

**Review of the Private Hospitals
and Day Procedure
Centres Act 1988**

December 2000



REVIEW OF THE PRIVATE HOSPITALS AND DAY PROCEDURE CENTRES ACT 1988

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REVIEW OF THE PRIVATE HOSPITALS AND DAY PROCEDURE CENTRES ACT 1988

SUMMARY OF ISSUES RAISED

Discussion Point 1 (page 17)

Have all the restrictions on competition in the current legislation been identified?

Discussion Point 2 (Page 22)

Are there any other significant factors impacting on the market for private health facilities.

Discussion Point 3 (Page 24)

Have all the objectives of the Act been identified?

Discussion Point 4 (page 26)

Have all the problems in the market for private health facilities been identified? Do the identified problems necessitate legislative intervention by Government?

If so, how should the objectives of the Private Hospitals and Day Procedure Centres Act be framed?

Discussion Point 5 (page 36)

Submissions are invited on the costs and benefits of regulation of private health care facilities generally, and in particular, on the specific options for regulation.

Discussion Point 6 (page 36)

Submissions are invited on the most appropriate model for regulation of private health facilities. Submissions should include evidence of the costs and benefits of any preferred model.

Discussion Point 7 (page 38)

Submissions are invited to provide evidence of the costs and benefits to the community in restricting the overall patient capacity of private health care facilities in NSW.

Discussion Point 8 (page 40)

Submissions are invited on whether the current licensing system should be rationalised, including:

- *removing the separate licensing requirements for private hospitals and day procedure centres;*

- *redefining the basis upon which a facility is required to be licensed as a day procedure centre;*
 - *replacing the current framework for differential licensing standards with one that facilitates a more universal “outcome” based approach to standards. (Submissions on appropriate outcome based approaches are invited).*

Discussion Point 9 (page 40)

Submissions are invited on whether the Department of Health should have a role associated with undertaking of building development, alterations and extensions in private health care facilities.

Discussion Point 10 (page 41)

Submissions are invited to provide evidence of the costs and benefits to the community of the following requirements.

- *the appointment of a chief nurse, and*
- *a registered nurse on duty whenever the facility is being conducted.*

Discussion Point 11 (page 42)

Submissions are invited on the adequacy of the current provisions concerning fitness and propriety of applicants and licensees.

Discussion Point 12 (page 43)

Submissions are invited as to whether an Approval in Principle should be granted for the duration of a project rather than for a fixed period, subject to the applicant producing evidence of either a development application under the Local Government Act or Environmental Planning and Assessment Act or a signed building contract and development timetable.

Discussion Point 13 (page 44)

Submissions are invited as to whether the time in which action may be taken for an offence should be extended from six months to two years from the date of the alleged offence.

Discussion Point 14 (page 45)

Submissions are invited on whether the Act should provide for a power of entry and inspection into unlicensed premises, by authorised officers, if they reasonably suspect that services are being provided in violation of the Act.

Discussion Point 15 (page 46)

Submissions are sought on whether SEINS should be adopted for offences under the Act and Regulation.

1. BACKGROUND TO THE REVIEW

1.1 INTRODUCTION

The Private Hospitals and Day Procedures Centres Act 1988 establishes the statutory framework for the regulation of private health care facilities in NSW. The Act:

- provides that private hospital and day procedure centre owners must be licensed to operate in NSW;
- sets some minimum staffing standards;
- regulates planning, development and patient capacity of private health facilities;
- establishes requirements for the maintenance of registers;
- requires alterations and extensions to be approved.

In addition, the Act enables regulations to be made that:

- allow for the specification of standards for the design and construction of premises;
- specify a range of facilities and equipment which must be available in different classes of private health facility;
- sets operational standards including administrative, health care, safety, and infection control;
- sets standards for the content of medical records, confidentiality and patients' access to their records.

A private hospital is defined by the Act as:

“... Premises at which patients are provided with medical, surgical or other treatment, and with ancillary nursing care, for fee, gain or reward...”

A day procedure centre is defined as:

“... Premises at which patients are admitted and discharged on the same day for such medical, surgical or other treatment (for fee, gain or reward), and in such circumstances as may be prescribed by the regulations...”

The definitions exclude institutions conducted on behalf of the state, public hospitals and other facilities operated by area health services, and nursing homes. Private hospitals are excluded from the definition of day procedure centre.

1.2 THE CURRENT REVIEW

1.2.1 National Competition Principles Agreement

Following the report of the National Competition Policy Review Committee (the Hilmer Report) the Council of Australian Governments (COAG) endorsed the Competition Principles Agreement that commits all Australian governments to reviewing legislation with the aim of minimising or removing restraints on competition.

The Review of the Private Hospitals and Day Procedure Centres Act 1988 (the PH & DPC Act) is in fulfilment of the State's obligations under the Competition Principles Agreement between the Commonwealth, States and Territories which obliges all Governments to review current legislation with the aim of minimising and where possible removing any anti-competitive provisions.

The Terms of Reference for the Review are attached at **Appendix A**.

The review of anti-competitive legislation under the Agreement is aimed at removing unnecessary, cumbersome and costly impediments to conducting business in Australia. The guiding principle of the Agreement is that legislation should not restrict competition unless it can be demonstrated that the benefits to the community as a whole outweigh the costs of restricting competition, and that the objectives of the legislation can only be achieved by restricting competition.

Regulatory initiatives designed to promote the public good may have adverse consequences because they restrict competition. For example, a licensing system may restrict the number of people that can engage in a specific activity by ensuring that only those that hold certain qualifications provide services. In many cases this will be an effective means of protecting consumers from harm. However, restricting the number of people providing services may lead to a reduction in competition with a decline in standards and higher prices for services. It is also possible that regulation may stifle innovation, promote conformity within an industry and encourage maintenance of oligopolies.

However, it must be emphasised that the Agreement recognises that not all legislation which restricts competition will be contrary to the public interest. In many cases it may be necessary to restrict competitive conduct to protect the public from harm. It is the NSW Government's policy to ensure that review processes take into account the full range of public benefits, including limiting risks to public health and safety and improved information for consumers.

1.2.2 Principles for Best Practice Legislative Review

Legislation should only be used where policy aims cannot be addressed in less regulatory and restrictive ways. Even where legislative intervention is directed at addressing problems that are not a consequence of market failures, it is still necessary to properly assess the reasons for that intervention, and the likely impacts. To determine what is the most appropriate government response to a problem, consideration must be given to a wide range of factors to effectively respond to the identified problem. These factors include:

- The objectives of legislative intervention should be clearly specified, and outcome based as far as possible.
- Regulatory intervention through legislation and regulation needs to be appropriately assessed to ensure that it is directed towards correcting real and significant problems in an unregulated environment.
- The effectiveness of existing measures, including non-regulatory and legislative strategies (including general legislation such as fair trading requirements), need to be considered.
- Legislative strategies need to be assessed to ensure that they are appropriate and effective in achieving the objectives of the intervention. This should include an assessment of costs and benefits of the regulatory approach and, in the case of intervention that will impact on a competitive market, an assessment of the impact on competition. Similarly, the impacts on the rights of individuals need to be considered.
- A full assessment should be made of all regulatory options for intervention, including legislative and non-legislative options.

Other factors that should be considered in developing regulatory strategies include: the diversity of the practice, behaviours and commercial activities to be regulated in any situation; the need for transparency and consistency in decision making by those administering the strategies; the need for flexibility so that systems can respond to unforeseen developments and evolving practice and community values; and the response (or penalty) should be commensurate with the materiality of the risk to people or the environment that non-compliance generates.

1.2.3 Identification of Public Benefit Issues

Legislative intervention to achieve public benefit goals will often occur because problems have been identified and failure to address these problems could result in undesirable outcomes for society as a whole. As noted above, legislation will often be directed at protecting the public from harm that may arise in an unregulated

market for goods and services. Some examples of where public benefit issues might arise include:

- **Information problems:** Consumers may not have sufficient information, experience or ability to make informed decisions when seeking goods or services. The inability to make informed decisions could lead to physical or financial injury or harm because an unsafe or inappropriate product or service is used. In other cases, the consumer could incur unreasonably high costs in seeking a service provider appropriate for their needs.
- **Impact on third parties or the public generally:** The provision of goods or services may result in a third party incurring costs. For example injuries to a consumer caused by substandard or unsafe products or services may impose costs on the state or other individuals or businesses in providing the injured person with additional welfare or support. This could also have an unintended impact on other carers or family members of the person.

There is a range of other public benefit issues that might arise in circumstances that do not involve the provision of goods and services. These are too extensive to list here but could include:

- individual conduct may expose others to the risk of injury or harm; and
- Government may not be able to obtain sufficient information to assist it in discharging functions or providing services that the public reasonably expects it to provide in an effective manner.

In assessing the need for legislative intervention, it is essential that the problems or rationale for that intervention is clearly identified.

1.2.4 Overview of Regulatory Models

To prevent over-regulation but to ensure the public interest is protected a full assessment of appropriate options needs to be made to ensure that any regulatory response is targeted, effective and measured. It is appropriate to consider both regulatory and non-regulatory options in order to determine the best means of meeting stated goals. **Appendix B** includes a range of non-regulatory alternatives that may be appropriate in various circumstances.

1.3 THIS REVIEW

The broad aims of the Review are to assess whether or not the objectives of the Act remain valid; to determine whether the Act imposes limitations on competition in the private health facility industry and whether or not any such current restrictions are to the net benefit of the NSW community; and to assess whether legislation is the best

way of achieving the objectives of the legislation. Part of this assessment requires an examination of the nature and impact of the broader environmental changes and to determine whether the Act continues to meet the needs of consumers, industry and government in this context.

The aim of the Issues Paper is to identify and open up for public comment those matters which are of interest to the public generally and stakeholders in particular and to pose questions in a manner which encourages people to respond and put their views to the Department. Copies of the Private Hospitals and Day Procedure Centres Act 1988, the Private Hospitals Regulation 1996 and the Day Procedure Centres Regulation 1996 are available from the NSW Government Information Service (tel: (02) 9743 7200) and on the Internet site of the Australian Legal Information Institute (www.austlii.edu.au).

All submissions received will be considered by the Department of Health and a report to the Government prepared.

Submissions taking issue with any of the views expressed are welcome. Submissions on matters that are within the terms of reference for the review, but are not raised in this paper are also welcome. However, it should be emphasised that the primary purpose of this review is to consider whether there is a continuing need to regulate private hospitals and day procedure centres, and if there is, the kind of regulatory regime required, considering the nature of the industry and the need to protect consumers.

The Private Hospitals Regulation and the Day Procedures Centres Regulation were remade in 1996 in accordance with the requirements of the Subordinate Legislation Act 1987 and the Competition Principles Agreement. An opportunity to further review these regulations will arise following completion of the current review of the Act.

Submissions should be made to:

Legal and Legislative Services - Legal Branch
NSW Department of Health
Locked Bag No. 961
NORTH SYDNEY NSW 2059
Fax: 02 9391 9604
Ph: 02 9391 9606
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The closing date for submissions is **30 MARCH 2001**.

2. THE PRIVATE HEALTH FACILITY MARKET IN NSW

2.1 MARKET DESCRIPTION

2.1.1 The provision of services by health facilities

Private health care facilities operate within the broader market for the provision of services by health care facilities. Private health facilities in NSW primarily involve the provision of services to private patients (ie where a charge is rendered either to the patient or their insurer) .¹ Under the Australian Health Care Agreement between the Commonwealth and the States, NSW is required to provide hospital services free of charge to all eligible persons who elect to be public patients (ie, no charge is rendered). The treatment of public patients free of charge has, in NSW, remained almost exclusively the responsibility of public hospitals, with only a limited amount of public patient work being contracted by States to licensed private facilities.² Private patients may fund their private hospital treatment themselves, or through private health insurance.

ABS and AIHW data indicates that Australia wide, patients with private health insurance account for 76% of separations in private acute care and psychiatric hospitals. The remainder of patients are comprised of self-paying patients, compensable patients (ie, those who receive compensation for an illness or injury), Department of Veterans' Affairs patients, and public patients.

Public hospitals also provide treatment services to private patients. The Productivity Commission has suggested that about 19% of separations in public hospitals involved insured private patients.³ This level of involvement has declined significantly in recent years. However, despite this overlap there is much debate about whether public and private facilities operate in the same market. Some argue that the focus of the public hospital system is on treating the acutely and seriously ill and those with chronic conditions, whereas the focus of the private system is on treating those with less urgent clinical needs, including elective surgery. Many persons admitted as private patients in public hospitals attend a public hospital because the services they require are not available in private facilities.⁴ It should also be noted that the number of private patients in public hospitals has declined significantly in recent years.

Clearly there is some overlap in the services provided to private patients by public and private hospitals, particularly where the top separations are considered – see

1 Productivity Commission Private Hospitals in Australia: Commission Research Paper (1999) at page 5
2 Two privately owned hospitals provide treatment services for public patients in NSW under contract – Port Macquarie and Hawkesbury District Hospital
3 See footnote 1 at page 91
4 Ibid at page 91-2

table 2.1 below. Further some private health care facilities are commencing to provide services that have generally only been provided by public hospitals in the past. The debate remains as to whether the two sectors operate in distinct markets.

Table 2.1 – Top 10 DRGs by number of insured separations, private acute care hospitals and private patients in public hospitals, 1996-19975

Private Acute Care Hospitals	Private Patients in Public Hospitals
Gastroscopy	<i>Post abortion diagnoses</i>
Colonsocopy	Renal Dialysis (<i>Non-digestive disease</i>)
<i>Chemotherapy</i>	Gastroscopy
Renal Dialysis	Colonoscopy
Vaginal Delivery	<i>Other factors influencing health status</i>
<i>Lens Procedures</i>	<i>Oesophagitis</i>
<i>Knee Procedures</i>	<i>Digestive System diagnoses</i>
<i>Dental Extractions and Restorations</i>	Vaginal Delivery
<i>Major affective Disorders</i>	<i>Rehabilitation</i>
<i>Skin, subcut. tissue and breast procedures</i>	<i>After care of Malignancy</i>

2.1.2 Private Health Care Facilities

In NSW as of 1 December 1999 there were 86 licensed private hospitals with a total capacity to accommodate 6195 people, or about 15% of the total hospital capacity. In addition there were 86 licensed day procedure centres.

While private hospitals provide services on a day only basis, they are not required to be separately licensed as day procedure centres in such circumstances,

Private hospitals range in size from those with only a few beds, being day procedure centres that have converted to niche market private hospitals to the largest which has 320 beds. Growth in private hospitals in the niche market area has occurred as day procedure centres seek to expand into the area of 23 and 36 hour care, involving the performance of procedures with a recovery time which requires an overnight stay.

At the other end of the market, accommodation for more than 120 patients, new private hospitals are also being developed, primarily as co-located developments

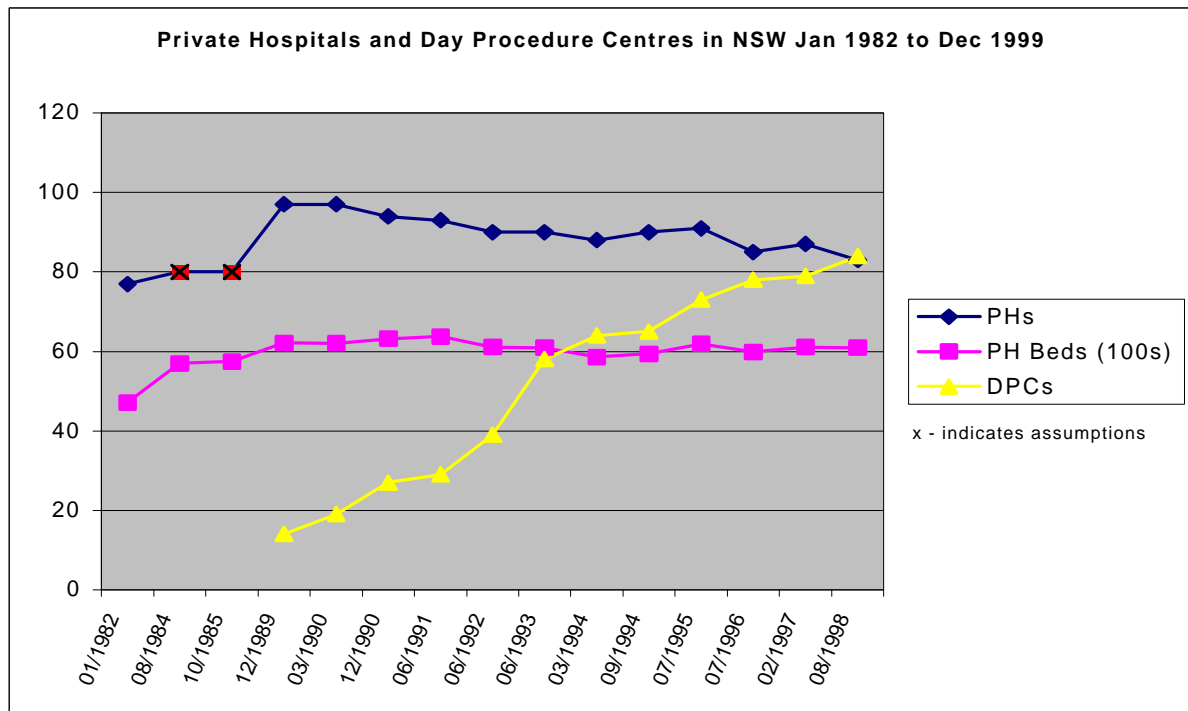
5 Reported in *Productivity Commission Private Hospitals in Australia* at page 92

with public hospitals or adjacent to public hospitals, but having no formal relationship to the latter. With size comes efficiency of functioning, and by being in close proximity to public hospitals, competitive advantages are provided to and through medical practitioners who can practice at both locations, the referral of privately insured patients from public hospital Accident and Emergency Units to the private hospital and the sharing of facilities. The other development encouraging larger private hospitals is integrated or "one stop health care" whereby a private patient can be provided with the full range of health services at the one location. This has involved an increase in the diversity and complexity of services offered, including specialised services such as intensive care, cardiac, neurological and oncology units.

Ownership of private hospitals is characterised by the presence of significant corporations, with one third of the patient capacity of private hospitals being owned by four corporations. A significant proportion of patient capacity is also licensed to religious and charitable organisations. Licensees that own a single hospital are in the minority. While a number of private hospital corporations are Australia wide, some having overseas interests, the entry of international health care providers into the NSW private health care sector has been a relatively recent development. More significant has been the purchase of ancillary health care services, such as pathology and x-ray services by private hospital corporations, to enable the provision of integrated health care services.

In contrast, the ownership of day procedure centres, the majority of which are either surgical or endoscopic class facilities, remains very much the province of the individual medical practitioner, resulting in a degree of specialisation in these facilities. This has led to the rapid growth in the number of licensed day procedure centres since licensing of these facilities was introduced in late 1992 - see *Figure 1*. Large corporate interests have not yet entered this field, and even partnership arrangements are in the minority.

Figure 1:



It was initially anticipated that the emergence of “stand alone” day procedure centres would result in the downsizing of the private hospital sector. Figure 1 above highlights the growth in the number of stand-alone day procedure facilities.

However this downsizing has not occurred. The Productivity Commission has shown that between 1991-92 and 1997-98 private hospital activity has increased significantly over the period, notwithstanding the growth in the number of day procedure centres. Separations in NSW private hospitals have increased by 32% over this period while the number of occupied bed days has increased by 22%. At the same time, the average length of stay has declined from 3.9 bed days to about 3.6 bed days. The number of private hospital beds has remained stable over the same period. Revenue from private hospitals in NSW has increased by about 67%.

While there has been a consolidation of the market with some smaller hospitals closing and the remaining facilities increasing their patient capacity, many private hospitals have developed day surgery facilities to complement their inpatient services. The net result is that the range of services provided through private hospitals has expanded. The Productivity Commission has suggested that, Australia-wide, most of the growth in revenue has come from the expansion of private hospitals into day only procedures.

2.1.3 Relationship between the public and private sectors

Public hospitals in NSW are of three types: hospitals operated by area health services, statutory health corporations, and hospitals operated by affiliated health organisations. These hospitals are regulated under the Health Services Act 1997. Area health services and statutory health corporations are under the direction and control of the Minister for Health. Affiliated health organisations (usually charitable and religious bodies) are provided with funding under the Health Services Act and are required to abide by certain conditions attached to that funding.

The Health Services Act governs the functions of these bodies, the appointment of visiting practitioners, and certain matters related to the employment of staff. Pursuant to the Australian Health Care Agreement, all eligible persons treated in public hospitals must be given the choice to be treated free of charge as public patients (in which case all services are provided by the hospital free of charge, including medical services rendered by practitioners nominated by the hospital) or a private patient (in which case the patient is charged for hospital accommodation and medical services).

The current relationship between the public and private sector rests on the co-existence of two separate and distinct health systems with links through the learned colleges and universities. There are further links through a range of practice forums, medical practitioners who practice in both sectors, the emergence of co-located facilities and a limited amount of contracting. In recent times the private sector has sought to redefine and restructure this relationship and adopt roles that traditionally have been the responsibility of the public sector. In particular, this is occurring with the training of health care practitioners, the development of private sector accident and emergency services and in the area of research.

However, the increasing interaction between the two systems at a structural level has revealed some artificial barriers to appropriate integration despite concerted efforts to develop principles upon which the private and public health facility sectors can function in a more integrated way. One of the principal barriers to integration has been the detailed legislative categorisation of private facilities upon which many health funds have based their decisions as to the level and type of rebates available from particular private facilities.

For example, private hospitals are categorised according to the facilities at the hospital. A private hospital may enter into arrangements to share facilities with, or utilise the facilities of, a public hospital or another private facility in order to expand the services it can provide. However, if these services fall outside the scope of its categorisation, health insurance funds may refuse to provide rebates for those services, because rebate structures are based on hospital categorisation (see para 2.2.2 for further discussion about categorisation of private hospitals).

2.2 OVERVIEW OF THE CURRENT ACT

2.2.1 Provisions of the Private Hospitals and Day Procedures Centres

A broad overview of the provisions of the current Act is provided in section 1.1. As noted there, the principal effect of the Act is to require private hospitals to be licensed.

Licensing of private health care facilities commenced with the proclamation of the Private Hospitals Act 1908. This Act was succeeded by the Private Health Establishments Act 1982, which commenced in 1988 and was repealed in 1990 following the proclamation of the Private Hospitals and Day Procedure Centres Act 1988 (the Act). While the 1908 and 1982 Acts provided for the licensing of private hospitals and nursing homes, separate legislation was not drafted until the 1988 Act. The licensing of day procedure centres, while first mooted in proposed amendments to the 1988 Act, did not commence until 1992, two years after the commencement of the Private Hospitals and Day Procedure Centres Act 1988.

The Act is given effect through separate regulations for private hospitals and day procedure centres. These set out a series of minimum requirements related to the provision of services, staffing, equipment and design requirements associated with clinical practice.

While the PH&DPC Act contains concepts which first emerged in its 1982 predecessor, it also contains concepts that readily identify it with the original 1908 Act including the requirements for licensing, staffing and maintenance of a register. The 1982 Act introduced a two stage licensing process, involving the granting of an approval in principle prior to the development commencing and the issue of a licence upon the completion of the development, subject to adherence to the conditions of the approval in principle. This provides applicants with some certainty of the outcome of their investment. However, the need for the Director-General to approve of plans and specifications for all alterations and extensions, which was carried forward from the 1908 Act, along with the capacity to issue notices requiring a licensee to undertake alterations, extensions, repairs and maintenance work, overlaps with similar powers under the Local Government Act and the Environmental Planning and Assessment Act.

It is noted that private hospitals are licensed throughout Australia. Day procedure centres in NSW, Queensland, Western Australia, Victoria and the ACT are licensed. In South Australia and Tasmania, they are subject to recommended guidelines that have to be complied with in order for a facility provider number to be issued by the Commonwealth.

2.2.2 Impact of the Legislation on Competition

The Act affects competition in a number of ways.

- **Licensing**

In requiring private health facility operators to be licensed and meet certain operational and probity standards, restrictions are imposed upon who may enter the market for operating private health facilities. This can lead to market distortions which may or may not have adverse impacts for consumers.

Potential adverse impacts include restrictions on consumer choice and additional service costs. However, the provision of substandard private health facilities carries with it a significant risk of physical injury or death which may require public health safeguards to the level intrinsic in a licensing system.

Business licensing is generally considered the most restrictive form of regulation and a demonstrated market failure involving serious consequences for consumers should be identified before deciding on such a regulatory intervention.

- **Limitations on Private Hospital Capacity**

Under the current legislation the Director-General may refuse an application for a licence where the approval would result in an increase in the number of patients that may be accommodated in private hospitals in NSW. Not only may this impose restrictions upon new entrants into the field, but it has also created a defacto market in private hospital “beds” which favours existing operators.

In addition, while this may have limited private hospital development, there are no similar restrictions placed upon the growth in day procedure centres. As an increasing number of procedures are conducted on a day only basis, the combination of the restrictions upon the expansion of the private hospital market and the lack of restriction upon the growth of day procedure centres may be to the detriment of private hospitals and result in resource allocation distortions.

- **Categorisation of Private Hospitals and Day Procedure Centres**

Presently, private hospitals are licensed as general, surgical, obstetric, rehabilitation and psychiatric class private hospitals. In addition, the admission of children, the performance of open heart surgery, cardiac catheterisation, dialysis, haemofiltration and haemoperfusion services, emergency services and the provision of intensive care and neonatal intensive care services all require additional licence endorsements.

Day procedure centres are licensed as endoscopic, surgical, cytotoxic and dialysis

class day procedure centres. In addition child patients may be admitted, and cardiac catheterisation services may be performed, in surgical class day procedure centres, if the license is so endorsed. Reflecting the separate development of private hospitals and day procedure centres, there are now nine classes of private health care facilities, with a further ten endorsements required for specific services.

The existence of licensing categories, each imposing specific requirements upon service providers, constitutes a restriction upon competition, as a service provider faces a legislative barrier to expanding the services available from the facility. That is, prior to offering a new service which is not covered by the existing categorisation of the facility, a categorisation covering that service must be obtained. Such restrictions might result in reduced flexibility for hospital operators in terms of the services they are able to offer.

- **Alterations and Extensions**

The current Act stipulates that any alteration or extension to a licensed facility requires the Director-General's approval. This has resulted in approvals having to be given for developments such as coffee and florists' shops in private hospitals. Not only does this duplicate the responsibilities of the Local Government under the Local Government Act and the Environmental Planning and Assessment Act, it may also hamper a facility's ability to provide a range of ancillary services (which are not hospital services) if the provision of that service requires a structural alteration or extension. Thus, a facility that can offer these services without alterations or extensions has an advantage over those which cannot.

Discussion Point 1

Have all the restrictions on competition in the current legislation been identified?

2.3 OTHER FACTORS IMPACTING ON THE MARKET

There are a range of factors that impact upon the private hospitals and day procedures centres market. Some of these factors may influence the degree of competition in that market.

2.3.1 Relevant accreditation mechanisms

Accreditation involves a formal structured process, whereby an individual or service is measured against and meets a defined set of standards. Independent reviewers from an accreditation organisation will examine a facility to assess its compliance with these standards, including its organisational structures and processes. The standards set by the accreditation organisation are based on the premise that

compliance with the standards indicates that quality of health care is provided. While the standards that are set may be broadly similar to those applying under a statutory licensing system, such systems generally operate without legislative support and are voluntary in nature.

The majority of private hospitals are accredited with the Australian Council on Healthcare Standards (ACHS), an independent, third party, self-funding accreditation agency that was established with a particular role in the accreditation of health services but with strong links to accreditation agencies in other industries.

Though technically still ‘voluntary’ there is a clear financial incentive offered to private hospitals by most private health insurance organisations to become and remain accredited. A number of insurers will not enter into contracts with private hospitals if they are not certified or accredited with a bona fide accreditation/certification agency.

However, a number of health organisations have been exploring other accreditation and certification models and bodies. These include the Australian Quality Award (AQA) framework that is sponsored by the Australian Quality Council (AQC), or the International Standards Organisation (ISO) certification in the 9000 series, currently being offered by a number of recognised bodies in Australia (however the former does not provide accreditation or certification). These organisations have only obtained access to a minor proportion of the health industry, although there are clear signs that the competition in this area is increasing.

With few private hospitals not accredited, it is impossible to make any judgements about whether accredited facilities are ‘better’ than non-accredited facilities in relation to quality of services, the numbers of complaints and the way they manage them.

Though the correlation is not automatic, an organisation’s preparation and maintenance of accreditation generally requires that the organisation has a robust organisational framework with a quality improvement focus, aimed at reducing any risks of complaints, injury or harm to people using, working in, or visiting the health service. Participation in accreditation is only one element of a quality program. There should also be a number of other quality evaluation strategies, including the evaluation of the services provided in terms of outcomes. Problems do occur when accreditation becomes the hub of an organisation’s quality improvement program. Accreditation does not equal quality, it is merely one indicator of quality.

There is no doubt that the preparation and maintenance of third party accreditation places a financial burden upon organisations, although there is increasing recognition that competent quality improvement systems actually reduce costs. Accreditation is a means of reviewing the sturdiness and cultural penetration of those quality systems.

The loss of accreditation status has significant financial implications for private hospitals. It would also be an issue that would go to the reputation of the organisation within the health industry, as accreditation status is public information. Although, it would be seen as a problem within the industry there is still some questions as to whether the community understands and values accreditation in the same way.

Although in previous years the rate of accreditation in day procedure centres has been lower than that for private hospitals, increasingly, day procedure centres are being accredited or certified. Accreditation or certification has become a requirement in the contracts with private health insurance companies enabling their members to claim benefits for care and services provided.

While it is noted that information directed specifically at consumers, provided in an understandable and accessible way (other than that published by individual organisations) detailing the accreditation of private health care facilities is not currently in the public arena, this is not to say that this could not occur in the future.

The NSW Association of Health Funds, in concert with the Private Hospitals Association, has developed a number of standards that it expects service providers to adhere to in return for the payment of benefits. This process is increasingly requiring evidence to be provided on specific interventions, consumer satisfaction and other indicators of the quality of health outcomes after an episode of care so that casemix adjusted payments can be made based upon the facility's performance. However, the nature of the relationship between service providers and the health insurance industry has tended to be confidential commercial contracts relating to the provision of a service for an agreed cost and not the actual standard of care provided, although, as discussed above, this seems to be changing. In addition, the contracts are selective and vary between insurers, added to which, not all facilities are involved in such arrangements.

2.3.2 Medical practitioners

While consumers of private health facility services generally exercise choice as to which medical practitioner they consult and can elect to seek the opinion of more than one practitioner, choice of practitioner necessarily limits choice of facility as not all practitioners have appointments to all private facilities. In many cases, choice of medical practitioner means accepting the facility or facilities at which the practitioner has visiting rights.

This is because medical practitioners do not have appointments conferring visiting rights at all private health facilities, but must apply for and be granted an appointment at the relevant facility. It is a matter for the medical practitioner to determine to which hospitals he or she will apply for visiting rights, bearing in mind

the appointments available at the hospital, the time commitment involved and other obligations the practitioner may have. Further, as part of a facility's quality assurance measures, the types of procedures that a practitioner may perform in a facility are determined by the facility's credentialling committee. Credentialling is a process whereby the skills and qualifications of the doctor are examined by the hospitals credentialling committee to determine a practitioner's clinical privileges, that is, the range of clinical services the practitioner is qualified and experienced to provide (and permitted to provide) in that particular facility (taking into account the facility's particular circumstances – eg equipment available, senior staff available for supervision etc).

Accordingly, if a patient wishes to be treated by a particular doctor in respect of a particular procedure, the patient must be admitted to a hospital where that practitioner holds an appointment and is permitted to perform that particular procedure.

If a consumer wishes to be treated at a particular private facility they may have to forgo their practitioner of choice, if that practitioner does not have an appointment to that facility. It is also noted that where medical practitioners have a pecuniary relationship with the operator of a facility to which they refer patients, there is a potential conflict between the pecuniary interest and professional judgement and advice.

The urgency of the required treatment may also impact upon consumer choice – there may be no choice if the consumer has to take the first available private health facility bed.

2.3.3 Accreditation of Health Professionals

The majority of health professionals practising in private health facilities are registered under relevant State legislation. Such legislation establishes criteria in terms of qualifications, competency and fitness that professionals wishing to be registered must meet. In addition there are established formal mechanisms for removing the registration of substandard practitioners.

Standards of patient care and safety are not exclusively determined by the standard of the individual health professional. The quality of the equipment, staffing levels, infrastructure and maintenance of the facility and administrative structures are also relevant.

2.3.4 Health insurance rebates

The nature of health insurance imposes distinct restrictions upon consumer choice of private health facilities. About 9% of separations in private hospitals are paid for

by patients themselves (and this comprises only about 4% of revenue) suggesting access to such facilities is fairly limited for people without private health insurance. This fact, coupled with universal free public hospital cover available under the Commonwealth Medicare arrangements, significantly restricts the potential market for private health facility services.

Consumer choice of private facility is impacted by the Commonwealth legislative initiative under which a health fund can enter into agreements with private facilities or practitioners. Where such agreements are in place, those facilities and practitioners agree to charge the health fund's clients for their services at a rate which is fully covered by the health fund rebate. In the case of such private health facility agreements the advantage to the consumer is that he/she has no out-of-pocket cost for the private facility's services (the so-called "gap" between actual cost and level of insurance rebate).

While a situation might arise where the consumer's health fund will not have agreements with every private facility thus limiting choice for a "no gap" stay, most funds currently have agreements with most private hospitals. Therefore a substantial proportion of private hospital separations in NSW are covered by a fund-hospital agreement to limit gap payments. However, increasingly it is expected that funds will limit the number of hospitals with which they have agreements, with one major fund having recently called for tenders from the private hospitals sector for such arrangements. This will further impact on consumer choice.

Both the Commonwealth and health insurance funds rely heavily on the State licensing system as a means of determining rebates to consumers for services provided by and in private health facilities. The Commonwealth requires private hospitals and day procedure centres to be licensed in their respective states before it will issue facility provider numbers. No rebates are available through the Commonwealth Medicare arrangements for medical services that are rendered in a private hospital that is unlicensed.

In addition, health insurance funds will not pay benefits for a service unless performed in premises the subject of a licence, which is appropriately endorsed for that type of service.

Clearly the Commonwealth, Health Insurance Funds and certain statutory bodies will not permit rebates in respect of facilities which are operating unlawfully (ie, are not licensed). Should the requirement for licensing be removed, those bodies would need to re-examine their pre-requisites for determining whether a facility is operating lawfully.

2.4 IMPACT OF ADVANCEMENTS IN HEALTH CARE

A significant factor in the provision of health care services is the advances in *health* technology, which have impacted on both private hospitals and day procedure centres, but most noticeably on stand-alone day procedure centres. Increasingly, this is resulting in procedures, which until recently required patients to stay in

hospital overnight, being done on a day only basis. The end result is that the distinction between private hospitals and day procedure centres is, from a licensing perspective, becoming increasingly artificial. While new technology may minimise the time taken to perform a procedure, it does not necessarily follow that the risk factors, particularly those associated with post-operative complications are also reduced.

Traditionally there was a general correlation between the level of sedation required for a procedure and the complexity and inherent risks of the procedure. This correlation, together with the inherent risk of anaesthesia itself, formed the basis of the requirement for those facilities to be licensed where anaesthesia beyond the level of simple sedation was administered. With the increased safety of anaesthesia and advances in medical technology resulting in more and more complex procedures being undertaken under simple sedation in doctors' rooms and other unlicensed facilities, the primary rationale for basing licensing requirements on the level of anaesthesia may no longer be valid.

Other risk factors have become recognised, such as the complexity of the fiberoptic instrumentation that poses infection control risks if not cleaned and sterilised appropriately.

As evidenced by the recently debated "office procedures" amendments to the Commonwealth *Health Insurance Act*, in the proposed *Approved Procedures Bill (1999)*, the Commonwealth, like the State, is becoming increasingly concerned about the standards of care provided by practitioners conducting high risk procedures in unregulated settings.

The continuing evolution of health technology poses significant challenges for any regulatory regime, which will need to be increasingly flexible and responsive to structural and technological change within the health sector.

This chapter has identified a number of factors which impact upon the market for private health facilities. Submissions may identify further factors which should be taken into account.

Discussion Point 2

Are there any other significant factors impacting on the market for private health facilities?

3. THE ACT AND ITS EFFECT ON COMPETITION

3.1 OBJECTIVES OF THE CURRENT ACT

The terms of reference for this review require an examination of the objectives of the Act and whether those objectives remain appropriate. In considering the objectives of the legislation, it is necessary to identify and consider the types of problems that the legislation seeks to address.

While the Act does not have any stated objectives, the long title of the Act is instructive:

“An Act to provide for the licensing and control of private hospitals and day procedure centres and for other purposes.”

The second reading speech introducing the legislation is also instructive in this regard. The then Minister for Health stated;

“.....this proposed legislation has four main objectives. The principal objective is the strengthening of standards to ensure patient care and safety; the second objective is the reduction of economic regulation of the private health sector; third, the elimination of arbitrary and trivial bureaucratic interference; and, fourth, the provision of a sound legislative base for day procedure centres for the first time.” (Hansard Assembly 29 November 1988 , p.3818)

Considering the functions and powers contained in the Act, it might be argued that the Act seeks to achieve the following objectives:

- minimise the potential risk of harm that would be posed by the entry of unscrupulous or substandard operators in the market providing private health facilities and to ensure that consumers can have some confidence regarding the standard of care provided in these facilities through:
 - (i) ensuring the probity of the persons managing the facility;
 - (ii) prescribing those policy and operational factors, such as staffing and equipment needs, which are concomitants to the provision of good clinical care by health care professionals;
- ensure the provision of appropriate clinical resources at each facility;
- support public health services planning by allowing State health authorities to control the number, size and location of both private and public hospitals.

Discussion Point 3

Have all the objectives of the Act been identified?

3.2 WHAT PROBLEMS DOES THE LEGISLATION SEEK TO ADDRESS

While this analysis would appear to describe the current objectives of the Act, further consideration needs to be given to the issue of whether these problems continue to exist in the market, thus establishing a basis for legislative intervention.

Addressing imbalances in information

The first dot point above would appear to be primarily directed at protecting consumers from harm, both physical and financial, which might arise in an unregulated market. Such an objective would be premised on a view that a risk of harm arises because consumers lack the knowledge to make informed choices when seeking out health care services. For the majority of the public being admitted to a hospital or day surgery unit is an infrequent event where the consumer relies heavily upon the treating medical practitioner to assess the need for private health facility services and the appropriate choice of those services.

Clearly there are a range of issues affecting the quality of service, for which the consumer may or may not be able to obtain information, for example:

- quality of theatre and other equipment;
- quality of arrangements in an emergency;
- appropriate staffing levels and qualifications of staff;
- procedures to minimise risks of harm, such as infection control standards.

This problem is affected by the mechanism through which consumers access private hospitals. As noted in the previous chapter, the visiting rights of the treating practitioner will have an influential role in selection of the relevant facility. Further, the choice of facility can also be influenced by the type of private health insurance and whether the insurance provider has an agreement with the relevant facility. Therefore even if a consumer has information, there may be restrictions on their ability to choose.

An argument could be made that because the insurance provider and treating practitioner may be able to act as an agent for the patient in selection of the hospital, this may address the imbalance in information. As noted in the previous chapter some health funds consider the quality of services when negotiating agreements with hospitals. However, consideration needs to be given to the issue

of whether these ‘agents’ also have the necessary capacity to process relevant information, and whether the interests of the agents will necessarily coincide with those of consumers, particularly where the need to maintain profitability and the cost of providing quality services do not necessarily coincide.

The Productivity Commission in its report considered the adequacy of information for consumers. While it found that there is extensive work progressing on the development of performance indicators in relation to the provision of health care services, this is still in its early stages and there is much debate about the nature and form of such indicators. Consideration should be given to the question of whether any imbalance in information necessitates government intervention.

Minimising Externalities

While the risk of harm to individuals through the imbalance of information can result in costs for consumers, it also needs to be recognised that this might result in costs for other parties. For example, a failure to adopt adequate standards could result in costs for the public health system where readmission is required because of inadequate treatment or an adverse event. Costs could also arise for a health fund given the large number of services provided under health insurance arrangements. Further assessment of the significance of these matters is required to determine whether Government action is required.

Planning Control

The Productivity Commission has noted that licensing legislation in most jurisdictions include planning controls. Underlying these controls are concerns that relying solely on the market to determine the location and level of private hospital services could lead to inappropriate outcomes such as:

- over-investment in, and use of, private hospitals, especially if those hospitals are owned by medical practitioners; and
- a geographical distribution of hospitals skewed in favour of metropolitan areas.

Further consideration needs to be given to the issue of whether this remains an appropriate objective of the current legislation.

3.3. THE NEED FOR INTERVENTION

The problems identified in the previous section may or not exist in an unregulated environment. A key issue for the review is to assess their significance and whether government intervention is necessary.

Discussion Point 4

Have all the problems in the market for private health facilities been identified? Do the identified problems necessitate legislative intervention by Government?

If so, how should the objectives of the Private Hospitals and Day Procedure Centres Act be framed?

4. LICENSING PRIVATE HEALTH FACILITIES - OPTIONS FOR REFORM

4.1 INTRODUCTION

Different regulatory models have different effects on the market for private health facilities, incurring different costs and benefits to the operators of facilities, medical practitioners, consumers, the broader community and government. To identify whether there are any unnecessary regulatory restrictions which can be removed, each of the options available for regulating private hospitals and day procedure centres in New South Wales needs to be explored. A range of models for regulating these facilities and those aspects of the Act which have an adverse impact on competition are outlined to assist a consideration of whether they are justified in the public interest.

The assessment of alternative legislative arrangements that might apply to the private health facility industry will depend on the nature and extent of identified problems (as discussed in the previous chapter), and on there being demonstrated inadequacies in the ability of other legislative or non-legislative mechanisms to redress these problems. The Competition Principles Agreement requires the licensing system to be assessed in accordance with the principle that legislation should not restrict competition unless it can be demonstrated that the benefits to the community as a whole outweigh the costs of restricting competition, and that the objectives of the legislation can only be achieved by restricting competition.

A wide range of factors need to be considered to effectively respond to risks to human health or safety. Consideration also needs to be given to the following factors:

- the diversity of the practice, behaviours and commercial activities to be regulated in any situation;
- the need for transparency and consistency in decision making by those administering the strategies;
- the need for flexibility to respond to unforeseen developments, and evolving practice and community values;

Non legislative strategies may involve less cost to industry and government in general. In addition, industry may be able to respond better to a changing environment under a non-legislative regime than a statutory regulation regime. However, this will depend upon the ability of industry to self-regulate effectively. Failure of industry to regulate itself may result in poor health outcomes and standards of services which themselves have significant costs to the community. Examples of non-legislative strategies include third party accreditation, voluntary

codes of practice, industry self-regulation, the establishment of an industry ombudsman to investigate complaints, community education programs to enhance the awareness of consumers and allowing market forces to determine the range and standard of services.

This chapter focuses on the primary restriction on competition, the requirement for licensing. Chapter 5 focuses on other restrictions and issues which also require assessment.

A range of models for regulating private health care facilities is outlined below. The options can be grouped into two broad, but not exclusive, categories: self regulation and external regulation. Self-regulation can be supported by strategies such as voluntary accreditation. External regulation can be further broken down into the categories of mandatory third party accreditation, negative licensing and regulation employing a statutory regime.

4.2 OPTIONS FOR REGULATION

4.2.1 Option 1 – No market specific regulation

Under this option, the Act would be repealed and not replaced. The following legal framework would regulate private hospitals and day procedure centres.

- The Fair Trading Act 1987 (NSW) and the Trade Practices Act 1974 (Cwlth) prevent private hospitals and day procedure centres from engaging in false, misleading or deceptive conduct. The Trade Practices Act also prevents private health facility providers from engaging in anti-competitive conduct such as price fixing and exclusive dealing.
- In relation to the enforcement of standards of care against the owner of a private health care facility, action could proceed through a civil claim in negligence or for breach of contract.
- The Local Government Act and Environmental Planning and Assessment Act would continue to regulate the construction and maintenance of premises and the Workers Compensation Act, occupational health and safety issues.
- Complaints could be made to the Health Care Complaints Commission (HCCC) regarding the nature of care provided and related concerns regarding standards of clinical practice. The HCCC is empowered by the Health Care Complaints Act 1993 to investigate complaints regarding the professional conduct of health practitioners or the care provided by any health service. A reassessment of the Commission's resources, in line with the expected increase in workload, would be required if this option were followed. The Commission's current powers would also need to be reassessed if it was expected to play a greater role in monitoring

private health care facilities.

- The various health professional registration legislation would regulate the conduct of registered health professionals such as doctors and nurses within private health facilities.
- Other public health legislation such as the Poisons and Therapeutics Goods Act, the Public Health Act and the Food Act would regulate various aspects of the activities of private health facilities.

The following observations can be made of the “no market specific regulation” approach:

- There is a range of potential market failures in an unregulated market for private health care facilities. These market failures relate to the type or lack of information available to consumers to enable them to make informed choices about particular services.
- Consumer legislation would assist consumers in the choices they make by precluding owners of private health care facilities from engaging in false, misleading and deceptive conduct, but this may not address the issue of information imbalance discussed at 3.2. While this imbalance may be addressed through medical practitioners providing advice to their patients, the consumers, and even their medical practitioners, may not be in a position to identify which facilities are best able to meet their needs in the absence of a transparent information system.
- Professional indemnity insurers, health funds, consumers and other interested parties could play an increased role in monitoring and improving standards of care. For example, insurers could implement a system whereby the withdrawal of accreditation by recognised standards bodies may result in insurers not paying insurance benefits in respect of treatment rendered in the non-accreditation facility. This could create an incentive for private health care providers to maintain a certain level of service. It may or may not result in the public being better informed. Withdrawal of accreditation or benefits could serve as a signal to consumers and their medical practitioners and result in improved consumer information. However as the reasons for accreditation being withdrawn, or the refusal by a health insurance fund to pay benefits, may not be publicly available, the information to consumers and practitioners may be deficient in content and breadth of dissemination.
- In an unregulated market, operators may be commercially compelled to become more responsible for the maintenance and enhancement of professional standards. Accreditation systems may assume increased commercial significance and accreditation status may play a greater role in providing information to consumers on the standards of individual facilities. However,

commercial imperatives to reduce costs and increase profits may result in a lowering of industry standards and cutting corners in critical areas such as infection control.

- Where there is no regulation, no advantages, through limiting entry to the market, are conferred on particular stakeholder groups.
- There could be greater scope for the development of more innovative forms of service delivery that would better meet the needs of consumers.
- There would be no regulatory costs directly associated with licensing to be passed on to consumers.
- The community has high expectations concerning the standards of care in health care facilities, be they public or private. Whichever regulatory option is preferred must be capable of satisfying this expectation and ensuring consumer confidence. Self-regulation may not engender the necessary consumer confidence, particularly if there is a real risk of serious personal injury or even death from substandard operators.

4.2.2 Option 2 – Government Information Campaign on Voluntary Third Party Accreditation

Third party accreditation consists of a private hospital or day procedure centre adopting the standards set down by an agency other than the State. This option would involve third party accreditation on a voluntary basis in lieu of statutory regulation. The option of third party accreditation in combination with statutory regulation is discussed in option 5.

Examples of third party accreditation models used in the private health care industry are:

- the Australian Council on Health Care Standards (ACHS) Accreditation Program, which is the most common model of accreditation in use;
- ISO 9000, promoted by Standards Australia;
- the requirements of the health funds.

As discussed in part 2.3 there is some usage of such systems in the market already.

If licensing were removed, accredited facilities could increase their marketing to consumers on the benefits of using their facilities. Government could also play a role both in encouraging operators to gain accreditation and in providing consumer information on the benefits of using accredited facilities and how to recognise which

facilities are accredited. The potential advantages of encouraging third party accreditation models in preference to particularised legislative requirements are:

- One layer of standard setting is removed and, in so doing, compliance costs to service providers, and in turn, consumers, are reduced;
- Such models are more flexible than statutory regulation and are more readily adapted to changing circumstances.
- Consumers could expect to experience a higher standard of care than occurs with legislated minimum standards on the basis that accreditation models are more able to develop optimum standards that reflect contemporary consumer views and contemporary clinical and management practices because of their links with key stakeholders and their non-regulatory focus.
- Facilities that are already accredited would not incur any additional costs of having to be licensed.
- Complaints could be made to the Health Care Complaints Commission regarding the nature of care provided and related concerns regarding standards of clinical practice.

Potential disadvantages associated with the use of voluntary accreditation models include:

- Non-enforcability of standards. Operators who are unable to meet accreditation standards or through complaints investigation are known to be sub-standard, could continue to operate in an unsafe manner.
- Lack of universality of standards. Not all facilities are accredited as the process is a voluntary one. Further, different accreditation bodies may adopt inconsistent standards. While the great majority of private hospitals are accredited with the ACHS, fewer day procedure centres are. However, as the health funds are increasingly requiring private health care facilities to be accredited with ACHS prior to benefits being paid, the percentage of ACHS accredited day procedure centres is expected to increase in the near future.
- Voluntary accreditation may not be a transparent process and may not adequately inform the public. Standards adopted by accreditation bodies are not subject to public scrutiny through a legislative process before they are made. Standards may be technical in nature and not easily understood or interpreted by consumers. A regulatory system resting on accreditation may not assist consumers to make an informed decision when considering which facility to use, as consumers may lack knowledge about the accrediting body and operators and health professionals could selectively promote different aspects of a facility's

accreditation status.

- The loss or lack of accreditation may not be a commercially significant event as some hospitals and many day procedure centres currently manage to function without the need for accreditation. The commercial significance of accreditation may increase, however, in a deregulated environment particularly if backed by an appropriate consumer information campaign.
- As currently structured, the health insurance industry and ACHS accreditation systems rest on the licensing of facilities as this determines the minimum standards of service. A regulatory model resting solely on either health insurance standards or ACHS accreditation may result in increased costs to consumers. This could occur as the standards imposed by the health insurance industry and ACHS may be above the minimum legislative standards and meeting those standards could result in operators of private health care facilities incurring costs which are passed onto consumers.
- Voluntary accreditation models may not offer sufficient protection to operators who are significantly disadvantaged by an adverse decision made by an accreditation body. For example, appeal mechanisms are currently available to operators under the Act where a licence application is refused or a licence is amended. These appeal rights allow for an administrative appeal (ie, resort to the courts is not necessary at first instance). A statutory right of appeal to the District Court is available where a licence is cancelled. Such extensive appeal rights may not be available under voluntary accreditation systems, and resort may need to be had to the courts in the first instance, which can be costly and time-consuming for operators.

4.2.3 Option 3 - Negative Licensing

Negative licensing models provide for minimum standards which must be adhered to. Under the model, service providers are able to establish a service and operate without restriction until excluded. Exclusion would occur as a result of complaints regarding the quality of service. Any person would be free to set up a private health care facility, and subject to other legislation, would not be required to submit to probity checks, nor would the proposed premises have to be assessed as to their suitability as a health facility.

A negative licensing model would require the development of standards against which complaints would be assessed to determine if grounds existed for excluding an operator from the market. In addition it would be necessary to provide for appropriate power to investigate complaints

As with the “self regulation” model, the following legal framework would regulate private hospitals and day procedure centres.

- The Fair Trading Act and the Trade Practices Act would prevent private hospitals and day procedure centres from engaging in false, misleading or deceptive conduct (eg, in making claims regarding the quality and extent of services provided and from engaging in anti-competitive conduct such as price fixing and exclusive dealing).
- In relation to the enforcement of standards of care against the owner of a private health care facility, action could proceed through a civil claim in negligence or for breach of contract.
- Complaints could be made to the Health Care Complaints Commission regarding the nature of care provided and related concerns regarding standards of clinical practice. The Commission's current powers and resources would need to be reassessed if it were expected to play a greater role in the investigation of complaints concerning private health facilities.
- The Local Government Act and Environmental Planning and Assessment Act would continue to regulate the construction and maintenance of premises and the Workers Compensation Act, occupational health and safety issues.
- The various health professional registration legislation would regulate the conduct of registered health professionals such as doctors and nurses within private health facilities.
- Other public health legislation such as the Poisons and Therapeutics Goods Act, the Public Health Act and the Food Act would regulate various aspects of the activities of private health facilities.

Many similar observations, including potential advantages and disadvantages, to those made about self-regulation can be made about negative licensing. However a negative licensing system has the additional potential advantages of:

- The development of an enforceable outcome orientated set of minimum standards (which would otherwise be determined through litigation) at less cost and more convenience to consumers generally than the completely deregulated option. The nature of civil action against unethical or incompetent operators can be expensive, relatively inaccessible and slow. Consumers will not take action on each occasion they are disaffected by private health facility providers.
- The universal application of such standards.
- The transparency and accountability of a legislatively based system.

The combination of option 2 (a government information campaign) with the negative

licensing model may further support the amelioration of potential disparities in market information whilst still imposing no direct regulatory costs on operators.

However, both options 2 and 3 impose administrative costs on Government. Option 2 involves the expenditure of resources to adequately provide the market with meaningful and detailed information. In the case of negative licensing, significant costs could be involved in terms of the level of compliance and enforcement activity required in monitoring the standards.

These regulatory models do not allow for recoupment of these costs through the imposition of a licence fee.

4.2.4 Option 4 – Retain Current Licensing System

Under this option the present statutory licensing system is retained, removing those anti-competitive elements further discussed in Chapter 5 which cannot be justified as being in the public interest. Modification of the current prescriptive licensing standards to achieve a more outcome or performance based set of standards could be incorporated into the current model, enhancing flexibility and removing barriers to competition. The following observations can be made of a statutory licensing scheme:

- Licensing provides a transparent, independent model of regulation, with the sole purpose of maintaining operational and probity standards, unaffected by commercial considerations. In being applied to all services, it provides a universal measure by which facilities, and the services they provide, can be evaluated and by which consumers can satisfy themselves as to the standard of care in any particular facility.
- A licensing system is enforceable, with provision for a range of penalties, including the ultimate sanction of prohibiting a person from operating a private health care facility by way of license cancellation. Unlike non-statutory regimes, operators adversely affected by licensing decisions have established appeal rights.
- The private health facility operators have the benefit of operating in a consistent environment in which the rules are not readily changed and where the actions of the licensing authority are subject to the requirements of administrative law, that is, the decisions made by the Director-General in respect of licensing are reviewable in terms of procedural fairness and reasonableness.
- Ensures that the operator is fit and proper and able to meet a defined minimum standard of patient care and safety before being permitted to provide services in an area where there is a significant potential for financial or physical injury or death from substandard or unscrupulous operators.

The following criticisms can be made of statutory licensing:

- Licensing restricts entry to the market through the imposition of requirements and standards which service providers have to meet and as such may restrain competition.
- Licensing imposes costs upon service providers which they would not otherwise incur, and which may be passed onto consumers.
- Statutory regulation may be unresponsive and inflexible. It has the potential to inhibit the evolution of innovative forms of service delivery, which do not fit into a statutory framework.

4.2.5 Option 5 – Legislative Recognition of Third Party Accreditation

Under this option, a statutory licensing system is maintained but the prescription of specific licensing standards is replaced by the requirement for facilities to have specified third party accreditation in order to be permitted to operate.

The advantages of both options 2 and 4 are incorporated into this model with the direct regulatory costs of the State inspecting and monitoring specific prescribed standards being removed. The system maintains the accountability and transparency of a statutory system and removes duplication for that significant number of facilities that have already gained accreditation. The State would continue to conduct fitness and probity checks of applicants for licences and would maintain a complaint handling and monitoring role. Loss of accreditation would result in licence removal.

However, in some cases, the costs of accreditation or certification may be significantly higher than existing licensing costs, noting that accreditation/certification standards are frequently based upon optimum rather than minimum standards. This may pose problems for smaller operators unable to meet these optimum standards because of the cost implications of doing so.

There is currently only one likely candidate for the role of third party accrediting agency, namely the ACHS. While there are some signs that this is changing with the entry of other agencies providing certification and accreditation services, in the interim period, this option may have the effect of giving a particular non-government body a legislative monopoly on accreditation for licensing purposes.

To address these potential disadvantages, the option could be adapted to permit a facility to obtain a licence either through accreditation with a recognised reputable standards body or through compliance with a set of prescribed minimum standards.

A variation on this option would involve introduction of legislation requiring all operators to hold accreditation with a recognised third party, thus removing the requirement for government licensing completely.

Discussion Point 5

Submissions are invited on the costs and benefits of regulation of private health facilities generally, and in particular, on the specific options for regulation.

Discussion Point 6

Submissions are invited on the most appropriate model for regulation of private health facilities. Submissions should include evidence of the costs and benefits of any preferred model.

5. REGULATORY REFORM – OTHER EXISTING LEGISLATIVE RESTRICTIONS

Even if it is concluded that there is a net public benefit to continuing some form of statutory licensing regime there remain a number of other anti-competitive restrictions in the current legislation which must be considered as part of this review.

5.1 LIMITATIONS ON PRIVATE HOSPITAL CAPACITY

Under the current legislation, the Director-General may refuse an application for a licence where the approval would result in an increase in the number of patients that may be accommodated in private hospitals in NSW. Not only may this impose restrictions upon new entrants into the field, but it has also created a *de facto* market in private hospital “beds” which favours existing operators, with “beds” which are no longer in use held “in reserve” by operators and traded on the open market.

As a consequence of these planning controls, applicants for new private hospital approvals have been required to identify the source of their proposed patient capacity from within existing bed stocks. This generally involves purchase of spare or reserve capacity “beds” from existing or former operators at market value.

Where applicants seek approval for “new” patient capacity for a new facility or the extension of an existing facility without purchasing existing or reserve beds on the open market, the Department has a range of policy criteria it considers in determining whether to grant the application and thereby increase overall patient capacity in the State. These criteria are:

- i) An identifiable demographic/geographic or other need for the service;
- ii) A meritorious, innovative clinical service;
- iii) A service that has been the subject of a Department sponsored tender process.

It has been Departmental practice in recent times to place conditions upon any new capacity which is granted, namely that it cannot be transferred to another facility or held in reserve. This renders such new capacity unable to be traded on the open market.

The Act places no similar restrictions on capacity in day procedure centres. As an increasing number of procedures are conducted on a day only basis, the combination of the restrictions upon the expansion of the private hospital market and the lack of restriction upon the growth of day procedure centres may be to the detriment of private hospitals. This may also result in the inefficient allocation of resources.

While it can be argued that similar restrictions should be imposed upon private hospitals and day procedure centres, the fundamental question remains as to the continuing utility of the restriction on capacity and whether it has a net public benefit or cost. It may be argued that regulating the capacity of private hospitals and day procedure centres can be a form of planning control to prevent over-servicing and to ensure minimum standards of health care.

However, any restriction upon the expansion of private sector health facilities is anti-competitive and it is necessary to demonstrate a net benefit to the community if it is to be retained. The Productivity Commission has identified the possible rationale for such restrictions, namely:

- facilitating orderly industry development, particularly through reducing the level of unused bed capacity in private hospitals;
- promoting equitable access to private hospital services;
- guarding against supplier induced demand;
- Containing health care costs by limiting access to expensive, high technology equipment.

Whether such objectives remain appropriate for state-based licensing legislation needs to be considered. The Productivity Commission raises questions in relation to each of the above rationales.⁶ If these are considered appropriate, the issue remains as to whether the current provisions are the most appropriate means of achieving these objectives.

Discussion Point 7

Submissions are invited to provide evidence of the costs and benefits to the community in restricting the overall patient capacity of private health care facilities in NSW.

5.2 CATEGORISATION OF FACILITIES

In order to be licensed, private health care facilities have to meet certain minimum standards set out in the Regulations which, during 1995/96, were subject to review under the Subordinate Legislation Act 1986. These requirements pose barriers to who may provide private health care services by requiring service providers to meet certain standards.

Presently, private hospitals are licensed as general, surgical, obstetric, rehabilitation and psychiatric class private hospitals. In addition, the admission of

6 Productivity Commission [Private Hospitals in Australia](#) Commission Research Paper (1999) at pp 101-103

children, the performance of open heart surgery, cardiac catheterisation, dialysis, haemofiltration and haemoperfusion services, emergency services and the provision of intensive care and neonatal intensive care services all require additional licence endorsements.

Day procedure centres are licensed as endoscopic, surgical, cytotoxic or dialysis class day procedure centres. In addition, child patients may be admitted, and cardiac catheterisation services performed in surgical class day procedure centres, if the license is so endorsed. Reflecting the separate development of private hospitals and day procedure centres, there are now nine classes of private health care facilities, with a further ten endorsements required for specific services.

While there are some licensing standards applicable to all facilities, the various classes of private facilities have led to the development of differential licensing standards.

Concurrent with this expansion in regulation, the former very clear demarcation between procedures performed in hospitals and day procedure centres is becoming increasingly blurred with some private hospital and day procedure centre regulations having similar or parallel requirements. For example, additional licensing standards for surgical hospitals are largely the same as for surgical class day procedure centres (Refer to the Day Procedures Regulation 1996 and the Private Hospitals Regulation 1996 for licensing standards). Reflecting this situation, many modern day procedure centres are better equipped and resourced than some small hospitals and are capable of performing a wide range of procedures and treatments. In addition, procedures which previously required overnight stays in hospital are increasingly being performed on a day only basis following the development of less invasive surgical techniques.

It is also noted that there is a small but growing number of inquiries from licensees of day procedure centres who wish to expand their activities to include procedures that require patients to stay overnight. Under the present legislation, this requires the day procedure centre changing its status to a private hospital.

Furthermore, as outlined earlier in the paper, there is a question as to whether the requirement to be licensed as a day procedure centre should continue to be based upon the level of anaesthesia administered at the premises. This may now be an artificial distinction having regard to the improvements in the safety of anaesthesia and the fact that more complex procedures carrying inherently greater risks are being performed in increasing numbers under simple sedation in premises which are not required to be licensed eg, doctor's surgeries. These premises may not have the accessibility and emergency backup required of licensed facilities.

If licensing is to be maintained, it will need to be rationalised to respond to the continuing advances in day only surgery. While there will continue to be some differences in the types of procedures undertaken in private hospitals and day

procedure centres, particularly in the area of major surgery, the future configuration of private health care facilities rests on technological change which any regulatory regime should be able to accommodate. Consideration also needs to be given to the issue of whether such standards can be less prescriptive and more performance orientated.

Discussion Point 8

Submissions are invited on whether the current licensing system should be rationalised, including:

- *removing the separate licensing requirements for private hospitals and day procedure centres;*
- *redefining the basis upon which a facility is required to be licensed as a day procedure centre;*
- *replacing the current framework for differential licensing standards with one that facilitates a more universal “outcome” based approach to standards. (Submissions on appropriate outcome based approaches are invited).*

5.3 ALTERATIONS AND EXTENSIONS

The current Act stipulates that any alteration or extension to a licensed facility requires the Director-General's approval. This has resulted in approvals being required for developments such as coffee and florists' shops in private hospitals, neither of which should be of Departmental concern. As noted in paragraph 2.2.2, the requirement to gain approval for such alterations and additions may confer an unfair competitive advantage upon facilities which already have the capacity to provide such services without making alterations or additions to their premises.

As Local Government is responsible for ensuring the structural integrity and fire safety of the building, the role of the Department of Health could be limited to certifying the design suitability of those areas of the building associated with clinical practice, and the related fittings, fixtures and equipment, associated with services that impact on patient care and safety.

Discussion Point 9

Submissions are invited on whether the Department of Health should have a role associated with the undertaking of building development, alterations and extensions in private health care facilities.

5.4 APPOINTMENT OF SPECIFIC NURSING STAFF

Section 41 prohibits the conduct of a private hospital or day procedure centre unless there is a person appointed to carry out the duties of chief nurse. The chief nurse is required to be a registered nurse who holds such additional qualifications as are prescribed. In addition, section 43 requires that there is to be a registered nurse on duty in the private hospital or day procedure centre at all times when the establishment is being conducted.

In both instances, in requiring the presence of staff with specific qualifications, restrictions are imposed that may be anti-competitive in that there may not be the flexibility to staff facilities according to their particular needs. It is therefore necessary to determine if the benefit of such a restriction outweighs the cost, and whether alternatives can achieve the objective of the legislation while minimising the impact on competition.

Discussion Point 10

Submissions are invited to provide evidence of the costs and benefits to the community of the following requirements:

- *the appointment of a chief nurse, and*
- *a registered nurse on duty whenever the facility is being conducted.*

5.5 FITNESS AND PROBITY ASSESSMENT

Probity assessment is undertaken to ensure that those persons who are either responsible for the conduct of a health care facility and/or in a position to influence decision making, or have a controlling interest, are of good character. While the present legislation requires applicants to be fit and proper, including the directors of corporations, it may be argued that the current provisions are not effective enough in the context of complex corporate arrangements.

The legislation provides that the Director-General may refuse an application for a licence if the applicant, or any of the applicants is not a fit and proper person. In addition, the Act makes it clear that in examining the fitness and propriety of a corporation, the fitness and propriety of each director and each person concerned in the management of the corporation may also be examined.

The current provisions provide little guidance as to the factors to be considered in assessing an applicant's fitness and propriety, unlike other legislative schemes such as the Commonwealth Broadcasting Services Act 1992. Under that Act, a potential licensee is assessed as to whether providing it with a licence would lead to a

significant risk of an offence being committed against the Act or a breach of licence occurring. In order to assess this risk, the licensing body must take into account the applicant's business record and its record in situations requiring trust and candour and whether the applicant has been convicted of an offence against the Act. Similar checks must be made in respect of individuals in a position to control the applicant.

The Department of Health takes the view that major shareholders in an applicant corporation can be scrutinised in the context of fitness and propriety. Further, in the case of *Australian Broadcasting Tribunal v Bond* (170) CLR 321 there is support for the view that the fitness of the controlling shareholder can be considered in determining an applicant's fitness. It may be desirable to expressly clarify in the legislation the ability to examine the fitness and propriety of all persons or companies in a position to influence a corporation, that is, directors, managers and major shareholders, where that corporation is an applicant for a licence or a licensee. Specific factors to be examined could be set out in the legislation. However, it should be ensured that any specified factors are relevant to the applicant's fitness to conduct a facility, and do not have the effect of excluding persons from the market on irrelevant grounds.

Factors that may be considered relevant are:

- the applicant's record in carrying on a business or profession;
- the applicant's record in situations requiring candour or trust;
- the business or professional record of other relevant persons and corporations, including directors, managers and major shareholders; and
- the business or professional record of other relevant persons and corporations, in situations requiring candour and trust.

Discussion Point 11

Submissions are invited on the adequacy of the current provisions concerning fitness and propriety of applicants and licensees.

5.6 APPROVAL IN PRINCIPLE OF LICENCE APPLICATIONS

Under the present legislation, an Approval in Principle (AIP) to build a private hospital or day procedure centre is granted by the Director-General upon the development being of a suitable design and standard and the applicant meeting the probity requirements. The AIP is valid for 12 months. Approval of the design gives an early indication as to whether the structure of the hospital meets certain licensing standards, thus avoiding the need for structural changes when the licence

application is considered.

The granting of an AIP is directly linked with the requirement to be licensed under the Act as the applicant must address the licensing requirements to obtain an AIP. Applicants must therefore consider the design and structural standards imposed by the Act and Regulations in preparing their application. Reform of the requirement to be licensed as discussed in Chapter 4 will necessarily impact on this process.

The AIP process has considerable merit as it means that an applicant can be sure that, provided all legislative requirements are met, a licence will be issued upon completion of the project.

Because an AIP is valid for twelve months, an expectation is created that a proposal, the subject of an AIP, will be completed within a twelve-month period. While this is often the case, some projects for a number of valid reasons run over the twelve-month limit. Extension beyond this date can be granted if the submission of a development timetable has been made as a condition of the AIP and there has been a reasonable attempt to comply with the timetable.

In addition, a significant number of AIPs have been granted for speculative projects which have been the subject of requests for multiple extensions. That is, applicants have applied for an AIP, knowing that it is not time limited, and believing it increases the value of the site and the proposed development project. This results in a cost to Government through the time taken to process such requests, although some of this cost is recovered through application fees.

It is therefore proposed that the granting of an AIP should be for the duration of the project, and subject to the applicant producing some evidence of a building development application or approval under the Local Government Act or Environmental Planning and Assessment Act. Where no approval is required under these Acts, it is proposed that an AIP be subject to the receipt of a copy of the signed building contract and a development timetable.

Discussion Point 12

Submissions are invited as to whether an Approval in Principle should be granted for the duration of a project rather than for a fixed period, subject to the applicant producing evidence of either a development application or approval under the Local Government Act or the Environmental Planning and Assessment Act or a signed building contract and development timetable.

6. ENFORCEMENT AND COMPLIANCE ISSUES

6.1 LIMITATION PERIOD

The Justices Act provides that an action in relation to a summary offence under NSW law must be commenced within six months of the alleged offence, unless some other period of time is specified in the relevant legislation. The PH&DPC Act does not specify any other period of time. This statutory limitation period has implications for investigating complaints, and prosecuting breaches of the legislation.

It is not unusual for complaints to take more than six months to be presented. This arises either because the nature of the complaint is such that the indicators of the breach do not emerge immediately after the event, or due to the time it takes for the affected parties to achieve a degree of equilibrium following a traumatic episode. When complaints are received that refer to incidents over six months old, while still investigated, no enforcement action can be taken in such matters, even when they are substantiated, because the six month time period has elapsed. The offence can only be prosecuted if the activity that led to the breach continues to be practised.

It is therefore proposed that the timeframe in which action may be taken should be extended to two years from the date of the alleged offence. This period provides a reasonable time for reporting and investigation of complaints without significantly prejudicing the defendant by allowing a long period of time to elapse before a prosecution is taken.

Discussion Point 13

Submissions are invited as to whether the time in which action may be taken for an offence should be extended from six months to two years from the date of the alleged offence.

6.2 POWERS OF ENTRY

The present Act provides that authorised persons may enter and inspect licensed premises and identified records. Difficulties arise when complaints are received concerning unlicensed premises, mostly concerning day procedure centres. The present Act restricts the entry of authorised officers to licensed premises and those premises the subject of an approval in principle. This makes it difficult to prosecute persons who operate unlicensed premises in contravention of the Act. At common law, authorised officers, like any member of the public, are able to enter and inspect premises with the permission of the proprietor, or the person in charge of the premises. However, should this permission be refused or withdrawn, officers have

no relevant power to rely upon in order to enter the premises or conduct an inspection.

While there have been no experiences of facilities being used illegally as private hospitals, cases of problematic medical and/or surgical care in unlicensed day procedure centres which, prima facie, suggest a violation of the Act, are not uncommon.

Potential breaches of the Act can be identified in various ways. For example, public hospital emergency departments can relate incidents of emergency transfers from unlicensed day procedure centres in response to the development of complications, usually associated with the administration of a form of sedation. However, in order to investigate potential breaches it is considered necessary to have a power of entry to premises reasonably suspected of operating in contravention of the Act.

It is not uncommon for legislation to contain a provision to enable a justice to issue a warrant to enter and inspect premises if the justice is satisfied that entry has been refused, or it is not appropriate to approach the person in charge of the premises as such an approach would be prejudicial to the investigation. As an alternative to approaching a justice, the Director-General could be empowered to authorise entry, if satisfied that there exists sufficient need to enter and inspect.

Discussion Point 14

Submissions are invited on whether the Act should provide for a power of entry and inspection into unlicensed premises, by authorised officers, if they reasonably suspect that services are being provided in violation of the Act.

6.3 SELF ENFORCING INFRINGEMENT NOTICE SCHEME (SEINS)

The traditional enforcement strategy available when a breach under an Act or Regulation is detected is to prosecute the offender in the courts. While appropriate for some offences, it is not uncommon for the legal costs of such an action to exceed the penalty, even in undefended matters involving a breach of subordinate legislation. Such prosecutions have the effect of clogging up the court system, resulting in undue delays in other matters.

As a response, SEINS was introduced to reduce the cost to government and defendants of enforcement action and to minimise the time it takes to have a matter heard. SEINS is also aimed at easing the burden on the court system for offences of a minor nature. Under SEINS, referral of an offence to a court only occurs if the defendant wished to contest the matter. One example of the operation of SEINS occurs under the Motor Traffic Act. Under this Act the police are able to issue on-the-spot fines for a wide range of traffic offences, such as exceeding the speed limit.

Further benefits arising out of the use of SEINS are:

- because of the opportunity of finalising a matter administratively, there is no need for the defendant to spend time at court and the expense of retaining legal representation is reduced;
- if the penalty is paid, no criminal conviction is recorded;
- the defendant is not disadvantaged, as the option to defend the matter remains;
- the array of options provided to respond to regulatory breaches is enhanced, meaning that more appropriate responses can be made;
- matters which previously had to wait for months before being heard are able to be disposed of quickly; and
- the scale of investigations and the time taken to conduct them can be reduced, producing savings for business and government.

When an offence is detected, evidence is collected in the normal way (in the event that the matter is contested) and submitted to a senior officer with a recommendation that an infringement notice be issued. If issued, it would then be up to the defendant to either pay the fine or defend the matter.

In relation to private hospitals, SEINS may be appropriate for lesser offences which do not involve a serious and continued breach of licensing conditions, for example, single offences in relation to patient registers. SEINS is also being considered in relation to other public health legislation, such as the Public Health Act 1991.

Discussion Point 15

Submissions are sought on whether SEINS should be adopted for offences under the Act and Regulation.

APPENDIX A – TERMS OF REFERENCE

1. The New South Wales Department of Health will review the Private Hospitals and Day Procedure Centres Act 1988 in accordance with the terms for legislative review set out in the National Competition Principles Agreement. The guiding principles of the review are that legislation should not restrict competition unless it can be demonstrated that:
 - (i) the benefits of the restriction to the community as a whole outweigh the costs; and
 - (ii) the objectives of the legislation can only be achieved by restricting competition.
2. Without limiting the scope of the review, the Department shall:
 - (i) clarify the objectives of the legislation and their continuing appropriateness;
 - (ii) identify the nature of the restrictions on competition;
 - (iii) analyse the effect of the identified restrictions on competition on the economy generally;
 - (iv) assess and balance the costs and benefits of the restrictions; and
 - (v) consider alternative means for achieving the same results, including non-legislative approaches.
3. When considering the matters in (2), the review should also identify and consider:
 - (a) potential problems for consumers seeking to use the services of Private Hospitals and Day Procedure Centres, and other market failures, which need to be, or are being addressed by the legislation; and
 - (b) whether the effects of the legislation contravene the competitive conduct rules in Part IV of the Trade Practices Act 1974 (Cth) and the NSW Competition Code.
4. In addition to considering the matters identified above, the Department will consider the effectiveness of the current Act.
5. The review shall consider and take account of relevant regulatory schemes in other Australian jurisdictions, and any recent reforms or reform proposals, including those relating to competition policy in those jurisdictions.
6. The review shall consult with, and take submissions from, the profession, relevant industry groups, Government and consumers.

APPENDIX B – OVERVIEW OF REGULATORY MODELS

Non-legislative Strategies

The following are some examples of non-legislative mechanisms that may be used instead of, or in conjunction with, regulatory action:

- **Government Information campaigns:** Public benefit goals can be achieved using information campaigns or strategies to help inform consumers about options available to them in any given situation or to encourage consumers or the market to operate in a desired way.
- **Provision of information by organisations:** Government can encourage activities by organisations, such as industry associations or community organisations, which focus on providing consumers or individuals with material to assist them to make informed choices.
- **Financial incentives:** Rather than directing individuals, businesses or organisations to take certain measures or comply with standards, an alternative option is to provide financial incentives to encourage such groups to undertake certain steps.
- **Reliance on controls in existing legislation:** Existing legislation can be effective in achieving public benefit goals. In the case of the private health facilities market this could include reliance on Commonwealth legislation and existing state legislation such as the Poisons and Therapeutic Goods Act.
- **Voluntary codes of practice, guidelines and certification:** Rather than requiring that certain standards be met by organisations or business, Government can provide assistance to encourage such organisations to develop and meet standards without legislation, eg. through accreditation, certification or benchmarking exercises.
- **Litigation:** In many cases, litigation and its potential financial consequences may be an effective means to prevent people from exposing others to the risk of injury or harm. Government intervention to improve access to such remedies, such as the establishment of advocacy services, facilitation of class actions or broadening standing requirements so that organisations can sue on behalf of individuals may be an effective means of securing public benefit objectives. Equally, there are circumstances where litigation may be an inefficient, costly and ineffective means of achieving these goals.

Legislative Intervention

There are numerous options for legislative and regulatory intervention and these are broadly outlined below. It is important to remember that where legislation is utilised the preference is always for the lowest level of intervention required to achieve the stated aims.

- ***Mandatory information disclosure to the public:*** Requiring service providers to publish information can be an effective means of assisting the public to avoid products that may cause injury or harm or promote public health awareness of their rights. Examples are requirements to provide people seeking access to residential care with information about the quality of services; to disclose any interest their medical practitioner may have in the facility; and information about the complaints policy of the organisation.
- ***Information disclosure to government:*** Disclosure of information by service providers may be of little assistance because consumers may lack the skills, knowledge and experience to interpret that information. One regulatory option is to require businesses or organisations to provide certain information to the Government, which can then decide whether or not to issue a warning or other information to the public.
- ***General prohibitions on conduct:*** Legislative objectives can be achieved through a prohibition on certain specified conduct. For example, private hospitals are prohibited from accommodating more patients than they are licensed for.
- ***Legislative standards:*** The most common form of legislative intervention in response to public benefit issues is the setting of legislative standards that must be complied with. Failure to comply with the standards can result in imposition of a penalty or revocation of a license.
- ***Performance based regulation:*** Rather than specifying the manner in which services or businesses are meant to achieve a certain goal or outcome, for example by mandating the process to be used, legislation may set targets or 'performance standards' to be met. The regulatory system is focussed on the end to be achieved, rather than the means. Setting statutory 'outcome standards' such as those in the Commonwealth Aged Care Act is an example of this approach.
- ***Voluntary certification:*** Rather than specifying that all suppliers or service providers must meet certain standards, legislation would establish a system for certifying those that elect to meet the standards. While others can continue to provide the service, those that elect to be certified gain the right to use a specific title or accreditation symbol.
- ***Third party certification:*** Rather than relying on Government to certify that a product meets certain standards, legislation can provide that third parties may conduct the necessary inspections and issue a certificate specifying that the

product or service complies. Again, this can be structured so that those that elect to be certified gain the right to use a specific title or accreditation symbol. Accreditation by the Australian Council of Health Care Standards is an example of this.

- **Negative licensing:** Under this system, operators are required to meet certain legislative standards. Although no pre-approval is required before operation, where they fail to meet the standards they can be prohibited from engaging in the activity, either permanently or until they meet certain conditions, which may include third party certification.
- **Registration:** The requirement to meet certain standards can be supplemented by a requirement that all those wishing to provide the service or product must be registered. Although registrants may not be required to establish that they can meet certain requirements before being registered, where they fail to meet the standards, their registration can be cancelled and they are prevented from providing the service. The advantage of this system over negative licensing is that government maintains a register of service providers which enables inspections to be carried out more readily and inappropriate providers removed from the market.
- **Activity or business licensing:** This is generally considered the most restrictive form of regulation. Those wishing to provide a service must demonstrate to the relevant Government agency that they are capable of meeting the legislative standards. This is generally done by specifying that only certain people may apply, by requiring detailed inspections, or by requiring that certain equipment be used. A variant of this approach would involve recognition of membership of a professional association or standards organisation.
- **Approval processes:** Products or plans are required to be submitted to a Government agency for formal approval before they may be used or marketed.
- **Self-certification and auditing:** Under this arrangement, service providers would certify that their goods or services meet certain standards and provide certain information to Government agencies. The Government agency would then audit this information in appropriate cases to ensure that standards are being complied with.
- **Market based regulation -** Market orientated regulatory strategies place responsibility for the maintenance of standards with those making commercial decisions but establish a proper “market” in which this can occur. It may, for example, overcome an information imbalance between buyers and sellers of services, so that a market can operate more effectively, with the aim of promoting cost-effective strategies, creating flexibility and the opportunity for innovation.