

**PUBLIC BENEFIT TEST****REVIEW OF HYPERBARIC CHAMBERS LEGISLATION**

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## PUBLIC BENEFIT TEST

### REVIEW OF HYPERBARIC CHAMBERS LEGISLATION

#### 1. Synopsis

Queensland is the only Australian jurisdiction with specific public health legislation (ie Part 6 of the *Health Regulation 1996*) that restricts the possession and/or use of hyperbaric oxygen chambers.

While there are recognised risks associated with the use of hyperbaric chambers, the risks are no greater in Queensland than in other Australian jurisdictions, and are not significantly greater than risks associated with other activities that are *not* subject to this type of restriction.

To a significant extent, the current legislative requirements under Part 6 of the *Health Regulation 1996* duplicate other regulatory controls impacting on hyperbaric chambers, whether they are used for medically recognised ‘orthodox’ purposes or for ‘non-orthodox’ purposes.

For example, medically approved use of hyperbaric oxygen therapy is subject to the Commonwealth’s Medicare arrangements, which specify the requirements for hyperbaric facilities and personnel qualifications. In addition, the proposed Patient Care Standards under Queensland’s *Private Health Facilities Act 1999* require compliance with specified guidelines, including the Hyperbaric Oxygen Therapy Facilities Industry Guidelines. Registered health providers in Queensland are also accountable to their respective Registration Boards for clinical standards.

Other regulatory safeguards to protect consumers apply to both medical and non-medical providers, eg the Commonwealth’s Therapeutic Goods legislation and Queensland’s Fair Trading legislation. Workplace Health & Safety requirements in Queensland require hyperbaric chambers to be registered; for workers to be appropriately trained; and for plant to be used in a way that ensures the health and safety of workers, and the public.

In addition, there is a legislative mechanism in Queensland for consumer complaints to be made under the *Health Rights Commission Act 1991* about health services provided by all health providers, including medical and other registered health professionals, and alternative and ‘other’ providers of health services.

Non-regulatory approaches, such as industry-developed Guidelines for the safe use of hyperbaric chambers, are widely accepted and complied with, and an Australian Standard is also currently under development.

Other Australian jurisdictions, which do not have the legislative restrictions that apply in Queensland, rely on similar regulatory and non-regulatory controls as outlined above, and these jurisdictions have not reported adverse outcomes for public health and safety.

The legislative restrictions under review are thus not considered to be essential to protect public health and safety, and, since they also restrict consumer access to, and choice of, hyperbaric services, there is no net public benefit from retaining the restrictions.

**The Public Benefit Test has therefore concluded that the legislative restrictions under Part 6 of the *Health Regulation 1996* should be discontinued.**

## 2. Background

A hyperbaric chamber is a cubicle or container allowing oxygen to be administered to a person under pressure greater than that experienced in the surrounding atmosphere. Hyperbaric chambers are also referred to as **recompression** and **decompression** chambers, and are included in a category of containers known as pressure vessels.

Hyperbaric chambers may be:

- **Multi-place** (for use by more than one person). These may be used for acute problems, eg critically ill patients who require an attendant within the chamber.
- **Mono-place** (for use by a single person). These may be used to treat patients with non-acute medical conditions who do not require an attendant in the chamber with them.

The relevant legislative restrictions are contained in Part 6 of *the Health Regulation 1996*. The Regulation is due to expire on 1 July 2002.

Queensland is the only Australian jurisdiction with legislation restricting the possession and/or use of hyperbaric chambers.

A review of the legislative restrictions has been undertaken to consider their current relevance, as required under the Government's National Competition Policy (NCP) obligations to review all legislation that restricts competition.

Under NCP, legislation that restricts competition is to be reformed by the year 2000, unless it can be demonstrated that:

- (a) the benefits of the restriction (to the community as a whole) outweigh the costs to the community, and
- (b) the objectives of the legislation can be achieved only by restricting competition.

In accordance with NCP requirements, a Public Benefit Test (PBT) was undertaken to identify the benefits and costs of the current legislative restrictions, and to examine whether the objective/s of the legislation can be achieved *without* restricting competition.

**For this review, the assessment of public benefit includes consideration of health and safety issues associated with the use of hyperbaric oxygen therapy chambers.**

The respective impacts, costs and benefits associated with the current legislation and any other options must be identified in the PBT.

If, at the conclusion of the PBT process, a decision is made to continue a restriction, it must be reviewed again after 10 years.

### 3. The Legislation under Review

The legislation under review is Part 6 – Hyperbaric Chamber Therapy - of the *Health Regulation 1996*<sup>1</sup>.

#### 3.1 Legislative Objective

Although not explicitly stated, the objective (or intent) of the current legislation is to protect public health and safety by prohibiting the provision of hyperbaric oxygen therapy except where a provider meets the criteria prescribed in the legislation. The potential risks of hyperbaric oxygen therapy are outlined in Section 6 below.

#### 3.2 Legislative Restrictions

Section 62 of the *Health Regulation 1996* prohibits:

- the use of a compression/recompression chamber<sup>2</sup> for therapeutic purposes using hyperbaric oxygen, air or any other gas or mixture; and
- the possession of a portable compression (recompression) chamber that is capable of being used for a therapeutic purpose<sup>3</sup>.

Section 61 of the Regulation provides that the above prohibitions do not apply to:

- Therapeutic recompression for dysbaric illness, including decompression sickness and gas embolism, by persons qualified in diving supervision and in the operation of recompression facilities [as prescribed in the Regulation];
- A person who is qualified in the operation of a portable compression (recompression) chamber, as certified upon completion of a course approved by the chief executive [of Queensland Health];
- A medical practitioner who is qualified and experienced in underwater and hyperbaric medicine [with qualifications/training prescribed in the Regulation]
- A hospital or intensive care facility equipped with full resuscitation facilities and being used under the supervision of a medical practitioner [with qualifications as prescribed in the Regulation]
- A person using a chamber in relation to the health and safety of persons engaged in underwater diving [with the qualifications as prescribed in the Regulation];
- A compression chamber being used for a therapeutic purpose approved by the chief executive [of Queensland Health].

A person who is found guilty of a breach of Section 62 of the Regulation can be fined up to \$1500 (or up to \$7500 if a company is involved).

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<sup>1</sup> The *Health Regulation 1996* consolidated a number of health regulations, including the former *Hyperbaric Chamber Therapy Regulation 1989*.

<sup>2</sup> The Regulation defines a compression chamber as a chamber in which a person may be subjected to a pressure greater than that experienced at sea level atmospheric pressure or 1 atmosphere absolute, and includes a hyperbaric oxygen therapy chamber

<sup>3</sup> A therapeutic purpose is defined in the Regulation as a purpose of or in connection with:

- (a) preventing, diagnosing, curing or alleviating any disease in any person;
- (b) influencing, inhibiting or modifying a physiological process in any person.

#### 4. Review Options and Review Process

On 26 March 1999, letters were sent to more than 100 persons and groups with a potential interest in the review, enclosing the Terms of Reference and PBT Plan for the review and asking for submissions from interested parties. The PBT Plan proposed three options by which a policy objective of protecting the public could be achieved:

- Option 1** No statutory regulation (the Commonwealth *Therapeutic Goods Act 1989* would continue to regulate the importation and manufacture of hyperbaric chambers. [NB: Other regulatory and non-regulatory controls (as outlined in Section 8 below) would also remain in place].
- Option 2** Prohibition of the use of chambers other than by persons who are competent to use same (eg who possess specific qualifications)
- Option 3** A two tiered, risk-based approach, whereby the use of hyperbaric chambers operating at no higher than 3 atmospheres [absolute] would not be regulated, and those operating at a level higher than 3 atmospheres [absolute] would be limited to clinical settings, and restricted to persons who are competent to operate same.

On 27 March 1999 an advertisement was also placed in the Courier-Mail advising of the review, and calling for submissions from interested parties. Submissions to the review were subsequently received from the following fifteen (15) groups/persons:

- 1 Multiple Sclerosis Society of Queensland
- 2 Aviation Services, Department of Emergency Services
- 3 Hyperbaric Technicians & Nurses Association Inc (HTNA)
- 4 Diabetes Australia – Queensland
- 5 Dr J Knight, Editor, South Pacific Undersea and Hyperbaric Medical Society (SPUMS) Journal and SPUMS representative on Standards Australia Committee SF/17 and SF/46
- 6 The Wesley Centre for Hyperbaric Medicine
- 7 Australian & New Zealand Hyperbaric Medicine Group (ANZHMG)
- 8 Department of Diving & Hyperbaric Medicine, Fremantle Hospital
- 9 Submarine and Underwater Medicine Unit, HMAS Penguin
- 10 Hyperbaric Oxygen Treatment Association of Australia Inc (HOTAA)
- 11 Hyperbaric Oxygen Therapy Systems (Aust) (HOTS)
- 12 Bob Ramsay, Chairman, Hyperbaric Oxygen Treatment Facility Group (HOTFIG) Committee
- 13 Mr M Johnson, consumer
- 14 Australian Medical Association – Queensland Branch
- 15 Hyperbaric Medicine Unit, Townsville General Hospital

The submissions to the review have been considered, and officers of the Legislative Projects Unit, Queensland Health, have also undertaken additional research and consultation. Discussions have taken place with:

**Public Benefit Test****Review of Hyperbaric Chambers Legislation**

- Workplace Health and Safety Division of the Department of Employment, Training and Industrial Relations, in relation to safety and training requirements in relation to hyperbaric chambers
- The Commonwealth office of Therapeutic Goods Administration, in relation to requirements under the *Therapeutic Goods Act 1989*
- The Commonwealth Department of Health and Aged Care, in relation to a review of hyperbaric oxygen therapy being undertaken by the Medicare Services Advisory Committee supporting committee for hyperbaric oxygen therapy. The committee's work includes an assessment of the safety and effectiveness of hyperbaric oxygen therapy in indications for adjunctive care (eg the 'problem wound' category), and a cost-effectiveness analysis of such usage. The review has not yet been finalised, but an outcome is expected by the end of this year (2000).
- Directors of Hyperbaric Medicine Units in Australia
- the coordinator of an 'adverse events' register related to hyperbaric oxygen therapy
- Health Department officers in other Australian jurisdictions.
- Queensland Health officers (Legal & Administrative Law Unit; Office of the Chief Health Officer)

## 5. Industry analysis

### 5.1 The market in Australia

The range of providers and users of hyperbaric oxygen therapy throughout Australia includes:

- Hospitals (private and public)
- Dive Schools
- Diving operations on vessels (eg. armed forces, undersea mining operations)
- Sports Clinics
- Chiropractic/back pain clinics
- Commercial operations (eg. pearl farming)
- Alternate health facilities (eg for cosmetic and ‘well being’ purposes)
- Personal use (anecdotal information indicates that the sale of ‘personal use’ mono-place chambers was being promoted at a 1999 Body/Mind/Spirit Festival in Sydney).

The Australian market is quite small, ie a total of 33 chambers throughout the country, distributed as follows:

State/Territory	Number of hyperbaric chambers
ACT	1
NSW	4
Northern Territory	2
South Australia	4
Tasmania	2
Victoria	11
Western Australia	6
Queensland	3
<b>Total</b>	<b>33</b>

The Australian market could be described as comprising two separate markets, ie

- 1) A market for the provision of medically accepted ‘orthodox’ services (including for diving-related purposes, ie treatment of ‘the bends’), and
- 2) A market for the provision of other ‘non-orthodox’ services, eg sports injuries, back pain, ‘feel good’ and ‘cosmetic’ purposes

Of the 33 hyperbaric chambers throughout Australia:

- 22 are used for medically accepted ‘orthodox’ medical and diving-related purposes (2 in NSW, 3 in the Northern Territory, 4 in South Australia, 2 in Tasmania, 4 in Victoria, and 6 in Western Australia);
- 11 are used in sports centres, chiropractic clinics, and for other ‘non-orthodox’ purposes (2 in NSW, 7 in Victoria, 1 in the ACT, and 1 in Queensland).

Queensland is the only Australian jurisdiction to have legislative restrictions on the ownership and/or use of hyperbaric chambers, however all jurisdictions have other regulatory controls, eg workplace health and safety requirements. An overview of other Australian jurisdictions is attached as **Appendix 1**.

## 5.2 The market in Queensland

Within Queensland, there are currently only **three** known providers of hyperbaric oxygen therapy:

- (i) The Hyperbaric Medicine Unit, Townsville General Hospital;
- (ii) The Wesley Centre for Hyperbaric Medicine, Auchenflower; and
- (iii) The Runaway Bay Sports Super Centre at the Gold Coast.

The first two (hospital) facilities provide ‘orthodox’ (medically approved) services. They have multi-place chambers, for which a Medicare rebate may be paid when used for approved conditions<sup>4</sup>. Both these facilities meet the criteria provided under section 61 of the *Health Regulation 1996*, and so are ‘exempted’ from the legislative prohibition under section 62 of the Regulation.

The third (non-hospital) facility has a mono-place chamber, and provides ‘non-orthodox’ services, ie treatment of sports injuries, for which no Medicare rebate is payable. Queensland Health’s approval for this facility was given in May 2000.

Another (former) provider had a mono-place chamber, initially at the Broncos Stadium and subsequently at the Centenary Medical Centre, Spring Hill<sup>5</sup>, however in 1998 this chamber was sold to an interstate university medical centre.

There are indications that there may be other *potential* providers who may wish to enter the Queensland market. For example:

- An article published in 1998 in a regional Queensland newspaper<sup>6</sup> indicated that a Queensland group proposed to establish ‘health clinics’ in regional Queensland, Brisbane, Sydney and possibly another State capital, using both mono-place and multi-place chambers. The article referred to claims of turning ‘back the aging clock ... , enhancing memory, restoring pigmentation to grey hair and increasing the sex drive.’ The article also referred to 1,200 hyperbaric oxygen therapy systems in Russia, 800 in China and 300 in the United States, but gave no details as to where those figures were obtained. Data from a reliable source indicates that, in 1993, there were around 300 clinical chambers operating in the United States<sup>7</sup>. However, other (anecdotal) information indicates that there may be many more chambers in the US, eg approximately 650 mono-place chambers and 50–60 multi-place chambers, used mainly within the diving industry.
- A 1998 guest editorial in a US Journal of Sports Medicine suggested that the use of hyperbaric chambers for sports injuries is encouraged by ever-increasing competition in sports and increasingly high rewards for athletes, which places pressure on physicians to provide new, fast-acting treatments to shorten rehabilitation times. The authors noted that, although hyperbaric oxygen therapy is often promoted as a ‘quick-fix’ treatment, the benefits of using this therapy for soft tissue injuries remain unproven, while the risks are significant. The article suggested

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<sup>4</sup> See Section 8.8 for an overview of Medicare arrangements in relation to hyperbaric chambers.

<sup>5</sup> The Chief Health Officer gave approval for the operation of a Monoplace Chamber at Centenary Medical Centre on 14 March 1997. The approval rescinded the previous approval for a hyperbaric therapy unit at the Brisbane Broncos Stadium.

<sup>6</sup> Fassifern Guardian, (1998) ‘High oxygen therapy may help beat aging’, March 18, page five.

<sup>7</sup> Eric Kindwall, MD, ‘A History of Hyperbaric Medicine’, in Eric Kindwall (Editor), Hyperbaric Medicine Practice, Best Publishing Company, 1995, p. 15.

that physicians who do not deliver fast acting rehabilitation services to athletes face a perceived threat of being replaced, ie by another doctor who will<sup>8</sup>.

- An article in an Australian medical journal in 1998<sup>9</sup> referred to hyperbaric oxygen therapy as a “hot” new trend in sports medicine, often used to get injured athletes back into their sports quickly. This article, which referred to the high costs of treating sports injuries with hyperbaric oxygen therapy (for which there is no Medicare rebate), also noted the uncertain ratio of benefits to risks in using hyperbaric oxygen therapy for sports injuries.
- Internet searches reveal a number of US sites that promote the use of hyperbaric chambers for unsubstantiated purposes, including reduction of skin wrinkles in aging skin, recovery from laser resurfacing, post-operative healing after cosmetic surgery, and improved function in cerebral palsy.

The extent to which these *potential* providers are inhibited by the current legislative restrictions is unknown. However it is reasonable to assume that they may be discouraged from entering the market by the necessity to apply for Queensland Health approval, and the associated business costs that may be involved in obtaining such approval. Such costs could include, for example, obtaining and providing supporting information about the chamber and its proposed therapeutic use, delays in start-up while such approval is being obtained, obtaining legal advice where necessary, and other potential business costs.

### 5.3 ‘Orthodox’ and ‘non-orthodox’ usage of hyperbaric chambers

Hyperbaric chambers are used to deliver hyperbaric oxygen therapy for purposes that may be classified as ‘orthodox’ and ‘non-orthodox’:

- ‘Orthodox’ uses are treatments for medical conditions for which there is either strong scientific evidence of hyperbaric efficacy (eg decompression sickness, severe carbon monoxide poisoning) or strong suggestive evidence (eg radiation induced injury, prolonged failure of wound healing)<sup>10</sup>;
- ‘Non-orthodox’ uses are those for which there is no (medically recognised) evidence of benefit, including treatment of sports injuries, treatment of back pain, reversal of the aging process, and treatment for a range of health conditions, eg smoke inhalation, non-healing fractures, Multiple Sclerosis, Cerebral Palsy, Tinnitus.

#### 5.3.1 ‘Orthodox’ (medically approved)

‘Orthodox’ medical conditions for which hyperbaric chambers are commonly used<sup>11</sup> include:

- Decompression sickness (bends)
- Skin grafts and flaps (compromised)
- Carbon monoxide poisoning and carbon monoxide poisoning complicated by cyanide poisoning
- Carbon monoxide poisoning complicated by cyanide poisoning

<sup>8</sup> Editorial, American Orthopaedic Society for Sports Medicine (1998) Hyperbaric Oxygen Therapy in Sports, The American Journal of Sports Medicine, Vol. 26 pp. 489-90.

<sup>9</sup> Locke, S. *New goal in speed treatment: a HOT trend in sports medicine*, The Australian Doctor, 15 May 1998.

<sup>10</sup> Leach, R. Rees, P. Wilshurst, P. (1998) Clinical Review: ABC of oxygen. Hyperbaric Oxygen Therapy, British Medical Journal, 317:1140-1143.

<sup>11</sup> Indications for HB02: <http://www.uhms.org/Indications/indications/htm> accessed 26.05.00

- Necrotizing soft tissue infection
- Air or gas embolism
- Delayed radiation injury
- Acute anaemia (exceptional blood loss)
- Refractory osteomyelitis
- Crush injury, compartment syndrome, other acute traumatic ischemias
- Enhancement of healing in selected problem wounds
- Gas gangrene (clostridal myositis and myonecrosis)
- Thermal burns
- Intracranial abscess

Because hyperbaric oxygen therapy is generally provided over a period of time, usage is measured in terms of treatment sessions. The duration of single treatments of hyperbaric oxygen therapy may vary from 45 minutes for carbon monoxide poisoning to almost 5 hours for some severe decompression disorders. For treatment of problem wounds that do not respond to debridement or antibiotics, an average of 20 to 30 treatments lasting for 90 minutes can be expected<sup>12</sup>.

### 5.3.2 Available data for 'orthodox' hyperbaric services

Queensland Health data indicates that the number of episodes of in-patient hospital care provided in a decompression chamber in Queensland was as follows: 1996/97: 107 episodes of care; 1997/98: 615 episodes; and 1998/99: 1,321 episodes<sup>13</sup>. This data relates to admitted *in-patients* only, ie it does not include episodes of care provided to out-patients. The apparent increase in services between 1998/98 and 1998/99 may be due to commencement of the Wesley Centre for Hyperbaric Medicine in August 1998.

Townsville Hospital provided further information to the review that indicates that the total number of hyperbaric oxygen treatments provided at that facility (ie for in-patient and out-patient treatments) has been fairly stable, ie: 1996/97: 2,398 treatments; 1997/98: 2,690 treatments; and 1998/99: 2,581 treatments.

The Wesley Centre for Hyperbaric Medicine commenced operations in August 1998, but was not fully operational in terms of service provision until approximately one year later. However, in the 1999/2000 year, the Wesley Centre provided 2,812 services<sup>14</sup>.

In Australia, Medicare benefits for hyperbaric oxygen therapy are payable by the Health Insurance Commission for a restricted range of conditions and where the facilities meet certain conditions.

Data was sought from the Commonwealth to establish the number of hyperbaric oxygen services provided in Queensland *for which a Medicare benefit was paid* (ie for services provided to private patients in both public and private hospital facilities). However, their data had been collected on the basis of the address of the patient to whom the service was rendered, ie not the State where the service was actually provided, and thus was not considered to provide useful information for the purposes of this review.

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<sup>12</sup> Tibbles, P. Edelsberg, J. (1996) Hyperbaric Oxygen Therapy, New England Journal of Medicine, 334:1642-1648.

<sup>13</sup> Data provided by Health Information Centre, Queensland Health, September 2000.

<sup>14</sup> Information provided by Dr Simon Mitchell, Medical Director, Wesley Centre for Hyperbaric Medicine, October 2000.

As well as the hospital-based provision of hyperbaric oxygen therapy outlined above, information provided to the review indicates that there are 11 diving-related hyperbaric oxygen therapy chambers throughout Australia<sup>15</sup>, although one of these chambers may not be functioning. There may also be other hyperbaric chambers on ships in Australian waters.

### 5.3.3 'Non-orthodox' uses of hyperbaric oxygen therapy

Hyperbaric oxygen therapy is used for a number of non-orthodox purposes, including sports injuries, chiropractic use (back pain), and cosmetic purposes (eg anti-aging effects and to speed recovery after cosmetic surgery). Information provided to the review also indicates that (despite a lack of scientific evidence of benefit), it is also used to provide treatments for medical conditions such as Multiple Sclerosis, Tinnitus, non-healing fractures, traumatic brain injury, Cerebral Palsy and other conditions).

There may be significant potential for non-orthodox uses to become more common in the future.

Treatment of sports injuries appears to be a growing hyperbaric treatment area, and a hyperbaric chamber has recently been acquired by the Australian Institute of Sport in Canberra, where it is understood that scientific research to assess the efficacy of hyperbaric oxygen in sports medicine commenced in late 1999.

Spinal/back care treatments may also be a growing hyperbaric treatment area; a recent media article indicated that a 'Spinal Rehabilitation Group' in Melbourne had reported giving 'more than 21,000 treatments since its commencement in 1996'<sup>16</sup>.

Hyperbaric oxygen therapy has also been advertised to treat a range of conditions such as baldness, arthritis and senility. It has been claimed that such promotions have tainted the field of hyperbaric oxygen therapy with claims of 'quackery'<sup>17</sup>.

Hyperbaric oxygen therapy has also been used in the treatment of multiple sclerosis and cerebral palsy, however there is no scientific evidence to support its efficacy. A randomised control trial was recently undertaken at McGill University, Canada, to establish the effects (if any) of hyperbaric oxygen therapy on children affected by cerebral palsy. The results of the trial indicated that hyperbaric oxygen therapy offered no benefit; ie both the treatment and the control groups improved. That is, the placebo effect of extra care and attention led to the improvement in the children's symptoms<sup>18, 19</sup>.

It has been argued that non-orthodox uses of hyperbaric oxygen therapy for inappropriate and/or 'unproven' purposes may adversely affect the standing of genuine hyperbaric medicine and so discourage appropriate referrals for patients who could legitimately benefit from hyperbaric therapy.

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<sup>15</sup> 1 in NSW, 1 in Tasmania, 3 in SA, 1 in Victoria, and 5 in WA (including 1 Navy and 1 associated with the pearling industry).

<sup>16</sup> *The Age*, 1/1/2000.

<sup>17</sup> Dr Mike Bennett, <http://www.powh.edu.hyperb.htm> (accessed April 1999)

<sup>18</sup> Discussion with Dr Simon Mitchell, Diving and Hyperbaric Physician, Medical Director, the Wesley Centre for Hyperbaric Medicine, 28 June 2000.

<sup>19</sup> Details of this research have been submitted to a peer reviewed medical journal for publication. These research findings were also provided to the 2000 Annual Scientific Meeting of the Undersea Hyperbaric Medical Society.

On the other hand, contemporary trends suggest that consumers have increasing expectations about the 'right to choose' among various types of health-care, both 'orthodox' and or 'other' (non-orthodox) care. There has been increasing use of 'other' forms of health-care in recent decades, and there is little doubt that consumer relationships with medical practitioners, health departments and other health care professionals have changed in recent years<sup>20,21</sup>. These trends are likely to continue in the future, and consumer demand for 'other' treatments, including hyperbaric oxygen therapy treatments, could increase. However, financial constraints (ie, the costs of hyperbaric oxygen therapy, and the absence of a Medicare subsidy for non-approved uses) may limit this demand. Cost issues are discussed at Section 5.4 below.

#### 5.3.4 Available data for 'non-orthodox' hyperbaric services

There is presently only one 'non-orthodox' hyperbaric oxygen facility in Queensland; this facility has only recently been approved (May 2000), so there is no data available concerning the number of services provided by this facility.

Data relating to the use of hyperbaric oxygen therapy in 'non-orthodox' facilities throughout Australia is, in any event, anecdotal only. Information obtained from interstate Health Departments and Directors of Hyperbaric Medicine Units in public hospitals indicates that, Australia-wide, there are eleven hyperbaric oxygen chambers that may be wholly or partly used for non-orthodox purposes (ie, non-diving purposes and/or non Medicare approved purposes). Those uses include sports medicine uses (eg treatment of sports-related injuries), treatment of multiple sclerosis (as discussed at 5.3.3 above) and chiropractic use (eg treatment of chronic back pain<sup>22</sup>). An overview of service providers outside Queensland (including non-orthodox providers) is included at **Appendix 1**.

The number of chambers in existence for personal (home-based) use is unknown, however it is understood that in New Zealand, some parents of children with cerebral palsy have hyperbaric chambers in their backyards. Presumably this could also be the case in Australia.

Some anecdotal information was given about an interstate 'oxygen rejuvenation' clinic offering hyperbaric oxygen therapy for general wellbeing, sports injuries and cosmetic purposes. The clinic had reputedly attracted little business<sup>23</sup>.

A number of staff in hyperbaric medicine units have commented that, as the Australian market is fairly small, most personnel have a reasonable knowledge of existing facilities or events that take place in the hyperbaric field. Consequently, the above outline of hyperbaric chambers available for alternate use is likely to be reasonably accurate.

## 5.4 Costs of hyperbaric oxygen therapy treatments

### 5.4.1 Costs to providers – establishment and operating costs

The costs of establishing a hyperbaric oxygen facility in Queensland would include:

<sup>20</sup> Opper, I. The new players: consumer and community representation in Queensland's health system. Brisbane: Consumer's Health Advocacy (1996).

<sup>21</sup> Cox, K., Doctor & patient: exploring clinical thinking. Sydney: University of NSW Press Ltd. . 1999.

<sup>22</sup> Information provided by ANZHMG discussion list in June 1999.

<sup>23</sup> Information provided by ANZHMG discussion list, June 1999.

- Purchase of a chamber (eg \$100,000-\$200,000 for a mono-place unit; \$1-2 million for a multi-place chamber);
- Provision of trained staff to operate the chamber;
- Installation costs (eg ‘plumbing in’) of multi-place chambers; and
- Operating costs (information provided to the review suggests that operating costs for a multi-place hyperbaric facility would be in the vicinity of \$1 million per year).

**In addition**, for facilities that do not automatically qualify for exemption under the current legislation (eg sports centres, chiropractic clinics), their establishment expenses would also include costs associated with obtaining Queensland Health’s approval based on safety and quality issues. These expenses would include, for example, costs associated with providing supporting information about the chamber and its proposed therapeutic use, potential delays in start-up while such approval is being obtained, obtaining legal advice where necessary, and other potential business-related costs to obtain approval<sup>24</sup>.

#### 5.4.2 Costs to consumers – treatment costs

Treatment costs to consumers for hyperbaric therapy may vary significantly according to:

- whether the treatment is for a medically approved ‘orthodox’ treatment, or for a ‘non-orthodox’ treatment; and
- whether a ‘medically approved’ treatment is provided to a public patient in a public hospital, or to a private patient in a public or private hospital.

##### 5.4.2.1 Approved treatments for ‘orthodox’ purposes

For ‘medically approved’ treatments, public patients in public hospitals are not charged for hyperbaric oxygen therapy (funding of public hospitals is a State matter).

Treatment costs for private patients in public hospitals, and for services provided in private hospitals, attract a Medicare rebate (provided the treatment meets the applicable Medicare criteria), and may also attract a private health fund benefit.

For private patients in recognised public and private hospitals, Medicare and private health insurance rebates are available for approved treatments. The ‘scheduled fee’ under Medicare (for treatments of between 90 minutes and 3 hours) is currently \$199.10, however, since medical practitioners may charge a higher fee than the Medicare ‘scheduled’ fee, the cost of a private treatment of up to 3 hours is probably over \$200.

##### 5.4.2.2 Medicare rebates

For Medicare approved treatments in hospitals that meet Medicare required standards, the following rebates<sup>25</sup> apply:

Table 3 Medicare rebates

Item #	Scheduled fee	Medicare Benefit
13020 Hyperbaric Oxygen therapy performed in a comprehensive hyperbaric medicine facility for a period in the hyperbaric chamber of between 1 hour 30 minutes and 3 hours, including any associated attendance	\$199.10	75% \$149.35 85% \$159.25

<sup>24</sup> Queensland Health approvals may currently be processed in approximately 1-3 months.

<sup>25</sup> See Medicare Benefits Schedule Book operating from 1 November 1999, group T1 Miscellaneous Therapeutic Procedures.

Item #	Scheduled fee	Medicare Benefit
<b>13025</b> Hyperbaric Oxygen therapy performed in a comprehensive hyperbaric medicine facility for a period in the hyperbaric chamber greater than 3 hours, including any associated attendance – per hour (or part of an hour)	\$89.05	75% \$66.80 85% \$75.70
<b>13030</b> Hyperbaric oxygen therapy performed in a comprehensive hyperbaric medicine facility where the medical practitioner is pressurised in the hyperbaric chamber for the purpose of providing continuous life-saving emergency treatment, including any associated attendance – per hour (or part of an hour)	\$125.75	75% \$94.34 85% 106.90

#### 5.4.2.3 Private Health Fund benefits

Discussions with representatives from MBF and Medibank Private indicated that full or partial private health cover is provided for hyperbaric oxygen therapy treatments given to hospital in-patients.

For example, under MBF arrangements, medical practitioners may agree to accept the MBF payment (as well as the Medicare benefit rebate for hyperbaric oxygen treatment), with no further costs to the patient.

Medibank Private pays a benefit towards in-hospital hyperbaric oxygen treatment. For out-of-hospital treatments, there could be some rebate to the consumer if hyperbaric oxygen treatments were supplied by accepted ‘extras’ cover providers (eg physiotherapists). However, these rebates would only be for a *consultation* with an approved provider, and the provider would have to be registered with Medibank Private.

#### 5.4.3 Costs of non-orthodox treatments

Hyperbaric treatments for ‘non-orthodox’ purposes do not attract a Medicare rebate. It has been suggested that medical practitioners in attendance at sports medicine and/or chiropractic clinics may bill clients for their *consultations* (which could attract a Medicare rebate), however, Medicare rebates for *hyperbaric oxygen treatments* are payable only for specified (Medicare-approved) conditions and in Medicare approved facilities.

Little information is available about the costs to consumers of hyperbaric oxygen therapy for treatments that are not recognised for Medicare rebates (eg sports injuries, sports recovery, post-cosmetic surgery treatments, anti-aging, etc).

Anecdotal information suggests that treatment could cost around \$200 or more for each session of treatment. As previously noted, hyperbaric oxygen therapy may involve multiple treatment sessions, so the costs of a ‘course’ of treatment could be quite significant.

Some consumers, eg athletes and members of sports clubs, may be prepared to bear the entire cost of hyperbaric oxygen therapy treatments themselves, and, it can be argued, should have the right to choose and access such treatments. However, in doing so, consumers also face the potential risks associated with hyperbaric oxygen therapy (see Section 6 below).

## 6. Risks associated with Hyperbaric Oxygen Therapy

There is a wide range of literature indicating the risks associated with hyperbaric oxygen therapy, and the need for medical assessment prior to treatment. A recent US paper<sup>26</sup> suggested that, when used according to standard protocols, with oxygen pressures not exceeding 3 atmospheres and treatment sessions limited to a maximum of 120 minutes, hyperbaric therapy is safe. Submissions to the review, however, indicate that other practitioners may not agree that there is any difference in risks relative to whether a chamber is above or below 3 atmospheres.

### 6.1 Absolute and relative contra-indications for hyperbaric oxygen therapy

A recently published US text on hyperbaric medicine indicates that there are some *absolute contraindications* for hyperbaric oxygen therapy (eg untreated pneumothorax, treatment with Disulfiram, Cis-Platinum and Mafenide Acetate), and some *relative contraindications* (eg upper respiratory infections and chronic sinusitis, seizure disorders, emphysema with CO<sub>2</sub> retention, high fevers, history of spontaneous pneumothorax, history of thoracic surgery, history of surgery for otosclerosis, viral infections, congenital spherocytosis, and history of optic neuritis)<sup>27</sup>.

### 6.2 Complications and side-effects

The same US text referred to in 6.1 above, also notes a range of complications and side effects from hyperbaric oxygen therapy, including barotrauma of the ear, round window blowout, sinus squeeze, visual refractive changes, numb fingers, dental problems, claustrophobia, seizures and pulmonary oxygen toxicity<sup>28</sup>.

Australian literature also notes various complications and side effects from hyperbaric oxygen therapy, including barotrauma (ear pressure), oxygen toxicity, as well as gastrointestinal pain and discomfort<sup>29</sup>. The following list indicates the range of contraindications and precautions for hyperbaric oxygen therapy (please refer to the source for full details).

**Table 4: Contraindications and precautions for use of Hyperbaric Oxygen therapy**<sup>30</sup>

Pneumothorax	Particular care must be taken with patients who give a history of chest trauma or thoracic surgery
Asthma	Small airway hyper-reactivity may result in air trapping & pulmonary barotrauma
Upper Respiratory Tract Infections	Relative contra-indications due to difficulty such patients may have in clearing their ears and sinuses. Elective treatment best postponed
Viral Infections	Viral infections may be worsened after HBO, however no studies to give convincing evidence of this
High Fevers	Fevers >38.5 deg C tend to lower seizure threshold due to O <sub>2</sub> toxicity

26 Tibbles, P. and Edelsberg, J. (1996), Hyperbaric Oxygen Therapy, New England Journal of Medicine, 334: 1642-1648.

27 Eric P Kindwall, MD, 'Contraindications and Side Effects to Hyperbaric Oxygen Treatment', in Kindwall (Ed), Hyperbaric Medicine Practice, Best Publishing Company, Arizona, 1995, pp.46-51.

28 Kindwall, op.cit., pp. 51-54.

29 Bennett, M. Medical Director, Prince of Wales Hospital, <http://www.powh.edu.au/hyperb.htm> (accessed April 1999)

30 Bennett, M. Medical Director, Prince of Wales Hospital, <http://www.powh.edu.au/hyperb.htm> (accessed April 1999).

Emphysema with CO <sub>2</sub> retention	Caution should be exercised with high pressures + concentrations of oxygen
Treatment with Doxorubicin	This drug, an antibiotic used in various malignant diseases, becomes increasingly toxic under pressure
Treatment with Cisplatin	There is some evidence that this drug, used in the treatment of some tumours, retards wound healing when combined with HBO
Treatment with Disulfiram	Evidence to suggest that this alcohol deterrent drug blocks the production of superoxide dismutase and may severely effect the body's defences against oxygen free radicals. Experimental evidence suggests that single exposure to HBO is safe but subsequent treatments may be unwise
Optic Neuritis	Reports in patients with a history of optic neuritis of failing sight and even blindness after HBO therapy – extremely rare, but of tragic consequence
Congenital spherocytosis	Such patients have fragile red blood cells (due to excess quantities of haemoglobin) and treatment may result in massive haemolysis
History of middle ear surgery or disorders	Such patients may be unable to clear their ears, or risk further injury with vigorous attempts to do so. ENT consultation for possible placement of grommets is wise
History of seizures	HBO therapy may lower the seizure threshold
Pregnancy	Exercise caution, ie limit treatment of pregnant women to emergency situations

Some literature indicates that the above list may be overly cautious. For example, Dr Kindwall in the US notes that research in Russia between 1979 and 1983 concerning 700 pregnant women failed to demonstrate any maternal or fetal complications or mortality<sup>31</sup>.

Dr Kindwall also notes that many of the above side-effects listed above may be minor (eg numbness of the fingers), temporary (eg vision changes), rare (eg dental pain, seizures), or unusual (eg claustrophobia)<sup>32</sup>. In Australia, it has also been suggested that, to date, the incidence of complications arising from side effects from hyperbaric oxygen therapy is extremely low<sup>33</sup>.

Reversible myopia is said to be the most common side effect of hyperbaric oxygen therapy, and a few patients may experience mild-to-severe pain from rupture of the middle ear, the cranial sinuses, and in rare cases, the teeth or lungs as a result of rapid pressure changes. Rarely, generalized seizures may occur, but these are self-limiting, and cause no permanent damage. With repeated exposure, some patients have reversible tracheo-bronchial symptoms (eg chest tightness, a sub-sternal burning sensation, cough and reversible decrements in pulmonary function). Claustrophobia can occur in mono-place chambers, and approximately one patient in 10 will have severe anxiety. Sometimes treatment can be attempted later with appropriate sedation<sup>34</sup>.

### 6.3 Pre-Treatment Precautions:

Literature examined during the review indicates that a range of pre-treatment precautions should be taken prior to providing hyperbaric oxygen therapy, eg:

- Pre-treatment medical examination to check ears, lungs, eyes, etc
- Alcohol should not be consumed for at least eight hours before treatment

<sup>31</sup> Kindwall, *op.cit.*, p.48.

<sup>32</sup> Kindwall, *op.cit.*, pp. 51-54.

<sup>33</sup> Dr David Wilkinson, Senior Registrar in hyperbaric medicine with Royal Adelaide Hospital, quoted by Dr Phil Hamdorf in *Hyperbaric Medicine: The new frontier*, Sports Health (publication details unknown, copy article from Manly Hospital Library 13/5/99).

<sup>34</sup> Kindwall, *op.cit.*, pp.51-54.

- Skin products that have alcohol or petroleum in them (eg hair spray, most cosmetics, aftershave, oils, creams) should not be used
- Only 100% cotton garments should be worn inside the chamber
- Items such as watches, dentures, hearing aid, jewellery, contact lens, wigs, hairpieces and other prostheses should be removed before entering the chamber
- Smoking is prohibited during entire period of hyperbaric therapy, in addition to smoking material (such as lighters and matches) inside the chamber

#### **6.4 Fires in hyperbaric oxygen therapy chambers**

Several submissions to the review raised the risk of fires in hyperbaric chambers, although one stakeholder submission to the review commented that “fire in a boarding house or nightclub in Australia is of higher risk value”. While that comment is not necessarily supported, the risk of hyperbaric fires in Australia does not appear high, based on the findings of an international research paper on hyperbaric fires.

The 1997 research paper<sup>35</sup> indicates that throughout the world, 77 fatalities occurred in 35 hyperbaric chamber fires between 1923 and 1996. The paper notes that 19 of the 25 fires in clinical hyperbaric chambers occurred in Asia, resulting in 58 fatalities.

The paper also notes that chamber fires before 1980 were principally caused by electrical ignition, but that, since 1980, chamber fires have been primarily caused by prohibited sources of ignition that an occupant carried inside the chamber. An analysis of the 17 fires occurring since 1980 indicates that electrical ignition sources have been virtually eliminated from hyperbaric chambers, with the exception of China, where 83% (9 of 11) of fires were reported as ignited by electrical components or static electricity.

The paper notes that the other eight fires that have occurred since 1980 were all ignited by items that an occupant carried into the chamber, eg butane hand-warmers (Japan), spark-producing toys (China, Italy), a lit cigarette (China), a microwave-heated blanket (USA), and one unknown (Russia).

The paper notes that medical and technical personnel who operate clinical hyperbaric facilities should know the potential for fire in chambers, and must be especially vigilant to prevent its occurrence.

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<sup>35</sup> Sheffield, P. Desautels, D. (1997), Hyperbaric and hypobaric chamber fires: a 73 year analysis, Undersea and Hyperbaric Medical Society Inc.

## 7. Risks from other health related procedures/devices

The risks associated with hyperbaric oxygen therapy have been outlined above, however it could also be argued that there are serious risks associated with other health and pseudo-health equipment and procedures, especially if provided by an unqualified or incompetent provider, or if a device is used inappropriately. However, in many cases there are no legislative restrictions on those procedures or equipment. Examples could include:

- Facial treatments by beauty therapists using Level 1 or Level 2 lasers to provide laser resurfacing services.
- The provision of ‘colonic irrigation’ treatments (which involve the insertion into the body of tubes and liquids to ‘wash out’ the bowels), could also be considered a risky procedure, particularly when performed by a person without appropriate clinical training and/or without appropriate infection control procedures.
- Some home health-care products may also cause injury; for example, home-based electrical equipment (TENS<sup>36</sup>) for pain relief may inflict painful burns.
- Sports equipment (whether in sports centres or domestic use) may also cause injury if used inappropriately. For example, ‘Gravity Boots,’ where a person wears boots attached to a bar and hangs upside down are available in some sports stores in Australia and are said to provide a form of traction and to have other alleged health benefits. There are risks of severe injury if the bar collapses while the subject is suspended in mid air. It is understood that the Commonwealth’s Therapeutic Goods Administration is currently investigating a complaint with regard to a number of unsubstantiated health claims made by a manufacturer about this product<sup>37</sup>.

The above examples are given to demonstrate that restrictive legislative controls do not apply to a range of other products and services that provide (or allegedly provide) health benefits, and from which consumers may also be at risk.

It is useful to note that all persons involved in the provision of therapeutic interventions (both orthodox and non-orthodox) have common law responsibilities to ensure:

- (i) That they avoid causing harm to other persons; and
- (ii) That, before providing a service to a consumer, they have provided sufficient information to gain that person’s *informed consent* to the procedure<sup>38</sup>.

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<sup>36</sup> TENS (Transcutaneous Electro Neuromuscular Stimulation)

<sup>37</sup> A complaint was made to the Therapeutic Goods Administration during research for this PBT document (June 2000).

<sup>38</sup> *Informed consent* involves (i) provision of relevant information (including information about potential risks) about a proposed treatment by the health-care provider, (ii) understanding of that information on the part of the health-care consumer, and (iii) voluntary consent to the treatment by the consumer (who must be capable of providing such consent).

## 8. Other regulatory and non-regulatory controls on hyperbaric chambers

Apart from the legislation under review (outlined in Section 3), there are a range of other regulatory and non-regulatory controls that apply to the possession and/or use of hyperbaric oxygen chambers, including:

- *Workplace Health and Safety Act 1995*
- *Fair Trading Act 1989*
- *Therapeutic Goods Act 1989* (Commonwealth)
- *Health Insurance Act 1974* (Commonwealth)
- *Trade Practices Act 1974* (Commonwealth)
- Australian Standards
- Industry Codes of Practice (eg Hyperbaric Technicians and Nurses Association (HTNA) standards)
- *Private Health Facilities Act 1999*
- *Health Rights Commission Act 1991*
- *Health Practitioners (Professional Standards) Act 1999*

### 8.1 The Workplace Health and Safety Act 1995 (WH&S Act)

The WH& S Act mandates a duty of care for:

- employers to take steps to ensure the safety of employees at work, and;
- employers and self-employed persons to conduct their business in a manner which ensures their own health and safety, the health and safety of people not in their employment, *and the health and safety of members of the public who may be affected (emphasis added)*.

Significant penalties apply under the WH & S Act for failing to discharge obligations, eg, maximum penalties of:

- 800 penalty units (up to (\$60,000) or 2 years imprisonment if a breach causes death or grievous bodily harm
- 500 penalty units (up to \$37,500) or 1 year imprisonment if a breach involved exposure to a substance that is likely to cause death or grievous bodily harm
- 500 penalty units (up to \$37,500) or 1 year imprisonment if the breach caused bodily harm.

Companies may receive fines of up to **five times** the maximum fine that an individual receives, for example the imposition of 800 penalty units on a company could result in a fine of up to \$300 000.

Consultation with Workplace Health & Safety officers indicates that a basic element in fulfilling the duty of care under the Act is ensuring that workers have appropriate knowledge of hazards and risks associated with the workplace for themselves and others. This includes the provision of appropriate training, and Workplace Health & Safety officers have indicated that they would require a hyperbaric chamber operator to be trained to a standard that includes essential knowledge concerning risks and hazards of the equipment.

Australian Standard 2815.3 (Training and certification of occupational divers), includes training on a number of aspects of hyperbaric chambers, such as their uses and limitations, chamber operation skills and maintenance, and patient observation/medical

observation (under direction). However, the Director of a Hyperbaric Medicine Unit has indicated that the provisions of this Standard would not be suitable for treatment with hyperbaric oxygen therapy that is not related to diving<sup>39</sup>.

### **8.1.1 Access to WH&S requirements**

Under the WH&S legislation, there is a requirement to register hyperbaric chambers with Workplace Health and Safety, and to observe the Code of Practice for Plant<sup>40</sup> (see below). As noted in the preceding paragraph, there is also an expectation that hyperbaric chamber operators will have a certain level of training.

It was noted during this review that WH&S requirements in relation to hyperbaric chambers are not easily located in that legislation, for example:

- the WH&S duty of care requirements are mandated under the *Workplace Health & Safety Act 1995*;
- the requirement to register hyperbaric chambers is dealt with under various components of the *Workplace Health & Safety Regulation 1997* (see below); and
- risk management requirements are dealt with in the Advisory Standard for Plant (see below).

Workplace Health & Safety officers have indicated that their agency could explore the possibility of providing an ‘information link’ to make the requirements more readily accessible. The ‘information link’ could be made available either as ‘hand-outs’ and/or as a link on the WH&S Internet site, and could provide a summary of what is required in relation to hyperbaric chambers in Queensland.

### **8.1.2 Workplace Health and Safety Regulations**

Part 2 of the *Workplace Health and Safety Regulation 1997* requires that all hyperbaric oxygen therapy chambers be registered with the Division of Workplace Health and Safety and that the design of chambers also be approved. The relevant sections of the Regulation are sections 10, 11 and 12, and Schedules 3, 4 and 9 (Schedule 3 deals with registration of plant; Schedule 4 deals with design of registrable plant; and Schedule 9 defines ‘registrable plant’). The relevant criteria for registration is compliance with Australian Standard 1200 and PVHO/1 (pressure vessels for human occupancy) in relation to manufacturing requirements, and AS 2971 in relation to design of a pressure vessel (including a hyperbaric oxygen therapy chamber).

### **8.1.3 Workplace Health & Safety Advisory Standard for Plant**

The WH&S Advisory Standard ‘Plant 2000’ imposes obligations on manufacturers, importers, suppliers, erectors and installers, employers, managers, principal contractors and workers at a workplace that uses plant (which includes hyperbaric chambers).

An Advisory Standard gives practical advice on how to identify and manage exposure to risks. Those who have obligations under this Standard must either comply with the provisions of the Code, or adopt another method that demonstrates that proper diligence and reasonable precautions have been met.

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<sup>39</sup> Personal communication, June 2000.

<sup>40</sup> Division of Workplace Health and Safety, Advisory Standard: Code of Practice for Plant, “Plant 2000.”

Employer's obligations include ensuring that the workplace health and safety of the employer's workers and others is not affected by the way the employer conducts his or her business and work activities. Risk management procedures must be in place.

Workers who are likely to be exposed to plant risks and anyone supervising these workers should be trained and provided with information on:

- The nature of the hazards and risks associated with the plant and systems of work
- The need for, and correct use and maintenance of control measures
- Operation of plant and the procedures for safe use of the plant
- The use, fit, testing, maintenance and storage of any personal protective equipment required
- Emergency procedures in case of a plant malfunction or other incident
- The location of information relating to safe use of plant

Safe work practices and operating procedures relating to the use, maintenance and inspection of plant should be developed, widely distributed, and updated regularly.

Consideration must be given to the competency of staff. This could be, for example by the person's qualifications, information from referees, and past work experience.

Persons in control of workplaces must make sure that the risk of injury or illness from the plant is minimised when the plant is used properly.

Workers must take reasonable care for other people's safety, and use health and safety measures appropriately<sup>41</sup>.

## **8.2 Trade Practices Act 1974 (Commonwealth) and Fair Trading Act 1989 (Qld)**

The objective of the Commonwealth's *Trade Practices Act 1974* (TPA) is to enhance the welfare of Australians through the promotion of competition and fair trading and provision for consumer protection. The Act proscribes certain anti-competitive conduct and unconscionable, misleading, deceptive or false trading practices. The TPA also mandates requirements in relation to product safety standards.

Generally, the Act applies to the business and commercial activities of (a) corporations and (b) sole traders or partnerships whose activities cross State boundaries, take place within a Territory, or are conducted by telephone or post, or use radio or television.

The Australian Competition and Consumer Commission (the ACCC) is responsible for compliance with, and enforcement, of the TPA. Health and safety issues are regarded as a priority area for the ACCC, and in recent years, it has taken enforcement action on a number of 'misleading advertising' matters in the health sector, eg impotency treatments, haemorrhoid treatments, hair removal, and laser eye surgery.

In a recent Court case, *ACCC v On Clinic Australia Pty Ltd, Men Only Medical Clinic Pty Limited, and Potent-C-Clinics (Australia) Pty Ltd* (1996) ATPR 41 – 517 at (42, 458), Justice Tamberlin discussed a breach of section 52 of the TPA. This relates to service providers being required to tell the truth or refrain from giving an untruthful

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<sup>41</sup> Department of Employment, Training and Industrial Relations, Advisory Standard *Plant 2000*.

impression. He stated that...*assertions should be true as a matter of fact, if they are not to mislead and contravene the norms of conduct prescribed by the Act*<sup>42</sup>.

In *Taco Co of Australia Inc v Taco Bell Pty Ltd* (1982) 42 ALR 177, Justice Franki confirmed that a ... *matter is to be considered by reference to all persons who come within the relevant section of the public including the astute and the gullible, the intelligent and the not so intelligent, the well-educated and the poorly educated*<sup>43</sup>.

The ACCC recently undertook legal action against *Giraffe World Australia* for promoting and marketing a product known as an 'ion mat', with claims that it can displace positive ions in the body, and create health benefits such as reduced stress and fatigue, improved circulation, the reduction of cancer causing cells, building up the immune system, and curing insomnia, etc. The Court declared that Giraffe World's conduct breached the misleading or deceptive provisions of the Act, and imposed injunctions, and gave leave to the ACCC to seek orders for compensation on behalf of affected consumers<sup>44</sup>.

Civil remedies can also apply for breaches of sections 51AB, 52 or 74 of the TPA, such as damages, corrective advertising and injunctions to stop the conduct<sup>45</sup>.

The duty to provide information, including details about risks, is greater where procedures are elective or not medically necessary. Under the TPA, advertising includes oral statements made by practitioners. Information must be honest, accurate and complete. Claims regarding cures for diseases such as HIV/AIDS and asthma should not be made unless they can be verified by scientific evidence, for example anecdotal information from consumers about the product or service would not usually be sufficient to verify unsubstantiated claims<sup>46</sup>.

The objective of Queensland's *Fair Trading Act 1989* is to provide for an equitable, competitive, informed and safe market place. The *Fair Trading Act 1989* mirrors the Commonwealth TPA. For example, section 40 of this Act includes a prohibition against representing that goods or services have sponsorship, approval, performance, characteristics, accessories, uses or benefits they do not have.

This Act applies to corporations and natural persons, (including incorporated businesses that do not operate across State boundaries)<sup>47</sup>. An individual who was found guilty of a breach of section 40 of the *Fair Trading Act 1989*, for example, could face a maximum fine of \$40,500 (up to \$202 500 for a corporation).

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<sup>42</sup> *Submission to the NSW Inquiry into Cosmetic Surgery* April 1999, page 8. <http://www.accc.gov.au> accessed 22/06/00

<sup>43</sup> *Submission to the NSW Inquiry into Cosmetic Surgery* April 1999, page 9. <http://www.accc.gov.au> accessed 22/06/00

<sup>44</sup> *Fair Treatment? Draft guide to the Trade Practices Act for the promotion of Health and Medical Services, October 1999, p.21.*

<sup>45</sup> *Submission to the NSW Inquiry into Cosmetic Surgery, April 1999.* <http://www.accc.gov.au> accessed 22/06/00

<sup>46</sup> *Fair Treatment? Draft guide to the Trade Practices Act for the promotion of Health and Medical Services, October 1999.* <http://www.accc.gov.au> accessed 22/06/00

<sup>47</sup> *Submission to the NSW Inquiry into Cosmetic Surgery* April 1999. <http://www.accc.gov.au> accessed 22/06/00

### 8.3 Therapeutic Goods Act 1989

The Therapeutic Goods Administration is a Commonwealth body which regulates the supply of therapeutic goods in Australia, with the intention of protecting health care workers and the Australian public by ensuring the safety, quality and efficacy of therapeutic goods.

The Therapeutic Goods Administration has advised the review that, before a transportable hyperbaric chamber may be supplied within Australia, it must be listed in the Australian Register of Therapeutic Goods (ARTG)<sup>48</sup>.

To obtain a listing in the ARTG, the sponsor of a hyperbaric chamber product must first complete an application form providing substantial information about the product<sup>49</sup>, and must provide a declaration that the chamber complies with prescribed standards, including standards for manufacturing, electrical safety and electro-magnetic compatibility.

Sponsors of therapeutic devices must notify, in the application form for ARTG listing, accurate details of any regulatory action against them by any government authorities, both in Australia and overseas, in relation to therapeutic devices.

Sponsors of therapeutic devices must also notify the ARTG whether any of the devices listed in the application have been refused registration in another country; or are subject to any bans, recall or product correction; any investigation in relation to performance, quality, safety and efficacy; or any restrictions or conditions relating to the fitness of use of the device for certain purposes or categories of patients following supply.

Sponsors of therapeutic devices are required to notify any safety issues/adverse incidents to the TGA, and the TGA also encourages users to report any issues/incidents of concern. If the TGA has safety concerns about any therapeutic device, it may issue a hazard alert or product recall order. The sponsor of the device is responsible for compliance with such notices/orders and must bear any associated costs.

The TGA has also advised that **all** therapeutic goods (including both transportable *and* fixed hyperbaric chambers) must comply with the labelling and advertising standards prescribed under the *Therapeutic Goods Act 1989*. The Act allows for the Minister to publish standards for various therapeutic goods (or classes of therapeutic goods).

The TGA is currently developing a new regulatory system for medical devices, and proposes to release an Exposure Bill for industry comment later this year, and to conduct information seminars in most capital cities throughout Australia<sup>50</sup>.

### 8.4 Medicare arrangements under the Health Insurance Act 1973

At present, Medicare rebates are payable only for Hyperbaric Oxygen treatments given in a comprehensive hyperbaric medicine facility<sup>51</sup>, ie, a separate hospital area which can provide the following:

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<sup>48</sup> Hyperbaric chambers that are permanently plumbed/wired into a facility are not required to be listed in the ARTG.

<sup>49</sup> The 36 page TGA application form for therapeutic devices is available at <http://www.health.gov.au/tga/docs/html/dr4.htm>

<sup>50</sup> Update information is available at <http://www.health.gov.au/tga/docs/html/mdharmon.htm>.

<sup>51</sup> Explanatory Note T1.1 for Miscellaneous Therapeutic Procedures (Hyperbaric Oxygen Therapy), provided by the Health Insurance Commission, May 1999.

- hyperbaric oxygen therapy at a treatment pressure of at least 2.8 atmospheric pressure absolute at all times
- mechanical ventilation and invasive cardiovascular monitoring within a multiplace chamber for the duration of the hyperbaric treatment at all times
- support from at least one specialist anaesthetist, consultant, physician or medical practitioner who holds the Diploma of Diving and Hyperbaric Medicine of the South Pacific Underwater Medicine Society who is rostered and immediately available to the hyperbaric facility during working hours
- support from a registered medical practitioner who is present in the hospital and immediately available to the facility at all times when patients are being treated at the hyperbaric facility
- support from a registered nurse with specific training in hyperbaric patient care to the published standards of the Hyperbaric Technicians and Nurses Association who is present during hyperbaric oxygen therapy.

In addition to meeting the above requirements, the Health Insurance Commission also has a list of indications for which hyperbaric oxygen therapy is approved. This list is very similar to that of the Under-Sea and Hyperbaric Medical Society (see Section 8.10) and does not include, for example, multiple sclerosis or cerebral palsy.

However, as noted earlier, Medicare reimbursement is only applicable for hyperbaric oxygen treatment provided in private hospitals, for private patients in public hospitals, or for privately referred outpatients in public hospitals. It is possible that treatment for non-Medicare approved purposes occurs in public hospitals, but anecdotal information suggests that, if it occurs, the scale of such usage is unlikely to be great.

The range of Medicare rebates currently available for hyperbaric oxygen therapy was outlined at Section 5.4.1.1.

#### **8.4.1 Review of Medicare Arrangements**

A review of Medicare arrangements in relation to hyperbaric oxygen therapy is currently being undertaken by a supporting committee to the Medicare Services Advisory Committee (MSAC).

The primary focus of the MSAC Review was to seek extension of Medicare rebates for treatments provided in mono-place (transportable) chambers. The review also considered the range of specific clinical indications for use of hyperbaric oxygen therapy.

If Medicare rebates are extended to mono-place chambers, it is possible that the benefits will be payable for a more limited range of specified conditions than at present. The final Medicare requirements may also include that providers must meet certain qualifications/standards in order to obtain Medicare benefits.

The outcome of the MSAC review will be notified after comments from key stakeholders have been received and assessed, and recommendations have been considered by the relevant Commonwealth Minister and the Medical Benefits Advisory Committee.

If changes to the Medicare arrangements do provide for Medicare benefits to be paid for approved treatments in mono-place (transportable) units, this may result in the wider

provision of 'orthodox' hyperbaric services, eg in areas/regions of Australia that do not currently have access to hospital-based hyperbaric oxygen services.

### 8.5 Australian Standards

Compliance with Australian Standards is not mandatory (unless the Standard is referenced in legislation). However, a person's compliance with a Standard may be useful as evidence of what is an accepted standard of care or quality in a given field or industry.

Where a person performs a task that involves the exercise of special skills, the law of negligence requires that the person exercise that skill to the standard of a reasonably competent person possessing those skills. A person who fails to comply with that standard in exercising their skill will be in breach of their duty of care to the person who is injured or suffers a loss.

Compliance with an Australian Standard would not necessarily provide definitive or irrefutable evidence of the accepted standard of care. Evidence of the standard of care provided by other service providers in the same field, would also be relevant to establish the standard that a person must meet in providing the service.

Hyperbaric Oxygen Units are *pressure vessels*, which are covered by Australian Standard AS1210. In addition, an Australian Standard specifically for Hyperbaric Chambers may become available in the near future, based on the Hyperbaric Oxygen Therapy Facilities Industry Guidelines (HOTFIG), published by the Hyperbaric Technicians and Nurses Association<sup>52</sup>.

A draft Australian Standard for Work in compressed air and hyperbaric facilities was released on 15 August, for comments before 31 October 2000.

Information provided to the review indicates that the primary thrust of the Standard is that anyone who operates a hyperbaric chamber should be competent to do so, ie have appropriate training and experience as set out in the Standard.

### 8.6 Industry Guidelines: HOTFIG

The HOTFIG document referred to above was developed by hyperbaric nurses and technicians, the Australia and New Zealand Hyperbaric Medicine Group (ANZHMG), hyperbaric chamber operators, and suppliers of hyperbaric chambers. It appears to be well accepted and recognised by both orthodox and other providers throughout Australia, although this is not equivocal. Hospital hyperbaric oxygen therapy chambers in hospitals are said to generally operate to a standard as high, or higher than, that outlined in the HOTFIG document.

The objective of the HOTFIG Guidelines is to provide designers, manufacturers and operators of hyperbaric treatment facilities (other than those used in support of underwater diving operations), with a set of recommendations so that hyperbaric exposures of all persons involved in the operation of such facilities may be safely conducted<sup>53</sup>. The HOTFIG Guidelines are based on the Undersea and Hyperbaric

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<sup>52</sup> Hyperbaric Technicians and Nurses Association, 1998, *Hyperbaric oxygen therapy facilities industry guidelines*, Prince of Wales Hospital, Randwick, Sydney.

<sup>53</sup> Hyperbaric Technicians and Nurses Association, 1998, *Hyperbaric oxygen therapy facilities industry guidelines*, p.4.

Medical Society (UHMS) Guidelines for Clinical Multi-place Hyperbaric Facilities. UHMS is generally acknowledged as the principal professional society for the field of diving and hyperbaric medicine, and it is understood that the South Pacific Undersea Medical Society (of which ANZHMG is a subgroup) has accepted the HOTFIG Guidelines.

The introductory provisions of the Guidelines contain a list of Australian Standards referenced in the document, as well as explanatory notes and definitions. In addition, there are provisions regarding functional capacity and operational systems (eg chamber electrical systems), preventative maintenance, emergency procedures, duty of care to patients, personnel, training and qualifications, and course content for training programs. The provisions are detailed and appear to address potential health risks thoroughly. For example, the list of emergency procedures recommends that facilities should have written protocols for a number of potential adverse events, including suspected pneumothorax, claustrophobia, cardiac arrest, and loss of power. Regular practices and assessments of satisfactory staff performance should be carried out.

In addition, a table has been prepared that sets out the chamber type, patient classification (according to health status) and staff requirements (eg staff with a greater level of training are required for higher risk patients). This seems well considered and appropriate, and it would appear that, if HOTFIG Guidelines are widely followed at hyperbaric facilities, the risks associated with hyperbaric oxygen therapy should be effectively minimised.

### **8.7 Private Health Facilities Act 1999**

The *Private Health Facilities Act 1999*, which establishes a licensing framework to protect the health and wellbeing of patients, provides (in Part 3) that the Chief Health Officer may make Standards in relation to a wide range of matters. Before a licence may be issued for a private health facility, the Chief Health Officer must be satisfied that the facility will comply with the relevant Standards.

Although not yet finalised, the proposed *Patient Care Standard* under this Act will require that the facilities, equipment and resources of licensed private health facilities must comply with various Guidelines, Australian Standards, and appropriate college/professional body guidelines. These include the Hyperbaric Oxygen Therapy Facilities Industry Guidelines (HOTFIG) referred to in Section 8.10 above.

### **8.8 Health Rights Commission Act 1991 (HRC Act)**

Consumer complaints about providers of hyperbaric oxygen therapy could be made under the HRC Act, which establishes a legislative mechanism for complaints to be made about health services. The HRC Act defines a ‘**health service**’ as *a service provided to an individual for, or purportedly for, the benefit of human health*. Thus, consumer complaints about health services and ‘pseudo-health’ services may be dealt with under this Act.

Schedule 1 of the HRC Act specifies a range of Declared Health Services, which include services provided not only by registered health practitioners, but also by various ‘natural’ and other alternative health care providers. Recreational or leisure services, if provided as part of a health service, are also included.

The HRC Act provides that the Commissioner may provide a report in relation to a HRC investigation to:

- an employer of the person who provided the service;
- the person's professional association;
- the Minister; or
- any other person or body that has a function or power to take action on matters raised in the report.

Where a consumer complaint concerns a registered health provider, the complaint may also be referred to the practitioner's Registration Board to be dealt with under the *Health Practitioners (Professional Standards) Act 1999* (see below).

### **8.9 Health Practitioners (Professional Standards) Act 1999**

Registered health practitioners who may provide hyperbaric oxygen therapy (eg doctors, chiropractors, physiotherapists) are governed under their respective Registration Acts and the *Health Practitioners (Professional Standards) Act 1999*. Under section 48 of this Act, complaints may be made about *any aspect* of a registered health practitioner's conduct or practice *that appears to provide a ground for disciplinary action*. Section 124 of the Act specifies the range of grounds for disciplinary action, including that a practitioner *has behaved in a way that constitutes unsatisfactory professional conduct*.

In considering unsatisfactory professional conduct, the Act states that regard must be had to any relevant codes of practice. A relevant code of practice may be one that is made (or adopted) by a Registration Board pursuant to section 374 of the Act, and approved by the Minister.

If a ground for disciplinary action is established against a registered practitioner, the Act provides for a range of disciplinary actions, including suspension, imposition of conditions, and cancellation of the practitioner's registration.

## 9. Assessment of Base Case (existing legislation)

In the absence of relevant and useful data, this Review has adopted a *qualitative* rather than quantitative approach to assessing the benefits and costs of the Base Case and each of the proposed regulatory Options. Impacts on consumers, providers and government have been considered, and are detailed below. A summary of the Impacts is also provided in the Impact Matrix at **Appendix 2**.

### 9.1 Impact of the Base Case on consumers

The current legislation, which restricts the provision of services by providers who do not meet the criteria prescribed for ‘exemption under section 61 of the Regulation, aims to protect public health and safety by prohibiting the provision of hyperbaric oxygen therapy except where a provider meets certain criteria.

To a large extent, the level of consumer protection it affords is duplicated by other arrangements (as outlined in Section 8 above). Furthermore, ‘orthodox’ providers (eg hospitals) are generally exempt from the current restrictions, and there is currently only **one** approved ‘non-orthodox’ provider in Queensland. Thus, the extent of consumer protection that the current legislation actually provides could be said to be negligible.

The current legislative restrictions act as a barrier to market participation and competition, and may limit consumer choice and access to hyperbaric oxygen therapy services, particularly for ‘non-orthodox’ services (eg chiropractic, sports medicine, cosmetic). Providers of those services would be unlikely to meet the criteria for ‘exemption’ under section 61 of the *Health Regulation 1996*, and thus would be obliged to apply for Queensland Health approval before establishing a hyperbaric facility, and could incur business costs associated with obtaining such approval (see Section 5.4). This requirement could deter potential providers from entering the market.

If retained, the current restrictions could also, in the future, limit consumer access to *orthodox* (medically approved) services. For example, if Medicare requirements are changed to allow rebates for approved treatments in **mono-place** units, some medical providers may wish to establish smaller hyperbaric facilities in areas that do not currently have access to those services. Those potential medical providers may not automatically qualify for ‘exemption’ under section 61 of the *Health Regulation 1996* (ie, they may not have the facilities or the specialist qualifications required for exemption), and therefore would be obliged to apply for Queensland Health approval before establishing a small hyperbaric facility. In doing so, they could incur the same business costs as ‘non-orthodox providers (see Section 5.4), and may be similarly deterred from entering the market.

Thus the impacts for consumers from the deterrent effect of the current restrictions on potential new providers, is that consumer access to and choice of services is restricted.

In relation to consumer protection issues, there have been no reports of significant adverse impacts on public health and safety in other Australian jurisdictions which do not have any legislative restrictions on the possession or use of hyperbaric chambers, and where both ‘orthodox’ and ‘non-orthodox’ providers are operating,

## 9.2 Impact of the Base Case on providers

### (a) *Orthodox providers*

The current legislative restrictions (as described at Section 3.2) do not impact on the provision of ‘orthodox’ hyperbaric oxygen therapy services by the two current (hospital-based) orthodox providers, ie Townsville Hospital and the Wesley Medical Centre, both of which are ‘exempt’ under the legislation. Other potential hospital-type providers would also be likely to meet the criteria for ‘exemption’ under section 61 of the Regulation. Similarly, hyperbaric chambers used for diving purposes are exempt from the legislative restriction where they are used by persons who have qualifications in diving supervision and in the operation of recompression facilities as prescribed under the Regulation.

Hyperbaric chamber usage in hospital based facilities is generally restricted to treating medically accepted conditions, ie those for which a Medicare benefit is or would be payable. To qualify for a Medicare benefit, the facility must meet specified standards, and staff must be trained to the level required under the Medicare arrangements, which are more prescriptive and detailed than those listed under in the *Health Regulation 1996*.

Where hyperbaric oxygen therapy is provided in a private health facility in Queensland, the facility is **also** subject to the licensing requirements and standards made under the *Private Health Facilities Act 1999* (described at section 8.11).

Accordingly, it would appear that, so far as ‘orthodox’ hospital-based providers of hyperbaric oxygen therapy are concerned, the current legislative restrictions in Queensland have no impact.

Furthermore, those restrictions duplicate - to a significant extent - the regulatory controls present in the Commonwealth’s Medicare requirements and those under the *Private Health Facilities Act 1999*.

**Thus, while the current legislation may not restrict the ability of most ‘orthodox’ providers, it constitutes unnecessary regulatory duplication.**

It is possible that some potential medical providers may not meet the diving and hyperbaric medicine qualifications prescribed under the Regulation. Such providers would be obliged to apply for Queensland Health’s approval, if (for example) they wished to establish a mono-place chamber, for example in an area that is not currently serviced by a hospital-based facility. This scenario may become more likely if changes to the Medicare arrangements allow payment of a Medicare benefit for services provided in a mono-place facility.

Potential new providers could be discouraged by the potential business costs associated with obtaining Queensland Health approval, eg provision of supporting information about the chamber and its proposed therapeutic use, potential delays in start-up while such approval is being obtained, obtaining legal advice where necessary, and other business-related costs (see Section 5.4.1). This could deter potential providers from entering the market, however the *extent* to which that may impact on the market is unknown.

***(b) Non-orthodox providers***

As noted in Section 3, the use of hyperbaric chambers, and the possession of portable hyperbaric chambers, is prohibited under section 62 of the Regulation, unless 'exempted' or 'approved' under section 61. (Currently, only one 'non-orthodox' hyperbaric chamber has Queensland Health approval).

Providers which would be likely to need to seek Queensland Health approval would include for example, sports clinics, physiotherapy clinics, chiropractic/back pain clinics, cosmetic purposes, treatments for multiple sclerosis and cerebral palsy, and various 'pseudo-therapeutic' purposes (eg treatment of greying hair) and alleged 'feel good'/well being purposes.

These potential providers would be required to seek Queensland Health approval, and would thus incur business costs/delays in preparing an application and obtaining the necessary approval (as outlined in Section 5.8.1). The effect of this is that 'non-orthodox' providers may be discouraged from providing services in Queensland.

**9.3 Impact of the Base Case on Government**

The current legislation imposes ongoing costs on Government to maintain, administer and review the legislation. To a large extent, these costs represent a duplication of the costs associated with other regulatory controls (as outlined in Section 8).

## 10. Reform Options

The PBT Plan for the review of the existing legislation proposed **three** possible reform options, ie *Option 1*: no restriction; *Option 2*: prohibition other than on persons with specified qualifications; and *Option 3*: a two-tiered approach relative to whether a chamber is above or below 3 atmospheres. These options are outlined below in more detail. **No other options were proposed in submissions to the review.**

### **Option 1      Removal of existing restriction under the *Health Regulation 1996*.**

Under this option, the current restrictions would be repealed, however other regulatory and non-regulatory controls (as outlined in Section 8) would continue to apply, eg Therapeutic Goods legislation, Fair Trading legislation, Workplace Health and Safety requirements, Medicare requirements, Private Health Facilities legislation, Health Professionals legislation, Health Rights legislation, and Industry Guidelines/Australian Standards.

### **Option 2      Prohibition on the use of hyperbaric chambers other than by persons with specific qualifications.**

This option would require the development and enforcement of new legislation to (a) restrict the use of hyperbaric chambers to qualified persons only, and to (b) evaluate and specify the qualifications that such persons must hold.

### **Option 3      Two-tier option, ie no restriction on chambers operating below 3 atmospheres, with a requirement that chambers operating at above 3 atmospheres be restricted to clinical settings, and by persons who are competent to operate same.**

This option would require a two-pronged legislative approach:

- (a) the repeal of restrictions on hyperbaric chambers that operate *under* 3 atmospheres); and
- (b) the development of new legislation to restrict the use of hyperbaric chambers *above* 3 atmospheres to clinical settings only, and to be used only by persons with the competencies specified in the legislation.

#### **10.1 Impacts of Reform Options**

As noted at Section 9 above, a qualitative (rather than quantitative), assessment has been made of the base case legislation and the regulatory reform options. The following assessment considers impacts from each of the three reform options. A summary of the impacts is also available at **Appendix 2**.

#### **10.2            Option 1 (Removal of legislative restrictions)**

##### **10.2.1          Impacts on Consumers under Option 1**

Under this Option, consumer protection would continue through other regulatory and non-regulatory controls as outlined in Section 8, and consumers would have normal recourse to common law suits in relation to negligence actions. Consumers would also continue to have access to the consumer complaints mechanism available through the

Health Rights Commission. **This option would provide the same level of consumer protection as applies in all other Australian jurisdictions.**

This option could result in increased choice and access to services for consumers. That is, with the removal of the current restrictions, hyperbaric services may become more widely available in a variety of both orthodox (eg medical/hospital) and non-orthodox (eg sports centres, chiropractic clinics) settings.

The extent of any increase in consumer choice and access to services is dependent on the extent to which new providers enter the market following removal of the restrictions. The extent to which this may occur is unknown, however, given the relatively small Australian market (a total 33 chambers, of which 22 provide 'orthodox' services), it is not likely to be significant.

In relation to 'orthodox' hyperbaric services, the extent to which these may increase if the current restrictions are removed may be dependent on the outcome of the MSAC review (as outlined in Section 8.4.1). That is, new 'orthodox' providers may be more inclined to enter the market (particularly in areas where consumers do not currently have access to hospital-based hyperbaric treatments) **if** the outcome of the MSAC review results in payment of Medicare benefits for treatments provided in mono-place units.

No assessment can be made as to whether costs to consumers would change under this Option, since (a) 'orthodox' treatments are largely governed by Medicare and private health fund rebates, and (b) until very recently, there have been no 'non-orthodox' providers in Queensland on which to base potential future costs.

### **10.2.2 Impacts on Providers under Option 1**

#### **(a) 'Orthodox' providers**

Removal of the current regulatory restrictions would have no impact on the two existing 'orthodox' (hospital-based) providers in Queensland, who are 'exempt' under Section 61 of the Regulation. These providers would continue to operate in much the same way as at present, and would still be subject to the range of regulatory and non-regulatory controls outlined at section 8, including compliance with Medicare requirements and the legislation applying to health professionals and private health facilities.

This Option may, however, encourage potential new 'orthodox' providers to enter the market, since they would not be restrained by the current legislative requirements, eg, to have hyperbaric qualifications/experience or to otherwise apply to Queensland Health for approval.

If new 'orthodox' providers do enter the market, it is probable that this would be with mono-place chambers, *particularly* if the MSAC review results in Medicare benefits being payable for treatments provided in mono-place chambers. If new providers do enter the market, it is considered probable that this would occur particularly in larger regional centres that do not currently have a hospital-based facility, and where the population base may have treatment needs for such services (eg an aging population). It is also possible that such potential providers could also consider establishing a hyperbaric facility in partnership with other health providers, eg physiotherapists.

It is not expected, however, that any future increase in the market would be significant (given the relatively small hyperbaric market throughout Australia).

**(b) ‘Non-orthodox’ providers**

Option 1 (removal of the current legislative restrictions) would have no impact on the one ‘non-orthodox’ provider who currently has Queensland Health approval. However, Option 1 would allow potential new ‘non-orthodox’ providers to more readily enter the market to provide hyperbaric oxygen therapy in a variety of settings, eg sports centres and chiropractic clinics (and perhaps in partnership with medical practitioners providing ‘orthodox’ treatments).

Non-orthodox providers would still be required to meet many of the same requirements as orthodox providers, ie, Therapeutic Goods requirements and Workplace Health & Safety requirements. In addition (although it is not compulsory), compliance with HOTFIG Guidelines and/or Australian Standards appears to be fairly common practice<sup>54</sup>. In addition, to the extent that they provide a health service, ‘non-orthodox’ providers would also be subject to the jurisdiction of the Health Rights Commission (see section 8.1.2).

The development of an additional hyperbaric market in Queensland (ie in chiropractic clinics, sports centres, etc) may increase small business employment and training opportunities in the State. However, the extent to which a ‘non-orthodox’ market would develop in Queensland is probably limited. In other Australian jurisdictions, where there are no restrictions, the ‘non-orthodox’ market remains quite small (ie 11 chambers throughout Australia).

### **10.2.3 Impacts on Government under Option 1**

Removal of the current legislative restrictions would reduce the burden on government to maintain, apply, enforce and review the current legislation. As previously noted, the current legislation duplicates, to a large extent, other regulatory controls.

## **10.3 Option 2 (Qualifications required)**

### **10.3.1 Impacts on Consumers under Option 2**

This Option may provide assurance to consumers that only qualified persons provide hyperbaric services. However, this assurance is of minimal value in respect of medical providers, since it largely duplicates other ‘qualifications’ requirements (eg the qualifications required under the Medicare arrangements for hyperbaric services).

A ‘qualifications’ requirement may have some value in respect of ‘non-orthodox’ providers who are not subject to the Medicare qualifications requirements. However, such providers are already subject to Workplace Health & Safety training requirements (as outlined in Section 8), and, like orthodox providers, they may also comply voluntarily with the qualifications outlined in the HOTFIG Guidelines/Australian Standards.

Under this Option (as with the Base Case and Option 1), consumer protection is also provided through the other legislative and non-legislative controls outlined in Section 8.

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<sup>54</sup> Compliance with Industry Guidelines and/or Australian Standards is good business practice, since such compliance may serve as evidence of having an acceptable standard of care, ie in the event of a consumer taking legal action against a provider for negligence.

Therefore, it is not anticipated that Option 2 would provide any significant increase in consumer protection; nor would it improve consumer choice and access to services. It is also anticipated that there would be no change in costs to consumers under this Option.

### **10.3.2 Impacts on Providers under Option 2**

This option would have slightly different impacts on the two provider groups, ie ‘orthodox’ and ‘non-orthodox’.

#### **(a) Orthodox providers**

Orthodox providers are already subject to ‘qualifications’ requirements, eg Medicare requirements, thus new legislation specifying qualifications requirements would be most unlikely to have any impact on the two orthodox providers currently operating in Queensland.

However depending on the level of qualifications prescribed under this Option), it could have an adverse impact on potential new orthodox providers (eg if the qualifications prescribed were *higher* than those specified in the current legislation or by the Medicare requirements). Such providers may face additional costs of complying with new ‘qualifications’ requirements, and accordingly may be deterred from entering the market.

#### **(b) ‘Non orthodox’ providers**

Depending on the level of qualifications prescribed, this Option could possibly impact adversely on the sole current approved ‘non-orthodox’ provider, unless the legislation allowed for ‘grand-fathering’, ie for that provider’s existing approval to continue under the new legislative arrangements.

This Option would also impose new compliance costs on potential new ‘non-orthodox’ providers, ie costs of obtaining the required qualifications. Depending on the nature of qualifications required, such providers could be deterred from entering the market. If a ‘hyperbaric medicine’ qualification was required, the deterrent effect could be significant.

### **10.3.2 Impacts on Government under Option 2**

This Option would incur new costs to Government, ie costs associated with:

- Research and policy development to establish appropriate qualification requirements;
- Development and enactment of new legislation;
- Enforcement of new ‘qualifications’ requirements.

This Option would also involve on-going costs to Government to maintain and review the new legislation.

It would be difficult to justify such costs, since the qualifications requirements would be very likely to duplicate existing ‘qualification’ requirements (eg under Medicare, Private Health Facilities legislation, Workplace Health & Safety training requirements, and AS/HOTFIG qualifications).

### **10.4 Option 3 (Two tier approach)**

Briefly, the impacts from this Option represent a combination of the impacts of:

- Option 1, ie removal of restrictions for hyperbaric chambers that operate under 3 atmospheres); and
- Option 2, ie qualifications required for chambers that operate above 3 atmospheres. In addition, chambers above 3 atmospheres would be restricted to clinical settings only.

This Option was first proposed in the Public Benefit Test Plan on the basis that risks in hyperbaric chambers operating at higher than 3 atmospheres absolute may pose a higher risk than chambers operating at less than 3 atmospheres.

Some stakeholders have a view that hyperbaric chambers used to treat diving decompression sickness (involving pressurised air between 3 – 6 atmospheres) is a highly specialised area and should be dealt with differently under legislation (this is not the case under the current legislation).

However, information provided by clinical stakeholders indicates that there is no scientific basis to support a two-tiered approach.

Since the Option was proposed in the PBT Plan, its potential impacts have been considered as part of this PBT report, and are outlined below.

#### **10.4.1 Impacts on Consumers under Option 3**

There is no assurance that public health and safety would benefit under this Option, since there is no scientific evidence to support a differentiated risk category for chambers above or below 3 atmospheres. In fact, one submission to the review from a clinician commented that most hyperbaric oxygen treatments occur between 2.4 and 2.8 bars of pressure, as mandated by most of the scientific literature. Another submission suggests that the risks of hyperbaric oxygen therapy above 3 atmospheres may be **less** than for compression between 2 and 3 atmospheres, since compressions above 3 atmospheres are usually only made for divers (who are generally young and fit people, rather than patients with multiple health conditions).

There could be *some* increase in consumer choice and access to services under this Option, since a new market **may** develop in chambers *under* three atmospheres (for which there would be no legislative restrictions). The extent to which this may occur is unknown, but is likely to be minor.

#### **10.4.2 Impacts on Providers under Option 3**

##### **(a) ‘Orthodox’ providers**

This Option would have no effect on the current two orthodox providers, who would continue to operate as at present, ie regardless of whether their chamber was above or below 3 atmospheres. That is, they would most likely meet the new qualifications and ‘clinical setting’ requirements for chambers above 3 atmospheres, and would continue to meet the other regulatory and non-regulatory requirements already required under the current legislation, for chambers both above *and* below 3 atmospheres.

In relation to potential new providers, however, this Option is likely to have different impacts, depending on whether a provider wished to enter the market with a chamber above or below 3 atmospheres. Since Option 3 would restrict the provision of hyperbaric oxygen chambers above 3 atmospheres to ‘clinical settings’, it would

probably impact most on potential providers who wish to provide diving-related services outside of a hospital setting.

Depending on the level of qualifications required for chambers above 3 atmospheres, Option 3 could impose new costs relating to new qualifications, which could deter such providers from entering that particular sector of the market (as with Option 2).

However, this Option would remove market barriers in relation to chambers below 3 atmospheres, and would allow potential new providers to explore new market opportunities.

**(b) *‘Non-orthodox’ providers***

This Option would increase the market barriers already in place for ‘non-orthodox’ providers in relation to chambers above 3 atmospheres, since it removes the current provision that allows for Queensland Health approval to be given for a chamber. It is considered most unlikely that ‘non-orthodox’ providers would be able to satisfy both the qualifications requirement and the ‘clinical settings’ requirement for chambers above 3 atmospheres. However, since it appears that chambers above 3 atmospheres are principally used to provide diving decompression treatments, it is anticipated that the restriction would have a negligible impact on ‘non-orthodox’ providers.

This Option would remove the existing market barriers applying to hyperbaric services below 3 atmospheres, and may encourage new providers to explore market opportunities for that sector. The extent to which a market for chambers below 3 atmospheres would develop under this Option is unknown, but, as with Option 1, any growth in the market is likely to be small.

### **10.4.3 Impacts on Government under Option 3**

This ‘two-tiered’ Option would incur some new costs to Government, ie costs associated with:

- Research and policy development to establish appropriate qualification requirements for chambers above 3 atmospheres;
- Development of new legislation for chambers above 3 atmospheres;
- Enforcement of new ‘qualifications’ and ‘clinical settings’ requirements for chambers above 3 atmospheres.

This Option would also involve on-going costs to Government to maintain and review the new legislation applying to chambers above 3 atmospheres.

As with Option 2, it would be difficult to justify such costs, since the qualifications and ‘clinical setting’ requirements for chambers above 3 atmospheres would be very likely to duplicate existing requirements (eg under Medicare, Private Health Facilities legislation, and HOTFIG qualifications).

## 11. Summary

The current legislation in Queensland restricts restraint entry to the market in hyperbaric services and inhibits the development of potential new markets. It also restricts consumer choice and access to hyperbaric oxygen therapy services, particularly for purposes that are not recognised as medically approved therapeutic purposes (eg sports injuries, chiropractic, cosmetic and other uses).

Submissions to the review in 1999 were generally in favour of maintaining the current restriction because of (a) concerns about public health and safety, and (b) concerns that ‘non-orthodox’ or ‘fringe’ uses could bring the entire field of hyperbaric oxygen therapy into disrepute.

However, stakeholder comments<sup>55</sup> during November 2000 (in response to the *Draft Public Benefit Test*) indicate a shift of opinion. For example, two stakeholders now support removal of the restriction (and a third does not object), while one still seeks retention of the restrictions, but does not provide any new information to support that position.

In relation to concerns about public health and safety, in other Australian jurisdictions, where there are no legislative restrictions on hyperbaric chambers, there is no evidence of adverse impacts on public health and safety. Nor is there any evidence that ‘non-orthodox’ hyperbaric oxygen services have proliferated to any significant degree, for example there are only 11 such chambers throughout Australia.

In relation to concerns about ‘fringe’ uses bringing the field of hyperbaric medicine into disrepute, similar arguments could be mounted about other ‘fringe’-type practices that may reflect on orthodox medicine, but which are nevertheless not restricted. In any event the legislation under review has the objective of protecting public health and safety, not the protection of a particular field of medical practice.

There is a range of regulatory and non-regulatory controls (as outlined in Section 8) that provide protection to users of both orthodox and non-orthodox hyperbaric services. These include Workplace Health and Safety requirements, consumer protection/fair-trading laws, the Commonwealth’s Therapeutic Goods legislation and the legislative mechanism for consumer complaints to be made under the *Health Rights Commission Act 1991*. Industry developed standards also appear to be well accepted and observed. In addition, the use of hyperbaric oxygen therapy for medically recognised and approved purposes is appropriately managed through the Medicare requirements and other legislation applying to health facilities and to registered health practitioners.

It would therefore appear that public health and safety concerns can be satisfactorily addressed without the current legislative restrictions contained in the *Health Regulation 1996*.

Removal of the restrictions will remove barriers to market participation, and may result in an increase in the number of services provided in Queensland. However, based on the

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<sup>55</sup> Five stakeholders provided written comments on the Draft PBT Report. The MSAC provided information about the current status of its own review, but did not comment on the regulatory options or the Draft PBT’s conclusions.

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relatively small market throughout Australia, any future increase in services in Queensland (whether 'orthodox' or 'non-orthodox') could be expected to be very small.

**After considering the regulatory Options, the Public Benefit Test supports Option 1 (removal of the legislative restrictions), having concluded that this Option will remove restrictions on competition, without having adverse consequences for public health and safety.**