Queensland Government
Queensland Health

REGULATORY IMPACT STATEMENT

Private Health Facilities Regulation 2000 and Standards under the Private Health Facilities Act 1999

August 2000

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INTRODUCTION

This Regulatory Impact Statement has been prepared under the provisions of the *Statutory Instruments Act 1992*. The matters presented in this document are intended for discussion and do not represent Government policy.

You are invited to consider the issues raised and make a response to those issues.

For reference purposes, the *Private Health Facilities Act 1999* may be purchased from Goprint and is also available electronically on the Internet. The relevant Internet address is www.legislation.qld.gov.au/Bills/Bll49_99.htm.

The Regulatory Impact Statement can also be electronically accessed on the Internet at www.health.qld.gov.au/lpu/private.htm

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Responses and comments on the proposals presented in the Regulatory Impact Statement must be made in writing and should be sent to:

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The closing date for comments is 11 September 2000.

REGULATORY IMPACT STATEMENT

Private Health Facilities Act 1999

PRIVATE HEALTH FACILITIES REGULATION 2000

TITLE

Private Health Facilities Regulation 2000

BACKGROUND

Private hospitals and day hospitals ("private health facilities") are currently regulated in Queensland under Division 4 of Part 3 of the *Health Act 1937*. This legislation is to be repealed and replaced by the *Private Health Facilities Act 1999*, which was passed by the Legislative Assembly on 23 November 1999.

The *Private Health Facilities Act 1999* ("the Act") was developed following a comprehensive review process which involved extensive consultation with key stakeholders.

The commencement of the Act is planned to coincide with the introduction of the *Private Health Facilities Regulation 2000* ("the Regulation") and the making of standards relating to private health facilities.

This Regulatory Impact Statement outlines the Government's proposals regarding the development of the Regulation and standards relating to private health facilities. The Queensland Government invites you to participate in the development of the Regulation and the Standards, by commenting on any of the matters contained in the Regulatory Impact Statement.

AUTHORISING LAW

Section 151 of the Act provides the general head of power for the making of a regulation. Specific provisions regarding the matters to be covered by the Regulation are contained in sections 10, 12, 23, 48, 144, 147, 154, 155, 156 and Schedule 3 of the Act.

Section 12 of the Act empowers the Chief Health Officer to make standards for the protection of the health and wellbeing of patients receiving health services at private health facilities. Standards may be made about the following matters:

- the particular types of health services to which patients at a private health facility must have access (whether or not the services are provided at the facility) when other health services are provided at the facility;
- processes for:
  - evaluating the credentials of medical practitioners providing, or seeking to provide, health services at private health facilities; and
  - deciding which health services may be provided by the medical practitioners at the facilities;
- processes for deciding ethical issues;

- processes for monitoring, evaluating and improving the quality of health services at private health facilities;
- the day to day care and safety of patients, including admission and discharge procedures and patient records;
- management and staffing arrangements;
- minimum patient throughput for health services provided at private health facilities and prescribed under a regulation;
- equipment, fittings and furnishings at private health facilities;
- infection control; and
- any other matter prescribed by regulation.

Under the Act, it is a condition of licensing that the licensee must comply with the Standards relevant to the private health facility to which the licence relates.

It should be noted that the Standards will not be subordinate legislation. However, section 12 of the Act stipulates that the Minister for Health must publish a gazette notice about the making of a standard, and any such gazette notice shall be subordinate legislation. It is therefore appropriate that the proposed Standards be considered as part of this Regulatory Impact Statement.

POLICY OBJECTIVES

All health care interventions involve the risk that the patient may suffer harm through the occurrence of an adverse patient outcome. In the hospital environment, the risk of harm is particularly prevalent in the case of surgical or other invasive procedures or procedures involving the use of sedation or anaesthetic.

The public expect that appropriate standards of care will be provided in private health facilities and that all reasonable steps are taken to minimise the risk of harm to patients.

The policy objective of the Act is to protect the health and well-being of patients receiving services at private health facilities by minimising the risk of harm through ensuring that appropriate standards of care are provided at those facilities.

The principal objective of the Regulation is to give effect to particular provisions of the Act which seek to ensure that health services provided in private health facilities meet appropriate standards. Similarly, the Standards have been developed so that compliance with the standards, as required by the Act, will minimise the risk of harm to patients. Therefore, the objective of the Regulation and the Standards is consistent with the objective of the Act.

HOW THE POLICY OBJECTIVES WILL BE ACHIEVED

Private Health Facilities Regulation 2000

Day Hospital Health Services

The Act will apply to day facilities at which "day hospital health services", as defined in section 10 of the Act, are provided. The purpose of the definition of "day hospital health services" is to ensure that day facilities which provide higher risk health services are licensed so as to minimise the risk of harm to patients receiving services at those facilities.

The health services covered by this definition fall into two categories, namely:

- procedures performed by medical practitioners involving specified types of anaesthetic or sedation; and
- prescribed procedures performed by, or at the direction of, a medical practitioner which involve a significant risk that the patient may, because of cardiac, respiratory or other complications, require resuscitation.

The Regulation will prescribe the procedures for the purposes of the second of the above categories. These specific procedures have been identified as involving a level of risk of harm to the patient which justifies the licensing of the facility at which they are performed.

Minimum Patient Throughput Standard

A standard may be made by the Chief Health Officer under section 12 of the Act about the minimum number of patients required to receive a particular health service at a private health facility during a stated period to maintain the clinical skills of the staff providing the service (eg. the minimum annual caseload for a cardiac surgery unit).

The Regulation will specify those health services about which minimum throughput standards may be made.

Quality Assurance Requirements

Section 48 of the Act imposes, by way of conditions of licensing, a number of obligations upon licensees of private health facilities including that the licensee must:

- within 90 days after the issue of the licence, start a prescribed quality assurance program, conducted by a prescribed quality assurance entity, for the facility;
- within 3 years after the issue of the licence, receive certification from the quality assurance entity that the facility operates under a quality assurance system; and
- ensure that the facility continues to be so certified while licensed.

The Regulation will give effect to these obligations by prescribing the quality assurance programs, and the respective quality assurance entities, for the purpose of compliance by licensees with these obligations.

Miscellaneous Matters

The Regulation will also specify:

- the types of matters about which approval holders or licensees must notify the Chief Health Officer if any change occurs since they were disclosed in an application under the Act;
- the times at which licensees must give reports to the Chief Health Officer to monitor the quality of the health services at private health facilities and for other purposes;
- the agreements under which the Chief Executive of Queensland Health may give to the Commonwealth or another State, information obtained in connection with the administration of the Act; and

- the fees to be charged under the Act.

Specific details about the provisions to be contained in the Regulation are set out in Attachment 1.

Standards

As previously stated, section 12 of the Act empowers the Chief Health Officer to make standards for the protection of the health and wellbeing of patients receiving health services at private health facilities about the specific matters set out in that provision.

The Standards will set out the measures designed to minimise the risks of harm associated with the provision of health services at private health facilities. Many of the Standards will adopt or be based on recognised standards, guidelines or protocols published by bodies such as the Medical Colleges, the Standards Association of Australia and the National Health and Medical Research Council.

Specific details about the provisions to be contained in the Standards are set out in Attachment 2.

OPTIONS AND ALTERNATIVES

The policy objectives of the Act cannot be fulfilled without the making of supporting subordinate legislation and standards. For this reason, it is not appropriate to consider any alternative to making the Regulation or the Standards. The Regulation and the Standards will assist in achieving the objectives of the Act by, for instance:

- specifying, under the Standards, the measures necessary to minimise the risks of harm associated with the provision of health services at private health facilities. The Act requires, as a condition of licensing, that a licensee of a private health facility must comply with the Standards relevant to the facility.

- ensuring that licensing requirements are met in day facilities at which procedures are performed involving a significant risk that the patient may require resuscitation, by prescribing the specific procedures identified as falling within this category. These procedures, as well as procedures involving specified types of anaesthetic or sedation, will only be able to be performed in a day facility if the facility is licensed under the Act.

- ensuring that all licensed private health participate in quality assurance activities, by prescribing the quality assurance programs, and the respective quality assurance entities, for the purpose of compliance by licensees with the quality assurance obligations under the Act.

- enabling the Chief Health Officer to be made aware of circumstances which might adversely affect a person's suitability to hold, or continue to hold, an approval or a licence under the Act, by prescribing the changes of circumstances in respect of which notification must be given to the Chief Health Officer.

COST-BENEFIT ANALYSIS

An analysis of the costs and benefits of implementing the Regulation and the Standards has been undertaken for community, industry and government stakeholders likely to be affected. The analysis is set out below.

Community

Benefits

The Regulation and the Standards will potentially improve the quality of services provided to patients at private health facilities. For example, the Regulation will give effect to the provisions of the Act which impose quality assurance requirements and extend coverage of licensing requirements to all day facilities performing "higher risk" procedures. An improvement in the quality of health services is likely to reduce the rate of adverse patient outcomes and increase public confidence in the private health care system.

A reduction in the rate of adverse patient outcomes will benefit the community by reducing the social costs (eg. permanent disability/death of a patient and the impact of this on the patient's family/carers) and economic costs (eg. hospital/medical costs incurred through an extended hospital stay or re-admission; loss of income/earning capacity) which can flow from adverse patient outcomes.

Costs

Compliance with the requirements of the Regulation and the Standards may result in additional costs (discussed below) for operators of private health facilities. However, it is not considered that these costs will have any significant negative flow-on effects for consumers in relation to the cost or availability of health services.

Industry

Benefits

Operators

Adverse patient outcomes in private health facilities may lead to damages claims being brought against the operator of the facility (eg. where an adverse outcome resulted from an unsafe physical/clinical environment in the facility). Therefore, a reduction in the rate of adverse patient outcomes in private health facilities could potentially reduce the likelihood of the operators of the facilities being exposed to damages claims and incurring consequential costs (eg. uninsured losses, increased insurance premiums).

The Regulation and the Standards will, in conjunction with the Act, provide greater transparency than the existing legislation in relation to licensing criteria and the obligations of licensees. This will benefit existing and potential licensees and facilitate compliance with the legislation.

Consumer confidence in private health facilities could potentially increase if consumers perceive that the new legislation will improve the quality and safety of services provided in

private health facilities. This may lead to increased utilisation of private health facilities and a consequential increase in profits for operators.

Health Professionals/Professional Indemnity Insurers

Adverse patient outcomes at private health facilities can result in legal action and/or disciplinary action against individual health professionals practising in the facility. Such actions can arise directly or indirectly from licensing-related matters. For example, an adverse outcome resulting from an unsafe physical or clinical environment may result in a claim against the health practitioner as well as the operator of the facility. The Regulation and the Standards, in conjunction with the Act, could potentially reduce the rate of adverse patient outcomes and thereby reduce legal costs for health professionals and professional indemnity insurers and professional indemnity premiums/insurance payouts for those respective groups.

Private Health Insurance Funds/Health Insurance Commission

Adverse patient outcomes in private health facilities can result in an increase in payouts by private health insurers (eg. if an increased length of stay in hospital is required) and Medicare payments by the Health Insurance Commission (eg. for treatment provided to patients as a result of the adverse outcome). As noted above, the Regulation and the Standards will potentially reduce the rate of adverse patient outcomes and thereby reduce these costs.

Quality Assurance Bodies

Increased industry participation in quality assurance programs through compliance with requirements of the new legislation would result in additional income for quality assurance bodies as well as consultants providing services to health facilities participating in quality assurance programs. However, the potential benefits for these groups are not expected to be significant on the basis that there is already a high level of participation in quality assurance programs by the private health care industry, either on a voluntary basis, or to meet health insurance requirements.

Costs

Existing Licensees

Existing licensees of private health facilities will incur additional costs by way of payment of fees under the Act and in complying with the Standards and the reporting requirements under the Act. However, these costs are not expected to be significant as the principal fees will be based on the fees under the existing legislation with increases in line with the Consumer Price Index. In addition, many of the obligations imposed under the Standards and the reporting requirements are already being met by licensees under the existing legislation or as a consequence of membership of professional bodies eg. Medical Colleges.

The costs of complying with the quality assurance requirements in the new legislation will only affect about 10% of current licensees as around 90% of licensed private health facilities are already accredited/certified by a quality assurance entity, or have entered into a quality assurance program but have yet to achieve accreditation/certification.

Operators of Day Hospitals

The new definition of "day hospital" contained in the Act means that licensing requirements will apply to a number of day facilities which are not required to be licensed under the existing legislation. Operators of these facilities will have 6 months from the commencement of the legislation to apply for an approval and a licence for the facility and meet the requirements of the legislation. The main licensing compliance costs to be met by these operators will be the payment of fees and the costs of complying with the Standards and the quality assurance requirements.

Compliance costs associated with the quality assurance requirements will include on-going fees payable to the relevant quality assurance body. For example, the annual membership fee for day facilities participating in the accreditation program conducted by the Australian Council on Healthcare Standards is currently $2900. Operators entering into a quality assurance program may also engage consultants to provide training as to how the program works and what is required to achieve accreditation/certification.

Government

Benefits

In conjunction with the Act, the Regulation and the Standards will enhance the government's ability to ensure that appropriate standards are maintained in private health facilities and thereby more effectively meet public expectations about the government's role in protecting consumers from the inherent risk of harm associated with health care interventions.

Costs

The cost of administering the new legislation is likely to be slightly higher than the cost associated with the current licensing regime. This is because it is expected that a small number of day facilities that are not required to be licensed under the current legislation will be subject to licensing as they will fall within the new definition of a "day hospital" in the Act.

FUNDAMENTAL LEGISLATIVE PRINCIPLES

The proposed Regulation and the Standards have sufficient regard to the rights and liberties of individuals and the institution of Parliament.

ATTACHMENT 1

PRIVATE HEALTH FACILITIES REGULATION 2000

LEGISLATIVE PROPOSAL

DAY HOSPITAL HEALTH SERVICES

The new legislation will apply to private hospitals and day hospitals as defined under the Act. Section 10 of the Act defines a "day hospital" as a facility at which day hospital health services are provided to persons who are admitted to, and discharged from, the facility on the same day, but does not include a facility operated by the State.

Section 10 of the Act also defines a "day hospital health service" as a diagnostic, surgical or other procedure:

(a) performed by a medical practitioner and:
- involving the administration of a general, spinal or epidural anaesthetic; or
- sedation, other than simple sedation;

(b) performed by, or under the direction of, a medical practitioner and:
- involving a significant risk that a person on whom the procedure is performed may, because of cardiac, respiratory or other complications arising from the performance of the procedure, require resuscitation; and
- prescribed under a regulation.

Specific procedures need to be prescribed under (b) above as they have been identified as involving a level of risk of harm to the patient which justifies the licensing of the facility at which they are performed.

It is therefore proposed that, for the purposes of the above definition, the Regulation will prescribe the following procedures:

- Cardiac Stress Testing;
- Haemodialysis;
- Cytotoxic Infusion; and
- Endoscopy excluding Proctoscopy, Sigmoidoscopy and flexible Cystoscopy.

MINIMUM PATIENT THROUGHPUT STANDARD

A standard may be made by the Chief Health Officer under section 12 of the Act about the minimum number of patients required to receive a particular health service at a private health facility during a stated period to maintain the clinical skills of the staff providing the service (eg. the minimum annual caseload for a cardiac surgery unit).

It is proposed that the Regulation will specify that the health services about which minimum throughput standards may be made are as follows:

- Cardiac Surgery;
- Cardiac Catheterisation;
- Intensive Care; and
- Obstetrics.

QUALITY ASSURANCE REQUIREMENTS

Section 48 of the Act imposes, by way of conditions of licensing, a number of obligations upon licensees of private health facilities including that the licensee must:

- within 90 days after the issue of the licence, start a prescribed quality assurance program, conducted by a prescribed quality assurance entity, for the facility;
- within 3 years after the issue of the licence, receive certification from the quality assurance entity that the facility operates under a quality assurance system; and
- ensure that the facility continues to be so certified while licensed.

It is proposed that, for the purpose of compliance by licensees with the above requirements, the Regulation will specify that the relevant quality assurance entities and quality assurance programs are as follows:

- Australian Council on Healthcare Standards - Evaluation and Quality Improvement Program;
- International Standards Organisation - ISO 9000 Series; and
- Institute for Healthy Communities Australia Inc. - Quality Improvement Council Limited's Australian Health and Community Services Standards.

Certification from any one of the above entities will constitute compliance with the relevant requirements under the Act.

The Regulation will also specify that facilities at which procedures involving assisted reproductive technology are performed must also be accredited by the Fertility Society of Australia under that body's Assisted Reproductive Technology Accreditation Committee's Code of Practice for Centres using Assisted Reproductive Technology.

FEES

Under the Act, fees may be charged for various matters relating to approvals and licences, for the replacement of approvals and licences (eg. that have been lost), and for applications to make a "prescribed alteration" under section 63 of the Act. A new fee structure is proposed which is largely based on the fees payable under the existing legislation with increases in line with the Consumer Price Index.

It is proposed that the Regulation set out that the following fees are to be charged under the Act:

Approvals

Application

The application fee for an approval will be $255.

Extension of Term of Approval

The fee for an application to extend the term of an approval will be $100.

Changes to an Approval

The fee for an application to change the particulars about the proposed facility stated in an approval will be $100.

Replacement of Approval

The fee for the replacement of an approval that has been lost, stolen, destroyed or damaged will be $10.

Licences

Initial Application

The fee for an initial application for a licence will have two components, an application fee and a licence fee.

The application fee will be $255.

The amount of the licence fee will depend on the term[1] of the licence and will be:

- for 1 year or less $65
- for more than 1 year but not more than 2 years $130
- for more than 2 years but not more than 3 years $195

Renewal of Licence

The fee for an application to renew a licence will be the relevant licence fee as above (whereas an applicant for a new licence must pay a licence fee and an application fee).

Changes to a Licence

The fee for an application to change the particulars about the facility stated in a licence will be $100.

Replacement of Licence

The fee for the replacement of a licence that has been lost, stolen, destroyed or damaged will be $10.

Transfer of Licence

The fee for an application to transfer a licence will be $255.

[1] Under section 50(2) of the *Private Health Facilities Act 1999*, the term of a licence must not exceed 3 years if the facility has been certified as operating under a quality assurance system, or otherwise, 1 year.

Approval of prescribed alterations

The fee for an application for approval of a prescribed alteration (ie. a change in the purpose for which part of the facility is used or a change to the physical structure of the facility) will be $100.

Refund of fees

It is proposed that the Regulation specify that the licence fee payable on an application for the grant or renewal of a licence is to be refunded if the Chief Health Officer refuses the application or the applicant withdraws the application before it is decided.

The application fee payable on an application for the grant of a licence will be retained to cover the administration costs associated with the processing of the application.

MISCELLANEOUS

Notification of Changes in Circumstances

Under sections 23 and 48 of the Act, the holder of an authority (an approval or licence for a private health facility) must notify the Chief Health Officer if there is a change, of a kind prescribed under a regulation, in a matter disclosed by the authority holder in an application under the Act. Notification must be provided within 21 days after the change occurs. A similar obligation is imposed under the transitional provisions in sections 154-156 of the Act.

This requirement is to ensure the Chief Health Officer is made aware of any changes in circumstances which may affect the person's suitability to hold an authority under the Act.

It is proposed that the Regulation will specify that the notification requirement will apply to changes in any of the following matters:

- name of authority holder or associate[2];
- address/registered office of the authority holder;
- name of the quality assurance entity and quality assurance program for the facility (in relation to the quality assurance requirements under section 48 of the Act);
- the proposed date on which the facility is to be reviewed by the quality assurance entity prior to initial certification or re-certification by that entity;
- any recommendations made by the quality assurance entity as a consequence of a review;
- name of the executive officers of a corporate authority holder/associate;
- name of the person who has the day to day management of the facility;
- name and registration number of the registered nurse who is in charge of the nursing staff at the facility;

[2] "associate", of an applicant for an authority or an authority holder, is defined under the Act to mean:
- a corporation of which the applicant or authority holder is a subsidiary; or
- a party to an arrangement with the applicant or authority holder for the operation of the private health facility to which the application or authority relates; or
- a partner of the applicant or authority holder for the operation of the facility to which the application or authority relates.

- names of shareholders of corporate authority holders (excluding publicly listed companies);
- whether the authority holder has an associate;
- whether the authority/associate (or executive officer thereof) has been convicted of an indictable offence or an offence against a corresponding law (eg. licensing legislation of another State or Territory);
- whether an authority held by an authority holder/associate under a corresponding law has been suspended or cancelled;
- whether an authority holder/associate is affected by any of the matters specified in section 80(3) or (4) of the Act (eg. bankruptcy, winding up); and
- the death of an individual who held an authority jointly with 1 or more other individuals.

Provision of Information

Reporting

Section 144 of the Act requires licensees of private health facilities to give reports to the Chief Health Officer at the times prescribed under a regulation. The purposes of the reports are to:

- monitor the quality of health services provided at private health facilities;
- enable the State to give information to the Commonwealth or another State under agreements prescribed under section 147 of the Act (see below); and
- monitor the general state of health of the public having regard to the types and numbers of health services provided at the facilities.

Two types of reports will be required to be provided. The first type involves the provision of patient identification and diagnosis data required for purpose of the *Queensland Hospital Admitted Patient Data Collection* administered by Queensland Health. This type of data is currently collected from all public hospitals and licensed private health facilities in Queensland and is used for a number of purposes including:

- meeting Queensland's obligations under the Australian Health Care Agreement (eg. to substantiate the number of occupied bed-days in private and public hospitals); and
- assisting research into diseases and health related problems by providing clinical and socio-demographic data profiles of patients over a period.

The other type of report required will involve the provision of clinical indicator data. Clinical indicators are selected process or outcome variables which can be statistically compared for a particular health facility against other health facilities with a view to identifying any aspects of the health service provision in that facility that may require examination or closer monitoring. For example, data in this category that will be required to be provided will indicate the incidence rate of adverse clinical events (eg. unplanned re-admissions or transfers to intensive care) in each facility.

It is proposed that the Regulation will specify that the reports containing patient identification and diagnosis data must be given within 35 days after the end of each calendar month and the reports containing clinical indicator data be given every six months.

Agreements

Section 147 of the Act prohibits the disclosure of information that has been obtained in the course of a person's involvement with the administration of the Act. Information that is protected under this provision includes information about a person's health that identifies, or is likely to identify, the person.

The Act specifies a number of exceptions to the prohibition against disclosure. One of these exceptions applies if the information is given in circumstances where:

- the Chief Executive gives the information to the Commonwealth or another State, or an entity of the Commonwealth or another State, under an agreement prescribed under a regulation; and
- the Chief Executive is satisfied the giving of the information is in the public interest.

There are currently two agreements under which Queensland is required to provide information to the Commonwealth, or a Commonwealth entity, about health services provided in private health facilities. These are the Australian Health Care Agreement (between Queensland and the Commonwealth) and the National Health Information Agreement (between Queensland and the Australian Institute of Health and Welfare).

Although the information required to be given under these agreements is primarily statistical in nature, there is potential for patients to be identified from the information. Therefore, it is proposed that both agreements be prescribed in the Regulation to ensure that Queensland can meet its obligations under those agreements.

ATTACHMENT 2

PROPOSED STANDARDS UNDER THE *PRIVATE HEALTH FACILITIES ACT 1999*

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INTRODUCTION

Section 12 of the Act empowers the Chief Health Officer to make standards for the protection of the health and wellbeing of patients receiving health services at private health facilities. Standards may be made about the following matters:

- the particular types of health services to which patients at a private health facility must have access (whether or not the services are provided at the facility) when other health services are provided at the facility;
- processes for –
  - evaluating the credentials of medical practitioners providing, or seeking to provide, health services at private health facilities; and
  - deciding which health services may be provided by the medical practitioners at the facilities;
- processes for deciding ethical issues;
- processes for monitoring, evaluating and improving the quality of health services at private health facilities;
- the day to day care and safety of patients, including admission and discharge procedures and patient records;
- management and staffing arrangements;
- minimum patient throughput for health services provided at private health facilities and prescribed under a regulation;
- equipment, fittings and furnishings at private health facilities;
- infection control; and
- any other matter prescribed by regulation.

Under the Act, it is a condition of all private health facility licences that licensees must comply with the Standards relevant to the facility.

The Standards will set out the measures designed to minimise the risks of harm associated with the provision of health services at private health facilities. Many of the Standards will adopt or be based on recognised standards, guidelines or protocols published by bodies such as the Medical Colleges, the Standards Association of Australia and the National Health and Medical Research Council. In addition, the Standards will draw on various Queensland Health guidelines, some of which currently apply to public sector health facilities. The *Guidelines for Clinical Services in Private Health Facilities*, which are referred to extensively in the Standards, can be accessed on the Internet at www.health.qld.gov.au/lpu/clinical.htm.

A number of Australian Standards are referred to in the proposed Standards. General information about Australian Standards may be found on the Internet at www.standards.com.au.

Building Standards

The Standards will not deal with building-related matters. However, in conjunction with the development of the Regulation and the Standards, a draft code has been prepared which specifies the building requirements for licensed private health facilities. The code will be incorporated into the Queensland Appendix of the Building Code of Australia and will replace the building requirements in the existing legislation under which private health

facilities are licensed. Comments are invited from interested parties in relation to the draft code, which may be accessed on the Internet at www.health.qld.gov.au/lpu/bca.htm.

Specialty Health Services

STANDARD

- Patients at the health facility who receive specialty health services must also have access to the ancillary health services necessary to ensure the health and wellbeing of those patients.

In this Standard, "specialty health services" mean any of the following:

- Assisted Reproductive Services;
- Cardiac Catheterisation – Diagnostic and/or Therapeutic;
- Cardiothoracic Surgery;
- Clinical Haematology (Bone Marrow Transplant);
- Coronary Care;
- Day Surgery;
- Ear, Nose and Throat Surgery;
- Emergency Services;
- Gastroenterology;
- Intensive Care;
- Mental Health Services including Drug and Alcohol Services;
- Neonatal;
- Neurosurgery;
- Obstetrics;
- Oncology - Medical and/or Radiological;
- Orthopaedic Surgery;
- Paediatric Medicine and/or Surgery;
- Palliative Care/Acute Hospice;
- Plastic Surgery;
- Primary Health Care Services;
- Radiology;
- Rehabilitation Services;
- Renal Transplantation and/or Dialysis;
- Respiratory Medicine;
- Urology; and
- Vascular Surgery.

This Standard is not satisfied unless:

- The provision of specialty health services is in accordance with the Queensland Health *Guidelines for Clinical Services in Private Health Facilities* and appropriate college/professional body guidelines/policy documents[1].

[1] All guidelines/policy documents as updated from time to time.

Credentials and Clinical Privileges

STANDARD

- A process must be in place to evaluate, monitor and review the credentials of medical practitioners providing, or seeking to provide, health services at the facility.

- The granting of clinical privileges must ensure that only appropriately qualified and experienced medical practitioners undertake clinical care within the constraints imposed by the available resources.

This Standard is not satisfied unless:

- A credentials and clinical privileges committee is established.
- The members of the committee include:
  - the Director of Medical Services, or equivalent;
  - at least one member of the nursing staff; and
  - suitably qualified peers of the practitioner whose credentials or clinical privileges are to be considered by the committee.
- The majority of the members of the committee are medical practitioners.
- Any member of the committee whose credentials or clinical privileges are being considered by the committee is excluded during such consideration.
- The functions of the committee include:
  - evaluating the credentials of all medical practitioners providing, or seeking to provide health services at the facility, having regard to advice received from appropriate clinical colleges and/or health professional registration authorities;
  - considering applications for the granting of specific clinical privileges requested by medical practitioners or for the extension of existing clinical privileges;
  - evaluating the particular health services available at the facility including those services required to support the clinical privileges requested or held;
  - reviewing clinical privileges at least every 5 years;
  - making recommendations to the licensee in relation to the granting or review of clinical privileges; and
  - monitoring and reviewing, when necessary, the continuing practice of the individual clinical practitioner.
- The licensee only grants clinical privileges to medical practitioners recommended by the committee as clinically competent to provide the health services.

Reference:

- Queensland Health *Credentials, Clinical Privileges and Appointments for Medical Practitioners, August 1993*

Ethics

STANDARD

- Clinical practice and research undertaken must be conducted ethically at all times.

This Standard is not satisfied unless:

- All research undertaken at the facility is approved, monitored and reviewed by an ethics committee constituted in accordance with:
  - the *National Statement on Ethical Conduct in Research Involving Humans, 1999*[1] published by the National Health and Medical Research Council (NHMRC) (if the research involves humans); and
  - the *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes, 1997*[2] published by the NHMRC (if the research involves animals).
- Patient consent meets the requirements of the NHMRC's *National Statement on Ethical Conduct in Research Involving Humans.*
- Clinical practice at all times reflects the ethical principles of respect for persons, beneficence and justice.

References:

- Australian Medical Association's Code of Ethics
- Faculty of Intensive Care & Australian and New Zealand College of Anaesthetists *Statement on Ethics and Patients' Rights and Responsibilities* 1997.

[1] As updated from time to time.
[2] Supra

Continuous Quality Improvement

STANDARD

- The licensee of the health facility must strive to continually improve the quality of care and services provided.

This Standard is not satisfied unless:

- The licensee complies with conditions of the licence under section 48(1)(b) and (c) of the *Private Health Facilities Act 1999* [1]
- Prior to receiving certification from a quality assurance entity (in compliance with the conditions of licence as above), a quality policy is prepared for the facility and implemented by the licensee.
- Processes and mechanisms are established to:
  - implement any recommendations made by the Chief Health Officer or quality assurance entities as to how the quality of care and services could be improved;
  - monitor, evaluate and implement strategies to reduce continuous risk of adverse clinical events; and
  - change and improve systems.

In this Standard, an "adverse clinical event" means *an unintended injury to a patient which resulted in temporary or permanent disability, a prolonged length of stay or death and which was caused by health care management and not the patient's underlying disease.*

References:

- The Australian Hospital Care Study 1992; AS 2561 - 1982 Guide to the determination and use of quality cost
- AS 3900 Quality management and quality assurance standards
- AS 3904 Quality management and quality elements
- AS 3912 Quality assurance requirements for measuring equipment
- AS 3941 - 1990 Quality control - Guide for number nonconforming charts
- AS 3942 - 1993 Quality control - Variables charts - Guide
- AS/NZS 3906:1994 Quality of service - Guide to customer expectations
- AS/NZS 3907:1996 Quality management - Guidelines for configuration management
- AS/NZS ISO 10013:1996 Guidelines for developing quality manuals (ISO 10013:1995)
- AS/NZS ISO 8402:1994 Quality management and quality assurance – Vocabulary
- AS/NZS ISO 9000 Quality management and quality assurance standards
- AS/NZS ISO 9001:1994 Quality systems - Model for quality assurance production, installation and servicing (ISO 9002:1994)
- AS/NZS 3905.14:1998 Guide to AS/NZS ISO 9001, 9002 and 9003 for health services

[1] Under s.48 (1)(b) and (c) of the Act:

- within 90 days after the issuing of a licence, the licensee must start a quality assurance program, conducted by an quality assurance entity, for the facility; and
- within 3 years after the day of issue of a licence, the licensee must receive certification from the quality assurance entity that the facility operates under a quality assurance system.

References (cont'):

- AS/NZS ISO 9002:1994 Quality systems - Model for quality assurance production, installation and servicing (ISO 9002:1994)
- AS/NZS ISO 9003:1994 Quality systems - Model for quality assurance in final inspection and test (ISO 9003:1994)
- AS/NZS ISO 9004 Quality management systems and quality system elements.

Patient Care

STANDARD

❑ Clinical care must be provided to meet patient needs.

This Standard is not satisfied unless:

- The process of entry to the facility is facilitated by an effective admission system which fully informs and prepares the patient for the episode of care.
- A record is developed by the appropriate health professionals in consultation with the patient and/or carer which covers:
  - patient assessment;
  - the plan for management of the patient's care:
  - treatment provided;
  - regular evaluation of the patient's condition; and
  - discharge plan.
- The number, qualifications and experience of nursing, medical and support staff are appropriate having regard to:
  - the number of patients;
  - co-morbidity:
  - other patient risk factors; and
  - casemix.
- Facilities, equipment and resources comply with the Queensland Health *Guidelines for Clinical Services in Private Health Facilities*, Australian Standards and appropriate college/professional body guidelines/policy documents[1].
- Patients have access to a document which explains their rights and responsibilities.
- Patients are informed in a culturally appropriate manner about:
  - their condition;
  - any necessary clinical investigations relevant to their condition;
  - any treatment proposed: and
  - the likely outcomes and risk of complications.
- The process of separation is facilitated by an effective discharge system which fully informs and prepares the patient for subsequent appropriate care.
- Processes are established for the receipt, documentation and review of all complaints relevant to the provision of patient care.

References:

- Australian and New Zealand College of Anaesthetists Policy Documents.
- Faculty of Intensive Care & Australian and New Zealand College of Anaesthetists *Statement on Ethics and Patient's Rights and Responsibilities* 1997.

[1] All guidelines/policy documents, standards and publications as updated from time to time.

References (cont'):

- AS 4269 - 1995 Complaints handling
- AS 2639 - 1994 Laminar flow cytotoxic drug safety cabinets - Installation and use
- AS 3695 - 1992 Wheelchairs - Product requirements
- AS/NZS 2211.1 Supp 1:1999 Laser safety - Equipment classification, requirements and user's guide - Application guidelines and explanatory notes
- AS/NZS 2211.1:1997 Laser safety - Equipment classification, requirements and user's guide
- AS/NZS 3825:1998 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles
- AS/NZS 4173:1994 Guide to the safe use of lasers in health care
- AS/NZS 4236:1994 Respiratory therapy equipment - Jet nebulizers and jet nebulizer air pumps
- AS/NZS 4237:1994 Respiratory therapy equipment - Peak expiratory flow meters
- The Cardiac Society of Australia and New Zealand Practice Guidelines
- The Australasian College for Emergency Medicine (1997) Policy Document
- Hyperbaric Oxygen Therapy Facilities Industry Guidelines, 1998
- The Fertility Society of Australia Reproductive Technology Accreditation Committee (1997), Code of Practice for Centres Using Assisted Reproductive Technology.
- The Faculty of Intensive Care (1997) Policy Document
- National Mental Health Policy (April 1992)
- United Nations: Principles on the Protection of People with Mental Health Illness.
- National Standards for Mental Health Services - Mental Health Strategy December 1996
- Minimum Service Standards for Mental Health Services in Queensland (1993)
- National Health and Medical Research Council (1992), Guidelines for Renal Dialysis and Transplant Services, Australian Government Publishing Service, Canberra.
- Standards for Hospice & Palliative Care Provision Australian Association for Hospice & Palliative Care, March 1994

Information Management

STANDARD

- Every patient must have a medical record which:
  - facilitates effective patient care management prior to, during and after their stay in the health facility;
  - provides for effective communication between health care providers; and
  - enables evaluation of the patient's progress and health outcome.
- Patient clinical records must be retained and stored for specified minimum periods.
- Permanent registers of patient activity must be maintained for medico-legal/legislative requirements.
- All stored personal information must be protected from unauthorised access, alteration or loss through the use of appropriate security measures.

This Standard is not satisfied unless:

- *Medical Records*:
  - The health facility's medical records comply with Australian Standard 2828 - 1985 (Hospital Medical Records).
  - Each patient, including each infant born or treated at the health facility, has a medical record which includes the following:
    - Information required for the provision of reports to the Chief Health Officer under section 144 of the *Private Health Facilities Act 1999*;
    - Progress notes which include the patient's medical history, the nature of the principal condition of the patient and the nature of any other condition, including adverse events, treated during the patient's stay in the health facility;
    - The nature of any surgical/diagnostic procedure performed on the patient during an episode of care;
    - A daily record of all medical and nursing care given in relation to the patient's medical, physical, psychological and social needs and responses;
    - Details of all medication; and
    - Record of informed consent for the performance of any surgical and/or potentially harmful diagnostic procedures.
- *Retention and Storage:*
  - The minimum period for the retention and storage of medical records is:
    - For clinical records - 10 years after the last clinical attendance or last medico-legal action, whichever is the later;
    - For minors' clinical records and obstetric records - 10 years from the child attaining adulthood (18 years);
    - For patients with a condition affecting their decision-making capacity (eg. intellectually disabled relating to traumatic brain injury, dementia, or severe mental illness) - 10 years from the date the patient's decision-

making capacity is no longer limited, or 80 years from the date of birth of the patient.

- All records of Assisted Reproductive Technology procedures are retained according to National Health and Medical Research Council guidelines.
- If the licence for a health facility is to be transferred, the existing licensee ensures that all patient records are made available and transferred to the incoming licensee; and
- Prior to a facility ceasing to operate as a health facility, the licensee submits details of the safe keeping of the records to the Chief Health Officer for approval.

- *Registers:*
  - The following registers are available where relevant:
    - Admission and Discharge register:
      a) the patient's full name and usual residential address;
      b) the patient's gender and date of birth;
      c) the patient's unit record number;
      d) the date of the patient's admission;
      e) the name of the patient's attending medical practitioner;
      f) the patient's diagnosis on discharge; and
      g) the date of separation for the patient's episode of care.
    - Birth register:
      a) the mother's full name;
      b) the mother's unit record number;
      c) the name of the mother's attending medical practitioner;
      d) the date and time of delivery of each infant;
      e) the gender of each infant;
      f) whether or not the infant was born alive;
      g) the method of delivery; and
      h) the name of the midwife and medical practitioner in attendance for the delivery.
    - Operation/theatre or procedure register:
      a) the patient's full name, gender, date of birth and unit record number;
      b) the date and time the operation or procedure was performed;
      c) the serial number of the operation or procedure;
      d) the nature of the procedure;
      e) the name of the surgeon, assistant surgeon, anaesthetists and scrub nurse
      f) the nature and identification number of any prosthesis used during any procedure; and
      g) any complications that may have occurred during a procedure.
    - Mental health register:
      a) information required under the relevant Mental Health legislation.

- *Security:*
  - Security of records complies with Australian/New Zealand Standard AS/NZS 4444: 1996 on Information Security Management.

References:

- AS 2828-1999 - Paper-based health care records
- AS 4390 Records management
- AS 4400 - 1995 Personal privacy protection in health care information systems
- The National Health and Medical Research Council (NHMRC) 1996, *Ethical Guidelines on Assisted Reproductive Technology*.

Management and Staffing Arrangements

STANDARD

- The provision of health services at the facility must be organised and administered to provide optimum patient care according to the goals and objectives of the facility and to meet the needs of the patient population being served.

This Standard is not satisfied unless:

- A copy of the licence for the facility is on display for public viewing.
- An organisational chart shows clearly established lines of responsibility, authority and communication within each health service and between appropriate health services provided at the facility.
- Relevant professional guidelines and statutory requirements are documented and regularly updated.
- Policies and procedures reflect current professional principles and practices for each health service and are consistent with the goals and objectives of the facility.
- Policies reflecting contemporary human resource management practices are developed and implemented.
- A registered nurse is appointed in charge of the nursing staff at the facility.
- A service agreement, which is updated every 3 years, exists with:
  - The Queensland Ambulance Service;
  - Providers of ancillary services required to support the provision of health services within the facility in accordance with the Queensland Health *Guidelines for Clinical Services in Private Health Facilities* [1]; and
  - A public and/or private health facility to accept patients on referral when required for the provision of a higher level of care.
- All staff members receive, on appointment, documented and dated job descriptions and appropriate orientation.
- Processes to recognise and regularly review employee and visiting health practitioners' qualifications, skills and competence are documented.
- Professionals providing health services within the facility maintain registration with the relevant health professional registration authority.
- Access is available to continuing education programs which maintain and augment knowledge and skills of employees and contract staff.
- All staffing, equipment and ancillary health services are in accordance with the Queensland Health *Guidelines for Clinical Services in Private Health Facilities.*
- Information management systems meet the needs of patient care delivery and the organisation.

References and Related Legislation:

- *Anti-Discrimination Act 1991*

[1] As updated from time to time.

References (cont'):

- Commonwealth Department of Human Services and Health (1994), Better Health Outcomes for Australians, National Goals, Targets and Strategies for Better Health Outcomes Into the Next Century, Australian Government Publishing Service, Canberra.
- *Equal Opportunity in Public Employment Act 1992*
- *Workplace Relations Act 1997*

Minimum Patient Throughput for Prescribed Health Services

STANDARD

- Patient throughput at each health facility providing prescribed health services must be at a level sufficient to maintain the clinical skills of the staff providing the health service.

In this Standard, "prescribed[1] health services" are:

- Cardiac Catheterisation
- Cardiac Surgery
- Intensive Care
- Obstetrics.

This Standard is not satisfied unless:

- The minimum number of patients who receive prescribed health services are as follows:
  - Cardiac Catheterisation - Therapeutic:
    - 900 interventional procedures per year.
  - Cardiac Surgery:
    - 400 procedures per year.
  - Intensive Care:
    - 350 mechanically ventilated patients per year in a Level III unit[2].
  - Obstetrics:
    - 40 births per obstetric bed per year.
- If numbers fall below these levels, a formal affiliation exists with an appropriate health service which provides a higher level of care in accordance with the Queensland Health *Guidelines for Clinical Services in Private Health Facilities*[3], to ensure staff maintain skill levels.

References:

- The Cardiac Society of Australia and New Zealand Practice Guidelines
- NSW Guideline for the Development of New Cardiac Catheterisation Laboratories, NSW Health Department, March 1996
- Superspecialty Service Guidelines for Acute Cardiac Interventions, A Report by the Australian Health Technology Advisory Committee, March 1995
- Shearman Report (1989), The Ministerial Task Force on Obstetric Services in NSW

[1] Health services to which this Standard applies must be prescribed by regulation under s.12(2)(g) of the *Private Health Facilities Act 1999*

[2] The Faculty of Intensive Care Australia and New Zealand College of Anaesthetists (1997) *Minimum Standards for Intensive Care*

[3] As updated from time to time

Physical Environment

STANDARD

- The physical environment within the health facility must ensure the health and safety of patients, visitors and staff.

This Standard is not satisfied unless:

- The facility and all equipment, furnishings and fittings in the facility comply with:
  - Queensland Health *Capital Works Guidelines*;
  - Relevant Australian Standards, National Health and Medical Research Council Guidelines and college/professional body guidelines/policy documents[1].
- All curtains and bed screens consist of, or are treated with, fire retardant and are treated with fire retardant after laundering.
- In order to reduce the risk of scalding, a system exists to control the outlet temperature of hot water to every bath, shower and hand-basin used by patients and staff.
- The generating plant or other equipment capable of providing an emergency power supply to the facility is properly maintained and tested regularly.
- Buildings, equipment, apparatus, furniture, fittings, electrical installations and wiring, bedding and other articles used in connection with the provision of health services in the facility are:
  - maintained in good repair and operational order[2]; and
  - kept clean and free from hazards.
- Regular safety inspections of the facility are carried out and the findings documented and remedial action taken, where necessary, to ensure the health and safety of patients, visitors and staff.
- A report, issued by an "authorised fire officer" within the meaning of the *Fire and Rescue Authority Act 1990*, is provided to the Chief Health Officer every 3 years stating that the licensee has complied with the requirements of Part 9A of that Act and with the *Building Fire Safety Regulation 1991*.

References and Related legislation:

- Building Code of Australia
- *Workplace Health and Safety Act 1995* and *Workplace Health and Safety Regulation 1995*
- *Food Act 1981* and *Food Hygiene Regulations 1989*
- Private Hospital Guidelines - Guidelines for the construction, establishment and maintenance of private hospitals and day procedure facilities, 2nd edition 1996
- AS 1169 - 1982 Minimizing of combustion hazards arising from the medical use of flammable anaesthetic agents
- AS 1199 - 1988 Sampling procedures and tables for inspection by attributes
- AS 1319 - 1994 Safety signs for the occupational environment

[1] All guidelines/policy documents, standards and publications as updated from time to time
[2] This is a condition of licensing under s.48(1)(g) of the *Private Health Facilities Act 1999*

References (cont'):

- AS 1399 - 1990 Guide to AS 1199 - Sampling procedures and tables for inspection by attributes
- AS 1470 - 1986 Health and safety at work - Principles and practices
- AS 1851 - Maintenance of fire protection equipment
- AS 2220.2 Emergency warning and intercommunication systems in buildings - System design, installation and commissioning
- AS 2508 Safe storage and handling information card
- AS 2569 Guide to the lifting and moving of patients
- AS 2675 - 1983 Portable first aid kits for use by consumers
- AS 2786 - 1985 Symbols - Health care in hospitals
- AS 2899.3 - 1986 Public information symbol signs - Hospital signs
- AS 3186 – 1998 Management of Clinical and Related Wastes
- AS 3745 - 1995 Emergency control organization and procedures for buildings
- AS 3780 - 1994 The storage and handling of corrosive substances
- AS 4083 - 1997 Planning for emergencies - Health care facilities
- AS/NZS 2500:1995 Guide to the safe use of electricity in patient care
- AS/NZS 3009:1998 Electric installation – Emergency power supplies in hospitals
- AS/NZS 4360:1999 Risk Management
- AS/NZS 4452:1997 The storage and handling of toxic substances
- AS/NZS 4804:1997 Occupational health and safety management systems - General guidelines on principles, systems and supporting techniques

Infection Control

STANDARD

- The licensee must develop and implement an effective facility-wide program for the surveillance, prevention and control of infection.

This Standard is not satisfied unless:

- An Infection Control Management Plan for the facility is developed and implemented which:
  - states the objectives of the Plan;
  - identifies, and assesses, all the infection risks specific to the facility which the licensee knows, or ought reasonably to know, exist or might exist;
  - states the particulars of training for persons who provide services at the facility that involve infection control risks; and
  - states how the licensee proposes to monitor and review the implementation and effectiveness of the Plan.
- The Infection Control Management Plan contains written policies and associated procedures, having regard to the infection risks identified in the Plan, which are consistent with the Queensland Health *Infection Control Guidelines 1999* and the *National Health and Medical Research Council Guidelines*[1,2] and relate to:
  - the use of "standard precautions" and "additional precautions" within the meaning of those terms in the NHMRC Guidelines;
  - isolation protocols and screenings to control infectious organisms within the facility;
  - the management of patients and health care workers who are known, or suspected, to be infected with contagious or highly transmissible pathogens;
  - the collection of information relating to infection rates, infection trends and other infection control information;
  - environmental cleaning; and
  - the evaluation of infection control risks associated with all purchases.
- A multi-disciplinary infection control committee is established which has the function of monitoring, and annually reviewing, the Infection Control Management Plan.
- An on-going infection control education program is conducted at the facility.

References:

- Standards for the Operation of Sterile Supply/Services in Health Care Facilities, National Co-ordinating Committee on Therapeutic Goods, January 1995
- Sterilising Services, December 1997
- AS 4187 - 1998 Code of Practice for cleaning, disinfecting and sterilising reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities
- AS/NZS 2817:1997 Implants for surgery - Care and handling of orthopaedic implants

[1] *Infection control in the health care setting: Guidelines for the prevention of transmission of infectious disease*, NHMRC: April 1996

[2] All guidelines as updated from time to time.