective action for health services that don't meet standards |
| Consumers | • Potential for some increase in service costs associated with newly accredited services passing on additional costs. | • Potential for reduced risk of harm<br>• Potential for access to comparable information on accredited health services<br>• Increased trust in health services known to be meeting standards that are nationally consistent |
| System | • Standards development costs, met from the Commission's operating budget.<br>• Investment in time by experts, health services and other stakeholders in the development and maintenance of Standards.<br>• Total cost of implementing change. | • Access to comparative information from accredited health services to use in the development of whole of system improvement, education programs, support tools and guidance and revision of standards.<br>• Safety and quality standards that specifically address priority areas identified by health sector, governments, the Commission and/or the community.<br>• Higher level of trust in a sector known to be participating in systematic national safety and quality accreditation in priority areas |

| | |
|---|---|
| | • Potential for improved reliability and validity of data from standardisation of processes, rating systems and requirements.<br>• Standards are developed with broad consultation and are accessible publicly. The guidance documentation and training tools will also be freely available.<br>• The Standards will provide a single, uniform set of requirements against which all services can be assessed.<br>• A simple and consistent rating system has the potential to increase the validity and reliability of accreditation outcomes.<br>• Governance issues of separation of standard setting and assessing will be addressed.<br>• Increased involvement of those accountable for the delivery of health care (at all levels) in the design, implementation and endorsement of the Standards. |

Of the 21 respondents, fifteen support the implementation of this option. The HDAA view was that option 2 provided consistency and would reduce confusion that had the potential to improve safety and quality through a greater awareness of the intent of the standards, a common language and a greater acceptance of the Standards by organisations and individuals.

The Australian and New Zealand Society of Blood Transfusion Ltd however suggest that hospitals will face substantial initial and recurrent costs in implementing the Standards, particularly in relation to training and competency assessment of staff and monitoring of safety and quality interventions.

AGPAL/QIP noted this option was more workable than option 1, and suggested the initial focus should be on educating the health system and providing support to meet standards, rather than on regulatory compliance.

NPAAC raised two concerns in relation to this option. Firstly that pathology services in Australia use an international framework for their standards that allows specimens to be referenced across countries. Varying the existing processes for the development of Standards and integration with international standards processes would be problematic.

Secondly, NPAAC report that the technology used by pathology laboratories is manufactured and distributed by a small number of multi-national companies, who have incorporated the requirements for monitoring, calibration and reporting required by the international standards into their equipment. The small market share held by Australian pathology laboratories would be insufficient to influence the changes required to meet the requirements of the national Standards. As previously noted, the Commission does not consider that pathology services fall within the definition of high risk services and thus will be required to meet the national Standards.

Sydney Adventist Hospital Ltd indicated that a process of mapping current work practice against the Standards and realigning working groups will require additional human resources, which they estimate will be 0.5 FTE in the first year. However, after the initial additional expenses, they do not anticipate additional recurrent costs.

## Alternative Option

ACHS recommends the introduction of a combination of option 1 and option 2, which would allow for the release of the national safety and quality standards, reporting against a single and consistent set of clinical safety and quality standards, while also allowing the assessment against the additional EQuIP standards which cover other organisational performance domains. This would address the ACHS concerns that the national Standards address only clinical safety and quality and so significantly narrow the focus of accreditation. They note the EQuIP standards provide a comprehensive review of health service systems.

ACHS provided comment on one of the options identified in the RIS as not feasible. They suggested that using the existing EQuIP standards would have been more cost effective. These standards are owned and maintained by ACHS as national accreditation standards, and those same standards are currently used by ACHS as the basis for conducting their accreditation business. The ACHS suggest the competition policy challenges identified in the RIS could be resolved. They indicated that *"ACHS would have seriously considered supporting the use of its standards (including foregoing our proprietary rights), the format and its framework for implementation for wider use in the expanded application of accreditation as a national strategy around safety and quality".* It is of note that the instructions from Health Ministers, issued in November 2006 required the Commission to develop an alternative model for accreditation including a national set of standards by which health services would be assessed. Further a primary tenet in the development of the reforms, articulated at every phase of this process, has been the separation of the responsibility to develop standards and assessment against standards.

In the report to be submitted to Health Ministers in November 2010, the Commission is recommending that regulators, including States, Territories and the Commonwealth, would specify any additional standards that should be included as part of a health service's accreditation. The individual health service organisation could then choose an approved accrediting agency to provide an assessment that covers all of the health service's accreditation requirements. In this way health services could choose to seek accreditation of their processes and systems against the national Standards and any other standards that are being offered by accrediting agencies such as ACHS.

ACHS appears to have interpreted option 2 as a proposal to replace EQuIP, an established accreditation program, with an alternative program, without acknowledging that only the clinical safety and quality components of its standards will be standardised across accreditation programs. ACHS therefore suggests a combined option 1 and 2.

ACHS is only one of a number of accrediting bodies, utilising one set of standards, albeit that their standards are used across a high proportion of Australian health services. It is not anticipated that a change in standards will destabilise health services, given that they plan for changes in standards on a regular basis, including the EQuIP standards that are changed on a recurring 4-5 year cycle.

ACHS has however stated their intention is to map the national Standards with EQuIP and remove any redundancy in the EQuIP standards.

The view expressed by NATA is that the two options are not radically different and they would both incur similar increases in costs. These costs would be associated with mapping the standards, training for lead assessors, reporting protocols and administrative costs of supplying information. NATA did not believe it was possible to predict the benefits for patients from the proposed changes within the laboratory sector.

## Other Comments

The Australian Dental Association (ADA) provided verbal input on 18 October 2010, but did not state a preference for either option 1 or 2. ADA representatives indicated that they supported the introduction of an industry led accreditation program, with the Association fulfilling the role of regulator for the industry.

They have indicated that if a desk top audit model of accreditation is introduced, the following costs to dental practices will be incurred:

- Approximately 20 hours of review and audit time to collate the evidence required to demonstrate they meet the Standards
- Staff training and education in relation to the requirements of the Standards and the processes of accreditation

The ADA notes that in taking on the role of regulator it would require an estimated 0.5 FTE in the national office and depending on the roles taken on by state branches, additional staff may also be required. As the ADA and state branch offices are funded from membership fees, these are all additional costs to members.

NSW Health noted in their submission the significant additional cost associated with licensing an increased number of high risk services. They also noted there is not a direct overlap between the Standards and NSW Private Health Licensing requirements and suggest accreditation and licensing should be clearly distinguished. Further they recommend state and territory licensing system be harmonised nationally to encourage Australia wide compliance and reduce business costs for health care providers operating nationally.

The Australian Medical Association (AMA) response proposed that neither option be implemented without further analysis of the costs and benefits followed by voluntary introduction of the Standards supported by payment of both compensation for implementation costs, and also rewards for medical practitioners, hospitals and accrediting agencies for adopting and gaining accreditation. The AMA submission raises a number of concerns with the process and with the Standards and their use in the model national accreditation scheme. These are discussed below.

- The AMA is concerned about the increase in costs, which they describe as significant. They suggest that hospitals will know the costs for gaining and maintaining accreditation, developing documentation and training staff. Once extracted, this could then be used to model the anticipated increased costs for accredited services and new costs that will be incurred by unaccredited health services.

The Commission has attempted to extract this cost information on a number of occasions from health services, initially in a Cost Analysis of Safety and Quality Accreditation in the Australian Health System, January 2008; again as part of a review of costs for the report to Health Ministers 2010 and as part of the pilot of Standards. Considerable effort has been made to establish quantitative data to enable an analysis to be undertaken. However, it is evident that separate, identifiable data are not collected purely in relation to the costs of health service accreditation. Further, health services involved in costing projects have expressed a strong sentiment that the activity required to achieve accreditation is essentially perceived as part of core business in the hospital and GP sector and that many of the costs required to meet the Standards would be incurred as part of quality or good practice.

- The AMA is concerned that there is limited evidence of the effectiveness of accreditation and the resulting benefits that reform of the current accreditation system will bring.

The available evidence has shown that accreditation promotes change in health organisations; however the direct link between accreditation and improved health outcomes is yet to be quantitatively established. The Commission is supporting research being undertaken by the University of NSW that is to consider the efficacy and cost benefit of accreditation. The accreditation process does however have face validity and enormous industry support. Governments, organisations and individuals have invested in accreditation for over 3 decades in Australia and use it as a mechanism for driving change and measuring quality. The notion that a system once implemented can not be improved is inconsistent with the concept of quality improvement.

- The AMA states that the RIS cannot be fully considered without an implementation plan and timetable.

Work on an implementation plan has commenced and is outlined in section 10. Health Ministers must first endorsed the Standards and determined how and when the model will be implemented, before these plans can be finalised. A communication plan is being forwarded to Health Ministers which addresses timeframes for implementation and its implementation will involve broad consultation with stakeholders.

- The AMA is concerned about the number of national safety and quality standards.

The Commission has developed ten national safety and quality standards. It is intended that these standards apply broadly across all health services. Even with ten standards there are some that will not apply to all health services. For example, the Blood and Blood Product standard will not apply in dental practices. There are few other areas of significant safety and quality concern that will apply across all health services about which additional standards could be drafted. The Bill before Federal Parliament for the establishment of the Commission as a permanent body does anticipate the need to draft clinical guidelines that are specific to a disease or service type, however these will not form part of the National Safety and Quality Health Service Standards.

- The AMA sought clarity in relation to accrediting agencies, if a new/alternative agency or the existing agencies would assess against the standards.

The Commission has indicated that accrediting agencies currently accrediting health services are all likely to seek approval to accredit against the national Standards. However, new or existing agencies not currently in the market place, that meet the criteria for approval may choose to commence work with health services. The Commission is keen for a strong and competitive accreditation industry to provide health services with choice at a reasonable cost.

- The AMA raised the issue of public reporting and information feedback to health services.

In the period since the Commission commenced this project, the level of information provided to consumers has increased, but it still does not provide a comprehensive picture of health service performance of which accreditation outcome is one part. The major health system reforms agreed to between the Commonwealth, States and Territories (except WA) include the establishment of a National Performance Authority. The scope of its role is still being determined. The reporting to be undertaken by the Commission will be on safety and quality trends, and will not include reports on individuals or individual hospitals. As with now, feedback to health services will be from accrediting agencies. Accrediting agencies will also provide feedback to regulators, who will be responsible for any action taken when there is poor or under performance against the Standards.

- The AMA has interpreted the Commission documentation to mean that all medical practices currently accredited will need to comply with the Standards.

Regulatory mechanisms do not currently exist to require all medical practices to participate in accreditation. The Commission's proposal is that only high risk services be accredited. The Commission will work with industry bodies around self regulation. The insurance sector may also decide to require accreditation against the Standards as part of their business processes. For those medical practitioners already accredited, they may choose to be accredited against the Standards.

The AMA was the only organisation that did not support the implementation of the reforms.

NATA holds that multiple standards are not problematic if they are fit for purpose and that the standards used by NATA are the most appropriate for its client base.

# 8. Consultation Process

In September 2010, a Consultation Regulatory Impact Statement was developed by the Commission and approved by the Office of Best Practice Regulation for distribution to stakeholders. Prior to its release, the Commission has advised stakeholders at national conferences, workshops and committee meetings that a RIS was due for release, that it would be seeking their comment on the impact of the reforms and outlining both the process and content of the RIS documentation.

Once approved, copies of the Consultation RIS document were emailed to Commission stakeholder organisations and individuals. More than 250 people received the email with a request to forward the RIS through their email network to other people who may be interested in this paper. Included in this process were accrediting agencies, consumers, Aboriginal health service organisations, technical experts and health service representatives. The Commission is not able to estimate the total number of stakeholders ultimately receiving the RIS.

In addition, members of all of the Commission's standing committees, including Commission members, Inter Jurisdictional Committee, Primary Care Committee and Private Hospital Sector Committee, and the Commission Program committees, including the Accreditation Implementation Reference Group, Blood Workshop participants, Recognising and Responding to Clinical Deterioration Program Advisory Committee and consumer representative organisations.

An invitation to comment on the RIS was issued in the Australian newspaper on Monday, 27 September 2010.

The Commission conducted consumer workshops in September and October in six States and Territories at which the RIS was discussed and requests for written input sought from interested participants.

The Australian Private Hospital Association is the peak industry body for private hospitals and day procedure services. It alerted its members to the Consultation RIS in its weekly newsletter to members on 3 October 2010. The Australian Dental Association provided the RIS to members via email.

## Previous consultation processes

The Commission reviewed written submissions from previous consultation processes to extract any comment provided on the costs of implementing the Standards. Of the 90 written submissions on the initial five Standards received in February 2010, only two respondents discussed costs. Both responses highlighted the cost burden on small practice implementing the Standards. One specifically noted the proportionally higher cost of regulatory compliance paid by small rural services. Neither provided detailed costings.

## Consultation RIS

The Consultation RIS sought comment from stakeholders on the following questions:

1. Which option do you believe would be the most effective way of improving safety and quality for patients?
2. What do you believe are the cost, benefits and other impacts of this option, for your organisation, for consumers and/or for the health system? Please include any information or analysis to quantify and support your position.
3. Are there other standards that could be more cost or clinically effective and still meet Health Ministers requirements of a national safety and quality standards?

The Commission is recommending Option 2:

4. Please quantify any likely direct one off and/or recurrent cost impact of this option on your organisation?
5. Please quantify any likely indirect costs or other impacts for staff or other resources from the implementation of this option.
6. Are there changes to the options you believe are necessary for more effective implementation?
7. Do you have any comments in relation to the proposal to implement the Standards?

Following the release of the consultation RIS, 20 written submissions were received and one organisation provided verbal feedback. A breakdown by category of respondent, issues raised and an indication of support for the options is outlined below:

Table 8: Written submissions (+verbal response) by category of respondent

| Stakeholder Category | Number of submissions |
|---|---|
| Professional or Member Organisation | 5 |
| Accrediting or certifying bodies | 5 |
| Private or Charitable Health Service | 4 |
| AHMAC or Health Dept | 3 |
| Other Government Body | 2 |
| Private Company | 1 |
| NGO | 1 |
| TOTAL | 21 |

# 9. Conclusion and Recommended Option

The consultation RIS represents the final process in an extensive round of consultations on the National Safety and Quality Health Service Standards and a model national accreditation scheme. The Commission received 20 written respondents and one verbal response on the consultation RIS and the options it contained. Options 1 was supported by three respondents, of these two had misinterpreted the requirements of the reforms and are not required to be accredited against the national Standards under the current proposal. Option 2 was supported by 14 respondents. A hybrid of option 1 and 2 had support from one respondent, while one respondent did not see the difference between the two options. Two respondents did not state a preference.

Consultation with stakeholders regarding the content of the National Standards during September and October 2010 indicated strong support for the Standards and model national accreditation scheme.

Respondents noted the options will have costs implications, but the majority of respondents considered the greatest benefit would flow from the introduction of option 2.

### Option 1

The cost of implementing option 1 for accrediting agencies will primarily be associated with mapping the national Standards to existing standards and managing the gaps in coverage. The potential benefits for accrediting agencies comes from expanded business opportunities with the introduction of accreditation to new industry groups.

The costs for health services for this option come from meeting which ever standards they are being assessed against. There are additional costs for unaccredited health services associated with participating in accreditation. The potential benefits for health services come from improved health care due in part to improved standards leading to reduced length of stay for patients.

Consumers may be exposed to increased health care costs from this option. These costs come may come from higher costs of care driven by the health services passing on the cost of meeting the Standards. However, the benefit to consumers comes from a reduction in the risk of harm from health care.

As there will continue to be multiple sets of standards, health services will continue to be assessed at different levels. Variability in the way health care provision is assessed will mean avoidable costs will continue to be incurred. This option provides no significant benefit to the health system.

The costs of option 1 appear to be similar to those of option 2. However, option 1 has limited overall benefit to patients and the health system as it does not achieve harmonization and therefore does not address the variations within the standards which result in administrative burdens and poorer health outcomes. Option 1 is therefore be unlikely to achieve a large overall net benefit.

### Option 2

There are additional costs for accrediting agencies from Option 2. They relate to training of staff and surveyors in different assessment measures, reporting systems and loss of comparability with previous assessment outcomes. However, there is the potential for costs to be recouped through increased membership from expanded business opportunities.

For health services, training staff in new standards, and implementing systems to meet the requirements of the standards, particularly additional auditing of systems, will incur costs. Health services in their responses to this RIS have indicated additional staff may be required and the costs of this will depend on the type of service. Additional staff requirements will range from additional part time staff working for a few weeks up to half an additional staff member per year.

As with option 1, additional costs to consumers may come from health services passing on the costs of meeting the Standards. However, there is the potential to reduce the risks of harm from health care. Safer care will also ultimately increase for community trust in the health care system.

For the health system, the cost of option 2 comes from the development and maintenance of the Standards. However there are significant benefits that accrue to the health care system from option 2. These benefits come from creating for the first time, formal and clearly necessary linkages between Health Ministers, accrediting agencies, standards setting bodies, health services and regulators. Further, there is the potential for increased productivity of the health system and of consumers from a reduction in patient harm.

The costs of option 2 are of the same magnitude as the previous option. The benefits of option 2, however, are seen to be substantially greater and the option would be likely to achieve an overall net benefit. This partly reflects that the option more specifically addresses the inefficiencies resulting from a lack of consistency from the use of multiple standards which currently occurs. These benefits include reduced harm to patients because of the specific and consistent focus on areas of high patient risk; improved community productivity from fewer incidents of harm to consumers and an improvement in the productivity of the health system due to a reduction in avoidable costs and the more effective use of available human, capital and financial resources. An important additional benefit is the improved consumer trust in the healthcare system coming from greater access to information about the quality of care and risks of harm.

### Alternative Option

The alternative option suggested is a combination of option 1 and 2. This option will incur similar costs for option 1, without necessarily achieving the benefits identified for option 2.

### Health Services new to Accreditation

Health services that are new to accreditation face the greatest increase in costs from the introduction of the national Standards. Costs will be incurred to meet the requirements of Standards, whether the standards are national or those utilised by a particular accreditation agency, and to meet the costs of accreditation. In addition, policies and procedures are likely to need to be documented and staff not previously exposed to accreditation will require training. The phased introduction, supported by professional associations should allow health services to plan and budget for the introduction of the Standards. The potential benefits for health services from this option relate to reduced harm to patients leading to reduced costs of caring for patients and the follow on effects of this including reduced compensation, insurance and legal costs from fewer adverse events.

### Costs

This RIS has identified the difficulties in accurately costing the proposed changes. However, it has been estimated that the total transition costs for all accrediting bodies to train surveyors/auditors and implement new assessment processes will be:

- One-off costs of $1.058 million incurred by all agencies over three years; and
- Recurrent maximum costs of approximately $60,000 per annum incurred by each agency depending on the use of e-Learning, the need to engage an additional staff member to assist with additional reporting requirements and the size and complexity of the agency involved. This may in part be off set by increased income.

These costs will be influenced by a range of factors, including the current business model of the accrediting agency, the sophistication and adaptability of their IT systems, the frequency of and level of training already provided to the surveyors/auditors, the support available from industry to develop resources, provide communication and support change.

The costs have not been quantified for regulators, however for both option 1 and 2 they could incur costs associated with receiving accreditation outcomes data and with responding to identified deficiencies in health services that need to be remedied. Costs will vary according to the current level of resourcing to access and analyse accreditation data about their health service performance and there response responding to these data.

If regulators choose to use licensing to mandate accreditation for high risk medical rooms, this will also incur additional costs.

### Standards

There is overwhelming support for the national Standards which is evident from both the RIS process and the multiple consultation processes conducted by the Commission. Stakeholders have supported the content and structure of the standards and the opportunity to consistently apply standards across all health services. This support has come from health services, regulators, insurance industry, professional organisations, industry organisations, accrediting agencies and from AHMAC and AHMC.

The national Standards specifically address issues of safety and quality in health care. It is not intended that the Standards cover all areas a health service or regulator may wish to have assessed during an accreditation process or cover all the requirements of private health facilities licensing. Assessment against other standards is a matter for health services and/or regulators to determine.

Following consideration of the benefits and impacts of implementing the Standards, it will be recommended to Health Ministers that implementation of the Standards in the context of a model national accreditation scheme should commence but that the implementation timeframes be such that a phased transition by health services is possible.

The advantages of this approach are that it minimises the risk of disruption to health services in the transition and initial implementation phases. It also provides an opportunity to finalise the outstanding issues in consultation with stakeholders and for the Commission to develop education material, resources and communication materials that will assist in the implementation.

Consultation with stakeholders in the development of the National Safety and Quality Health Service Standards and the model national accreditation scheme has involved over 4 years of consultation. A strategy employed by the Commission to involve stakeholders in this process was to call for written submission. In four rounds of submissions, over 300 submissions were received. The Commission received only 21 responses to the RIS. The Commission believes this comparatively low response rate is due to the extensive consultation that has preceded the RIS call for submissions and reflects the high degree of support across the system for the proposed changes.

### The Recommended Option

The Commission recommended Option 2 in the consultation RIS. This position was supported by the majority of respondents and is consistent with position the Commission has consulted on since Health Ministers approved in principle the model national accreditation scheme in April 2008.

The Commission considers that this option generates the greatest net benefit for the community, while meeting the requirements set by Health Ministers. For many health services striving to provide high quality care, the standards represent adjustments to existing processes rather than an overhaul of their current system. There will be some increase in costs, however compared with the potential savings in health care expenditure, the change and implementation costs are comparatively small. Improvements in productivity will also results from reduction in mortality and in particular morbidity as better health outcomes have economic and social benefits.

Option 2 involves implementation of the National Safety and Quality Health Service Standards, where:

- The National Safety and Quality Health Service Standards are endorsed by Health Ministers
- Health Ministers require the adoption of the Standards by all high risk health services for accreditation and by all other services as part of their internal safety and quality assessment processes,
- The Commission maintains currency and relevance of the Standards; and
- Accrediting agencies accredit against the Standards without modification and provide compliance and accreditation outcomes data to the health services, relevant regulators and the Commission.

# 10. Implementation and Review

RIS respondents have raised a range of issues that will be addressed in the planning for implementation. In particular, transition to full implementation of the model scheme for accreditation is anticipated to occur over a 4 year period. Once the model is endorsed by Health Ministers, the key tasks to be undertaken and the timetable for implementation would be as follows:

| Year | Activities |
|---|---|
| 2010-11 | • Finalise the National Safety and Quality Health Service Standards and develop implementation tools.<br>• Develop information and training material for the Standards.<br>• Collaborate with jurisdictions and accrediting agencies and other relevant bodies to establish a nationa accreditation reporting framework.<br>• Finalise unresolved elements of the model.<br>• Identify and communicate which standards and /or items are not applicable for which service settings.<br>• Finalise criteria for approving accrediting agencies in conjunction with industry stakeholders and establish approved accrediting agency listing.<br>• Support the Regulators to advise all high risk services of the need to participate in an accreditation program.<br>• Liaise with Regulators to support their systems for implementation.<br>• Support approved accrediting agencies to register high risk health services in an accreditation program, if not already participating in a program.<br>• Commence the implementation of a Communication Strategy.<br>• Commence evaluation process. |
| 2011-12 | • Establish a mechanism for assessing applications for exemptions from standards and /or items that are not applicable for a health service.<br>• Commence evaluation of the model scheme.<br>• Commence the education for health services and accrediting agencies.<br>• Approved accrediting agencies commence assessment of high risk services against the Standards in already accredited health services.<br>• Commence registration of unaccredited high risk health services into accreditation programs<br>• Further development of training and support materials for surveyors and health services implementing the Standards.<br>• Collaborate with the Regulators to ensure high risk services not currently accredited are registered with an approved accrediting agency.<br>• Collaborate with jurisdictions and accrediting agencies (and the National Performance Authority once established) to implement the national accreditation reporting framework.<br>• Ongoing implementation of a Communication Strategy. |
| 2012-13 | • Develop and negotiate a process for sharing health services information with approved accrediting agencies for the accreditation process<br>• Collaborate with jurisdictions to assess the first year accreditation data and evaluate appropriateness of data and determine reporting format, frequency etc.<br>• Evaluation of program ongoing. |
| 2013-14 | • Commence review of the Standards.<br>• Collect and report on accreditation outcomes to date.<br>• Review the appropriateness and coverage of public reporting on accreditation of health services.<br>• Report on the evaluation of the program. |

Implementation will require that the following issues be addressed.

### Finalising the Standards - Core and developmental items

To address differences in the risk of harm between service types it is proposed that the individual measures within the standards be designated either core or developmental. The initial work to designate core and non-core items is incorporated into the piloting process. It will be essential that health services meet all of the core measures and they will also need to demonstrate they have commenced implementation of the developmental measures.

Agreement will need to be reached with key stakeholders, including jurisdictions on the practical application for health services and accrediting agencies, of an assessment system that incorporates developmental measures. Finalising this work will involve jurisdictions, health services and accrediting agencies in conjunction with the Commission.

Maintaining the National Safety and Quality Health Services Standards

The Standards will require regular updating so they continue to reflect current best practice, changes in knowledge, technological advances, and incorporate resources, tools and guidelines to support practice. The Commission's method of operation is to involve technical experts, health services, jurisdictions, consumers and a broad range of stakeholders in consultation. In addition, it is proposed any changes will be reviewed by the Commission's program and standing committees, including the Inter Jurisdictional Committee, Private Hospital Sector Committee, Primary Care Committee and the Commission.

### Including high risk services in accreditation processes

High risk services are defined as health services that undertake 'invasive' procedures into a body cavity or dissecting skin while using anaesthesia or sedation. This captures a range of services that are already accredited and additional services, such as dental practices, some medical practices performing invasive procedures and other practices not currently participating in accreditation.

### Notifying the Regulator of health service performance

Currently, when accrediting agencies identify issues with performance of a health service, the matter is addressed directly between the two parties. A reform that provides a clear role for the regulators as systems managers will require that they also be notified of under performance. To meets its obligation to report on safety and quality, the Commission will use information from the accreditation of health services. This information will be provided to the Commission by accrediting agencies regularly, although infrequently. Information will be de-identified and focus on safety and quality trends.

The reporting framework and the triggers for notification need to be clarified with Regulators and accrediting agencies as part of the implementation of the model.

### Harmonising the variation in sanctions for not meeting the Standards

For health services whose participation in accreditation is mandated by legislation, the ultimate sanctions to be applied are articulated in the legislation. For public hospitals any sanctions applied will be determined by Health Ministers. This means different sanctions could be applied for similar breaches in standards. There may be some benefit in looking at opportunities to harmonise not only the ultimate sanctions, but the steps to be taken in escalating the response to standards not being met.

### Reviewing the Scope of Accreditation

The process of implementation will involve identifying indicators of success that can be applied over the 3 years to full implementation of the model national accreditation scheme. This will include reviewing the participation in accreditation by self regulated health services. This information will inform any proposals to extend the scope of accreditation or amend the regulatory base for health services to be accredited. Any changes in scope would be accompanied by a regulatory impact assessment.

### Evaluating the impact of the reforms

The Commission recognises the need to build into the implementation of the model national accreditation scheme mechanisms for evaluating the processes and outcomes of the reform process. Both internal and external evaluation processes are planned.

The external review will be conducted in partnership with the University of NSW and collaborating accrediting bodies. It is one of twelve research projects that will examine accreditation, and specifically the impact of implementing the National Safety and Quality Health Service Standards and model national accreditation scheme and its implementation into high risk health services. The research will look at the gains achieved from national coordination of accreditation and the impact from implementing the National Safety and Quality Health Service Standards.

The evaluation program will commence in 2012 and continue through to 2015. Information from the 12 research projects will be used to inform any future reform of accreditation. Broadly the research that is planned will:

a. Evaluate the effectiveness of the current accreditation processes on quality of care and performance

b. Analyse the costs and benefits of accreditation

c. Review opportunities to enhance accreditation

d. Develop and apply new standards on consumer involvement in accreditation

The research is being conducted by Professor Jeffrey Braithwaite, Director of the Australian Institute of Health Innovation (AIHI) and will involve twelve interrelated studies into accreditation. These studies aim to strengthen organisational performance through accreditation. The grant totals $2.35 million over five years.

# 11. Previous Consultation on the National Safety and Quality Health Service Standards and the Model National Accreditation Scheme

The Commission has consulted extensively throughout the development of the National Safety and Quality Health Service Standards and their use in a model national accreditation scheme.

The following consultation processes were undertaken:

(a) Phase one consultations on the model scheme

- Release of Discussion Paper: National Safety and Quality Accreditation Standards November 2006 [5];
- 40 national focus group meetings with over 420 participants;
- Analysis of 90 written submissions; and
- Release of Report on Initial Stakeholder Consultation on the Review of National Safety and Quality Accreditation Standards, July 2007 [26].

(b) Phase two consultation on the model scheme

- Release of Consultation Paper: An Alternative Model for Safety and Quality Accreditation of Health Care, Aug 2007 [27];
- Eleven national stakeholder forums;
- Analysis of 55 written submissions;
- Release of a Draft Report on Stakeholder Consultation on the Review of National Safety and Quality Accreditation, November 2007 [28];
- Release of a Draft Alternative Model for Safety and Quality Accreditation, November 2007 [29]; and
- National Workshop, where over 140 key national stakeholders participated, held in November 2007.

At each stage of the consultation the model scheme for accreditation was amended and refined to incorporate feedback.

(c) Phase three consultations on the National Safety and Quality Health Service Standards comprise:

- Consultation with jurisdictions, health services and accrediting agencies prior to release of Cost Analysis of Safety and Quality Accreditation in the Australian Health System in January 2008 [30]
- Release of Final Report on the Review of National Safety and Quality Accreditation Standards, April 2008 [21]
- Release of Proposals on An Alternative Model for Safety and Quality Accreditation and Matters Relating to Costs and Duplication of Accreditation Processes, February 2008 [31]
- The development of the draft Standards which involved a large number of participants who are technical experts advising Commission programs, and /or members of working groups and/or Commission Standing Committees; or workshop participations specifically brought

together by the Commission to develop and review preliminary drafts of individual standards.

  - Inter Jurisdictional Committee
  - Private Hospital Sector Committee
  - Accreditation Implementation Reference Group
  - Healthcare Associated Infection Implementation Advisory Group
  - Healthcare Associated Infection Surveillance Expert Working Group
  - Medication Reference Group Committee
  - Patient Identification Expert Working Group
  - Clinical Handover Expert Advisory Group
  - Recognising and Responding to Clinical Deterioration Advisory Committee
  - Workshop of key stakeholders involved in Blood and Blood Products
  - Teleconference with jurisdictional representatives responsible for Pressure Ulcers
  - Teleconferences with the National Pressure Ulcers Advisory Panel
  - Workshop of key technical and consumer representatives
- Release of a consultation paper on the Draft National Safety and Quality Healthcare Standards, November 2009 [5]
- Analysis of 92 written submissions
- Focus groups involving consumers in four states - one in each Queensland, Victoria, South Australia and Western Australia.
- Piloting the Standards in 26 health services across Australia that undertook a self assessment against the standards and an evaluation of the processes involved.

In addition, 9 accrediting agencies are currently pilot the assessment of the standards in 10 health services.

At each stage of the consultation the Standards were amended and refined to incorporate feedback.

This draft Regulatory Impact Statement is the next phase of consultation being undertaken by the Commission.

# Attachments

Attachment 1

## Pilot of the initial five Standards – Estimate of assessment costs

Average hours by service type spent in completing the assessment processes for Standards 1-5 and the estimated cost by service type.

| Service type | No of services | Average of hours spent completing the assessment process. | Estimated cost, using $50 per hour |
|---|---|---|---|
| Hospitals | 11 | 27.0 | $1,350 |
| Day Procedure Centres | 3 | 37.3 | $1,855 |
| Dental Practices | 4 | 27.5 | $1,375 |
| Medical Rooms performing high risk service | 2 | 45 | $2,250 |

*Note: not all pilot sites provided information on hours spent on assessment processes*

Hospitals and dental practices completed the assessment of their services against the Standards in approximately 3½ days, while day procedure services and doctors in their rooms took between 5 and 6 days. A mid range salary point of $50[ϕ] per hour has been used to estimate the time costs of this assessment process.

It should be noted as a result of the pilot, duplication of items and measures within the Standards has been reduced, the language more clearly defined and guidance documents are being developed which should assist in reducing the time required to complete the assessment process.

Percentage of Core and Development items in the initial set of five Standards that were not met by service type

| Service type | No of services | Percentage Core items Not Met n =102 | Percentage Developmental items Not Met n =16 |
|---|---|---|---|
| Hospitals | 11 | 8% | 15% |
| Day Procedure Centres | 3 | 9% | 40% |
| Dental Practices | 4 | 35% | 66% |
| Medical Rooms performing high risk service | 2 | 39% | 50% |

All of the participating hospitals and day procedure centres participating in the pilot had previously been accredited. This was evident from the smaller percentage of core items that the health services did not meet. For these health services, the initial costs to meet all 102 core items in the Standards is likely to be minimal, and in the medium term costs to implement systems to meet the developmental items will also be less than services that have not previously been accredited.

Previously unaccredited health services, including dental practices and medical rooms, identified a greater number of items in the Standards that they did not meet for both core and developmental items. The subsequent cost of meeting these items is likely to be greater for unaccredited services than health services already participating in an accreditation program.

[ϕ] $50 per hour represents a salary of approximately $100,000 per annum. Websites including Jobsense, Seek and CareerOne list a practice manager salary at $70,000 to $90,000 and a dental practitioner at $ $110,000 to $140,000. As both are likely to be responsible for implementing the Standards, a midway point has been used.

Attachment 2

## One off and Recurrent Cost of Implementing Reforms by Accrediting Agencies

The following table sets out Commission estimates of one off and recurrent costs associated with the reforms.

| COST CATEGORY | $ |
|---|---|
| **One off Costs** | |
| Training of Existing Surveyors/Auditors: | |
| One-off face to face training and development of existing surveyors/auditors to learn interpret, apply and score the NSQHS Standards: | |
| • 1,000 Surveyors/Auditors | |
| • 40 Surveyors/Auditors per session | |
| • 1 days training per group | |
| • 25 groups at 1 day each | |
| • $2,000/day training fees plus room hire of $800/day plus catering $50/person plus one return airfare | $137,500 |
| • Development of training materials for 10 standards – 5 days per standard at APS 6 rates | $ 16,000 |
| • Printing of training materials for 10 standards – 1000 copies x 10 standards x 40 pages/standard by 15c/page | $ 60,000 |
| Sub Total of Training for existing Surveyors/Auditors | $213,500 |
| Training of New Surveyors/Auditors: | |
| Training of additional new surveyors/auditors to meet increased demand based on the above methodology | |
| • 120 Surveyors/Auditors | |
| Total for new surveyors/auditors | $24,000 |
| Additional Production Costs | |
| Estimated number of NSQHS Standards manual inserts and guidance material | |
| • For hospitals and free standing day surgery units currently accredited 1,314 | |
| • For high risk services not accredited 9,654 | |
| • 10 NSQHS Standards per manual; | |
| • 45 pages per NSQHS Standards & Guidance material 160 pages in total | |
| • 15c per page | |
| Total for Additional Production Costs | $740,300 |
| Note: this is a high estimate as it is anticipated much of the standard and guidance distribution will occur electronically. In addition estimate represents total cost over 3 years. | |
| E-Learning Modules as an optional alternative/addition: | |
| Develop of e-Learning training modules for 10 new standards (initial one-off development cost of $8,000 per module) | |
| Total for new surveyors/auditors | $80,000 |
| Estimated total transition costs for all agencies combined (One off over three years). | $1,057,800 |

| Recurrent Costs | Indicative Cost per Agency |
|---|---|
| Annual E-Learning costs associated with 10 new standards (maintenance and hosting): | $20,000 |
| Additional reporting requirements: | |
| • Estimated 0.5 FTE per accrediting body | |
| • No. of accrediting bodies 12 | |
| • Estimated salary of APS6 $79,567 ($40,000 for 0.5 FTE) | |
| Total | $40,000 |
| Total Estimated Maximum Recurrent Costs per agency | $60,000 |

It is important to note that the above costing allows for both face to face training and the development and use of an e-Learning training tool. As a result, this cost assumes a "worst case scenario" from a costing perspective (i.e. costs may be lower if e-Learning is utilised rather than face to face training).

Because of the significant variation in size, business model, client base and focus of accrediting agencies, the organisational changes required to implement the model national scheme cost estimates have not been included, but functions would include:

- Staff training
- Organisational realignment, including developing or adapting assessment tools, restructuring human resources functions and expanding capacity
- IT and systems changes
- Communication and marketing to health services
- Meeting the approval criteria required to assess against the Standards.

In summary, transition costs for all accrediting bodies to train surveyors/auditors and implement new assessment processes are estimated to be in the order of:

- One-off costs of $1.058 million incurred by all agencies over three years; and
- Recurrent maximum costs of approximately $60,000 per annum incurred by each agency depending on the use of e-Learning, the need to engage an additional staff member to assist with additional reporting requirements and the size and complexity of the Agency.

Costs will be influenced by a range of factors, including the current business model of the accrediting agency, the sophistication and adaptability of the IT systems, the frequency of and level of training already provided to the surveyors/auditors, the support available from industry to develop resources, provide communication and support change.

## Assumptions in the estimation of costs for accrediting agencies

### Timing

- Transition to the agreed national scheme for safety and quality accreditation in healthcare will commence in July 2011 and move to full implementation over a three year period.
- Health Services already accredited will commence preparation for the Standards in year one and will be accredited under the standards when they are next due for an accreditation survey.
- Health Services not previously accredited will have a staggered start up period over three years.

### Financial

- The cost of national coordination will be funded from the Commission budget.
- All costs are based on today's dollar value – CPI has not been estimated for the out years.
- Accreditation costs are based on known charges as identified through web sites and other published information and consultations.
- Financial costs are based on the rollout of all 10 Standards.
- There are approximately 1,000 surveyors/auditors and/or auditors currently involved in health service accreditation. Each of these will require training on the new standards and assessment process
- Costs for training additional surveyors/auditors has only included training for the Standards as accrediting agencies will cover any other training costs through the standard accreditation fee process.
- Travel and accommodation costs have been based on Commonwealth Public Service standard rates.

### Service

- Approved accrediting agencies will provide accreditation services. The Commission will approve these agencies to accredit against the Standards.
- Health Services currently accredited will transition to the Standards over a three year period as each health service re-accreditation falls due.
- Health Services not currently accredited and who are considered to be high risk services will commence in 2011 and have three years in which to complete an accreditation cycle.
- Legislative change required at the jurisdictional level to create the legal framework for accreditation reform will be developed through the routine jurisdictional legislative process.
- The Commission will not have a role in determining the business model of accrediting agencies and will have no regulatory powers.

Attachment 3

Organisations providing written/verbal responses to the Consultation RIS

| Submission | Organisation | Preferred Option |
|---|---|---|
| 1 | Healthscope | Option 2 |
| 2 | Medical Technology Association of Australia | Option 1 |
| 3 | Australian and New Zealand Society of Blood Transfusion Ltd | Option 2 |
| 4 | The College of Nursing | Option 2 |
| 5 | Australian and New Zealand College of Anaesthetists | Option 2 |
| 6 | St Vincent's Health Australia | Option 2 |
| 7 | National Blood Authority | Option 2 |
| 8 | AGPAL /QIP | Option 2 |
| 9 | St John of God Health Care | Option 2 |
| 10 | Performance Activity and Quality WA Department of Health | Option 2 |
| 11 | Australasian College of Podiatric Surgeons | Option 2 |
| 12 | Department of Health, Victoria | Option 2 |
| 13 | Pharmacy Guild of Australia | Option 1 |
| 14 | National Pathology Accreditation Advisory Council | Option 1 |
| 15 | Australian Council on Healthcare Standards | Alternative option |
| Verbal | Australian Dental Association | Not stated |
| 17 | Australian Medical Association | Neither |
| 18 | NSW Health Department | Option 2 |
| 19 | Sydney Adventist Hospital Ltd | Option 2 |
| 20 | Health and Disability Auditing Australia Pty Ltd | Option 2 |
| 21 | National Association of Testing Authorities | Neither |

Attachment 4

**Australian Government**

**Department of Finance and Deregulation**
Office of Best Practice Regulation

Reference: 11631
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Ms Margaret Banks
Senior Programs Adviser
Australian Commission on Safety and Quality in Health Care

Sent by email

Dear Margaret

**National Safety and Quality Health Service Standards and their use in a Model National Accreditation Scheme Decision RIS**

Thank you for forwarding the Office of Best Practice Regulation (OBPR) the draft decision Regulation Impact Statement (RIS) on the National Safety and Quality Health Service Standards and their use in a Model National Accreditation Scheme.

The RIS contains an adequate level of analysis and meets the Council of Australian Government's (COAG) best practice regulation requirements.

The OBPR maintains an online RIS register and COAG requires that RISs be posted within five business days of a regulatory decision being publicly announced. We would appreciate you advising us when a decision on this proposal is announced and forwarding a final copy of the RIS in a form meeting Australian Government online publication requirements. (If a pdf version of the document is sent, please also provide a rtf or doc version.) The OBPR should be consulted if the RIS is amended. It is the Ministerial Council preparing the RIS, not the OBPR, which is responsible for the content of the published RIS. Please note that the OBPR proposes to publish all RISs under a Creative Commons by Attribution copyright where possible. Please advise us if this causes you any concerns.

Please retain this letter as a record of the OBPR advice. Our reference number for this issue is 11631. If you have any further queries please contact me (phone (02) 6215 2441 or email eric.swan@finance.gov.au) or Stephen Rowley (phone (02) 6215 1961 or email stephen.rowley@finance.gov.au).

Yours sincerely

Eric Swan
Director
4 November 2010

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