

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

Consultation Regulatory Impact Statement

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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 establish a model national accreditation scheme for safety and quality in health care. The model includes 10 National Safety and Quality Health Service Standards (the Standards) and revised processes 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 model and the Standards by the Commission.

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 is 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.

The RIS informs stakeholders of the proposals that will be referred to the AHMC for consideration in November 2010. Section 10 details consultation questions and Section 11 contains information on how to make a submission.

2. Development of a model national accreditation scheme

Context

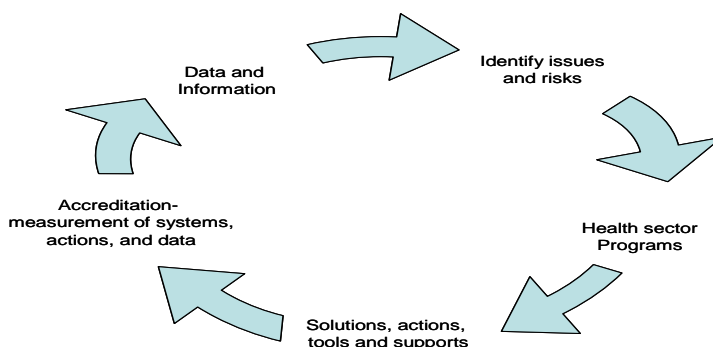
Health services have progressively sought to improve the safety and quality of health care through external assessment against standards. This process is known as accreditation. These processes commenced in the mid 1970s and have progressively expanded in scope and coverage from acute care hospitals 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.



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.

Background

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. From 2000, 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 setting, 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/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 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, providing State, Territory and Commonwealth governments with access to information about health services accreditation outcomes and 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 was presented with an update on the Commission's work program that noted significant progress 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.

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. It listed the functions of the 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.

The Commission has 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 produced
- 234 written submissions received
- over 70 presentations to health sector participants.

3. National Safety and Quality Health Service Standards

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
- 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 have been 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 last 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. They incorporate the amendments to format, structure and language recommended by stakeholders. 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. They 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*** which creates a consumer-centred health system by including consumers in the design and delivery of quality health care
3. ***Healthcare-Associated Infection***, which 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***, which describes the standard expected to ensure clinicians prescribe, dispense and administer appropriate and safe medication to informed patients
5. ***Patient Identification and Procedure Matching***, which specifies the expected processes for identification of patients and correctly matching their identity with the correct treatment
6. ***Clinical Handover***, which describes the requirement for effective clinical communication whenever accountability and responsibility for a patient's care is transferred
7. ***Blood and Blood-product Safety*** which sets the standard to ensure that the patients who receive blood and blood products are safe
8. ***Prevention and Management of Pressure Ulcers*** which 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*** which describes the systems required by health services responding to patients when their clinical condition deteriorates
10. ***Preventing Falls and Harm from Falls*** which describes the standards for reducing the incidence of patient falls in Health Service Organisations.

Standard 2, and 7-10 were released for public consultation August 2010.

It is important to note that 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.

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 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.

These Standards set the overarching requirements for effective implementation of the remaining eight standards which address clinically specific areas of patient care.

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 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.

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 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 standards being used to assess safety and quality of health services. This process involved the documenting of 17 sets of standards. The process showed that there is no one set of safety and quality standards that are 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 to meet the standards. Infection control is one such example. The JAS-ANZ 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 same accrediting agencies to 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 measured and health service performance is reviewed. While safety and quality plays its part in these decisions, concerns exist that business decisions can also be an influence.

While accrediting agencies that both set and review health standards in Australia consult broadly in the development of 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 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 sits below the standards can often be 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 is very difficult. 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, but 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 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].

There are still substantial gains to be made in safety and quality, and these could be facilitated in part by a more effective accreditation program which focuses on the development of 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 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 accredited. Improving the effectiveness of testing safety and quality systems and driving quality improvement using accreditation is an essential part of reducing harm.

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 healthcare, in particular for the effective sharing of information, and 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 therefore increasing consumers' ability to trust in the healthcare system by providing consumers with publicly available information about the accreditation status 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 accreditation scheme, as described in Section 8 and 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 seeks the view 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 achieving 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 the national coordinator, as outlined in the model national accreditation scheme.

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

This option involves the release of the National Safety and Quality Health Service Standards that apply uniformly and consistently across all health services, although there would be a phased introduction of accreditation to all high risk health services. 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. The data would be comparable 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 Services 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 in respect to for competition policy.

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

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 safety systems that ensure high quality 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.

Accredited 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 is accredited. By changing over to the new standards progressively, health services can plan to meet the service changes required and phase in any cost impact. These health services generally have well established safety and quality systems and have previously managed change processes to implement new safety and quality standards. However, training of key quality and safety personnel to inform them about the requirements of the Standards, gap analysis of existing systems against the standards, and the implementation of changes to meet the Standards will incur some cost.

Unaccredited Health Services

Stakeholders, throughout the Commission's consultation processes, have agreed that reform of accreditation should initially focus on high risk services. The Commission has defined high risk services as those services that undertake 'invasive' procedures into a body cavity or dissecting skin, while using anaesthesia or sedation.

In addition to hospitals and day procedure services, other health services such as dental practices and medical practices undertaking high risk procedures would be required to be accredited. It is estimated that there are 6,400 dental practices in Australia, and the number of medical practices that would be included is unknown. For these health services the impact of implementing the Standards will vary and depend on current practices and systems.

The most significant cost impact in the implementation of standards will be incurred by those health services who provide high risk services and therefore participate in accreditation for the first time. These health services will need to establish systems and processes for compliance with the standards and will incur costs associated with participation in accreditation processes.

A combination of once off and recurrent costs will apply to these health services. In preparing for the first accreditation process, health services may incur costs associated with establishing policies and procedures to meet the Standards, and potentially some investment in new infrastructure and equipment. Some health services may chose to contract external consultancy advice to assist in this preparation.

Once the initial accreditation cycle has been completed it is anticipated that ongoing costs will be limited to the accreditation fees and any further investment required to continue to meet the Standards.

Accrediting Agencies

Accrediting agencies operating in the health sector will be directly affected by the implementation of the Standards. Costs will be influenced by the option that is implemented, the current business model of the accrediting agency and the frequency of and level of training already provided to the surveyors/auditors.

Costs will be incurred in training existing surveyors/auditors and any additional surveyors/auditors, and in the preparation of guidance material. Accrediting agencies may also incur some ongoing costs associated with developing or adapting assessment tools, undertaking additional reporting and meeting the approval criteria required to assess against the Standards.

Potential resource impact

A preliminary analysis of the costs and benefits of meeting the Standards for each option is outlined below:

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

Modifying existing standards will require accrediting agencies to map the national Standards with their existing standards, and extract outcome data from the accreditation outcome. Costs will be incurred in mapping the standards and disaggregating outcomes data. Variation between accrediting agencies is likely to arise from the mapping and extraction processes. The resulting trend analysis and monitoring by a national organisation will be complex and prone to error.

There will be duplicative processes to maintain the currency and relevance of all sets of Standards.

Processes will be needed to address gaps in existing standards. Either there will need to be investment in new standards to ensure accrediting agencies cover all domains in the national Standards or have gaps in assessment processes.

Stakeholder	Costs	Benefits
Accrediting Agencies	<ul style="list-style-type: none"> • Cost of mapping standards and establishing reporting systems to extract data to meet reporting requirements. • Cost of developing additional standards where there are gaps in the standards mapped from the national Standards. 	<ul style="list-style-type: none"> • Expanded business opportunities from professional and industry groups commencing accreditation.
Health Services that are already accredited	<ul style="list-style-type: none"> • Cost of meeting the Standards associated with implementing safety and quality systems 	<ul style="list-style-type: none"> • The potential for improving health care would depend on extent to which the existing standards covered all of the requirements in the Commission's standard and the level at which they were assessed.
Health Services not yet accredited	<ul style="list-style-type: none"> • Cost of participating in accreditation • Cost of training staff • Cost of meeting the Standards associated with implementing safety and quality systems 	<ul style="list-style-type: none"> • The potential for improving health care would depend on extent to which the existing standards covered all of the requirements in the Commission's standard and the level at which they were assessed.
Consumers	<ul style="list-style-type: none"> • Potential for some increase in service costs associated with newly accredited services passing on additional costs. • 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. 	<ul style="list-style-type: none"> • Potential for reduced risk of harm • Increased trust in health services known to be meeting standards that are nationally consistent
System	<ul style="list-style-type: none"> • Cost of developing and maintaining the both the current standards and the national Standards to which they are mapped • There is continued proliferation of standards, and ongoing variation in assessment outcomes, that are not comparable. 	<ul style="list-style-type: none"> • Potential for reduced costs from reduced harm to patients.

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

The option represents the greatest change of the two options. New national Standards would be implemented by accrediting agencies across all health services that are currently accredited. There would be a process of phased introduction of accreditation to all 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.

However, improvements in the efficiency and effectiveness of patient care in areas of greatest risk may reduce avoidable harm to patients, reduce costs and generate the greatest net benefit to the community.

The greatest benefit of this option is not to individual health services, but to patients and to the health system as a whole.

Stakeholder	Costs	Benefits
Accrediting Agencies	<ul style="list-style-type: none"> • Training of surveyors in the use of the Standards • Adaption of assessment systems to comply with the Commission requirements 	<ul style="list-style-type: none"> • Expanded business opportunities from professional and industry groups commencing accreditation.
Health Services that are already accredited	<ul style="list-style-type: none"> • Cost of meeting the Standards associated with implementing safety and quality systems, which will vary across health services depending on existing systems and processes. • Cost of training staff 	<ul style="list-style-type: none"> • Increased capacity to improve safety of patient systems • Costs lowered by providing safer care such as from reduced compensation, insurance and legal costs from fewer adverse events to patients.
Health Services not yet accredited	<ul style="list-style-type: none"> • Cost of participating in accreditation • Cost of training staff • Cost of 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. 	<ul style="list-style-type: none"> • Increased capacity to improve safety of patient systems • Costs lowered by providing safer care such as from reduced compensation, insurance and legal costs from fewer adverse events to patients.
Consumers	<ul style="list-style-type: none"> • Potential for some increase in service costs associated with newly accredited services passing on additional costs. 	<ul style="list-style-type: none"> • Potential for reduced risk of harm • Potential for access to comparable information on accredited health services • Increased trust in health services known to be meeting standards that are nationally consistent
System	<ul style="list-style-type: none"> • Standards development costs, initially met from the Commission's operating budget. • Investment in time by experts, health services and other stakeholders in the development and maintenance of Standards. 	<ul style="list-style-type: none"> • Access to comparative information from accredited health services to use in the development of whole of system improvement, education programs, support tools and guidance. • Safety and quality standards that specifically address priority areas identified by health sector, governments, the Commission and/or the community. • Higher level of trust in a sector known to be participating in safety and quality accreditation in priority areas • Potential for improved reliability and validity of data from standardisation of processes, rating systems and requirements. • Standards are developed with broad consultation and are accessible publicly. The guidance documentation and training tools will also be freely available. • Standards development and assessment will be separated. • The Standards will provide a single, uniform set of requirements against which all services can be assessed. • A simple and consistent rating system has the potential to increase the validity and reliability of accreditation outcomes. • Governance issues of separation of standard setting and assessing will be addressed. • Increased involvement of those accountable for the delivery of health care (at all levels) in the design, implementation and endorsement of the Standards.

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 cost and benefits listed in the following table are those that are considered to be additional to the cost or benefits associated with existing standards and accreditation programs.

Costs	Benefits
1. Governance for Safety and Quality in Health Service Organisations (SQ)	
<ul style="list-style-type: none"> increased cost from integration of safety and quality into the organisations' risk management system and governance structure additional workforce education on quality and safety management costs associated with monitoring service processes and outcomes. 	<ul style="list-style-type: none"> integration of patient safety and quality in all management processes and decision making clearer statement of accountabilities and responsibilities for preventing and managing patient error focuses planning and implementation of patient centred care monitoring systems to increase the organisational responsiveness to patient safety risks
2. Partnering for Consumer Engagement (CE)	
<ul style="list-style-type: none"> cost of training and supporting consumer participation in health service design, planning, measurement and evaluation education of the workforce on the value of consumer engagement 	<ul style="list-style-type: none"> better patient experience of health care greater effectiveness of services from consumer participation safer systems of care greater consumer engagement in decisions, including resource allocation
3. Healthcare Associated Infection (HAI)	
<ul style="list-style-type: none"> cost of additional workforce training surveillance costs 	<ul style="list-style-type: none"> reduces risk of patient harm and death from infections clarifies roles, responsibilities and accountabilities for prevention and management of infections improves information about infection outbreaks and causes through surveillance identifies emerging issue of antimicrobial stewardship to address future efficacy of antibiotic use improves organisational governance that is more responsive to infection risks greater clarity of the requirements for tracking of invasive, reusable devices increases focus on specific evidence based strategies to reduce preventable infections, such as hand hygiene
4. Medication Safety (MS)	
<ul style="list-style-type: none"> costs of establishing, using and maintaining medication reconciliation processes and systems cost of additional workforce training 	<ul style="list-style-type: none"> increases information available to patients about medications medication management becomes part of an

<ul style="list-style-type: none"> information systems for reporting internally and externally 	<ul style="list-style-type: none"> integrated risk management system 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 (PI)	
<ul style="list-style-type: none"> costs of implementing three consistent unique identifiers for all patients cost of additional workforce training change management costs of introducing new systems 	<ul style="list-style-type: none"> reduces the risk of patient harm and death from patient mis-identification clarifies roles, responsibilities and accountability for patient identification and procedure matching involves patients in their own care and improves their experience of health care
6. Clinical Handover (CH)	
<ul style="list-style-type: none"> cost of implementing structured clinical handover, including change management and training the workforce monitoring and audit costs 	<ul style="list-style-type: none"> a new clinical standard based on new research in an area known to cause harm to patients reduces risk of patient harm and death from communication errors standardised structured systems applied consistently across health services
7. Blood and Blood Product Safety (BBP)	
<ul style="list-style-type: none"> costs of meeting requirements of the safe ordering, storage, prescribing and administration of blood and blood products cost of training the workforce 	<ul style="list-style-type: none"> nationally standardised safety and quality requirement for a product that costs Australia approximately \$1 billion annually integrates clinical and corporate governance system to maximise the efficient use of blood and blood products greater monitoring to reduce waste of a finite resource
8. Prevention and Management of Pressure Ulcers (PU)	
<ul style="list-style-type: none"> costs of safety systems for screening, identification and management of pressure ulcers cost of equipment to prevent and manage pressure ulcers cost of workforce training 	<ul style="list-style-type: none"> comprehensive requirement for screening, identification and management of pressure ulcers to reduce the frequency and improve the clinical management of pressure ulcers 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 (RR)	
<ul style="list-style-type: none"> cost of implementing response systems for detecting and managing patients whose clinical condition deteriorates cost of introducing standardised monitoring including observation charts cost of staffing response teams 	<ul style="list-style-type: none"> reduces patient harm and death from unrecognised clinical deterioration a new clinical standard based on new research in an area known to cause harm to patients the implementation of evidence based tools to trigger an early response to clinical deterioration
10. Preventing Falls and Harm from Falls (PFHF)	
<ul style="list-style-type: none"> cost of training multidisciplinary teams cost of equipment to prevent and manage patient falls 	<ul style="list-style-type: none"> reduces risk of patient harm and death from falls increase productivity associated with shorter length of stay multidisciplinary approach to falls prevention to improve falls prevention and management strategies decreases burden on society from lost independence of individuals resulting from falls

The Recommended Option

To generate the greatest net benefit for the community, the Commission is recommending Option 2 - Health Ministers require the adoption of 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.

8. The Proposed Model National Accreditation Scheme

Successful accreditation should lead to improved safety and quality for the patient, demonstrate safety and quality improvements over time and provide the system with a reliable and valid assessment of safety and quality systems in health services while not materially increasing the administrative or resource requirements of accreditation on health services.

The model of safety and quality accreditation proposed by the Commission builds on the strengths of the current accreditation system by:

- specifically targeting areas where there is the greatest risk of harm to patients
- applying a single set of safety and quality standards across all health services
- extending accreditation to cover all high risk services and highlighting to all health services the need to use internal quality assurance processes to meet the Standards
- building in more effective data analysis and feedback mechanisms
- addressing the lack of co-ordination, fragmentation and duplication in current accreditation systems
- using accreditation data to inform decisions about safety and quality improvements at a local, jurisdictional and national level.

Roles and responsibilities of participants in the model national accreditation scheme

The proposed model national accreditation scheme consists of five separate but related roles and responsibilities for participants to support the application of the Standards endorsed by Health Ministers. The roles of each are broadly as follows:

1. **Health Ministers** endorse the Standards and receive information on the system's performance against standards.
2. The **Regulators** including States, Territories and the Commonwealth would adopt the Standards, and require the participation by health services in accreditation processes undertaken by an approved accrediting agency to assess whether they meet the Standards. They will receive relevant accreditation data as a performance measure. Where the Standards are not met the Regulators could commence a series of escalating actions to ensure standards are met by health services.

Industry and Professional Organisations would adopt the Standards and support participation by health services in accreditation processes undertaken by an approved accrediting agency to meet the Standards.

3. The **Health Services** would meet the Standards and should certify that their meeting the Standards is ongoing and across the entire organisation.

They must engage an approved accrediting agency to assess whether they meet the Standards. The contractual agreement between the accrediting agency and individual health services would recognise that accreditation data will be provided to the Regulator and the national coordination program of the Commission.

It is not the role of an accrediting agency to examine every aspect of the service provided to all patients. Health services that do not initially meet the Standards, will progress to a process managed by the Regulator of escalating action to achieve the requirements in the Standards.

For health services that participate voluntarily in a self regulated program the mechanisms for action or support would be determined by the industry organisation with the advice and assistance of the Commission.

4. The **Approved Accrediting Agencies** would assess health service organisations against the Standards and provide relevant and appropriate accreditation information to those organisations, the Regulators and the national coordination program of the Commission.

An approved accrediting agency reviews the systems and structures to test if they are comprehensive, robust and being monitored, looking in detail at areas of risk or performance concern. The accreditation report is based on the available evidence of a health service meeting the Standards. It also would award a certificate of accreditation for those health services meeting the Standards. The Commission will not be involved in the process of assessment or awarding of a certificate of accreditation.

The Standards will be specifically applied as developed and would not be modified to fit existing processes or mapped to other safety and quality standards. To ensure this occurs, consistency in the application of the Standards and assessment processes is required. Approved accrediting agencies could assess against additional standards specified by the regulator or additional standards against which the health service chooses to be assessed.

Accrediting agencies will be responsible for the selection, training, support and performance management of surveyors and/or auditors. They will provide training for surveyors and/or auditors to develop and maintain knowledge of the Standards and assessment skills. They will have a role in working with the national coordination program to ensure there is a consistent and shared understanding of the Standards.

5. A program of *national coordination by the Commission* would:
- Develop and maintain the Standards
 - Advise Health Ministers (from time to time) on the scope of accreditation, ie which health services are to be accredited. The initial focus is on high risk services.
 - Approve accrediting agencies to assess against the Standards. In order to be approved by the Commission an accrediting agency will meet the following criteria:
 - Hold current accreditation with Joint Accreditation System of Australia and New Zealand (JASANZ) or the International Society for Quality in Health Care (ISQua) or other recognised international accrediting body.
 - Provide accreditation data on compliance and outcomes to health services, the national coordination program of the Commission and Regulators.
 - Participate in the national coordination program in relation to matters including:
 - i. Reviewing assessment methodologies to enhance effectiveness and efficiency of accreditation processes
 - ii. Supporting surveyor training and management to increase the reliability and validity of assessment processes
 - iii. Streamlining reporting and data collections
 - iv. Developing implementation documentation, training programs for surveyors, and guidance resources and tools.
 - v. Undertake ongoing liaison with regulators on opportunities to improve standards and accreditation systems.
 - Work with accrediting agencies to ensure consistency in the application of the Standards and assessment processes. This will involve all accrediting agencies using the Standards with a rating scale of 'met or not met' to assess if standards have been met.
 - Receive relevant accreditation data for the purpose of reporting to Health Ministers on safety and quality matters and inform consumers, develop tools and resources and maintain the standards. This information will be collated and analysed at a national level and form the basis of reporting to Ministers and the public on safety and quality. It will be the responsibility of accrediting agencies to provide agreed accreditation data to the Commission. The Commission will work with stakeholders to determine the format, frequency and content of data to be provided to the Commission.
 - Liaise with Regulators on opportunities to improve standards and accreditation systems.
 - Report to Health Ministers on the application and effectiveness of the Standards and safety and quality improvements of the system.

9. 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, 7 accrediting agencies will 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.

10. Regulatory Impact Statement Consultation Process

The Commission is consulting with stakeholders on the draft Regulatory Impact Assessment before preparing a final RIS for Health Ministers. The RIS is being prepared to assist Ministers in their consideration of the Standards and their use in a model national accreditation scheme. Ministers are scheduled to meet in November 2010.

The Commission is seeking comment on participation in an accreditation program for all high risk services. The following questions provide a guide for responses. Comments provided by stakeholders will be used to inform Health Ministers on the reforms. This will be presented to Health Ministers in the 'Decision RIS' along with the Commission's recommendations for the Standards and a model national accreditation scheme. The Decision RIS will be approved by the Office of Best Practice Regulation before it is submitted to Health Ministers.

In relation to the reforms outlined in this paper:

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?

Stakeholders may also seek to directly discuss the options with representatives of the Commission. This should be arranged by calling 02 9263 3363 or emailing mail@safetyandquality.gov.au before 14 October 2010.

11. Submissions

All submissions received will be published on the Commission's website, including the names and/or organisations making the submission. The Commission will consider requests to withhold part or all of the contents of any submission made. Any submission which includes personal information identifying specific individuals without their express permission may be withheld from publication or de-identified before submissions are published.

Written Submissions

Submissions can be sent by post, fax or email. All written submissions should be received by close of business on **14 October 2010** to be considered in the consultation process.

Written submissions marked "Consultation Regulatory Impact Statement Submission" can be forwarded to:

Consultation RIS
Australian Commission on Safety and Quality in Health Care
GPO Box 5480
SYDNEY NSW 2001

Or via email to: mail@safetyandquality.gov.au

Or fax: 02 9263 3613

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