

AUSTRALIAN COUNCIL FOR SAFETY AND QUALITY IN HEALTH CARE



Standard for Credentialling and Defining the Scope of Clinical Practice

**A National Standard for credentialling and defining the scope
of clinical practice of medical practitioners, for use in public
and private hospitals**

July 2004

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The Australian Council for Safety and Quality in Health Care was established in January 2000 by the Australian Government Health Minister with the support of all Australian Health Ministers to lead national efforts to improve the safety and quality of health care, with a particular focus on minimising the likelihood and effects of error. The Council reports annually to Health Ministers.

This document provides a National Standard for credentialling and defining the scope of clinical practice of medical practitioners, for use in public and private hospitals. It is an attachment to the Council's fifth annual report to Health Ministers, *Maximising National Effectiveness to Reduce Harm and Improve Care, Fifth Report to the Australian Health Ministers' Conference, 29 July 2004*.

Copies of this document and further information on the work of the Council can be found at www.safetyandquality.org or from the Office of the Safety and Quality Council on telephone: +61 2 6289 4244 or email to: safetyandquality@health.gov.au.

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PREFACE

The Australian Council for Safety and Quality in Health Care aims to reduce harm to patients and improve the safety and quality of health care. A critical part of the Council's work is assisting health care organisations to ensure that care is provided only by qualified professionals whose performance is maintained at an acceptable level.

Modern health care is one of the most complex activities ever undertaken by human beings. It is changing rapidly with the introduction of new clinical services, procedures and other technologies. Modern health care organisations provide different types of services and can cope with different levels of patient need and complexity, depending on the availability of skilled health care professionals and other necessary resources.

The processes of credentialling and defining the scope of clinical practice must also change, to enable health care organisations to be confident that health care professionals' performance is maintained. Ongoing performance is not, however, the sole responsibility of health care professionals. It also relies on support being provided by health care organisations to the extent necessary to enable safe, high quality practice.

While there has been a long tradition of health care organisations undertaking processes of credentialling and defining the scope of clinical practice of medical practitioners, the application of these processes has varied considerably. This Standard, which in part codifies current practice, should improve their consistency and effectiveness.

The Standard's aim, however, is not just to improve administrative processes, but to ensure that relationships between medical practitioners and health care organisations are always based on a mutual commitment to patient safety. It extends the concepts of credentialling and defining the scope of clinical practice to encompass shared responsibility for safe service provision in supportive environments. It acknowledges the importance of the input of medical practitioners in the process of improvement of safety and quality in health care organisations, and reinforces the responsibilities of health care organisations to provide resources to support the services they wish to offer.

Over time, the process of defining the scope of clinical practice should encompass individual agreements between medical practitioners and health care organisations about what is expected in terms of performance, and how it will be assessed. It also should reflect the commitment of each organisation to provide the resources and support necessary to enable the provision of safe, high quality health care.

The Standard recognises that peer assessment and the willingness of individuals to comment on their own skills and the skills of others are fundamental to successful processes of credentialling and defining the scope of clinical practice.

While the Standard has been designed to apply initially to medical practitioners working in hospital settings, its application may be extended in the future to support

credentialling and defining the scope of clinical practice of all health care professionals in a broad range of clinical settings.

The Standard contains seven parts. Part A describes the background to and application of the Standard. Part B addresses governance and organisational issues. Part C describes the credentialling process. Part D describes the process of defining the scope of clinical practice. Part E addresses review and appeal processes. Part F addresses credentialling and defining the scope of clinical practice in relation to new clinical services, procedures or other interventions and Part G describes processes of evaluating and reporting on performance.

Many people have contributed to the development of the Standard and the Council is grateful for their contributions.

It is anticipated that the Standard will be maintained and modified over time as approaches to credentialling and defining the scope of clinical practice change in response to changing expectations and environments within which health care services are delivered.

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PART A

BACKGROUND TO AND APPLICATION OF THE STANDARD

1. INTRODUCTION

1.1 Background

This Standard is the product of a project sponsored by the Australian Council for Safety and Quality in Health Care (the Council). The purpose of the project was to develop a Standard for use by public and private hospitals when verifying and evaluating the qualifications, experience, professional standing and other relevant professional attributes of medical practitioners and defining their scope of clinical practice within specific organisational settings.

Australian Health Ministers established the Council in January 2000 to:

- lead the way by developing a national strategy for improving safety and quality in health care, defining national standards, and influencing others to act to improve safety and quality;
- define a framework for action by identifying national priorities and recommending specific actions;
- form partnerships by working with health care professionals, the Commonwealth, States and Territories, professional associations, private, non-government and consumer organisations;
- coordinate existing activity to better achieve action in priority areas;
- put consumers first by making sure that safety and quality measures are practical and will make a real difference;
- encourage public understanding and increase the community's confidence in the steps being taken to improve safety; and
- promote monitoring and research.

The development of this Standard is one of a large number of initiatives sponsored by the Council, all within an overall framework for action, the objective of which is to improve the safety and quality of health care.

1.2 Definitions

The terms “credentialling” and “defining the scope of clinical practice” are used in a variety of ways within the health care industry. For the purposes of this Standard, the following definitions of these terms have been adopted:

Credentialling refers to the formal process used to verify the qualifications, experience professional standing and other relevant professional attributes of medical practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high quality health care services within specific organisational environments.

Defining the scope of clinical practice follows on from credentialling and involves delineating the extent of an individual medical practitioner’s clinical practice within a particular organisation based on the individual’s credentials, competence, performance and professional suitability, and the needs and the capability of the organisation to support the medical practitioner’s scope of clinical practice.

The term “clinical privileging” is also widely used as an alternative to the term “defining the scope of clinical practice” and was considered for use in this Standard. During consultation about the Standard, however, many medical practitioners and other stakeholders suggested that the term “clinical privileging” creates an undesirable perception of a unilateral conferral of a benefit by an organisation. They advised that they prefer the term “defining the scope of clinical practice”, which suggests a strong, mutual relationship between the employing or contracting organisation and each medical practitioner, centered on the safety and quality of the health care services provided.

For this reason, the term “defining the scope of clinical practice” has been used throughout this Standard.

For the purpose of this Standard, the following terms are defined as indicated.

(a) Accreditation

A status that is conferred on an organisation or an individual when they have been assessed as having met particular standards. The two conditions for accreditation are an explicit definition of quality (i.e. standards) and an independent review process aimed at identifying the level of congruence between practices and quality standards.

(b) Appointment

The employment or engagement of a medical practitioner to provide services within an organisation according to conditions defined by general law and supplemented by contract.

(c) Clinical leader

A senior medical practitioner who conducts clinical practice, and also has a formal management or leadership role, in a clinical unit, division, department or similar entity.

(d) Clinical practice

The professional activity undertaken by medical practitioners for the purposes of investigating patient symptoms and preventing and/or managing illness, together with associated professional activities related to patient care.

(e) Clinical privileges

The authorised extent of an individual medical practitioner’s clinical practice within a particular organisation (see “defining the scope of clinical practice” above).

(f) Competence

The demonstrated ability to provide health care services at an expected level of safety and quality.

(g) Contract of engagement

The legal agreement between an organisation and a medical practitioner that establishes the medical practitioner's status as an independent contractor to the organisation and defines the rights and obligations of each party.

(h) Contract of employment

The legal agreement that establishes an employment relationship between an organisation and a medical practitioner and defines the rights and obligations of each party.

(i) Council

The Australian Council for Safety and Quality in Health Care.

(j) Credentials

The qualifications, professional training, clinical experience, and training and experience in leadership, research, education, communication and teamwork that contribute to a medical practitioner's competence, performance and professional suitability to provide safe, high quality health care services.

For the purposes of this Standard, a medical practitioner's history of and current status with respect to professional registration, disciplinary actions, indemnity insurance and criminal record are also regarded as relevant to their credentials.

(k) Medical practitioner

A person who is registered to practise medicine within the relevant State or Territory.

(l) New clinical services, procedures or other interventions

Clinical services, procedures or other interventions that are being introduced into an organisational setting for the first time and that depend for some or all of their provision on the professional input of medical practitioners. They may, but will not necessarily, be innovative, complex or costly. They will, however, require more than incremental change in the way in which health care services are delivered within a specific organisational setting.

They may be clinical services, procedures or other interventions which:

- (i) have been established in other organisational settings and are deemed by a responsible body of professional opinion to be ones that will benefit patients;*
- or*

- (ii) *are experimental, and therefore subject to review by a properly constituted Human Research Ethics Committee or a Clinical Ethics Committee (as appropriate).*

They do not include new pharmacological products.

(m) Organisation

A public or private hospital or freestanding day procedure facility. The term includes a division or campus which is a component of a larger organisation but whose manager is responsible for credentialling and defining the scope of clinical practice of medical practitioners within a specific local environment.

(n) Organisational capability

An organisation's ability to provide the facilities and clinical and non-clinical support services necessary for the provision of safe, high quality clinical services, procedures or other interventions.

(o) Organisational need

The extent to which an organisation requires the provision of a specific clinical service, procedure or other intervention in order to provide a balanced mix of safe, high quality health care services that meet consumer and community needs and aspirations.

(p) Performance

The extent to which a medical practitioner provides health care services in a manner which is consistent with known good practice and results in expected patient benefits.

(q) Re-credentialling

The formal process used to re-confirm the qualifications, experience and professional standing (including history of and current status with respect to professional registration, disciplinary actions, indemnity insurance and criminal record) of medical practitioners, for the purpose of forming a view about their ongoing competence, performance and professional suitability to provide safe, high quality health care services within specific organisational environments.

(r) Right to practise

The contractual right to provide health care services within the constraints and according to the conditions of a medical practitioner's professional registration and terms of appointment to an organisation.

(s) Threshold credentials

The minimum credentials for each clinical service, procedure or other intervention which applicants for credentialling and definition of scope of clinical practice are required to meet before any application will be processed.

(t) Verification of credentials

Formal validation of the authenticity of the credentials presented to an organisation by a medical practitioner. Where possible, primary source documents should be used for verification.

1.3 The Rationale for Developing the Standard

Australian health care organisations have a long tradition of credentialling and defining the scope of clinical practice of medical practitioners, with the objective of maintaining and improving the safety and quality of health care services. These processes also protect medical practitioners by ensuring that the environments within which they practise support and facilitate safety and quality.

The rigour with which processes of credentialling and defining the scope of clinical practice have been conducted and documented has, however, varied considerably. The effectiveness and adequacy of credentialling processes was identified in the *Final Report of the Taskforce on Quality in Australian Health Care 1996* as an important area for improvement.

A number of factors contributed to the Council's decision to commission the development of this Standard. Developments in technology have resulted in a rapid increase in the availability of new and complex clinical services, procedures or other interventions. In addition, in the past medical practitioners in Australia tended to train and practice within defined geographical areas and professional communities, and most were familiar with the extent of their colleagues' skills and experience. More recently, medical practitioners have become more professionally and geographically mobile.

These changes have highlighted the need for more formal processes of verifying medical practitioners' credentials and defining their scope of clinical practice.

A further impetus for the development of the Standard was an increasing recognition that hospitals have a legal responsibility to ensure that services are provided in circumstances where the safety and quality of health care have been properly addressed.

As part of its *National Action Plan 2001*, the Council identified strategies to strengthen, develop and widely disseminate national standards and guidelines in priority reform areas. Credentialling and defining the scope of clinical practice of medical practitioners working in health care organisations were identified as particular areas for reform.

Under the leadership of the Queensland Health Department, the Council developed a paper entitled *Credentials and Clinical Privileges Guidelines – Working Draft for Consultation*, which was refined following extensive consultation and presented as *National Guidelines for Credentials and Clinical Privileges* to the Australian Health Ministers' Conference in mid-2002.

This Standard is based on those *National Guidelines for Credentials and Clinical Privileges*. It has been designed to apply initially to medical practitioners working in hospital settings. It is, however, based on common principles that should enable its application to be extended in the future to other health care professionals and to medical practitioners working in other organisational settings. With this in mind, nurses and allied health professionals have been consulted during its development.

The Standard will be accompanied by a support package to assist organisations and medical practitioners with its implementation.

1.4 Principles for Credentialling and Defining the Scope of Clinical Practice

The following principles represent the foundations on which this Standard has been developed.

Principle 1

Credentialling and defining the scope of clinical practice are organisational governance responsibilities that are always conducted with the objective of maintaining and improving the safety and quality of health care services

- boards and managers have a governance responsibility to ensure that health care services are only provided by competent medical practitioners in environments that support safe service provision;
- this responsibility reflects the reasonable expectations of patients and communities, which should be respected if community confidence in the health care system is to be maintained;
- there is face validity and intuitive good sense in the proposition that reliable processes of credentialling and defining the scope of clinical practice will reduce the potential for adverse safety and quality consequences which may occur if medical practitioners work outside their areas of competence, or within organisational environments that do not support safe service provision;
- the process of defining the scope of clinical practice follows the process of credentialling and is conducted in the context of the needs and capabilities of the particular organisation. A medical practitioner's scope of clinical practice will, therefore, always be organisation-specific;
- the processes of credentialling and defining the scope of clinical practice should be applied to all medical practitioners who have independent decision-making roles, regardless of whether their relationship with the organisation is one of independent contractor or employee;
- the processes of credentialling and defining the scope of clinical practice should be integrated with comprehensive organisational systems that assure the safety and quality of health care;
- while credentialling and defining the scope of clinical practice are organisational governance responsibilities, the collection of evidence of credentials and confirmation of their validity may be undertaken on behalf of an organisation by an external party (for example, a medical board or professional college, association or society) provided the organisation is satisfied that the external party's approach is rigorous and complete.

Principle 2

Processes of credentialling and defining the scope of clinical practice are complemented by medical practitioner registration requirements and individual professional responsibilities that protect the community

- all medical practitioners are required by legislation to hold registration in each State or Territory in which they wish to practise. The purpose of registration is to protect the community by defining those individuals who are eligible to practise medicine within the relevant State or Territory. The medical registration system does not define or limit the scope of clinical practice of the majority of medical practitioners;
- all medical practitioners also have an individual professional responsibility to limit their scope of clinical practice according to their own reasonably adjudged competence and performance.

Principle 3

Effective processes of credentialling and defining the scope of clinical practice benefit patients, communities, health care organisations and medical practitioners

- the goal of credentialling and defining the scope of clinical practice is to maintain and improve the safety and quality of health care services;
- health care organisations and medical practitioners share responsibility for ensuring the safety and quality of health care;
- robust, transparent and effective approaches to credentialling and defining the scope of clinical practice support medical practitioners in their work, enable organisational governing bodies to be confident that they are discharging their governance responsibilities effectively and enhance consumer and community confidence in the health care system;
- effective processes of credentialling and defining the scope of clinical practice encourage innovation by providing a framework within which new clinical services, procedures or other interventions can be introduced safely.

Principle 4

Credentialling and defining the scope of clinical practice are essential components of a broader system of organisational management of relationships with medical practitioners

- processes of credentialling and defining the scope of clinical practice should be implemented within robust organisational management systems that support strong and constructive relationships between organisations and medical practitioners, whether employees or independent contractors;
- organisational management systems should include systems to monitor and address concerns about the competence and performance of individual medical practitioners and clinical teams, as well as systems to monitor and address concerns about the

organisation's provision of the necessary support for medical practitioners to undertake their authorised scope of clinical practice.

Principle 5

Reviewing the scope of clinical practice should be a non-punitive process

- where there is an identified need to review a medical practitioner's scope of clinical practice, patient safety must be the first priority;
- a range of strategies is available to address concerns about a medical practitioner's clinical performance. Appropriate strategies include monitoring, additional supervision, retraining, mentoring, provision of additional organisational support or temporary or permanent restriction of the medical practitioner's scope of clinical practice;
- a medical practitioner whose scope of clinical practice has been restricted because of concerns about clinical performance should be supported to access appropriate education and retraining;
- under no circumstances should a review of a medical practitioner's scope of clinical practice be undertaken in a punitive manner;
- compliance with organisational policy on credentialling and defining the scope of clinical practice should, however, be enforced, and significant and/or deliberate non-compliance by medical practitioners should not be tolerated.

Principle 6

Processes of credentialling and defining the scope of clinical practice depend for their effectiveness on strong partnerships between health care organisations and professional colleges, associations and societies

- while responsibility for credentialling and defining the scope of clinical practice rests with each organisation's governing body, these processes rely wholly for their effectiveness on the considered, expert advice of the relevant professional peer group(s);
- many professional colleges, associations and societies have developed standards for the purposes of accrediting or endorsing medical practitioners to provide specific clinical services, procedures or other interventions. Professional accreditation or endorsement is a highly significant factor and should always be considered during the processes of credentialling and defining the scope of clinical practice;
- the assessment of a medical practitioner's competence, performance and professional suitability to provide services in specific organisational environments, and of organisational capability, should always be contributed to by peer medical practitioners with relevant experience in similar organisational environments. For example, processes of credentialling and defining the scope of clinical practice of rural general practitioners should always be contributed to by peer general practitioners with relevant rural experience.

Principle 7

Processes of credentialling and defining the scope of clinical practice must be fair, transparent and legally robust

- processes of credentialling and defining the scope of clinical practice of medical practitioners must:
 - ⇒ comply with relevant laws including those governing health services provision, privacy, competition, whistleblowing and equal opportunity;
 - ⇒ operate at all times according to the rules of natural justice and procedural fairness;
 - ⇒ be conducted fairly and with due regard for all stakeholders' reasonable expectations of, and legal rights to, privacy and confidentiality;
 - ⇒ be transparent, to enable patients and the community to be confident that governance and professional responsibilities are being fulfilled.

2. THE ROLE OF THE STANDARD

The Standard will be presented to Health Ministers, via the Australian Health Ministers' Conference, for their formal endorsement.

The Standard will provide health care organisations with a practical framework within which, in collaboration with medical practitioners and, in some cases, other stakeholders, they can develop and implement best practice in credentialling and defining the scope of clinical practice of medical practitioners.

One of the fundamental aims of this Standard is to extend the traditional concepts of credentialling and defining the scope of clinical practice to incorporate the concept of a strong, mutual relationship between the employing or contracting organisation and each medical practitioner, centered on the safety and quality of health care.

The processes of credentialling and defining the scope of clinical practice are conducted within the context of the mutual rights and obligations of the organisation and the medical practitioner, whether their overarching relationship takes the legal form of an employment agreement or an agreement with an independent contractor.

The scope of clinical practice of each medical practitioner should be defined in the context of the facilities and clinical and non-clinical support services to be provided by the organisation to enable the medical practitioner to provide safe, high quality health care services in the specific organisational setting.

The medical practitioner has an obligation to provide safe high quality health care services to patients, and the organisation has an obligation to provide the infrastructure and resources, both human and physical, which enable the medical practitioner to provide these services. The organisation's obligations might typically be referred to as the "kit".

Regular review should form a component of the relationship between the medical practitioner and the organisation. During this review, the medical practitioner's performance and the extent to which the organisation has met its commitment to provide resources and infrastructure support should be considered. The review should reinforce the mutuality of the relationship between the medical practitioner and the organisation, emphasising the underlying philosophy that they will work together to enhance all aspects of their performance.

Other aspects of the relationship between the organisation and the medical practitioner, including the management of disciplinary matters, should be dealt with separately through normal human resources management processes. The review of clinical performance that informs the processes of credentialling and defining the scope of clinical practice, however, also should inform those broader human resources management processes.

The Standard will also provide a foundation upon which the Council can broaden its current focus on credentialling and defining the scope of clinical practice to include all health care professional groups that have independent clinical decision-making responsibility.

The Standard will be accompanied by an organisational support package. Specific strategies to support the Standard's implementation will be considered following further national consultation. The practical utility of the Standard in addressing known problems being experienced with credentialling and defining the scope of clinical practice of medical practitioners will be a major factor that determines its success.

3. THE TERMINOLOGY IN THE STANDARD

The Standard describes each element of the processes of credentialling and defining the scope of clinical practice of medical practitioners in terms of:

- those which organisations may consider and adopt according to their local circumstances; and
- those which reflect best practice and should be adopted by organisations other than in exceptional circumstances.

The term “may” is used to describe practices recommended for adoption by organisations if appropriate in their local circumstances (for example, “The organisation *may* ...”).

The term “should” is used to describe practices that clearly represent best practice in credentialling and defining the scope of clinical practice of medical practitioners (for example, “The organisation *should* ...”). Departures from these practices should only occur in exceptional circumstances and organisations should not claim compliance with the Standard if a significant number of these practices are not adopted.

The rationale for any departure from any practices described in the Standard should be comprehensively documented.

4. THE APPLICATION OF THE STANDARD

The Standard provides a framework for credentialling and defining the scope of clinical practice of medical practitioners who have independent practicing rights in public and private hospitals, including public and private freestanding day hospital facilities.

The term ‘medical practitioners’ includes all medical officers (other than medical officers who are practising under direct supervision) who are registered to practise medicine within the relevant State or Territory.

The Standard does not address:

- (a) *Credentialling and defining the scope of clinical practice in settings other than public or private hospitals or day hospital facilities (e.g. private consulting rooms)*

Rapid advances in technology mean that an increasingly complex range of clinical services, procedures or other interventions can be provided in non-hospital settings. While the principles and concepts incorporated into this Standard have been developed to apply specifically to hospital settings, they should, nevertheless, be relevant to deliberations about the appropriate scope of service provision by medical practitioners in various settings.

- (b) *The appointment of medical practitioners, other than in relation to the interaction of appointment processes with processes of credentialling and defining the scope of clinical practice*

Credentialling and defining the scope of clinical practice contribute to the appointment process, but an effective appointment process also necessitates agreement on a range of non-clinical parameters and is associated with specific documentation requirements, which are not addressed in this Standard.

- (c) *Management of broader organisational relationships with medical practitioners*

Good relationship management extends beyond issues relating to the qualifications and experience required to competently perform a specific scope of clinical practice within a specific organisational environment, to a two-way interaction that encompasses all elements of the relationship between an organisation and its medical practitioners. These include, for example, general professional conduct, participation in education and training, leadership roles and responsibilities, relationships between each medical practitioner and other staff or contractors, responsiveness to administrative requirements and the provision by the organisation of mentoring and professional support.

The performance of individual medical practitioners may be influenced by many factors including their health status, motivation, personality, ethical standards and the broader professional environment within which they work.

Processes of credentialling and defining the scope of clinical practice of a medical practitioner impact on the overall relationship between the organisation and the medical practitioner insofar as they define the extent of the medical practitioner’s scope of clinical practice within a broader context of regular review of clinical performance. They are essential elements of the initial appointment and ongoing relationship management processes.

The Standard defines best practice in credentialling and defining the scope of clinical practice, but does not address broader relationship management issues, including disciplinary processes.

(d) Specific requirements for demonstrating competence in a particular clinical service, procedure or other intervention

Because defining the scope of clinical practice of medical practitioners is context and therefore organisation-specific, it is imperative to maintain local flexibility. The Standard is a procedural standard that will assist organisations to implement efficient and effective processes of credentialling and defining the scope of clinical practice. It does not establish competency requirements for specific clinical services, procedures or other interventions.

(e) Medical officers practising under supervision

Both public and private hospitals employ medical officers in service and designated training positions, whose clinical work is supervised by senior medical practitioners. They are responsible for a large component of service delivery in some organisations. While the Standard does not specifically address credentialling and defining the scope of clinical practice for these medical practitioners, it is nevertheless important that organisations verify their credentials and clearly delineate their scope of clinical practice.

(f) Medical students

The Standard applies only to registered medical practitioners who have independent practicing rights. It is nevertheless important that organisations verify the credentials and clearly delineate the scope of clinical practice of medical students.

PART B

GENERAL ISSUES

5. GOVERNANCE ISSUES

5.1 Background

The governing body is responsible for establishing a system of organisational governance that will ensure strong strategic leadership and control of all aspects of the organisation's performance.

In some jurisdictions, legislation specifies requirements for appointing, credentialling and/or defining the scope of clinical practice of medical practitioners. These legislative requirements should be complied with at all times.

Organisational governance systems should incorporate effective systems for supporting, monitoring and responding to the performance of individuals, clinical teams and the organisation as a whole. Processes of credentialling and defining the scope of clinical practice of medical practitioners should be integrated within these comprehensive governance systems.

The governing body should adopt a comprehensive policy that clearly allocates responsibility and ensures accountability for credentialling and defining the scope of clinical practice of medical practitioners.

The outcome of processes of credentialling and defining the scope of clinical practice should inform medical practitioner appointment processes. These appointment processes are contributed to in many organisations by medical practitioner appointments committees (however designated), which may be either advisory to the governing body or a senior manager, or have delegated authority to confirm medical practitioner appointments.

Different structural approaches are available. For example, the authority to appoint medical practitioners may be—

- (i) retained *in toto* by the governing body, which may be advised by a medical practitioner appointments committee or a senior manager;
- (ii) formally delegated by the governing body to a senior manager, who may be advised by a medical practitioner appointments committee; or
- (iii) formally delegated to a medical practitioner appointments committee that reports to the governing body or a senior manager.

Regardless of which structural approach is adopted, credentialling and defining the scope of clinical practice should be undertaken as discrete processes and should be fully documented. While in many organisations, these processes are conducted by a designated committee that is structurally and operationally separate from the medical practitioner appointments committee, such a structure is not mandatory. For administrative simplicity, for example, the processes of credentialling and defining the scope of clinical practice could be conducted by the medical practitioner appointments committee itself, provided the constitution and conduct of that committee complies with principles of good practice, and documentation is complete.

For this reason, this Standard does not mandate a specific structure for credentialling and defining the scope of clinical practice. Rather, it provides guidance on the proper composition and conduct of the body that undertakes these processes.

The effectiveness of processes of credentialling and defining the scope of clinical practice depends on the contribution of professional peers, who are able to ensure that thorough verification of credentials is undertaken, evaluate competence and performance, and recommend the appropriate scope of clinical practice in the context of the organisation's needs and capability.

Natural justice requires the establishment of an appeals body that is independent of the committee responsible for credentialling and defining the scope of clinical practice. In all cases this body should advise the governing body directly.

The transparency and effectiveness of processes of credentialling and defining the scope of clinical practice, in both the public and private sectors, is of interest to patients and communities. Good governance requires appropriate accountability to be demonstrated to individual patients and to the community.

5.2 The Role of the Governing Body

The governing body should—

- (a) demonstrate strong leadership in and commitment to an organisational culture of safety and quality;
- (b) establish comprehensive governance systems that enable appropriate leadership and control of all aspects of the organisation's performance, incorporating effective processes of credentialling and defining the scope of clinical practice of medical practitioners;
- (c) ensure that delegated authority for implementing and monitoring the performance of its governance systems is clearly defined; and
- (d) ensure that it receives regular, systematic reports on the organisation's performance, including the effectiveness of processes of credentialling and defining the scope of clinical practice of medical practitioners.

5.3 Establishing a Governance System for Credentialling and Defining the Scope of Clinical Practice

The governing body should—

- (a) formally adopt a policy on credentialling and defining the scope of clinical practice that:
 - ⇒ complies with all relevant legal requirements including relevant State/Territory and Commonwealth legislative requirements;
 - ⇒ clearly allocates to a defined organisational committee responsibility to ensure effective processes of credentialling and defining the scope of clinical practice;

- ⇒ incorporates a process for the committee responsible for credentialling and defining the scope of clinical practice to initially review its own recommendations if so requested;
 - ⇒ incorporates the establishment of a credentialling and scope of clinical practice appeals committee; and
 - ⇒ applies to all medical practitioners with independent practicing rights;
- (b) formally adopt a policy on the introduction of new clinical services, procedures or other interventions;
 - (c) incorporate a reference to these policies in the organisation's by-laws or other relevant constitutional documents;
 - (d) identify or establish an organisational committee that can assume responsibility for credentialling and defining the scope of clinical practice of medical practitioners;
 - (e) establish a credentialling and scope of clinical practice appeals committee, to be convened when required;
 - (f) identify or establish an organisational committee that can assume responsibility for advising on the safety, efficacy and role of new and/or ongoing clinical services, procedures or other interventions;
 - (g) endorse terms of reference for the committees that clearly delineate their roles and responsibilities;
 - (h) ensure that the terms of reference of the committee responsible for credentialling and defining the scope of clinical practice and the credentialling and scope of clinical practice appeals committee specify that equity and merit are to form the basis of all phases of the processes of credentialling and defining the scope of clinical practice, and that committees are required to act at all times in compliance with common law and legislation, including the rules of natural justice and procedural fairness;
 - (i) incorporate within the policy on credentialling and defining the scope of clinical practice provision for medical practitioners to administer necessary treatment outside their authorised scope of clinical practice in emergency situations where a patient may be at risk of serious harm if treatment is not provided, and no medical practitioner with an appropriate authorised scope of clinical practice is available;
 - (j) incorporate within the policy on credentialling and defining the scope of clinical practice provision for the processes of credentialling and defining the scope of clinical practice to be undertaken in emergency situations and situations where clinical expertise is required on a temporary basis, and clearly identify who has delegated authority to undertake these processes;
 - (k) incorporate within the policy on credentialling and defining the scope of clinical practice a description of the circumstances under which an unplanned review of a medical practitioner's credentials and/or scope of clinical practice may be initiated, the authorised persons and bodies within or outside the organisation from whom a

request for an unplanned review will be accepted, and how the results of such a review will be implemented;

- (l) identify within the policy on credentialling and defining the scope of clinical practice the maximum elapsed time following which the processes of credentialling and defining the scope of clinical practice will be repeated;
- (m) incorporate within the policy on credentialling and defining the scope of clinical practice provision for suspension (temporary or permanent, in part or full) of a medical practitioner's right to practise within the organisation if specific circumstances apply;
- (n) specify within the policy on credentialling and defining the scope of clinical practice that a medical practitioner's right to practise within the organisation is contingent at all times on the medical practitioner maintaining appropriate professional registration;
- (o) specify within the policy on credentialling and defining the scope of clinical practice that a medical practitioner's right to practise within the organisation will be concluded, terminated or suspended on conclusion, termination or suspension of the medical practitioner's appointment to the organisation;
- (p) specify within the policy on credentialling and defining the scope of clinical practice the maximum time periods for the conduct of the processes of credentialling and defining the scope of clinical practice and any appeals; and
- (q) specify within the policy on credentialling and defining the scope of clinical practice the extent to which the organisation will disseminate information about each medical practitioner's authorised scope of clinical practice.

5.4 Ensuring the Independence of Processes of Credentialling and Defining the Scope of Clinical Practice

5.4.1 Background

Some medical practitioners conduct clinical practice from within private hospitals and freestanding day hospitals in which they have a proprietary or management interest. In such circumstances, there is a potential for real or perceived conflicts of interest to impair the effectiveness of processes of credentialling and defining the scope of clinical practice.

For more information about conflict of interest see section 7.4 'Rules of Conduct of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice'.

5.4.2 Credentialling and Defining the Scope of Clinical Practice of Medical Practitioner Owners and/or Managers

Medical practitioners who own and/or manage an organisation in which they also conduct clinical practice should ensure that—

- (a) the organisation's system for credentialling and defining the scope of clinical practice is demonstrably independent from themselves as owner and/or manager; and

- (b) they, along with all other medical practitioners who practise within the organisation, are subject to processes of credentialling and defining the scope of clinical practice that are rigorous and independent.

5.2 Ensuring Transparency and Accountability

The governing body should—

- (a) endeavor at all times to demonstrate appropriate transparency with respect to the organisation's processes of credentialling and defining the scope of clinical practice, and their outcomes; and
- (b) ensure that the organisation has a clear policy addressing the extent of internal and external dissemination of information about the authorised scope of clinical practice of each medical practitioner.

5.6 Involving Consumers and Communities

The governing body should—

- (a) ensure that input and advice is obtained from individuals and organisations with expertise in consumer and community issues when developing its policy on credentialling and defining the scope of clinical practice;
- (b) ensure that there are systems in place for the organisation to obtain and consider comprehensive consumer and community advice when determining its need for specific health care services;
- (c) consider ways in which individuals and organisations with expertise in consumer and community issues may assist the organisation to monitor the effectiveness of its processes of credentialling and defining the scope of clinical practice; and
- (d) consider including amongst the members of the committee responsible for credentialling and defining the scope of clinical practice a nominee of a consumer or community organisation or a person who can bring to the committee expertise and skills in consumer and community issues.

6. ORGANISATIONAL ISSUES

6.1 Relationship with Contracts of Employment or Engagement

The organisation should ensure that its contract of employment or engagement with each medical practitioner incorporates—

- (a) the medical practitioner's agreement to comply with the organisation's policy on credentialling and defining the scope of clinical practice and the organisation's policy for the introduction of new clinical services, procedures or other interventions as they apply from time to time;

- (b) the medical practitioner's agreement to advise the organisation immediately if any of the following occurs during the term of employment or engagement:
- ⇒ any change in their authorised scope of clinical practice, or denial, suspension, termination or withdrawal of the right to practise (other than for organisational need and/or capability reasons), in any other organisation;
 - ⇒ any change in their professional registration status;
 - ⇒ any change in the extent of their professional indemnity insurance;
 - ⇒ any criminal investigation or conviction; or
 - ⇒ the occurrence of any physical or mental condition or substance abuse problem that could affect their ability to practise or that would require any special assistance to enable them to practise safely and competently;
- (c) the medical practitioner's consent to the organisation retaining comprehensive information about the processes of credentialling and defining their scope of clinical practice, and disseminating information about their authorised scope of clinical practice according to the organisation's policy; and
- (d) the organisation's commitment to providing appropriate mentoring, professional support and support for the medical practitioner's clinical practice.

6.2 Establishing Organisational Need and Capability

6.2.1 Background

Organisational need refers to the extent to which an organisation requires the provision of a specific clinical service, procedure or other intervention in order to provide a balanced mix of safe, high quality health care services that meet consumer and community needs and aspirations.

Organisational capability refers to the organisation's ability to provide the facilities and clinical and non-clinical support services necessary for the provision of safe, high quality clinical services, procedures or other interventions.

Policy considerations, as well as physical and workforce constraints, are factors that legitimately may influence an organisation's ability to satisfy all consumer and community health care needs and aspirations at a local level. Alternative arrangements for the provision of health care services may need to be explored.

Organisational need and capability for a specific health care service depend on various factors, including the type of organisation, its geographical location, the needs and aspirations of the community, whether the organisation is in the public or private sector and its role within the broader health care system.

Representatives of consumers and the community should be engaged to assist in determining organisational need.

Defining the scope of clinical practice involves matching the medical practitioner's competence and skills with the organisation's need and capability.

6.2.2 Preconditions to Recommending a Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice should only consider recommending a specific scope of clinical practice for a medical practitioner—

- (a) if a responsible body of medical opinion deems the relevant clinical service, procedure or other intervention to be one that will benefit patients; or
- (b) if the clinical service, procedure or other intervention is not so recognised, it has been reviewed by a properly constituted Human Research Ethics Committee or Clinical Ethics Committee (as appropriate) and its introduction has been deemed to be acceptable in the circumstances (with or without conditions); and
- (c) if the clinical service, procedure or other intervention is new to the organisation, it has been subject to the organisation's policy for the introduction of new clinical services, procedures or other interventions; and
- (d) each of organisational need, organisational capability and medical practitioner competence and, where relevant, performance, has been established.

6.3 Ensuring Ongoing Organisational Capability

The continuing safety and quality of clinical services, procedures or other interventions depends on the organisation continuing to provide necessary facilities and clinical and non-clinical support services. The organisation should—

- (a) regularly review, in conjunction with each medical practitioner, organisational capability relevant to the medical practitioner's scope of clinical practice.

If significant concerns are expressed at any time about the adequacy of organisational facilities and/or clinical and non-clinical support services, the organisation should—

- (b) obtain objective expert advice about the organisation's current and ongoing capability to support safe, high quality clinical services, procedures or other interventions; and
- (c) in consultation with the relevant medical practitioners, consider whether clinical services, procedures or other interventions should continue to be provided, or whether alternative arrangements should be made for patients to whom the organisation has an existing or future obligation.

6.4 Supporting Compliance with the Standard

The organisation should support compliance with this Standard by—

- (a) assisting all medical practitioners with an appointment to the organisation to maintain accurate records of their clinical activity and, where available, objective performance data;
- (b) routinely providing medical practitioners with a certificate of service at the conclusion of their appointment to the organisation, incorporating the following information:
 - ⇒ the period of employment or engagement;
 - ⇒ the medical practitioner's authorised scope of clinical practice at the conclusion of their appointment;
 - ⇒ whether the medical practitioner's scope of clinical practice was changed, denied, withdrawn or granted in a different form to that requested during the period of employment or engagement (other than for reasons relating to change in organisational need and/or capability);
 - ⇒ whether the medical practitioner was held in good standing by the organisation at the conclusion of their employment or engagement; and
- (c) with the consent of the relevant medical practitioner, responding promptly and accurately to requests by authorised individuals and organisations for information relating to the medical practitioner's credentials and their authorised scope of clinical practice.

6.5 Supporting Processes of Credentialling and Defining the Scope of Clinical Practice

Credentialling and defining the scope of clinical practice are administratively complex processes that require dedicated and expert support. The organisation should—

- (a) allocate adequate senior, well-trained administrative staff to support processes of credentialling and defining the scope of clinical practice, including appeals processes; and
- (b) ensure that the efficiency and effectiveness of processes of credentialling and defining the scope of clinical practice are monitored and maintained.

6.6 Maintaining Records

6.6.1 Background

Comprehensive records should be kept of all deliberations and recommendations relevant to the processes of credentialling and defining the scope of clinical practice of medical practitioners.

The period for retention of records should correspond with limitation periods defined by the various Statutes of Limitations. These periods may vary between jurisdictions, and over time. Extended limitation periods applying to minors should be considered when record retention periods are being determined.

6.6.2 Maintaining Comprehensive Records

The organisation should ensure comprehensive documentation of the deliberations of, any supporting information considered by, and the relevant decision(s) of—

- (a) the committee responsible for credentialling and defining the scope of clinical practice and the credentialling and scope of clinical practice appeals committee; and
- (b) the governing body, or its authorised delegate, in relation to credentialling and defining the scope of clinical practice of any medical practitioner.

Documentation in relation to credentialling and defining the scope of clinical practice, and/or any appeals or reviews, should incorporate at a minimum—

- (c) the names of the medical practitioners whose credentials were examined;
- (d) the specific credentials that were examined, and in what format;
- (e) which credentials were verified, and how they were verified;
- (f) whether any concerns were raised about the medical practitioner's competence or performance;
- (g) the evidence that was reviewed of the medical practitioner's competence or performance in the position or scope of clinical practice under consideration;
- (h) whether an invitation was extended to and accepted by the medical practitioner to present in person to the relevant committee or authorised delegate;
- (i) the identity of any support person who assisted the medical practitioner at any presentation;
- (j) the additional information that was presented by the medical practitioner;
- (k) the conclusions about the medical practitioner's competence and performance in the position or scope of clinical practice under consideration, and in particular their ability to provide health care services at the expected level of safety and quality;
- (l) the organisation's ability to provide the necessary facilities and clinical and non-clinical support services; and
- (m) the committee's or authorised delegate's recommendations or decisions regarding the medical practitioner's scope of clinical practice.

The committee responsible for credentialling and defining the scope of clinical practice, the credentialling and scope of clinical practice appeals committee, and the governing body, when considering issues relating to credentialling and defining the scope of clinical practice, should—

- (n) formally adopt at each meeting accurate records of the previous meeting.

The organisation should retain for a period of time corresponding, at a minimum, to the statutorily defined limitation periods—

- (o) for each individual medical practitioner a record of all decision(s) regarding credentials and scope of clinical practice;
- (p) the records of the committee responsible for credentialling and defining the scope of clinical practice, including any supporting information on which the committee relied;
- (q) the records of the credentialling and scope of clinical practice appeals committee, including any supporting information on which the committee relied; and
- (r) the records of the governing body and any authorised delegate, in relation to credentialling and defining the scope of clinical practice of a medical practitioner.

The organisation should ensure—

- (s) that each medical practitioner is aware of, and consents in their contract of employment or engagement to the retention of the above information.

6.7 Disseminating Information About the Scope of Clinical Practice

The organisation should—

- (a) establish procedures to ensure that information about each medical practitioner's authorised scope of clinical practice, including any changes, is promptly disseminated within and external to the organisation, according to the organisation's policy; and
- (b) in particular, ensure that the information is accessible at all times to staff in all relevant patient care areas.

6.8 Indemnifying Participants

6.8.1 Background

Members of committees responsible for credentialling and defining the scope of clinical practice, and members of credentialling and scope of clinical practice appeals committees, should be protected against potential adverse legal consequences of their participation in committee activities, particularly actions in defamation or negligence.

Qualified privilege (otherwise known as 'statutory immunity') legislation in some jurisdictions offers a degree of statutory protection for members of committees responsible for credentialling and defining the scope of clinical practice, provided they act in good faith.

6.8.2 Ensuring Appropriate Indemnity and Insurance

The organisation should—

- (a) indemnify and/or provide appropriate insurance for members of the committee responsible for credentialling and defining the scope of clinical practice and the credentialling and scope of clinical practice appeals committee;
- (b) ensure that all members are educated about their obligation to act at all times in ‘good faith’;
- (c) consider whether its jurisdiction’s qualified privilege (statutory immunity) legislation for health care quality activities is relevant to the work of the committee responsible for credentialling and defining the scope of clinical practice and the credentialling and scope of clinical practice appeals committee; and
- (d) if so, consider applying for a declaration under the relevant legislation.

7. APPROACHES TO CREDENTIALLING AND DEFINING THE SCOPE OF CLINICAL PRACTICE

7.1 Role of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice

The general role of the committee responsible for credentialling and defining the scope of clinical practice is to—

- (a) assist the organisation to ensure that clinical services, procedures or other interventions are provided by competent medical practitioners within environments that support the provision of safe, high quality health care services;
- (b) promote efficient processes;
- (c) minimise inconvenience to applicants; and
- (d) maintain comprehensive records of its proceedings.

Specifically, the committee responsible for credentialling and defining the scope of clinical practice may—

- (e) in consultation with the relevant clinical leader, advise the organisation on the range of clinical services, procedures or other interventions that can be provided safely in the specific organisational setting;
- (f) in consultation with the relevant clinical leader, advise the organisation on the facilities and clinical and non-clinical support services reasonably necessary to sustain the safe, high quality provision of specific clinical services, procedures or other interventions;

- (g) in consultation with the relevant clinical leader, advise the organisation on the minimum credentials necessary for a medical practitioner to fulfill competently the duties of a specific position or a scope of clinical practice, within the specific organisational environment;
- (h) advise the organisation on the information that should be requested of and provided by applicants for appointment to specific positions or for a specific scope of clinical practice;
- (i) accept requests to undertake the processes of credentialling and defining the scope of clinical practice:
 - ⇒ in relation to all medical practitioners applying for initial appointment to the organisation;
 - ⇒ at any time, from groups and individuals within or outside the organisation who are authorised by the governing body to request a review of a medical practitioner's scope of clinical practice (authorised groups and individuals may include, for example, the Board, the Chief Executive Officer, the Chief Medical Officer (or equivalent), senior clinical leaders or the medical staff group); and
 - ⇒ from any medical practitioner with an existing appointment to the organisation who requests a review of their scope of clinical practice;
- (j) ensure each medical practitioner's credentials are reviewed and verified according to organisational policy;
- (k) consider each medical practitioner's credentials, competence and performance in the context of the organisation's need and capability, and recommend the scope of clinical practice that is appropriate in the circumstances;
- (l) advise the governing body, the relevant senior manager or medical appointments committee, as appropriate, of its recommendations in relation to the scope of clinical practice of each medical practitioner; and
- (m) at the request of a medical practitioner with an existing appointment to the organisation, or of an authorised individual or body, undertake an initial review of its recommendations regarding the medical practitioner's credentials or scope of clinical practice.

7.2 Composition of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice—

- (a) should be comprised of a core membership of medical practitioners from a range of clinical disciplines, who have the necessary skills and experience to provide independent, high quality advice (for information about conflict of interest of members see section 7.4);

- (b) should be satisfied that it has the competency to reliably assess the credentials and consider the scope of clinical practice being requested;
- (c) should include amongst its members a member of senior management;
- (d) should either include amongst its members a member with high level skills and experience in human resources management, or have ready access at each meeting to a senior human resources professional with the relevant skills and experience;
- (e) should have the power to co-opt additional medical practitioners with specific clinical skills and experience relevant to the scope of clinical practice being requested;
- (f) may include amongst its core or co-opted members:
 - ⇒ a member or nominee of the governing body;
 - ⇒ a nominee of the relevant professional college, association or society;
 - ⇒ a university nominee who is a medical practitioner (as relevant);
 - ⇒ a member who brings expertise in consumer and/or community issues;
- (g) should have a designated quorum that includes a majority of medical practitioners and a member of senior management;
- (h) should not undertake any process of credentialling or defining the scope of clinical practice of any medical practitioner unless its core or co-opted membership includes at least one medical practitioner who practises in the field and specialty relevant to the scope of clinical practice being requested; and
- (i) should ensure that nominee members understand that their role is to bring to the committee experience and expertise relevant to the nominating organisation and its members, rather than to act as a representative of the nominating organisation.

7.3 Educating and Training the Members of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice

Members of the committee responsible for credentialling and defining the scope of clinical practice should—

- (a) participate in education and training specific to their role and responsibilities; and
- (b) be supported to access broader education and training opportunities relevant to credentialling and defining the scope of clinical practice, particularly in relation to the role of these processes in organisational governance and their contribution to safety and quality in health care.

7.4 Rules of Conduct of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice

7.4.1 Background

The committee responsible for credentialling and defining the scope of clinical practice must comply at all times with all legal requirements, including the common law and relevant State, Territory and Commonwealth legislation. Specifically, the committee must conduct itself according to the rules of natural justice, without conflicts of interest or bias, and in a manner, which does not breach relevant legislation, including privacy, trade practices, whistleblower or equal opportunity legislation.

Equity and merit must form the basis of all phases of the processes of credentialling and defining the scope of clinical practice.

Examples of situations where conflicts of interest might arise include—

- (i) where the decision-maker is in competition with the person under review and stands to benefit from any negative outcome for the person under review;
- (ii) where the decision-maker is related to a person in competition with the person under review and that related person stands to benefit from any negative outcome for the person under review; or
- (iii) where the decision-maker stands to benefit from a positive outcome for the person under review, either because he or she hopes to obtain a similar positive outcome if his or her practice was under review, or because he or she will gain some benefit from the work of the person under review.

Members of the committee responsible for credentialling and defining the scope of clinical practice should disqualify themselves from acting on any matter before the committee if they have a material personal (including but not limited to a pecuniary) interest in the outcome of the matter. They should also consider the desirability of disqualifying themselves if they have any apparent or perceived personal interest in the outcome.

7.4.2 Committee Rules of Conduct

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) ensure that all members are educated about their obligation to act at all times in ‘good faith’;
- (b) establish policies and procedures to ensure that any committee member who will stand to benefit directly or indirectly, financially or otherwise, from the outcome of any decision of the committee, is required to disclose any potential conflict of interest;
- (c) establish policies and procedures whereby any committee member who has a material conflict of interest is excluded from participating in the relevant

proceedings, and the reasons for such exclusion are documented in the record of meeting;

- (d) where a medical practitioner's scope of clinical practice is under review and may be changed in a manner that is likely to be detrimental to the medical practitioner's reputation or livelihood, give the medical practitioner:
 - ⇒ notice of the issues to be dealt with by the committee and of the time and place of any meetings at which the medical practitioner will be invited to present;
 - ⇒ an adequate opportunity to respond to all information, materials and allegations put before the committee; and
 - ⇒ an opportunity to appear before the committee and present their case;
- (e) establish procedures to ensure that necessary information is made available in a timely fashion to the governing body, senior manager or medical appointments committee as appropriate, according to the relevant policy; and
- (f) document comprehensively the reasons for any decisions made.

7.5 Frequency of Credentialling and Defining the Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) ensure review and, where necessary or according to the organisation's policy, verification of each medical practitioner's credentials and define the appropriate scope of clinical practice for each medical practitioner prior to their initial appointment to the organisation; and
- (b) thereafter, ensure that each medical practitioner's registration status and good standing is verified annually with the relevant professional registration board.

The committee responsible for credentialling and defining the scope of clinical practice should ensure that each medical practitioner's credentials are reviewed and, where necessary or according to the organisation's policy, verified, and their scope of clinical practice reviewed—

- (c) in conjunction with the organisation considering an application for a further appointment;
- (d) at any time, if requested by an authorised individual or body;
- (e) at any time, if the medical practitioner makes an application for review of their scope of clinical practice;

- (f) at any time, if there is a material change to the organisation's capability to provide appropriate facilities or clinical or non-clinical support services; and
- (g) in all circumstances, at intervals of no more than 5 years.

7.6 Confidentiality of Proceedings

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) establish policies and procedures that protect the confidentiality of its proceedings;
- (b) ensure all members are educated about the existence and purpose of those policies and procedures; and
- (c) require all members to sign an undertaking before joining the committee to abide by those policies and procedures.

PART C

CREDENTIALLING OF MEDICAL PRACTITIONERS

8. THE CREDENTIALLING PROCESS

8.1 Background

Credentialling refers to the formal process used to verify the qualifications, experience professional standing and other relevant professional attributes of medical practitioners for the purpose of forming a view about their competence, performance and professional suitability to provide safe, high quality health care services within specific organisational environments.

Defining the scope of clinical practice follows on from credentialling and involves delineating the extent of an individual medical practitioner's clinical practice within a particular organisation based on the individual's credentials, competence, performance and professional suitability, and the needs and capability of the organisation.

The process of defining the scope of clinical practice is conducted in the context of the needs and capabilities of the particular organisation. A medical practitioner's scope of clinical practice will, therefore, always be organisation-specific.

While credentialling and defining the scope of clinical practice are organisational governance responsibilities, the collection of evidence of credentials and confirmation of their validity may be undertaken on behalf of an organisation by an external party (for example, a medical board or professional college, association or society) provided the organisation is satisfied that the external party's approach is rigorous and complete.

However before an organisation establishes a position and recruits a medical practitioner the organisation needs to determine essential criteria for the particular position. Once determined the essential criteria form the basis for reviewing applications for appointment including the credentials an applicant needs to possess before being considered for a position.

Once the organisation has established the essential criteria for a position applications can be considered, credentials verified and the scope of clinical practice determined.

8.2 Establishing Essential Criteria for a Position

The organisation, with the advice of the relevant clinical leader and/or the committee responsible for credentialling and defining the scope of clinical practice, should—

- (a) consider the specific local environment, including organisational need and organisational capability, in which the proposed clinical services, procedures or other interventions will be provided;
- (b) review available objective, evidence-based criteria generally relevant to competence and performance in specific positions or for specific clinical services, procedures or other interventions, and consider their applicability to the local environment;
- (c) where appropriate, seek the recommendations of the relevant professional college, association or society in relation to the period and nature of the training and

experience necessary to develop competence and high level performance in specific positions or in specific clinical services, procedures or other interventions;

- (d) consider the relevant available evidence regarding the relationship between the volume of clinical services, procedures or other interventions performed and their safety and quality, and the likely impact of service volume on clinical outcomes in the local environment;
- (e) with the relevant clinical leader, establish minimum credentials (“threshold credentials”) for each specific position, service, procedure or other intervention for which applications for credentialling and defining the scope of clinical practice are, or are expected to be, received;
- (f) ensure that the threshold credentials address the minimum education (e.g. medical qualification), formal training (e.g. residency, fellowship, continuing education or other relevant training), clinical experience (e.g. years in independent practice, numbers of clinical services, procedures or other interventions performed), leadership experience (e.g. years in clinical leadership positions), teaching and training experience, research experience and communication and teamwork skills required for the specific position, clinical service, procedure or other intervention;
- (g) ensure that the threshold credentials are based on objective criteria about the necessary period and character of training and experience, rather than the possession of specific endorsement or accreditation by named professional colleges, associations or societies;
- (h) determine the precise education, training, experience and clinical outcome information that will assist with the processes of credentialling and defining the scope of clinical practice and therefore should be submitted by the applicant; and
- (i) determine the threshold credentials and relevant form and content of information that it should request from each medical practitioner who applies for appointment to the organisation or for a specific scope of clinical practice.

The organisation should advise each applicant for appointment or for a specific scope of clinical practice of—

- (j) the threshold credentials that they will be required to meet before any application will be processed; and
- (k) the specific form and content of information that they will be required to submit for consideration by the committee responsible for credentialling and defining the scope of clinical practice.

8.3 Establishing Policy on Verification of Credentials

The organisation should establish and document a policy defining its requirements for verification of each category of information provided by medical practitioners—

- (a) who apply for appointment to the organisation;

- (b) who apply for any change to their scope of clinical practice; or
- (c) whose scope of clinical practice is under review for any reason.

If the organisation accepts third party verification of credentials, it should—

- (d) clearly document the criteria by which third party organisations will be approved to undertake this role; and
- (e) ensure that its performance requirements are rigorous and complete, and appropriately documented in an agreement with each relevant third party organisation.

8.4 Establishing Policy on Professional Sanctions, Disciplinary Actions and Criminal Convictions

The organisation should establish and document a policy addressing whether any, and if so which types of, professional sanctions, disciplinary actions or criminal convictions may or will preclude—

- (a) the processing of a medical practitioner's application for credentialling and defining the scope of clinical practice; or
- (b) the initial or continuing appointment of a medical practitioner to the organisation.

8.5 Establishing Policy on Indemnity Insurance Requirements

The organisation should establish and document a policy defining its—

- (a) minimum professional indemnity insurance requirement of each medical practitioner; and
- (b) requirement for evidence of indemnity insurance policies to be available to the committee responsible for credentialling and defining the scope of clinical practice.

8.6 Information Required for Initial Credentialling

The following information should be requested of and provided by each medical practitioner when applying for initial credentialling—

- (a) details of lifetime professional registration history including evidence of current professional registration;
- (b) details of lifetime education and training history, together with certified copies of all diplomas, degrees and recognised post-graduate qualifications;
- (c) details of endorsement or accreditation by professional colleges, associations or societies for the provision of specific clinical services, procedures or other interventions;
- (d) details of all past and continuing health care-related employment;

- (e) details of current involvement in clinical audits, peer review activities and continuing medical education programs;
- (f) details of experience in teaching and research, where applicable;
- (g) details of experience in medical leadership positions;
- (h) whether the medical practitioner maintains an activity log book;
- (i) a summary of clinical activity undertaken over the past twelve months in all locations in which the medical practitioner provides health care services, including the approximate number, type, and location of patients; clinical services, procedures or other interventions performed; diagnoses treated; and consultations rendered;
- (j) where available, objective data on the outcomes of that clinical activity;
- (k) details of the specific scope of clinical practice requested;
- (l) the precise education, training, experience and outcome information that is required in relation to the requested scope of clinical practice;
- (m) evidence of the type and scope of current professional indemnity insurance (if organisational policy requires this to be held);
- (n) a declaration regarding any prior change to the defined scope of clinical practice, or denial, suspension, termination or withdrawal of the right to practise (other than for organisational need and/or capability reasons) in any other organisation;
- (o) a declaration regarding any prior disciplinary action or professional sanctions imposed by any registration board;
- (p) a declaration regarding any criminal investigation or conviction;
- (q) a declaration regarding the presence of any physical or mental condition or substance abuse problem that could affect the medical practitioner's ability to exercise the requested scope of clinical practice or that would require any special assistance in order to enable the medical practitioner to exercise that scope of clinical practice safely and competently; and
- (r) written consent for the committee responsible for credentialling and defining the scope of clinical practice and/or the organisation to verify with relevant individuals, external organisations and nominated referees the validity of all claims made, including explicit consent for the organisation to verify the medical practitioner's declaration regarding health status, professional registration history and criminal record.

8.7 Information Required for Re-credentialling

The following information should be requested of and provided by each medical practitioner whose credentials are under review for any reason—

- (a) evidence of current professional registration;

- (b) details of education and training undertaken, and any endorsement or accreditation awarded by a professional college, association or society since the previous declaration;
- (c) details of all health care-related employment undertaken since the previous declaration, including current employment;
- (d) details of involvement in clinical audits, peer review activities and continuing medical education programs since the previous declaration;
- (e) whether the medical practitioner maintains an activity log book;
- (f) a summary of clinical activity undertaken over the past twelve months, in all locations in which the medical practitioner provides health care services, including the approximate number, type, and location of patients; clinical services, procedures or other interventions performed; diagnoses treated; and consultations rendered;
- (g) where available, objective data on the outcomes of that clinical activity;
- (h) details of the specific scope of clinical practice requested;
- (i) the precise education, training, experience and outcome information that is required in relation to any new scope of clinical practice requested;
- (j) evidence of the type and scope of current professional indemnity insurance (if organisational policy requires this to be held);
- (k) either:
 - ⇒ a declaration that there has been no change to the previous information provided regarding:
 - ♦ any change to the defined scope of clinical practice, or denial, suspension, termination or withdrawal of the right to practise (other than for organisational need and/or capability reasons) in any other organisation;
 - ♦ any disciplinary action or professional sanctions imposed by any registration board;
 - ♦ any criminal investigation or conviction; and
 - ♦ the presence of any physical or mental condition or substance abuse problem that could affect the medical practitioner's ability to exercise the scope of clinical practice requested or that would require any special assistance in order to enable the medical practitioner to exercise that scope of clinical practice safely and competently;
 - or:
 - ⇒ a declaration describing the specific changes to the information previously provided relating to these aspects of professional status and performance.

- (l) written consent for the committee responsible for credentialling and defining the scope of clinical practice and/or the organisation to verify with relevant individuals, external organisations and nominated referees the validity of all claims made, including explicit consent for the organisation to verify the medical practitioner's declaration regarding health status, professional registration history and criminal record.

8.8 Verifying Credentials

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) ensure that all relevant information submitted by each medical practitioner to establish his or her professional credentials has been carefully reviewed; and
- (b) if required by organisational policy, ensure that the information has been verified through inquiry of the professional registration board, police, insurance provider, employer or other relevant body.

8.9 Professional References

The committee responsible for credentialling and defining the scope of clinical practice may—

- (a) develop a pro-forma request for references for medical practitioners whose credentials and scope of clinical practice are being considered or reviewed, incorporating questions about the approximate number, type and location of patients; clinical services, procedures or other interventions performed and diagnoses treated; and the medical practitioner's technical performance, communication skills and teamwork.

The committee responsible for credentialling and defining the scope of clinical practice should—

- (b) ensure current references have been obtained and documented from at least two individuals within the medical practitioner's specialty and/or in related specialties;
- (c) ensure that at least one reference is from an individual who can verify, preferably for at least a 12 month period within the previous three years, the approximate number, type and location of patients; clinical services, procedures or other interventions performed; and diagnoses treated; and provide evaluatory comments on the medical practitioner's technical performance, communication skills and teamwork; and
- (d) if necessary and according to organisational policy, question or authorise the questioning of the referees on any aspect of the medical practitioner's competence and performance.

8.10 Temporary Credentialling

Temporary credentialling of medical practitioners—

- (a) may be necessary to enable locums and other medical practitioners appointed on a short term basis to provide health care services;
- (b) should always precede temporary definition of the scope of clinical practice;
- (c) should require provision by the medical practitioner of all information required by the organisation from applicants for initial credentialling or re-credentialling, as applicable;
- (d) should enable medical practitioners whose credentials have not been formally reviewed and verified according to the organisation's standard procedures to have a scope of clinical practice defined on a time limited basis;
- (e) should involve an assessment of each medical practitioner's credentials and an interview with the medical practitioner by a team comprising, at a minimum, a senior manager with explicitly delegated authority and a senior medical practitioner who practises in the same specialty area as the applicant;
- (f) should involve, at a minimum:
 - ⇒ verification of identity through inspection of relevant documents (e.g. driver's licence with photograph);
 - ⇒ verification with the relevant professional registration board of the medical practitioner's professional registration history, good standing and past record of professional sanctions or disciplinary actions;
 - ⇒ review of lifetime health care-related employment history, and direct confirmation with the most recent employer of the medical practitioner's competence, performance and good standing;
 - ⇒ review of lifetime education and training history and confirmation with the relevant professional college, association or society of the medical practitioner's good standing; and
 - ⇒ confirmation by at least one professional referee of the medical practitioner's competence, performance and good standing;
- (g) should be fully documented; and
- (h) should be referred to the next meeting of the committee responsible for credentialling and defining the scope of clinical practice, for formal consideration according to the organisation's standard procedures at its next meeting.

8.11 Emergency Credentialling

Emergency credentialling of medical practitioners—

- (a) may be necessary in times of disaster or major emergency;
- (b) should always precede emergency definition of the scope of clinical practice, which should be conducted only on an exceptional basis;
- (c) should enable medical practitioners whose credentials have not been formally reviewed and verified according to the organisation's standard policy to assist in the provision of clinical care at times of disaster or major emergency;
- (d) should involve, at a minimum:
 - ⇒ verification of identity through inspection of relevant documents (e.g. driver's licence with photograph);
 - ⇒ immediate contact with a member of senior management of the organisation nominated by the medical practitioner as his or her most recent place of appointment, to verify claimed employment history and good standing;
 - ⇒ verification with the relevant professional registration board as soon as practicable of the medical practitioner's registration history, good standing and past record of professional sanctions or disciplinary actions; and
 - ⇒ confirmation as soon as practicable by at least one professional referee of the medical practitioner's competence and good standing;
- (e) should involve, where practicable, an assessment of the medical practitioner's available credentials by a senior medical practitioner who practises in the same specialty area as the applicant;
- (f) should be followed as soon as reasonably practicable by all procedures required for temporary or permanent credentialling; and
- (g) should be fully documented.

PART D

**DEFINING THE SCOPE OF CLINICAL PRACTICE OF
MEDICAL PRACTITIONERS**

9. THE PROCESS OF DEFINING THE SCOPE OF CLINICAL PRACTICE

9.1 Background

There is little, objective evidence that confirms a direct relationship between the safety and quality of specific clinical services, procedures or other interventions and the credentials of the medical practitioner or team. There is, nevertheless, a community expectation that medical practitioners' credentials, competence and performance will be evaluated in the context of organisational need and capability, for the purposes of defining medical practitioners' scope of clinical practice. There is also intuitive good sense in the proposition that such processes will reduce the risk of safety and quality problems caused by medical practitioners practising outside their areas of competence.

Community satisfaction with the safety and quality of health care depends on a range of parameters. While safety is a paramount community value, other parameters including accessibility are of prime importance to some communities. Community values should be considered when assessing organisational need and capability.

There are many important factors that will contribute to a decision to recommend or decline to recommend a scope of clinical practice for a medical practitioner. These decisions can be challenging and difficult. For example, the assessment of competing priorities for the provision of health resources; the scant data available upon which to make health planning decisions; the potential for health care services to be required on an emergency basis; community preference for local service delivery; the availability of alternative health care services within a reasonable geographic distance; the need to provide an integrated health care service to a particular community; and the need for specific support services to be available to sustain core health care services within a particular environment are all important considerations. A level of service that may be acceptable to a community in one setting may be completely unacceptable in another. The definitive question is: "Is it reasonable in the circumstances for this medical practitioner to provide this service in this organisational setting, and is this a service for which the organisation has identified a need?"

Consideration of these issues by the organisation and the medical practitioner highlights the mutuality of the process of defining the scope of clinical practice.

In undertaking this analysis, health care organisations and medical practitioners need to have regard to the volume of health care services able to be provided in the organisational setting. With regard to some clinical services, procedures or other interventions, a relationship between, on the one hand, the volume of clinical activity undertaken by a medical practitioner or a clinical team, and on the other hand the safety and quality of those health care services has been demonstrated, although the relationship is by no means direct or universal.

Increasingly, objective performance data are being collected and analysed for the purpose of improving the safety and quality of health care. National clinical registers through which such data are currently managed include the Australian and New Zealand Dialysis and Transplant Association (ANZDATA) register, the Australian and New Zealand Intensive Care Society (ANZICS) register and the National Joint Replacement Registry, established by the

Australian Orthopaedic Association with the support of a grant from the Australian Government. The feasibility of a National Cardiac Procedures Register is also being explored by the Council in conjunction with other stakeholders.

In the future, it is expected that more performance data will be available from such collections. The availability of such data should be taken into account when committees responsible for credentialling and defining the scope of clinical practice consider medical practitioners' competence and performance.

Professional college, association or society endorsement or accreditation status is also a highly significant factor, and should always be considered during the processes of credentialling and defining the scope of clinical practice. Such endorsement or accreditation provides significant evidence of competence to undertake a specific service, procedure or other intervention, provided the necessary facilities and clinical and non-clinical support services are available.

The process of defining the scope of clinical practice is, however, always organisation-specific. In some circumstances an organisation may determine that local needs and circumstances justify service provision by non-accredited or endorsed medical practitioners; or, alternatively, an organisation may be unable to provide the necessary support to enable the safe provision of specific clinical services, procedures or other interventions by medical practitioners who have, nevertheless, been accredited or endorsed by their professional college, association or society as competent to provide those clinical services, procedures or other interventions.

Organisations should consider whether a restricted scope of clinical practice may be appropriate in their specific situation. For example, a scope of clinical practice may be limited to certain clinical circumstances (e.g. elective rather than emergency circumstances) or to the treatment of patients with specific characteristics (e.g. patients at low physiological risk, or adult patients only), or may be authorised under specified conditions (e.g. at defined times when appropriate facilities and clinical and non-clinical support services are available).

It is important that the factors on which all material decisions are based are clearly documented.

9.2 Common Approaches to Defining the Scope of Clinical Practice

Various approaches to defining the scope of clinical practice are available, including—

- (i) Checklists of clinical services, procedures or other interventions. This is an exhaustive approach that depends on a detailed checklist itemising the clinical services, procedures or other interventions and/or conditions that can specifically be requested by applicants. Such lists are often used in surgical specialties but are not recommended.
- (ii) Categorisation. This approach refers to the development of well-defined categories or levels of scope of clinical practice. It identifies major clinical services, procedures or other interventions that are classified based upon the degree of complexity of the procedure or illness to be treated. Categorisation is used sometimes to delineate the scope of clinical practice in non-procedural specialties.

- (iii) Descriptive. This approach allows the applicant to describe, in narrative format, the scope of clinical practice being requested. Medical practitioners are not required to complete a checklist or use categories, but instead are asked to describe the areas in which they possess clinical competence.
- (iv) Combination. Organisations may find it useful to develop an approach based on a combination of various features of these methods. For example, it may be appropriate to list specific clinical services, procedures or other interventions within categories, or to use categories for some clinical services, procedures or other interventions and create lists for those that do not fit into the categories. Alternatively, a descriptive approach in combination with a list of clinical services, procedures or other interventions that need further consideration may be used.

Some organisations use a ‘core scope of clinical practice’ approach. Core scope of clinical practice refers to the range of clinical activities within a specialty or subspecialty that any appropriately trained medical practitioner would be expected to be competent to perform. In the core scope of clinical practice approach, medical practitioners who meet predefined criteria are eligible to apply for approval of a core scope of clinical practice, and those who can document additional training and experience can request special approval to perform additional specific clinical services, procedures or other interventions.

Defining the scope of clinical practice in non-procedural specialties and sub-specialties may be assisted by clear practice policies which state, in general, when a consultation is required, and how specialty-specific the care of certain clinical conditions should be.

9.3 Determining an Organisational Approach to Defining the Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) consider the various approaches to defining the scope of clinical practice; and
- (b) delineate, in a consistent and transparent manner, its preferred approach to defining the scope of clinical practice in each clinical area.

9.4 Defining the Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) review the clinical services, procedures or other interventions which have been requested for inclusion in the scope of clinical practice, and consider whether:
 - ⇒ a responsible body of medical opinion deems the relevant clinical services, procedures or other interventions to be beneficial to patients; or
 - ⇒ if the clinical services, procedures or other interventions are not so recognised, they have been reviewed by a properly constituted Human Research Ethics

Committee or Clinical Ethics Committee (as appropriate) and their introduction has been deemed to be acceptable in the circumstances (with or without conditions); and

- ⇒ if the clinical services, procedures or other interventions are new to the organisation, they have been subject to the organisation's policy for the introduction of new clinical services, procedures or other interventions;
- (b) review and consider the relevance to the specific circumstances in which the scope of clinical practice is requested of:
 - ⇒ policies or guidelines published by the professional colleges, associations and societies;
 - ⇒ requirements of the professional colleges, associations and societies for current trainees to gain experience in the requested scope of clinical practice; and
 - ⇒ credible publications relating to competence and performance (including the relationship between volume and quality) in the requested scope of clinical practice;
- (c) consider the volume of the relevant activity undertaken by the medical practitioner over the past twelve (12) months, and the implications regarding the medical practitioner's ongoing competence and performance;
- (d) review available sources of objective data about the medical practitioner's competence and performance, including any available registry data, and consider:
 - ⇒ their validity as measures of the safety and quality of health care services, including whether they are appropriately stratified and risk adjusted; and
 - ⇒ whether they contribute to a reliable assessment of the medical practitioner's competence and performance in the requested scope of clinical practice;
- (e) review current references and ensure that they confirm the medical practitioner's adequacy of clinical knowledge, technical skill, judgement, experience, competence and performance in each of the specific areas within the requested scope of clinical practice;
- (f) review referees' comments on the medical practitioner's communication skills and teamwork ability insofar as these are likely to contribute to clinical performance;
- (g) review referees' comments on overall professional performance; and
- (h) consider the specific local circumstances in which the clinical services, procedures or other interventions will be provided.

Based on this assessment, the committee responsible for credentialling and defining the scope of clinical practice should—

- (i) determine whether the clinical services, procedures or other interventions which have been requested for inclusion in the scope of clinical practice will benefit the patient population;
- (j) determine whether the organisation needs, and can support appropriately, the clinical services, procedures or other interventions which have been requested for inclusion in the scope of clinical practice;
- (k) determine whether the medical practitioner meets or exceeds the requirements for competence and performance in the clinical services, procedures or other interventions which have been requested for inclusion in the scope of clinical practice; and
- (l) if satisfied, based on all the available information, that the medical practitioner is competent to provide the designated clinical services, procedures or other interventions and has an acceptable record of performance, and the services are compatible with the organisation's need and capability, recommend the requested scope of clinical practice.

The committee responsible for credentialling and defining the scope of clinical practice should—

- (m) in instances where there is doubt about a medical practitioner's ability to perform the services, procedures or other interventions which have been requested for inclusion in the scope of clinical practice, consider:
 - ⇒ requesting a specific evaluation of the medical practitioner's performance by an external or internal professional peer;
 - ⇒ recommending a scope of clinical practice for a limited period of time followed by review;
 - ⇒ defining conditions or limitations on the scope of clinical practice requested; and/or
 - ⇒ requiring the relevant clinical services, procedures or other interventions to be performed under supervision or monitoring;
- (n) if the medical practitioner's credentials and assessed competence and performance do not meet the threshold criteria established for the requested scope of clinical practice, recommend refusal of the requested scope of clinical practice, and document the reasons for the recommendation.

The governing body, relevant senior manager or medical appointments committee that is advised by the committee responsible for credentialling and defining the scope of clinical practice—

- (o) should act on the recommendations of the committee, unless exceptional circumstances exist;
- (p) should not approve a scope of clinical practice wider than that recommended unless exceptional circumstances exist;

- (q) may refer the matter back to the committee if there are concerns with the scope of clinical practice recommended;
- (r) should not proceed with an initial appointment to the organisation if the medical practitioner is not recommended for the required scope of clinical practice; and
- (s) for existing appointees, should advise the medical practitioner in writing once a decision has been reached:
 - ⇒ of the decision and the reasons for that decision;
 - ⇒ of the review processes available to the medical practitioner at their request; and
 - ⇒ of the time limits within which a request for a review should be made, and to whom that request should be addressed.

9.5 Defining a Temporary Scope of Clinical Practice

Defining a temporary scope of clinical practice—

- (a) should enable medical practitioners whose credentials have not formally been evaluated and whose scope of clinical practice has not formally been defined to provide clinical services, procedures or other interventions on a temporary basis;
- (b) may be necessary to enable locums and other medical practitioners appointed on a short term basis to provide clinical services, procedures or other interventions;
- (c) should only be used where there is an urgent patient care need, or where appropriate as a temporary measure when a new applicant is awaiting initial appointment to the organisation;
- (d) should always be preceded by limited review and verification of credentials;
- (e) should involve a formal evaluation of the medical practitioner's credentials, competence and performance and the organisation's need and capability by a team comprising, at a minimum, a senior manager with explicitly delegated authority and a senior medical practitioner who practises in the same specialty area as the applicant and who is a core or co-opted member of the committee responsible for credentialling and defining the scope of clinical practice;
- (f) should only be undertaken by a senior manager with explicitly delegated authority; and
- (g) should be referred to the committee responsible for credentialling and defining the scope of clinical practice for formal consideration according to the organisation's standard policy at its next meeting.

Approval of a temporary scope of clinical practice should be—

- (h) time-limited and not continue beyond a designated period (for example, 120 days) or the next meeting of the committee responsible for credentialling and defining the

scope of clinical practice, whichever is sooner, unless an extension is endorsed by that committee; and

- (i) fully documented.

9.6 Defining the Scope of Clinical Practice in Emergency Situations

Emergency definition of the scope of clinical practice—

- (a) should enable medical practitioners whose credentials have not formally been evaluated and whose scope of clinical practice has not formally been defined to provide emergency services;
- (b) should be available only on an exceptional basis, where there is a critical patient care need that cannot be met from within existing resources;
- (c) may be necessary in times of disaster or major emergency;
- (d) should always be preceded by limited review and verification of the medical practitioner's available credentials;
- (e) should involve an evaluation of the medical practitioner's competence by a senior medical practitioner who practises in the same specialty area as the applicant;
- (f) should only be undertaken by a senior manager with explicitly delegated authority;
- (g) should be strictly time limited and not continue beyond a designated period (for example 7 days), during which period the processes of credentialing and defining the scope of clinical practice on a temporary or permanent basis should be invoked as soon as practicable; and
- (h) should be fully documented.

10. SUSPENSION OF THE RIGHT TO PRACTISE

10.1 Background

Organisations may suspend (temporarily or permanently, in part or in full) a medical practitioner's right to provide specific clinical services, procedures or other interventions, or the overall right to practise within the organisation, because the organisation's ability to provide clinical or non-clinical support services has changed; or because the organisation no longer needs the clinical services, procedures or other interventions which have previously been included within the medical practitioner's scope of clinical practice; or because of concerns about the competence and/or performance of the medical practitioner.

Suspension in part or in full of the right to practise within an organisation, particularly in response to concerns about the competence and/or performance of a medical practitioner, has

the potential to cause extreme detriment to the medical practitioner's clinical practice and/or reputation, and should only be contemplated in exceptional circumstances.

Where the organisation no longer needs or cannot support a specific clinical service, procedure or other intervention, or if there is broad concern about the safety, efficacy or role of a specific clinical service, procedure or other intervention, a medical practitioner's scope of practice may be altered by agreement. In other non-urgent situations, consideration should be given to referring a concern about a medical practitioner's scope of clinical practice for review by the committee responsible for credentialling and defining the scope of clinical practice, as an alternative to invoking a process of suspension of a medical practitioner's right to practise within the organisation.

10.2 Establishing a Process for Suspension of a Medical Practitioner's Right to Practise Within the Organisation

The organisation should develop and incorporate within its constitutional documents and/or governance policies a description of a process of part or full suspension of a medical practitioner's right to practise within the organisation which—

- (a) complies with relevant legislation;
- (b) may be temporary or permanent;
- (c) should generally only be invoked in situations where an urgent decision is required and:
 - ⇒ the organisation cannot or elects not to provide the facilities and clinical or non-clinical support services necessary for safe service provision and the medical practitioner's scope of clinical practice cannot be altered by agreement;
 - ⇒ the organisation no longer needs the clinical services, procedures or other interventions which have previously been included within a medical practitioner's authorised scope of clinical practice and the medical practitioner's scope of clinical practice cannot be altered by agreement;
 - ⇒ following review of an established specific clinical service, procedure or other intervention, its safety, efficacy or role is determined to be incompatible with the organisation's responsibility to provide safe, high quality health care services, and the medical practitioner's scope of clinical practice cannot be altered by agreement;
 - ⇒ a medical practitioner is not registered with the relevant registration board, for whatever reason;
 - ⇒ a medical practitioner's indemnity insurance is reduced below the level required by the organisation or is made subject to conditions that are unacceptable to the organisation;
 - ⇒ a medical practitioner is found to have made a false declaration, either through omission of important information or inclusion of false information;

- ⇒ a medical practitioner is subject to a criminal investigation about a serious matter (for example, a drug-related matter, or an allegation of a crime against a person) which, if established, could affect his or her ability to exercise his or her scope of clinical practice safely and competently and with the confidence of the organisation and the broader community;
- ⇒ a medical practitioner has been convicted of a serious crime, which could affect his or her ability to exercise his or her scope of clinical practice safely and competently and with the confidence of the organisation and the broader community; or
- ⇒ there is a belief, held in good faith, by the person(s) authorised to suspend a medical practitioner's right to practise within the organisation, that the competence and/or current fitness to practise of a medical practitioner is such that continuation of the authorised scope of clinical practice would raise a significant concern about the safety and quality of health care.

10.3 Authority to Suspend a Medical Practitioner's Right to Practise Within the Organisation

Authority to suspend a medical practitioner's right to practise within the organisation—

- (a) should in general be retained by the governing body; or
- (b) may be delegated by the governing body to a designated senior manager, for application only in situations that are judged by that senior manager to raise a significant concern about the safety and quality of health care and where it is not practical for the governing body to be convened immediately.

Any decision by a delegate of the governing body to suspend a medical practitioner's right to practise within an organisation should—

- (c) in all circumstances, be formally reviewed by the governing body as soon as practicable.

10.4 Suspension by an Authorised Person of a Medical Practitioner's Right to Practise Within the Organisation

If an authorised person is contemplating suspending a medical practitioner's right to practise within an organisation, he or she should (subject to any overriding statutory obligations)—

- (a) consider all relevant available documentation and information;
- (b) have access to legal and human resources management advice;
- (c) provide the medical practitioner with an opportunity to consider and respond (in writing, other than in extremely urgent situations) to any information, material and allegations and (other than in extremely urgent situations) to present in person any further relevant information;

- (d) allow the medical practitioner to be accompanied by a support person, who may be a barrister or solicitor or other person, whose role is to advise but not represent the medical practitioner when making his or her response; and
- (e) consider available advice of the committee responsible for credentialling and defining the scope of clinical practice and/or of independent medical practitioners with experience in the field in which the medical practitioner's scope of clinical practice is under review.

If the authorised person resolves to suspend a medical practitioner's right to practise within an organisation (temporarily or permanently, in part or in full) he or she should—

- (f) document fully the reasons for the decision;
- (g) immediately advise the medical practitioner in writing of the decision including specific reasons, and of his or her right to an immediate review of the decision by the governing body;
- (h) immediately advise all relevant areas of the organisation that will be impacted on by the decision (e.g. theatre, wards etc.);
- (i) arrange for the governing body to be convened as soon as practicable to review the decision;

If there is a belief, held in good faith, by the authorised person(s) that the competence and/or current fitness to practise of the medical practitioner is such that continuation of the right to practise in any other organisation would raise a significant concern about the safety and quality of health care, he or she should—

- (j) refer the matter to the relevant professional registration board; and
- (k) facilitate where appropriate the provision to the medical practitioner of any necessary professional and personal support.

10.5 The Role of the Governing Body

The governing body should—

- (a) review comprehensive information and documentation about the factors that led to a decision to suspend the medical practitioner's right to practise within the organisation, or a decision to refer the matter to the governing body;
- (b) seek advice from the organisation's committee responsible for credentialling and defining the scope of clinical practice, and/or from one or more independent medical practitioners who practise in the same field as the medical practitioner whose right to practise within the organisation has been suspended or is under review;
- (c) have access to legal and human resources management advice;
- (d) provide the medical practitioner with an opportunity to consider and respond in writing to any information, material and allegations and an opportunity to present in person any additional relevant information;

- (e) allow the medical practitioner to be accompanied by a support person, who may be a barrister or solicitor or other person, whose role is to advise but not represent the medical practitioner when making his or her response in person;
- (f) having considered all the available information and having heard the medical practitioner, make a final decision to either suspend or confirm the suspension of the right to practise within the organisation, reinstate the right to practise within the organisation with or without specific conditions, or confirm the continuation of the right to practise within the organisation, with or without specific conditions;
- (g) advise the medical practitioner in writing of the final decision;
- (h) if it holds in good faith a belief that the competence and/or current fitness to practise of the medical practitioner is such that continuation of the right to practise in any other organisation would raise a significant concern about the safety and quality of health care, ensure that the matter is referred to the relevant professional registration board; and
- (i) where necessary, ensure that the medical practitioner is provided with appropriate professional and personal support.

PART E

REVIEW AND APPEAL PROCESSES

11. THE INITIAL REVIEW PROCESS

11.1 Initial Review of the Recommendations of the Committee Responsible for Credentialling and Defining the Scope of Clinical Practice

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) receive requests for immediate review of its own recommendations in relation only to medical practitioners who have an existing appointment to the organisation, and in relation only to errors of fact;
- (b) receive requests at any time from medical practitioners for unplanned review of their credentials or scope of clinical practice;
- (c) receive requests at any time from authorised individuals or bodies for unplanned review of other medical practitioners' credentials or scope of clinical practice;
- (d) acknowledge receipt of such requests in writing;
- (e) provide an opportunity for the relevant medical practitioner and, if applicable, the authorised individuals and/or bodies, to present relevant documentation;
- (f) when asked to review the scope of clinical practice of a medical practitioner because of concerns about the safety, efficacy or role of an established clinical service, procedure or other intervention, consider seeking advice from the committee responsible for advising on the safety, efficacy and role of clinical services, procedures or other interventions;
- (g) provide an opportunity for the relevant medical practitioner and, if applicable, the authorised individuals and/or bodies, to present in person to the committee;
- (h) consider the documentation and information presented to it and seek any other relevant information from other sources;
- (i) conclude the review within a specified time frame; and
- (j) advise the governing body, relevant senior manager or medical appointments committee, as appropriate, of the outcome of the review.

The governing body, relevant senior manager or medical appointments committee should—

- (k) decide whether to accept the recommendation of the committee responsible for credentialling and defining the scope of clinical practice;
- (l) advise the medical practitioner (and the authorised individual or body who requested the review if relevant) of the outcome of the review;

- (m) if relevant, advise the medical practitioner of the availability of a further avenue of appeal through the credentialling and scope of clinical practice appeals committee;
- (n) if relevant, advise the medical practitioner of the time limits within which a request for appeal should be notified, and to whom that request should be addressed
- (o) if it holds in good faith a belief that the competence and/or current fitness to practise of the medical practitioner is such that continuation of the right to practise in any other organisation would raise a significant concern about the safety and quality of health care, ensure that the matter is referred to the relevant professional registration board; and
- (p) where necessary, ensure that the medical practitioner is provided with appropriate professional and personal support.

12. THE APPEAL PROCESS

12.1 Composition of the Credentialling and Scope of Clinical Practice Appeals Committee

The credentialling and scope of clinical practice appeals committee should, in all circumstances, be constituted according to the requirements of relevant legislation. Generally, the committee should—

- (a) be convened by the governing body within the relevant time frame established in the organisation’s policy on credentialling and defining the scope of clinical practice;
- (b) be chaired by a person who is trained in the principles of natural justice;
- (c) be satisfied that it has the expertise necessary to assess the decision being appealed;
- (d) have entirely independent membership from that of the committee responsible for credentialling and defining the scope of clinical practice;
- (e) consist of a majority of medical practitioners from a range of clinical disciplines who have demonstrated an understanding of processes of credentialling and defining the scope of clinical practice, and have the necessary skills and experience to provide informed, independent, high quality advice;
- (f) include within its membership:
 - ⇒ at least one (1) medical practitioner who practises in the field relevant to the scope of clinical practice being reviewed;
 - ⇒ a nominee of the relevant professional college, association or society;
 - ⇒ a nominee, who is a medical practitioner, of the person whose credentials or scope of clinical practice are the subject of the appeal;

- ⇒ a university nominee, when the scope of clinical practice for a position which has an affiliation with the university is being considered; and
 - ⇒ other members who bring to the committee specific expertise, as determined by the governing body.
- (g) have available, for the purposes of providing information and clarifying the reasons for prior decision-making, the chairperson or another nominee of the committee responsible for credentialling and defining the scope of clinical practice; and
- (h) have available on an advisory basis any other specialist expertise required, including legal and human resources management expertise.

12.2 Review by the Credentialling and Scope of Clinical Practice Appeals Committee

The credentialling and scope of clinical practice appeals committee should—

- (a) provide an independent forum for considering an appeal by a medical practitioner with an existing appointment to the organisation of a decision relating to his or her credentials or scope of clinical practice;
- (b) accept the request to review a decision regarding a relevant medical practitioner's credentials or scope of clinical practice from the governing body, and report to the governing body;
- (c) conduct its proceedings in private;
- (d) review and reconsider all relevant material previously available to the committee responsible for credentialling and defining the scope of clinical practice;
- (e) invite the medical practitioner whose credentials and/or scope of clinical practice are the subject of the appeal to submit any further documents or information relevant to the appeal, and to present to the committee in person;
- (f) allow the medical practitioner whose credentials and/or scope of clinical practice are the subject of the appeal to be accompanied by a support person, who may be a barrister or solicitor or other person, whose role is to advise but not represent the medical practitioner;
- (g) consider all information available to it, and formulate recommendations on the basis of that information;
- (h) document its recommendations and reasons for reaching them and advise the governing body, in writing, of these, within 90 days of being notified of the appeal; and
- (i) otherwise, be bound by strict confidentiality.

12.3 Final Determination by the Governing Body

The governing body should—

- (a) accept an appeal from a medical practitioner with an existing appointment to the organisation of a decision relating to his or her credentials or scope of clinical practice, and refer that appeal to the credentialling and scope of clinical practice appeals committee to consider and make recommendations;
- (b) receive the recommendations of the credentialling and scope of clinical practice appeals committee;
- (c) consider those recommendations and reach a conclusion about the matter under appeal;
- (d) advise in writing the medical practitioner whose credentials and/or scope of clinical practice are the subject of the appeal of the final decision regarding the appeal;
- (j) if it holds in good faith a belief that the competence and/or current fitness to practise of the medical practitioner is such that continuation of the right to practise in any other organisation would raise a significant concern about the safety and quality of health care, ensure that the matter is referred to the relevant professional registration board; and
- (k) where necessary, ensure that the medical practitioner is provided with appropriate professional and personal support.

PART F

**NEW CLINICAL SERVICES, PROCEDURES OR OTHER
INTERVENTIONS**

13. ORGANISATIONAL ISSUES

13.1 Background

For the purposes of this Standard, new clinical services, procedures or other interventions are clinical services, procedures or other interventions that are being introduced into an organisational setting for the first time. They may be clinical services, procedures or other interventions that—

- (a) have been established in other organisational settings and are deemed by a responsible body of medical opinion as clinical services, procedures or other interventions that will benefit patients; or
- (b) remain experimental, and therefore subject to review by a properly constituted Human Research Ethics Committee or Clinical Ethics Committee (as appropriate).

They may, but will not necessarily, be innovative, complex or costly. They will, however, require more than incremental change in the way in which health care services are delivered within a specific organisational setting.

The safety of new clinical services, procedures or other interventions, and their potential to improve patient outcomes, are overriding considerations in determining whether to approve their introduction. In addition, organisations will wish to consider cost, risks and cost-benefit.

Some organisations convene standing or *ad hoc* committees to oversee the evaluation of proposed new clinical services, procedures or other interventions. In other organisations, this task may be performed by the committee responsible for credentialling and defining the scope of clinical practice. Either of these structures is acceptable, provided the process is undertaken by professionals with the skills and experience to analyse rigorously and objectively the scientific and other relevant evidence and to reach a considered conclusion.

In general, requests for credentialling and defining the scope of clinical practice in relation to new clinical services, procedures or other interventions should not be considered by the committee responsible for credentialling and defining the scope of clinical practice until they have been assessed in relation to their safety, efficacy and role, and potential financial and operational implications.

13.2 Establishing a Policy on the Introduction of New Clinical Services, Procedures or Other Interventions

The organisation should establish and document a policy defining its requirements for the introduction of new clinical services, procedures or other interventions. The policy should—

- (a) incorporate a definition of ‘new clinical services, procedures or other interventions’;
- (b) define who may request assessments of new clinical services, procedures or other interventions, and the process by which they may submit requests for those assessments;

- (c) define the organisation's requirements for assessment of the cost, risks, efficacy and cost-benefit of the proposed new clinical service, procedure or other intervention, including whether external benchmarking data should be considered;
- (d) define the organisation's requirements for consideration of the broader health care context within which the new clinical service, procedure or other intervention is proposed to be introduced;
- (e) define the individuals or committees that are authorised to initiate an assessment of a proposed new clinical service, procedure or other intervention;
- (f) define the individuals or committees that are responsible for overseeing the assessment of a proposed new clinical service, procedure or other intervention;
- (g) define the organisation's requirement that new clinical services, procedures or other interventions, which have not been deemed by a responsible body of medical opinion as clinical services, procedures or other interventions that will benefit patients, and therefore remain experimental, are referred for consideration by a Human Research Ethics Committee or a Clinical Ethics Committee (as appropriate); and
- (h) define the individuals and/or committees to whom authority is delegated by the governing body to make decisions regarding the introduction of new clinical services, procedures or other interventions.

13.3 Determining the Safety, Efficacy and Role of New Clinical Services, Procedures or Other Interventions

The organisation should—

- (a) identify or establish an organisational committee responsible for advising on the safety, efficacy and role of clinical services, procedures or other interventions.

The committee responsible for advising on the safety, efficacy and role of clinical services, procedures or other interventions should—

- (b) be comprised of a majority of medical practitioners with expertise in the relevant clinical area;
- (c) have direct access to expertise in the critical appraisal of research and clinical information;
- (d) consider the efficacy of any proposed new clinical service, procedure or other intervention as reported by various credible sources including peer-reviewed medical literature, evidence-based assessments e.g. the Cochrane Collaboration, compared with the efficacy of currently available clinical services, procedures or other interventions;
- (e) review the status of evaluation of any proposed new clinical service, procedure or other intervention by the Medicare Services Advisory Committee, the Pharmaceutical Benefits Advisory Committee, the Therapeutic Goods Administration or other relevant reputable bodies;

- (f) determine whether the relevant professional college, association or society has established any guidelines or criteria relevant to the safety, efficacy or role of any proposed new clinical service, procedure or other intervention, and consider these if available;
- (g) consider the clinical risks associated with any proposed new clinical service, procedure or other intervention, compared with the clinical risks of currently available clinical services, procedures or other interventions;
- (h) for any proposed new clinical service, procedure or other intervention which it believes is experimental, consider the recommendations of the organisation's Human Research Ethics Committee or Clinical Ethics Committee (as appropriate);
- (i) consider whether any proposed new clinical service, procedure or other intervention would replace existing clinical services, procedures or other interventions;
- (j) advise on the facilities and clinical and non-clinical support services that are necessary to ensure that any proposed new clinical service, procedure or other intervention can be provided safely and at high quality;
- (k) formulate advice on whether a proposed new clinical service, procedure or other intervention is suitable for introduction in the organisational setting based on its safety, efficacy and role, and if so, under what circumstances and with what facilities and clinical and non-clinical support services; and
- (l) communicate its advice to the individuals and/or committees within the organisation to whom authority is delegated by the governing body to make decisions regarding the introduction of new clinical services, procedures or other interventions.

13.4 Determining the Financial and Operational Implications of New Clinical Services, Procedures or Other Interventions

The organisation should—

- (a) delegate responsibility to an individual, or identify or establish an organisational committee to advise on the financial and operational implications of any proposed new clinical service, procedure or other intervention.

The individual or committee responsible for advising on the financial and operational implications of any proposed new clinical service, procedure or other intervention should—

- (b) possess, or have access to, expertise in finance, business and hospital operations;
- (c) be informed by the advice of the committee responsible for advising on the safety, efficacy and role of new clinical services, procedures or other interventions;
- (d) consider the financial and operational implications of proposed new clinical services, procedures or other interventions;
- (e) formulate advice on the financial and operational implications of proposed new clinical services, procedures or other interventions; and

- (f) communicate its advice to the individuals and/or committees within the organisation to whom authority is delegated by the governing body to make decisions regarding the introduction of new clinical services, procedures or other interventions.

13.5 Approving in Principle the Introduction of New Clinical Services, Procedures or Other Interventions

The individual or committee responsible for decisions regarding the introduction of new clinical services, procedures or other interventions should—

- (a) consider the advice relating to the safety, efficacy and role, and financial and operational implications of a proposed new clinical service, procedure or other intervention;
- (b) seek advice from the organisation’s insurers about the insurance implications of providing the new clinical service, procedure or other intervention;
- (c) determine in principle whether the new clinical service, procedure or other intervention should be introduced;
- (d) determine the indicators against which the proposed new clinical service, procedure or other intervention should be monitored;
- (e) determine a time period after which the cost, risks, efficacy and cost-benefit of the proposed new clinical service, procedure or other intervention should be formally evaluated; and
- (f) determine who should be responsible for monitoring and evaluating the cost, risks, efficacy and cost-benefit of the proposed new clinical service, procedure or other intervention.

14. CREDENTIALLING AND DEFINING THE SCOPE OF CLINICAL PRACTICE IN RELATION TO NEW CLINICAL SERVICES, PROCEDURES OR OTHER INTERVENTIONS

14.1 Credentialling in Relation to New Clinical Services, Procedures or Other Interventions

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) ensure that the introduction to the organisation of a proposed new clinical service, procedure or other intervention has been approved in principle according to the agreed organisational process;
- (b) review the relevant work of the committee responsible for advising on the safety, efficacy and role of clinical services, procedures or other interventions, and

determine the threshold credentials required of medical practitioners who apply for the proposed new clinical service, procedure or other intervention to be included within their scope of clinical practice;

- (c) ensure that the credentials of medical practitioners who have applied for inclusion of the proposed clinical service, procedure or other intervention within their scope of clinical practice are formally validated and evaluated according to the committee's normal procedures; and
- (d) ensure that medical practitioners who have applied for inclusion of the proposed clinical service, procedure or other intervention within their scope of clinical practice possess adequate indemnity insurance coverage.

14.2 Defining the Scope of Clinical Practice in Relation to New Clinical Services, Procedures or Other Interventions

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) ensure that the organisation has available to it the facilities and clinical and non-clinical support services necessary to support the safe provision of the proposed new clinical service, procedure or other intervention; and
- (e) make a recommendation of inclusion or otherwise of the proposed new clinical service, procedure or other intervention within the medical practitioner's scope of clinical practice according to its routine procedures for defining the scope of clinical practice.

PART G

ENSURING EFFECTIVENESS

15. PERFORMANCE MONITORING AND REPORTING

15.1 Developing Key Performance Indicators

The committee responsible for credentialling and defining the scope of clinical practice should—

- (a) develop quantitative and qualitative key performance indicators that will assist it to monitor and evaluate its performance; and
- (b) ensure that its selected key performance indicators facilitate a comprehensive assessment of the committee's activity and compliance with this Standard and the organisation's policies on credentialling and defining the scope of clinical practice of medical practitioners.

15.2 Reviewing and Reporting on Performance

The committee responsible for credentialling and defining the scope of clinical practice should regularly—

- (a) review its composition, terms of reference and processes against this Standard and its selected key performance indicators;
- (b) assess its contribution to the development of constructive relationships between medical practitioners and the organisation, in the context of a mutual objective of maintaining and improving the safety and quality of health care; and
- (c) report to the governing body on its performance, its assessment of the organisation's compliance with this Standard, and any recommendations for improvement.

The governing body may—

- (d) implement mechanisms to enhance the transparency of its processes and outcomes of credentialling and defining the scope of clinical practice of medical practitioners, for example through public reporting via its annual report or quality of care report.