The Impact and Cost of Health Sector Regulation

Prepared by Julie Novak, Chris Berg and Tim Wilson

June 2010

ACHR
AUSTRALIAN CENTRE FOR HEALTH RESEARCH

AUSTRALIAN CENTRE FOR HEALTH RESEARCH LTD ABN 87 116 781 965
114 Albert Road, South Melbourne Victoria 3205 Phone 03 9697 0283 Website www.achr.com.au

Special Note: The objective of the Australian Centre For Health Research Limited (ACHR) is to undertake activities aimed at improving the provision of health and ageing services in Australia. To this end, the ACHR commissions independent research on topics of importance in health and ageing, in order to stimulate further exploration of areas of shared concern. The presentation of factual matters, and the ideas and conclusions expressed in the independent research reflect the views of the author of that research, and do not necessarily represent all of the views of ACHR or its individual officers.

The Impact and Cost of Health Sector Regulation

Julie Novak, Chris Berg and Tim Wilson[1]

Executive Summary

- The demands on Australia's health care sector will increase considerably as the Australian population ages.
- The regulatory burden on health care professionals is increasing and is coming at the expense of fulfilling their primary purpose of providing health care services.
- Health care providers may be required to liaise with up to 100 health care regulators with nearly 80 commonwealth regulators and between 15 and 20 in each state.
- There are now more than 22,600 pages of combined state and federal legislation across 305 different Acts of Parliament covering the health sector.
- There are unnecessary disparities in regulation for health care providers between States which cause confusion and increase the barriers to establishing new health care facilities.
- The cost of regulation is rising rapidly. For example, the estimated compliance burden on general practice for enhanced primary care has grown by nearly 900 per cent between 2002-02 and 2007-08.
- General Practitioners are becoming the interface for approval for Australians to access other government services such as welfare and support services draining their time to provide health care.
- Licensing arrangements for different health care facilities from state to state add confusion to the capacity for new and existing health care providers to operate across the country.
- The pharmaceuticals industry is one of the most heavily regulated industries in Australia and faces annual costs of at least $89 million to receive regulatory approval for sale. Much of this cost is duplicating work to seek regulatory approval already commenced or resolved overseas.
- The average time frame for regulatory approval for a new medicine can be as high as 160 days resulting in the slower introduction of life saving or extending medicines.
- The most effective way to decrease private health insurance premiums is not government regulation, but competition in health insurance products.
- Australia's health care needs significant regulatory reform to ensure it can deliver the services expected of it with an ageing population.

[1] Julie Novak and Chris Berg are Research Fellows at the Institute of Public Affairs; Tim Wilson is Director of the Intellectual Property and Free Trade Unit at the Institute of Public Affairs.

1 Australian health sector regulations in perspective

Overview

At some point most, if not all, Australians come into contact with the health care sector. According to the Australian Institute of Health and Welfare (AIHW):

- About 85 per cent of Australians visit a doctor at least once a year
- Ambulances attended over 2.7 million incidents nationally in 2006-07, of which 39 per cent were emergency incidents
- On a typical day in Australia there are 20,000 hospital separations and 124,000 non-admitted services provided by hospital emergency departments and outpatient clinics.[2]

Whether through a routine medical check from a general practitioner, the dispensing of pharmaceutical and other medical products, the delivery of a baby in the maternity ward of a large hospital or episodic surgery to tackle a life-threatening condition, the sector provides an array of goods and services critical to maintaining a healthy population.

As many Australians are acutely aware, the health care sector represents a complex web of financing, policy and regulatory interactions between a myriad of participants.

The commonwealth government has acquired significant responsibility for health services, including primary care and health insurance. The states and territories remain largely responsible for the provision of services including public acute hospital care, as well as public health (health promotion and disease prevention).

Local governments and non-government organisations are also involved in the delivery of health services.

(The federal government's proposed reforms to the health system are intended to dramatically change the balance between different levels of governments' provision of services. These reforms are likely to increase many of the problems identified on this paper.)

The private sector also plays a role in the financing and delivery of health care services. According to data published by the OECD, the proportion of health system expenditure attributable to the private sector was 32.3 per cent in 2006.[3] This figure was significantly above the average of 27 per cent for nearly 30 OECD countries.

In practice, the operations of private health care providers are heavily circumscribed by regulations imposed by governments. These regulatory impositions are enacted for a variety of reasons, including to ensure accessibility, safety and quality, and affordability in health care, as well as to ameliorate information asymmetries and other impediments facing market participants.

---

[2] Australian Institute of Health and Welfare (AIHW), 2008, *Australia's Health 2008*, AIHW, Canberra, p. 304.

[3] Organisation for Economic Cooperation and Development (OECD), OECD Health Data 2009 – Frequently Requested Data, http://www.oecd.org/document/16/0,3343,en_2649_34631_2085200_1_1_1_1,00.html (accessed 14 September 2009).

Given their underlying policy objectives, regulations may invoke benefits as well as costs. However, there is growing concerns that the cost burdens of health sector regulations have increased over time.

This increase in regulation – and the ensuing paperwork and other time- and energy-sapping burdens incurred to comply with regulation – compromises the ability of health businesses and their staff, including frontline medical practitioners, to provide quality care for those Australians who need it.

Growth in the health sector regulatory burden also has significant implications for the capacity of the private sector to finance and deliver affordable, efficient health services, particularly in the context of expected strong future demands for health services in an ageing population.

To ensure that Australians continue to enjoy the benefits of a world-class health system, it is incumbent upon governments to reduce the excessive burden of their regulations impacting the health sector.

Profile of Australian private health care sector

As noted above the private sector plays a crucial role in the financing and delivery of health services.

ABS statistics on the characteristics of Australian industries for 2002-03 show that there were approximately 84,400 establishments in the private health care sector.[4] This included about 49,300 medical and dental practitioners, 34,000 services in other health areas such as pathology, optometry and physiotherapy, and over 1,000 private acute care hospitals.

One way to quantify the economic contribution of the private health care sector is to consider the amount of value added, or the value of goods in excess of costs generated by the production process, that it generates.

According to the ABS Australian and New Zealand Standard Industrial Classification (ANZSIC) system, the private health and community services sector contains a range of activities including:

- private acute and psychiatric hospitals, and nursing homes
- general practice and specialist medical services
- pathology and diagnostic imaging services
- allied health services, including dental, optometry and optical dispensing, and chiropractic, osteopathic and physiotherapy services
- other health care services, including ambulance services
- veterinary services
- community services.

This definition of the private health care sector is not comprehensive, as it excludes the manufacturing, distribution and retailing of medicinal and pharmaceutical products as well as funding by private health insurance providers.[5]

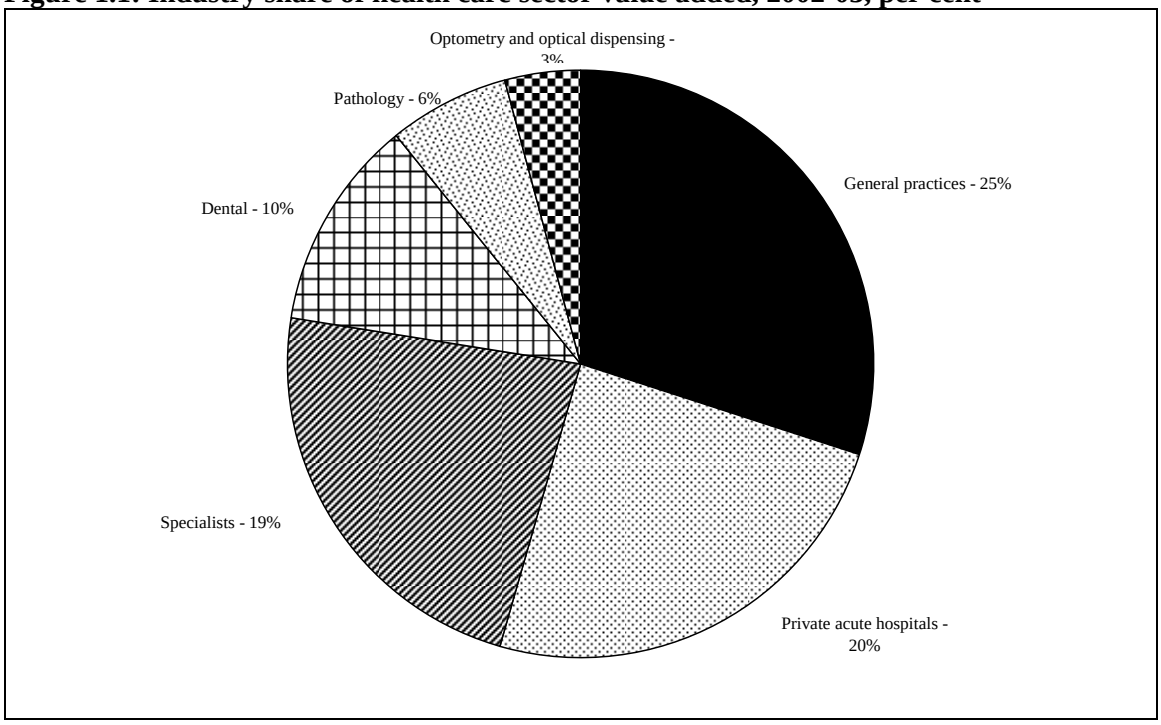
[4] Australian Bureau of Statistics (ABS), Australian Industry 2001-02 and 2002-03, cat. no. 8155.0

[5] According to the ABS, medicinal and pharmaceutical product manufacturing and retailing (including cosmetics and toiletries) generated about $3.9 billion on a value added basis in 2002-03.

Excluding veterinary and community services and nursing homes, the private health care sector generated about $19 billion in gross value added in 2002-03.

General practice medical services accounted for about 25 per cent of the total (Figure 1.1), followed by private acute hospitals (20 per cent), medical specialists (19 per cent), dental services (ten per cent) and pathology (six per cent). Optometry and optical dispensing accounted for the remainder of value added.

Figure 1.1: Industry share of health care sector value added, 2002-03, per cent

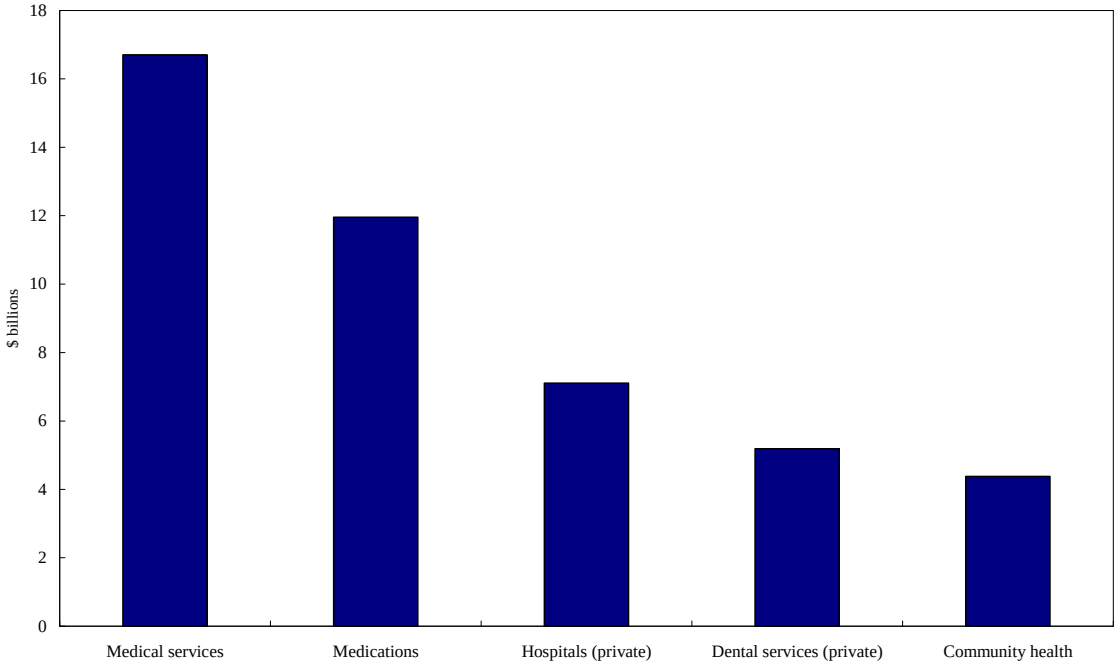


Value-added represents the value added by a sector to the intermediate inputs used by the sector. It is a measure of the contribution by entities, in the selected sector, to gross domestic product.
Source: ABS, Australian Industry 2001-02 and 2002-03, cat. no. 8155.0.

In 2006-07 about $87.3 billion was spent on recurrent health care services by governments (by implication, taxpayers), private health insurance funds, individuals and others.[6] Of this amount, about $45.3 billion was spent on private hospitals, medical services, private dental services, community health and medications (Figure 1.2).

[6] AIHW, Health Expenditure 2006-07.

Figure 1.2: Expenditure on selected health care services, 2006-07, $ billions



Includes government expenditure on health care services delivered by private sector operators. Some categories may incorporate services delivery by governmental entities, therefore overstating the amount of expenditure on private health care services.
Source: AIHW, Health Expenditure 2006-07.

The available evidence also suggests that private operators in the health care sector make a substantial contribution to employment:

- private hospitals and free-standing day hospital facilities employed about 49,000 staff[7]
- in 2006 there were 39,000 medical practitioners engaged by the private sector[8]
- there were 25,564 general practitioners who provided at least one Medicare service during 2006-07[9]
- in 2005 there were 8,300 private dentists in 2005 representing 83 per cent of the total dentist labour force.[10]
- according to data provided by Medicines Australia, there are about 14,300 people directly employed in the pharmaceutical industry.[11]

[7] ABS, Private Hospitals, Australia, 2006-07, cat. no. 4390.0.
[8] AIHW, 2008, Medical labour force 2006, National Health Labour Force Series No. 41, AIHW, Canberra.
[9] Ibid.
[10] AIHW, *Dentist labour force in Australia, 2005*, AIHW Dental Statistics and Research Unit Research Report No. 33.
[11] Medicines Australia, Australian pharmaceutical industry – Facts at a glance, http://www.medicinesaustralia.com.au/pages/images/Industry%20-%20facts%20at%20a%20glance.pdf, (accessed 24 September 2009).

Role of health sector regulation: A critical perspective

'The arguments for government intervention derive from the theory of the market and market failure … Markets only work to maximise health and wellbeing where they are perfect; which requires perfect information, no externalities, free entry and exit for suppliers, no capacity to exercise monopoly power, the absence of public goods attributes, etc. Everyone of these conditions is violated in relation to health' (Leonie Segal, personal correspondence, 10 September 2009).

The development of neoclassical economics during the twentieth century brought with it assertions of an extensive set of circumstances whereby the market could not satisfactorily allocate scarce resources efficiently. These circumstances have come to be known as 'market failure.' There are four main types of market failure identified by economists:

- public goods may exist where the provision of a good or service for one person means that it is available to all people at no extra cost, implying that private sector agents cannot recoup the costs of provision by extracting payment from users
- externalities, or costs or benefits received by parties not involved in a market transaction, may result in too many or too few goods and services being produced and consumed than is economically efficient
- information asymmetry occurs where one party to a transaction has more or better information about a given product than the other party, preventing individuals from making fully informed economic decisions
- imperfect competition in markets leads to one buyer or seller in a market having the ability to exert significant influence over the quantity or price of goods and services traded.

As the quote from Leonie Segal, member of the federal government's preventative health taskforce, suggests, the health care sector is often cited as being particularly susceptible to a range of market failures.

It is commonly regarded that externalities arise in health care in a variety of instances. For example, the provision of public goods such as clean air and water significantly reduces the incidence of communicable diseases such as cholera and dysentery. Immunisation against diseases such as measles, small pox and whooping cough offers benefits across the entire population.

Another frequently cited example of market failure in health comes in the form of information asymmetries about medical conditions, their diagnoses and treatment alternatives. Most individuals typically do not know the best way to treat a medical condition afflicting them, and may not be in a position to rigorously compare the price and quality of alternative treatments on offer.

The implied informational advantage of general practitioners and specialists over the patient is also considered to provide suppliers with considerable market power over purchasers, leading to such tendencies as supplier-induced demand in health care.

Similarly, issues of adverse selection and moral hazard are commonly regarded as traits pervading the area of health insurance. Adverse selection occurs in situations where unhealthy people on the one hand are more likely to purchase health insurance because they anticipate significant medical costs, and healthy people tend to select themselves out of the insured group on the other.

In the case of moral hazard, insured individuals may have an incentive to over-consume health care if the costs are borne by the insurance company. In other cases, people with insurance plans may not follow a healthy lifestyle leading to the cost of treatment being higher than it would otherwise be.

On the basis of these and other perceived failures in market operations, economists have insisted that governments intervene by regulating private health sector activities (and directly provide certain services, such as hospital care). As the following Chapters illustrate, the scope of such regulations in the Australian health care sector is widespread.

However, the notion that government can serve as an efficient coordinating force to resolve the market failures have not gone unchallenged. Indeed, there are a host of mutually consistent criticisms of the conventional market failure approach to policy analysis:

- the market failure paradigm implicitly compared an unachievable theoretical ideal of perfect markets against imperfection in the real world – a line of thinking referred to by economist Harold Demsetz as the 'nirvana fallacy'
- according to the Austrian dynamic adjustment model of markets, inefficiencies represent a source of entrepreneurial action and subsequent market correction without the need for government intervention
- the Hayekian knowledge problem states that policymakers cannot reliably intervene in (imperfect) markets because they lack the tacit, dispersed knowledge to effectively and efficiently redirect the production and exchange of resources
- the public choice theory of economics shows that government actions, performed by fallible politicians with self-interested incentives to maximise votes and political patronage, does not represent a costless solution to market failures.[12]

These criticisms suggest that government intervention may be unnecessary in some cases because market agents can discover their own correctives or, at worst, exacerbate the problems it intended to rectify, further diminishing economic welfare.

In fact, a cursory examination of selected activities in the health care sector suggests that the idea that market incentives cannot function in health is overstated.

As discussed above, the health care system in Australia is characterised by the financing and delivery of services by the private sector. Private hospitals, operating either on a for-profit or not-for-profit basis, together with an array of private primary and allied health care provide a range of services that could not be delivered by governments, at least in a fiscally sustainable manner.

Notwithstanding regulatory restrictions imposed on entities such as private hospitals, general practitioners, specialists and allied health providers, these entities compete with each other and with the public sector not only on price but in terms of the quality or attributes of services provided.

---

[12] Peter J. Boettke, Christopher J. Coyne and Peter T. Leeson, 2007, 'Saving government failure theory from itself: recasting political economy from an Austrian perspective', *Constitutional Political Economy* 18: 127-143; Julie Novak, 2005, *Sensory Order and Economic Order: The links between human cognition and economic freedom in Hayek's thought*, CIS Occasional Paper No. 101.

Health providers have developed their own self-regulatory arrangements over time. Medical practitioners and hospitals have invoked self-regulation through their own licensing, certification and accreditation procedures. For example, private hospitals across Australia benchmark their own performance against accreditation benchmarks set by the Australian Council on Healthcare Standards (ACHS) (Box 1.1).

Box 1.1: Australian Council on Healthcare Standards private hospital performance benchmarks

The Australian Council on Healthcare Standards (ACHS) is an independent not-for-profit organisation that measures and implements quality improvement systems for Australian health care organisations.

The Evaluation and Quality Improvement Program (EQuIP) is the core accreditation initiative of the ACHS, guiding organisations through a four-year cycle of self-assessment, organisation-wide survey and periodic review to meet ACHS standards.

Organisations that successfully achieve the ACHS standards through participation in EQuIP are awarded ACHS accreditation. Accreditation status serves as evidence of an organisation demonstrating compliance with industry-supported performance standards.

The ACHS National Report on Accrediation Performance 2003-2006 summarises the performance of private and public hospital EQuIP members on a range of performance criteria:

- care planning and delivery
- infection control systems
- consumer participation in health services
- consumer rights and responsibilities
- governance structures.

The report found that 14 private hospitals were recognised for their leading practices by being awarded at least one Outstanding Achievement (OA) rating.

It is the self-regulatory standards in health, such as those provided by organisations such as the ACHS, which provide powerful signals to patients about care performance, quality and safety, without recourse to government regulatory interventions.

Source: Australian Council on Healthcare Standards (ACHS), 2007, The ACHS National Report on Health Services Accreditation Performance: 2003-2006; Australian Private Hospitals Association, 2009, Submission to the National Health and Hospitals Reform Commission, http://www.apha.org.au/wp-content/uploads/2009/04/apha-nhhrc-submission.pdf (accessed 29 September 2009).

These standards not only serve to assure minimum quality standards, but can build reputational networks that reinforce incentives for private sector health care providers to promote the interests of the patient.[13]

Information technologies are also enhancing quality assurance in medical care, even for public sector health providers. Consumers are able to gain expertise, by learning of available therapies,

[13] Daniel B. Klein, 1997, 'How Trust Is Achieved in Free Markets', Cato Policy Report, http://www.cato.org/pubs/policy_report/cpr-19n6-1.html (accessed 29 September 2009).

obtaining knowledge from former patients of the performance of surgeons and other medical practitioners, and checking the credentials and affiliation of providers.

For example, in Canada, the United States and the United Kingdom individuals are able to monitor the risk-adjusted mortality rates of hospitals, and in some cases individual surgeons, publicly reported at regular intervals.[14]

The purpose of this section is not to dismiss market failure arguments out of hand, or to argue that markets will operate perfectly in the health care sector. Nonetheless, the presence of efficiency-enhancing market incentives underline the importance that any governmental regulatory involvement in the health sector imposes the lowest burdens possible and not compromise the ability of providers to deliver quality care.

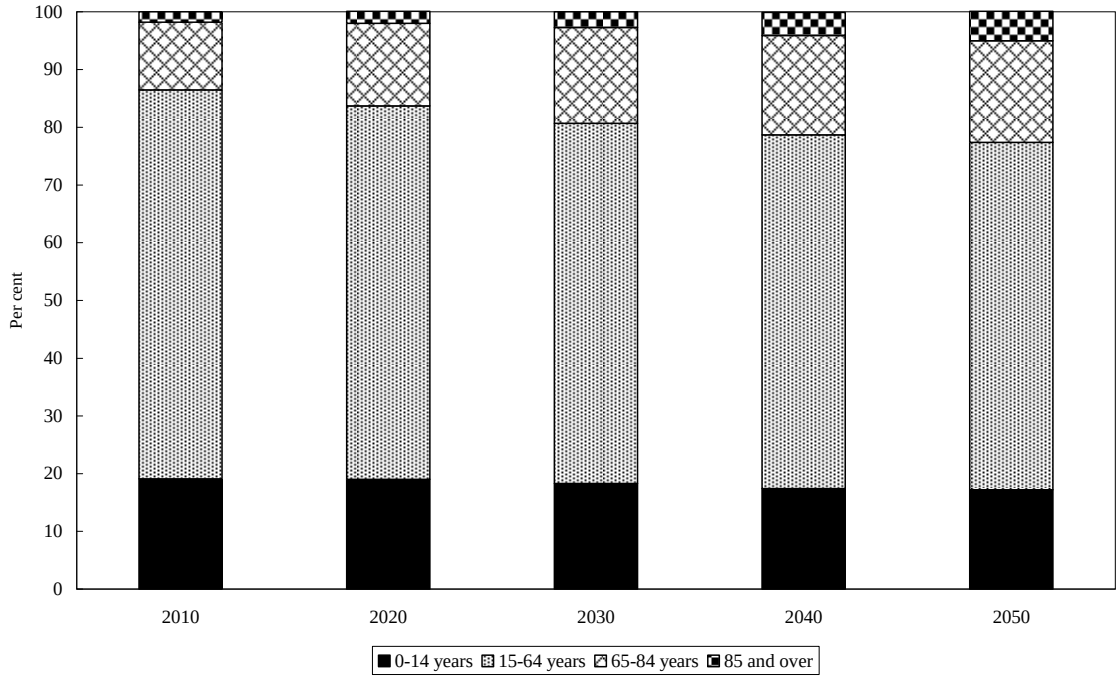
A challenging environment: Health sector regulations in an ageing population

It is well known that the structural composition of the Australian population is likely to change in coming decades. According to the third federal Intergenerational Report (IGR) released this year, the population is projected to grow and continue to age over the next four decades with the fastest rates of growth in the numbers of people aged 65 and over.

A mix of longer life expectancy, ageing of the 'baby boom' population and fertility below replacement rates means that about 25 per cent of the population is projected to be aged 65 and over by 2047 (Figure 1.3). By contrast, the proportion of the working age population (i.e. those persons aged 15 to 64 years) will decline over the same period.

[14] See, for example, California Office of Statewide Health Planning and Development, Coronary Artery Bypass Graft Surgery in California: 2005-2006 Hospital & Surgeon Data, http://www.oshpd.ca.gov/HID/Products/Clinical_Data/cabg2009/CABG0506.pdf (accessed 10 February 2010); Canadian Institute of Health Information (CIHI), 2009, Hospital Standardized Mortality Ratio (HSMR) 2009 Results, http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=hsmr_results_canada_e (accessed 10 February 2010); Care Quality Commission (UK), 2009, 'Care Quality Commission publishes NHS performance ratings', Press Release, 15 October, http://www.cqc.org.uk//newsandevents/pressreleases.cfm?cit_id=35456&FAArea1=customWidgets.content_view_1&usecache=false (accessed 10 February 2010).

Figure 1.3: Proportion of Australian population by age bracket



Source: Commonwealth Treasury, 2010, Intergenerational Report 2010 – Australia to 2050: Future Challenges, http://www.treasury.gov.au/igr/igr2010/report/pdf/IGR_2010.pdf (accessed 10 February 2010).

The IGR projects that the structural ageing of the population will lead to significant expenditure and service delivery pressures on the health care system. It is projected that commonwealth government spending on health care would increase from four per cent of GDP in 2009-10 to 7.1 per cent in 2049-50. (The IGR's projections do not take into account proposed reforms by the federal government.)

It is also expected that expenditure by state and territory governments will also increase significantly in coming decades as more older people demand hospital care and other subsidised services.

Whereas the expected growth in financial and operational burdens on government providers of health care services have been the main focus of policymakers and the general public in recent years, the implications of demographic change for private health providers have tended to be overlooked.

These developments have been somewhat puzzling, given that a strong and resilient private sector in many ways holds the key to maintaining sustainable delivery of services to an ageing population.[15] Specifically, the private sector has the potential capacity to expand services without invoking the 'fiscal crunch' of higher tax burdens that comes with governmentally provided health services.[16]

[15] Adele Ferguson, 2009, 'Ramsay Health Care has its finger on the pulse', The Australian, 7 September.
[16] The capacity for expansion by the private health sector is contingent on a number of factors, such as the availability of specialised capital and skilled medical and other labour.

There has however been a lack of clear analysis from those who assume that public patients can be readily transferred from an overcrowded public sector to take up the unused capacity in private hospitals. There are inherent difficulties. The Australian health system is heavily dependent on the willingness of a large number of citizens to voluntarily pay for their own health care by paying for private health insurance. They therefore add substantially to the pool of money available for health expenditure and a reduction of that money is an absolute reduction in the moneys available for health. The issue must be addressed that if there is an automatic entitlement for public patients to access private hospitals it diminishes the incentive to take out private health insurance. If this results in a disincentive to the take up of private health insurance the whole system will suffer. The implications will need to be examined before embarking on a substantial program.

In addition care will have to be taken to analyse the capacity of the private hospital system to accept numbers of public patients. Capacity will vary throughout Australia but some private hospitals are already suffering capacity restraints.

More analysis will also have to be given to the pricing structure of such an arrangement. Doctors in the private sector have a higher reward structure than in the public sector. The combination of pricing for the two sectors provides a higher average income and provides an incentive to maintain the number of specialists in Australia. A change to this arrangement would have to be carefully examined as to its implications. As well there are other issues such as the type and costs of prosthetics. The implications of a substantial application of such a policy have not been properly examined.

The capacity of the private sector to play a greater role in health care services delivery will critically depend on the maintenance of a best-practice regulatory policy framework by governments. Ensuring that government regulations are imposed with reference to a minimum effective benchmark, that meets its objectives at least cost, and that regulatory agencies provide a clear and transparent framework for private sector activity will be an important objective in this regard.

As the following Chapters indicate, an alarming range of regulations impose excessive burdens upon health care businesses hampering their capacity to achieve service efficiencies for patients and the general public.

More fundamentally, reforms to existing regulatory regimes will be needed in order to improve health services outcomes for Australians. A growing number of providers have expressed concerns that the excessive compliance burdens of regulation are diverting their efforts away from what they do best – delivering the best possible care for patients (Box 1.2).

Box 1.2: Concerns raised by health sector participants about commonwealth and state regulations

The following provides a selection of comments by key health sector participants about the existing regulatory framework imposed by governments:

‘The greatest reason for GPs to retire … is the bureaucratic nightmare of increasing paperwork’ (Comment on ‘Calling it quits’, Australian Doctor, 14 October 2009).

'Red tape restricts patient access to care with some estimates suggesting that general practitioners, for example, spend up to nine hours per week complying with red tape obligations. Every hour a GP spends doing paperwork equates to around four patients who are denied access to a GP' (Australian Medical Association, Submission to Productivity Commission Annual Review of Regulatory Burdens on Business – Social and Economic Infrastructure Services, 12 March 2009).

'What I would like to see is changes to things like PBS requirements so that they don't interfere with service delivery and responsibilities between different sectors … because at the moment the rules and regulations don't allow enough flexibility, and compromise patient health' (Comment by community pharmacist at National Health and Hospitals Reform Commission Listening Tour, Alice Springs, 11-12 June 2008).

'There are many components of the current regulatory regime that adversely affect industry competition and impose unnecessary barriers on private health funds achieving better health outcomes for their members. These barriers not only limit efficiency gains within the private health sector but also restrict potentially better health care for members' (Australian Health Insurance Association, Submission to Regulation Taskforce, November 2005).

'Currently, private hospitals report to a variety of entities on the safety and quality of their services. This is an ad hoc and wasteful series of multiple processes that have no capacity to either systematically monitor nor improve the safety and quality of private hospital services' (Australian Private Hospitals Association, Submission to National Health and Hospitals Reform Commission, 2009).

The problems raised concerning health regulations imply that reforms are urgently required to unleash the regulatory chains off health care providers, enabling the private sector to deliver more affordable health care while simultaneously improving care outcomes for all Australians well into the future.

2 Study framework and approach

Overview

As discussed in the previous Chapter, the burden of regulations has significant implications for the long term financial sustainability of the health care sector as well as its capacity to deliver world-class health outcomes.

To help ensure that regulations do not detract from the delivery of quality health care for all Australians, it is essential to understand the nature and extent of burdens that regulations impose at the outset. Where excessive regulatory compliance burdens faced by health care businesses are identified, opportunities are open for policymakers to take remedial action to reduce such burdens.

The aim of this Chapter is to develop an overarching analytical framework that will inform the more detailed assessment of key health sector regulatory burdens in subsequent Chapters.

Study coverage

Given the broad nature of health care services in Australia, and the inherent difficulties associated with identifying regulatory burdens, it is essential that this study is appropriately 'ring-fenced' by way of analytical coverage.

What industries?

The breadth of health sector activities undertaken by the private sector is extensive. According to the Australian and New Zealand Standard Industrial Classification (ANZSIC) system, the sector contains a range of activities such as:

- Private acute care hospitals and psychiatric hospitals
- General practice and specialist medical services
- Pathology and diagnostic imagining services
- Allied health services, including dental services, optometry and optical dispensing, physiotherapy, and chiropractic and osteopathic services.[17]

The extensive nature of the health sector is underpinned by the fact that other activities linked to health care, such as pharmaceutical manufacturing, distribution and retail and private health insurance services, are excluded from the ANZSIC classification of the health services sector.

It can be reasonably argued that the private health services most frequently accessed by Australians include those provided by general medical practitioners, pharmaceutical companies (manufacturing and retail activities), private health insurance funds and private hospitals. Accordingly, regulations affecting these four industries will be the focus of this study.

[17] Australian Bureau of Statistics (ABS), Australian and New Zealand Standard Industrial Classification (ANZSIC), 2006 – Codes and Titles, cat. no. 1292.0.55.002. Productivity Commission, 2006, *Potential Benefits of the National Reform Agenda*, Report to the Council of Australian Governments, Canberra.

On a value-added basis, these industries are significant in their own right. General practices ($4.7 billion, 2002-03) and private acute hospitals ($3.9 billion) are the single largest industries within the private health care sector ANZSIC classification (excluding veterinary services), while pharmaceutical manufacturing and retail activities generated $3.9 billion in value-added.[18] The private health insurance industry provides cover for over 11.2 million Australians for hospital and other medical treatments.[19]

What regulations?

Regulation can be defined as a principle, rule, law or other edict designed to control or govern conduct. Alongside taxation and expenditure, regulation is often used by government to shape incentives and influence how people behave and interact.[20]

Regulations can be categorised on the basis of the legal instrument by which it is made. They include principal acts and subordinate legislation, administrative decisions including policy guidelines, and quasi-regulation such as codes of practice, guidance notes, industry-government agreements and accreditation schemes.[21] The regulations examined in this study will be drawn from these categories.

It is not possible to conduct a detailed examination of the burdens imposed by all regulatory impositions affecting the health sector. This implies that the coverage of regulations assessed for the purpose of this study must be selective by nature.

Table 2.1 provides a list of the main categories of regulation to be examined. These incorporate a selected range of regulations specifically imposed on the general practice, pharmaceutical, private health insurance and private hospital industries respectively, as well as economy-wide regulations affecting these health care providers.

Complementing this list of health-specific and economy-wide regulations will be an assessment of the overall regulatory governance environment affecting the private health sector. For example, information could be obtained about the amount of legislation, or the number of government regulatory agencies, affecting health care operators.

Other issues, such as the degree of consultation with industry or a requirement by governments to complete a formal regulatory impact statement, influence the degree to which regulations are perceived as being onerous.

Information on regulatory governance can provide additional evidence about unnecessary regulatory burdens resulting from a growing amount and complexity of regulation.

---

[18] Pharmaceutical manufacturing includes medicinal products, and retail includes cosmetics and toiletries. ABS, Australia Industry, Experimental Estimates: Industry Performance by ANZSIC Class, Australia, 2002-03, cat. no. 8155.0.

[19] Australian Health Insurance Association (AHIA), Private Health Insurance Industry Statistics, March 2009.

[20] Productivity Commission, 2007, *Performance Benchmarking of Australian Business Regulation, Research Report*, Melbourne.

[21] PC, Ibid.

The coverage of regulations has been informed by direct consultations with industry participants, as well as evidence tendered by health sector stakeholders to government inquiries, about regulations that are likely to generate substantial burdens.

Table 2.1: List of assessed regulations

Coverage	Regulations
General practice medical services	• Practice Incentive Payments • Enhanced Primary Care • Compliance with government agencies
Pharmaceutical manufacturing and retailing	• Listing on the Australian Register of Therapeutic Goods • Clinical trials • Therapeutic Goods Administration marketing approvals • Pharmaceutical Benefits Schedule listing and pricing • Manufacturing quality standards and licensing
Private health insurance services	• Consumer information product disclosure • Premium approvals • Private health insurance rebate
Private hospital services	• Licensing provisions • Physical capital requirements • Safety and quality regulations

What regulatory burdens?

As discussed in the previous Chapter, regulations are imposed by governments upon the health sector on a number of grounds. Whereas these are typically predicated on the basis of promoting affordable treatments, and to improve the state of general health of individuals, concerns have been increasingly raised about the unnecessary, or excessive, burdens imposed by existing regulatory requirements.

As noted in recent studies by the Productivity Commission, the potential for unnecessary burdens arises from a number of sources:

- Problems with regulations themselves, including unclear or questionable objectives, conflicting objectives, overly complex or excessively prescriptive requirements, redundant regulation and 'regulatory creep'
- Poor enforcement and administration, including excessive reporting requirements, overzealous regulation, regulatory bias or capture and inexperience or lack of expertise of regulators
- Unnecessary duplication and inconsistency, including duplicated requirements across regulators, regulatory inconsistencies within or across jurisdictions and variations in regulatory definitions and reporting requirements.[22]

[22] Productivity Commission (PC), 2009, *Review of Regulatory Burden on the Upstream Petroleum (Oil and Gas) Sector*; PC, 2007, *Performance Benchmarking of Australian Business Regulation*; Regulation Taskforce, 2006, *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business*.

It is from these sources of burden that businesses bear the compliance costs of excessive regulations. These include the costs imposed on the administrative structures of a business, due to filling out forms and providing information to regulatory authorities, otherwise known as 'paperwork compliance costs.'

These paperwork costs also include other administrative costs, such as record-keeping and hiring external expertise (such as consultants and lawyers) to manage regulatory processes.

Unnecessary regulatory burdens also impose additional operating costs on a business ('non-paperwork compliance costs'), which can in turn affect underlying administration costs. They include:

- additional human capital investment (staff training and education) and physical investment costs (re-configurations to IT systems or other plant and equipment), and the costs of modifying output
- 'capital holding' and other costs associated with regulation-induced delays in business projects
- costs associated with dealing with inconsistent and duplicative regulation across jurisdictions
- time spent in meeting regulatory requirements, such as undergoing audits and inspections of premises or processes.[23]

As discussed below, this study will focus on the unnecessary burden of health sector regulations attributable to paperwork and non-paperwork compliance costs, collectively referred to in this study as 'administrative compliance costs.'

There are a range of other costs associated with government regulations. These include the economic costs of regulations where they affect the allocation of resources. Regulations can also affect competitiveness, innovation and entrepreneurial activities. Information on these impacts on the health sector is presented on a case-by-case basis where applicable.

Establishing compliance cost burdens

Ideally, the administrative compliance costs identified above would be directly observable enabling a relatively simple quantification of this aspect of regulatory burden. Further, these costs should be measured in terms of the incremental cost imposed on a business by one or more regulations – that is, the cost avoided if the regulations were withdrawn.[24]

In reality, it is not straightforward to measure these costs. Business accounting systems do not identify the incremental costs directly attributable to regulation. The counterfactual situation of what business cost structures would look like in the absence of regulation is usually very difficult to determine. This is further complicated by the fact that, in some cases, government regulations serve to codify practices that already occur in the private sector.

This study will seek to report on available estimates of administrative and other compliance costs. Where appropriate these estimates will be updated with reference to health costs and similar

[23] PC, 2007, Ibid.
[24] PC, 2007, Ibid.

indicators to provide a more contemporary reflection of the type and magnitude of burdens imposed upon the health care sector.[25]

As noted above, complementary indicators pertaining to regulatory governance will be used to provide supporting information on the extent of administrative compliance cost burdens faced by private health care operators.

Benchmarking compliance cost burdens across jurisdictions

The state and territory governments not only have extensive involvement in the provision and financing of health care, but impose a wide array of regulations in an attempt to fulfill their various objectives.

It is therefore necessary, with respect to state-based regulation, to also develop indicators providing comparisons between jurisdictions. Provided that the assessed regulations are designed to meet similar objectives, and that data supporting the indicators are collected in a consistent fashion, differences in regulatory burdens should (to some degree) reflect differences in administrative compliance costs across states.

The approval of a license application by a given state government will be dependent upon the applicant satisfying a range of administrative compliance requirements contained in legislation or policy guidelines. These may include filling out application forms, providing business plans and other information for assessment by applicable government agencies.

By way of an illustrative example, consider the hypothetical case of obtaining a license to establish a private (day surgery) hospital in one of three states (Table 2.2).

Table 2.2: Hypothetical scenario of benchmarking administrative compliance activities across three jurisdictions

Jurisdiction	Count of administrative compliance requirements
A	15
B	25
C	18

In the hypothetical example provided, jurisdiction B has the largest number of requirements of the three jurisdictions. Other things being equal, this may be indicative of greater (and perhaps unnecessary) compliance costs to establish a hospital in that jurisdiction compared to A and C.

[25] The results based on available studies are often not representative of the regulated population in statistical terms because of the limited sample size and non-random sample design of the measures to quantify regulatory burden.

3 General practices regulation

Overview

General practitioners (GPs) offer primary medical care services within the Australian health system. Indeed, for many they are the first port of contact when needing treatment.

According to the Australian Institute for Health and Welfare (AIHW), about 85 per cent of the Australian population visits a GP at least once a year. On average, every Australian spends around 83 minutes with a GP per year. On an international level, this is high: the average New Zealander spent 56 minutes with their GP, and the average American just 30 minutes per year.

The vast majority of patients are treated by GPs exclusively. In a typical 100 patient encounters, GPS provide 82 prescriptions, place 53 pathology and imaging test orders, but only make 12.5 referrals to specialists or allied health services.[26] (Since the late 1990s, referrals have been increasing.[27]) In 2007-08, there were 26,200 GPs billing Medicare in Australia.[28]

As well as providing the first point of contact, GPs have a *de facto* coordinating role in patient management. GPs can provide ongoing care, as well as treatment for those with chronic issues. GPs also have a critical role in management of health care subsidies and programs, providing information to third parties about eligibility for welfare payments, or subsidised services such as medicines under the PBS scheme.

As the first point of contact with patients, and, as non-specialists with wide discretion to direct patients around the medical system, general practice is particularly receptive to regulatory or financial changes. GPs deal with complex, undifferentiated illness, with which they must make the most efficient and effective diagnosis and treatment.

With such a broad purpose, the decisions made by GPs are heavily influenced by the regulatory frameworks and payment structures governing the sector. As this chapter argues, every stage of general practice interacts with the regulatory framework governing the sector.

What constitutes a regulatory burden in general practice?

> *'Red tape restricts patient access to care with some estimates suggesting that general practitioners, for example, spend up to nine hours per week complying with red tape obligations. Every hour a GP spends doing paperwork equates to around four patients who are denied access to a GP.'*[29]

Parsing out what is a regulatory burden and what is a 'natural' operational cost is extremely difficult. For example, GP participation in many of the government programs explored in this chapter is not mandatory, in that they are not compelled to participate. Furthermore, as the

---

[26] Australian Institute of Health and Welfare (AIHW), General practice activity in Australia 2007–08, Australian GP Statistics and Classification Centre.
[27] AIHW, General practice activity in Australia 1998–99 to 2007–08: 10 year data tables.
[28] Steering Committee for the Review of Government Service Provision (SCRGSP), 2009, *Report on Government Services 2009*, Productivity Commission, Canberra.
[29] Australian Medical Association, Submission to Productivity Commission Annual Review of Regulatory Burdens on Business: Social and Economic Infrastructure Services, 2009

Commonwealth Department of Health and Ageing argued in 2003, GPs are 'fully compensated for the costs incurred in participating' – the incentive schemes explored below are remunerative schemes, and the administrative costs of participation are, arguably, covered by that remuneration.

Furthermore, the structure of Medicare itself – compensation for government-nominated clinical practices – is itself a major contributor to the regulatory burden facing general practice. The Medicare Benefits Schedule (MBS) has, since it was introduced, been steadily added to and altered. MBS changes can have a significant impact on medical practice. Changing MBS items can favour certain treatments above other treatments, and can make others uneconomic to provide. As the Chair of the Australian Medical Association (WA) Council of General Practice has argued, Medicare Australia is a 'policy implementation instrument for the Commonwealth Department of Health and Ageing, an e-health driver, quality incentives platform ... and regulator.'

> *'… the department defines for we GPs, with inadequate consultation, how they think general practice and primary care is or should be working — then places item numbers with fees, descriptors, guidelines and complex paperwork requirements around them, regardless of whether they meet the "real world test".'*[30]

This multi-purpose role makes it extremely challenging to distinguish what constitutes a regulatory burden on the general practice sector and what constitutes a 'normal' administrative cost of performing general practice. General practice in Australia is privately operated but almost entirely shaped by policy decisions enacted through the Medicare system. In this chapter however we look at some of the most significant regulatory burdens which impact general practice in Australia.

One particular area which this chapter does not cover is the Pharmaceutical Benefit Scheme's authority script system. The authority script system was reformed in 2007, with the intention of saving 70,000 consultation hours per year. Nevertheless, the paperburden cost of the script system remains a common complaint among practicing GPs.[31] The Productivity Commission has argued that the authority script system be either further streamlined, or completely eliminated.

Significant regulatory changes

This regulatory system affecting GPs has been the subject of significant change over the last two decades. The direction of reform has been from moving general practice away from an autonomous professional discipline and integrating it within the broader health system and within health policy frameworks. William Coote also notes that there has been a similar integration between general practice and government direction of health goals:

> *'The political interface between general practice and the federal government evolved in parallel, from "corporatist" agreements initiated by national professional organisations, to processes initiated and managed by government with involvement of a broad range of medical and other groups.'*[32]

---

[30] Steve Wilson, 'MBS review a wasted opportunity', *Australian Doctor*, 30 June 2009.
[31] See, for example, *AMA War on Red Tape website*, available at http://waronredtape.blogspot.com
[32] William Coote, 2009, 'General Practice Reforms, 1989-2001', *Medical Journal of Australia* 191 (2).

The first major policy change that has a direct impact on regulatory compliance costs was the introduction of vocational registration linked to the payment of Medicare rebates, which was announced in March 1989. Vocationally registered GPs of the Royal Australian College of General Practitioners (RACGP) fellows are entitled to higher Medicare non-referred rebates. To achieve vocational registration, the RACGP administers a program of Quality Assurance and Continued Professional Development.

Similarly significant changes have been the introduction of Practice Incentive Program (PIP) and the Enhanced Primary Care (EPC) program, which grew out of the General Practice Strategy Review Group of 1998. Financial payments like the PIP and EPC programs are designed to give financial incentives to GPs to focus on certain areas of care. Incentive payments respond to the view that 'flat' Medicare payment schemes distort GPs focus away from optimal care:

> *'…in virtually all contexts it has been observed that on the margin, behaviour is altered by economic incentives and there are no reasons for supposing that doctors are different in this respect. Therefore a prediction is that there will be greater doctor enthusiasm for undertaking tasks which increase income, compared with those that are less well rewarded.'*[33]

Certainly, the structure of payment structures materially impact the types of treatment general practices administer. PIP payments are designed to militate against financial incentives to deliver quick consultations, rather than take the necessary time to conduct preventative healthcare, as well as the incentives GPs have to prescribe, order tests and refer to specialists. As an article in *Australian Private Doctor* argued, payment incentives are themselves designed to alleviate some for the perverse consequences of the Medicare funding arrangements:

> *'Government controls the number of doctors by controlling educational places and immigration; it controls the allocation of work between doctors and doctor substitutes by licensing and accreditation and the award of Medicare item numbers and adjustments to pay through variations to Practice Incentive Payments; it controls the prescribing habits of doctors by nominating what drugs will be on the NHS and for what drugs an authority to prescribe will be required; it directs the work that doctors will do by providing incentives to perform preventive health checks, carry out immunization, engage in mental health programs, perform chronic care plans and so on and on, and; it directs what research will be carried out by controlling research grants.'*[34]

The drive for incentive payments closely resemble a traditional regulatory 'cat-and-mouse' game, where actors operating within a regulatory framework adjust their behaviour to reap maximum benefit around those rules; incentive payments are an attempt to readjust the framework to compensate. This need not be deliberate, but the structure of a regulatory framework can subtly alter the behaviour of the regulated entity.

Unfortunately, one of the most well-documented results of such regulatory gamesmanship is added regulatory complexity. As Edward Kane writes in the context of financial regulation,

---

[33] Quoted in Andrew Boyden & Rob Carter, 2000, 'The appropriate use of financial incentives to encourage preventive care in general practice' Centre for Health Program Evaluation, Research Report 18.

[34] 'More of the same', Australian Private Doctor [available at http://www.privatedoctors.com.au/index.php?id=98].

> *'Market institutions and political imposed restrains reshape themselves in a Hegelian manner, simultaneously resolving and renewing an endless series of conflicts between economic and political power. The approach envisions repeating stages of regulatory avoidance (or loophole mining) and re-regulation, with stationary equilibrium virtually impossible.'*[35]

This complexity can manifest itself in increasing costs and paperwork burdens.

The first PIP payment, the General Practice Immunisation Incentive, was introduced in 1998. There are now 12 PIP payments available: incentives to provide afterhours care, employ practice nurses in rural and regional areas, extra training about new medicines, hosting undergraduate students, conduct cervical screening, asthma, diabetes and domestic violence initiatives, provide GP services to aged care homes, and, as of August 2009, to keep up to date with improvements in eHealth programs.

In order to receive PIP payments, practices must gain accreditation against RACGP standards – two hundred indicators covering medical services, patients' rights, quality assurance, administration and equipment. Accreditation lasts for three years, and obtaining accreditation involves a fee payment and extensive interviews with medical and non-medical staff.

The Enhanced Primary Care program is a separate incentive based program introduced in 1999 to encourage greater preventative care for older Australians and those with chronic conditions. Unlike PIP payments, the EPC program is delivered through the Medicare Benefits Schedule.

Enhanced Primary Care was given a major revision in 2005 with the introduction of new MBS items for Chronic Disease Management to provide practitioners more options and flexibility for the management of patients with chronic conditions. The items provide for GP Management Plans and Team Care arrangements, and absorb the pre-2005 EPC care plans. Up to five allied health visits per patient per year are available under the CDM items.

Other incentive programs include the Mental Health Nurse Incentive Program.

These programs, PIPs and EPC items, provide extra revenue streams for GPs for doing certain policy-favoured activities. They can provide significant extra income to GPs, often mitigating against rising practice costs. But they also bring substantial paper-burden costs.

General practitioners have for a long time been negatively affected by the paperwork and bureaucratic burden of government policy settings. GPs have cited PIPs as a major contributor towards paperwork burden, as well as other interactions with government services such as Centrelink. This paperwork can have major consequences for workload and practitioner welfare.

Specifically, bureaucratic burdens feed directly into the three major causes of stress in general practice – excessive workload, the economic factors necessary to run a business, and 'medicopolitical' factors, that is, the political and regulatory environment within which practices operate. According to a 1998 study – on the cusp of the introduction of the major incentive payment schemes:

---

[35] Edward J Kane, 1981, 'Accelerating Inflation, Technological Innovation and the Decreasing Effectiveness of Banking Regulation', *The Journal of Finance* 36 (2).

> *'The most common sources of dissatisfaction or frustration were a belief that the contribution of GPs is not appreciated by government, apprehensiveness about the changes and reforms in general practice, a belief that government was interfering in the ability to make clinical decisions, pressure to bulk bill patients, and the introduction of "blended" payments (remuneration through a mixture of fee-for-service and non-fee-for-service payments).'*[36]

Fittingly, the 1998 study, which comprised of a survey of 500 GPs in Australian metropolitan areas, found that 'paperwork' was listed the second largest contributor towards GP stress, just below 'time pressure to see patients.' Perhaps just as significantly, these pressures created by regulatory settings were reported far more commonly that the widely perceived stressors of 'threat of litigation.' While litigation, when it occurs, is the most stressful, with its very low frequency, paperwork and workload are more significant day to day pressures GPs face.

The 2009 *Medical Observer* Stress Test found that of the GPs who reported worrying stress levels, the majority laid the blame on bureaucracy and red tape. The same study found that bureaucracy and red tape was the second largest contributor to negative health consequences from general practice work. Three-fifths of respondents claimed that the increase in stress was higher than two years ago.[37]

In a limited survey of GPs in the Osborne General Practice Division in Western Australia, 77 per cent felt that the combined there was either too much or far too much red tape involved in Medicare, PIP and PBS services.[38]

The administrative burden of Enhanced Primary Care

The Enhanced Primary Care (EPC) package was introduced in 1999. In the 2002, the Productivity Commission's inquiry into General Practice Compliance costs found that organisation of Enhanced Primary Care plans was the third highest administrative cost incurred by GPs.

Prior to the 2005 changes EPC use was declining, in part because of the administrative burden involved. Some of these administrative burdens are one time only, as one GP put to the Productivity Commission, nevertheless, ongoing costs are still substantial:

> *'To set up a system for Care Plans in our practice took me at least 60 hours. I employ someone for around 10 hours a week to administer it. The doctors all complete the Care Plan paperwork in home time.'*[39]

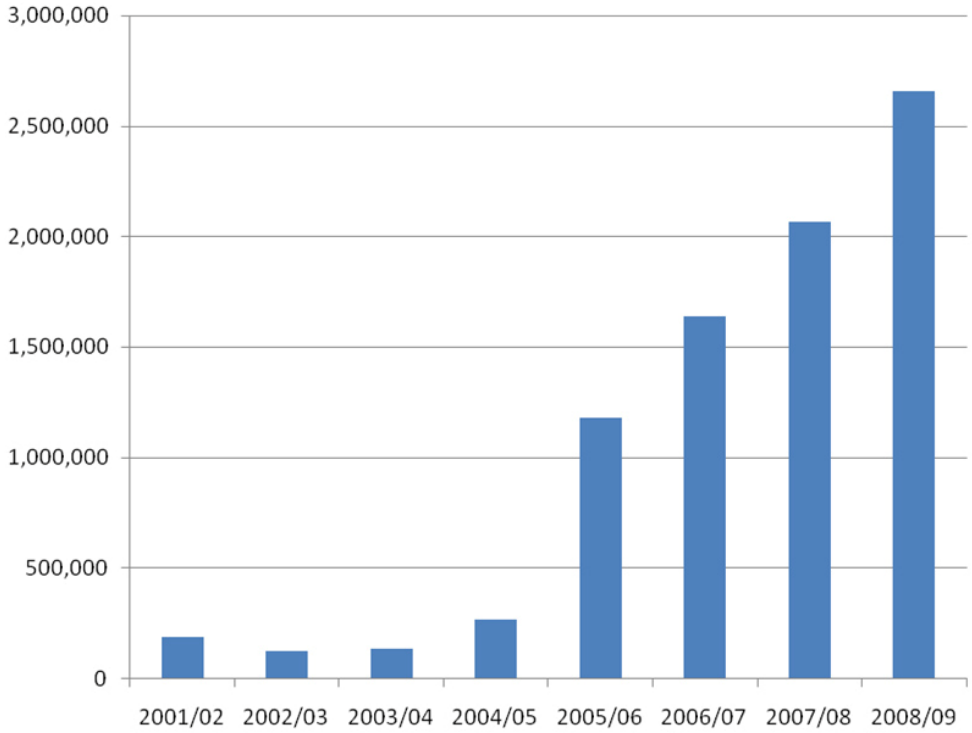
The 2005 changes meant a dramatic increase in the use of EPC by practitioners.

The new Chronic Disease Management (CDM) items have doubled in uptake since 2005. Compiling the use of EPC items pre- and post-2005, Medicare statistics show that since the Productivity Commission's 2003 study that increase is even more dramatic: from 184,952 to 2,657,190 items billed. (See Figure 3.1)

---

[36] Peter L Schattner and Greg J Coman, 1999, 'The Stress of Metropolitan General Practice' *MJA* 169.
[37] 'Stress snapshot', *Medical Observer*, 17 July 2009.
[38] Osborne Division GP comments, Submission to the Productivity Commission Inquiry into General Practice Compliance Costs. 2003
[39] Australian Divisions of General Practice Ltd. Submission to the Productivity Commission on the General Practice Compliance Costs Study. 2003

Figure 3.1: The Use of Enhanced Primary Care Medicare Items, 2001-2009



Source: Medicare Australia statistics

The number of participating GPs has also dramatically increased. In 2003-04, 7109 GPs were utilising the EPC items, or 40.9 per cent. In 2007-08, 93 per cent of all GPs were using EPC items.

The Productivity Commission's 2009 Report on Government Services speculates that the sharp increase from 2005 to 2009 is due to the steady introduction of further CDM items, but given the documented low levels of knowledge about MBS items, both when items are first introduced, and for recent GP registrars, it is likely cultural changes within general practice and increased education about CDM items are factors as well.

The Vice-chairman of the General Practice Registrars Australia was quoted in *Australian Doctor* arguing that 'the requirements and training required to access these numbers seem to change every 12 months' and 'the government has made a lot of changes to the MBS over time, which seem to be based more on political expediency than improved patient care.'[40]

Delays in adoption are common after Medicare changes; the use of Service Incentive Payments was extremely low in the first year after their introduction.[41]

The administrative burden of the enhanced primary care items is substantial. For MBS item 721 – which constitutes a large bulk of the CDM items – the rules and regulations covering the item are comprised in a 52 page document. Box 3.1 outlines the extensive administrative tasks involved in

[40] Heather Ferguson, 2009, 'Crunching the Numbers', Australian Doctor, 3 September.
[41] Campbell Research & Consulting, 2003, 'General Practice Compliance Costs', 24 February.

organising a EPC Team Care Arrangement, including the development of a GP Management Plan, extensive documentation, and arranging the cooperation of allied health providers.

Box 3.1: Referring patients to allied health workers under a EPC Team Care Arrangement

- The GP must contact the proposed providers and obtain their agreement to participate, realising that they may wish to see the patient before they provide input but that they may decide to proceed after considering relevant documentation, including any current GP Management Plan (GPMP);
- The GP must collaborate with the participating providers to discuss potential treatment/services they will provide to achieve management goals for the patient;
- The GP must document the goals, the collaborating providers, the treatment/services they have agreed to provide, any actions to be taken by the patient and a review date i.e. completing the TCA document; and
- The GP must provide the relevant parts of the TCA to the collaborating providers and to any other persons who, under the TCA, will give the patient the treatment/services mentioned in the TCA.
- The collaboration between the coordinating GP and participating providers must be based on two-way communication between them, preferably oral, or, if this is not practicable, in writing (including by exchange of fax or email, but noting that the means of communication used must enable privacy to be safeguarded in relation to patient information). It should relate to the specific needs and circumstances of the patient. The communication from providers must include advice on treatment and management of the patient.

To develop Team Care Arrangements for a patient, at least two health or care providers who will be providing ongoing treatment or services to the patient must collaborate with the GP in the development of the TCA. This includes people who will be organising or coordinating care services for the patient that will be provided by their organisation.

Each of the health or care providers must provide a different kind of ongoing care to the patient. One of the minimum two service providers collaborating with the GP may be another medical practitioner (normally a specialist or consultant physician but not usually another GP).

The patient's informal or family carer may be included in the collaborative process but does not count towards the minimum of three collaborating providers.

One GP has written:

> *'Red tape makes team care arrangement planning cumbersome. We have to draft the care plan, copy it to two other providers and wait for their feedback before we can claim for the service, and the providers have to send their feedback before they have seen your patient, which is a bit absurd.'*[42]

As the AMA points out, these burdens need to be seen in the context of a Medicare Benefits Schedule which now comprises of 4400 items – the MBS is now so unwieldy that the Department of Health and Aging has ceased producing a hard copy. New items added onto the MBS come with detailed restrictions, including how limitations on how often those services may be provided

[42] *AMA War on Red Tape website*, 16 February 2009, available at http://waronredtape.blogspot.com

to patients, how those services must be delivered and so on. The AMA argues that 'these requirements will often disturb existing systems and processes that operate effectively.'[43]

The cost and compliance burdens are not only borne by GPs. Allied health workers report similar issues with uncompensated paperwork requirements when referred patients through CDM items.[44]

The Productivity Commissions' 2003 report into General Practice Regulations allows us to estimate the regulatory burden of Enhanced Primary Care items. The substantial increase in the number of GPs using EPC items, and the number of EPC items used has led to a dramatic increase in the compliance burden of enhanced primary care. The Productivity Commission estimated that the total compliance burden from EPC items was $17 million per year. If the relative burden remains steady, that compliance burden will have increased to $156 million per year.

Table 3.1: Estimated Enhanced Primary Care compliance burdens, 2001-2002 & 2007-2008

	Number of services	Number of GPs	Practice staff salaries – hourly rates ($)				Estimated compliance burden ($)
			GP	Nurse	Practice Manager	Receptionist	
2001-2002[a]	184,952	6,951	63.84	19.34	20.10	15.64	17,676,169
2007-2008	2,657,190[b]	17,736[c]	77.50[d]	23.48[d]	24.40[d]	18.99[d]	156 551 395

a) 2002-2003 figures from Productivity Commission Report into General Practice Regulation, 2003. b) Medicare Australia statistics. c) Steering Committee for the Review of Government Service Provision (SCRGSP), 2009, *Report on Government Services 2009*, Productivity Commission, Canberra. d) Hourly rates reported in 2003 Productivity Commission study, adjusted for general health inflation.

Red tape and blended payments

It is widely recognized that delivering health outcomes through blended payments – whatever their benefits – is a leading cause of regulatory complexity and paper burden. Nevertheless, despite this burden, preventative measures that some blended payments seek to encourage are supported by the general practice profession.

The political drivers behind the expansion of blended payments provide cause for concern however. The 2009 National Preventative Health Taskforce provides an example of blended payments being used for political ends with little acknowledgement of the compliance constraints such payments place on general practice. In order to develop an 'integrated' health service, the PHT recommends

> *'blended payment models that provide for payment of clinicians through a combination of fee for service, salaries, capitation and performance-based payments accompanied by a single*

[43] Rosanna Capolingua, *Australian Medical Association Submission to Productivity Commission's Annual Review of Regulatory Burdens on Business – Social and Economic Infrastructure Services*, March 2009.
[44] See, for example, *Simplifying the Mechanics of Patient Care Under Medicare for Dietitians in Private Practice: An Evaluation of Dietetics Medicare Services for Chronic Disease Management*, Monash Institute of Health Services Research, July 2008.

> *funds holder for primary and community care and public healthcare, ideally funded through a 'needs adjusted' capitated formula.'*[45]

Such adjustments to the regulatory framework governing general practice need to be carefully studied for the impact on paper burden, and their impact on GP capacity. Indeed, the AMA has argued that the compliance costs imposed by blended payments can act as a de facto rationing mechanism.

> *'[The] Commonwealth Government uses red tape as a blunt rationing mechanism to discourage medical practitioners from providing more services and in some cases actively limiting the number of services [they] can provide to patients and thus contain health costs.'*[46]

Without seriously engaging the paper burden costs of blended payments, the expansion of such payments could have deleterious consequences for the access and equity of the Medicare system.

General Practitioners as government service administrators

One of the major paper burdens faced by GPs is a consequence of their position within the health system as gatekeepers – GPs are increasingly shouldering the burden of assessment for welfare, pension, and other government services.

The mechanisms by which federal and state governments assess qualifications for such services, and by which those qualifications are reassessed, places GPs in a central position. The individual paperwork requirements for assessing whether a patient qualifies for government services are a substantial burden on general practice.

Commonwealth and state government programs in which GPs play a key or facilitative role include:

- The Disability Support Pension Sickness Allowance
- Newstart Allowance
- Youth Allowance
- Mobility Allowance
- Carer Payment & Carer Allowance
- Mobility / Disabled Parking Permits
- Telstra Priority Assistance
- Workcover
- Social housing support forms.
- Taxi subsidy schemes

In most cases, the GP is required to fill out documentation with the patient, including description of symptoms, patient history, details of treatment, and whether a patient's condition is improving, deteriorating or static. The extent of detail required for each application can vary significantly.

---

[45] National Preventative Health Taskforce, *Australia: the healthiest country by 2020 – National Preventative Health Strategy 2009*, September 2009, page 40

[46] Rosanna Capolingua, *Australian Medical Association Submission to Productivity Commission's Annual Review of Regulatory Burdens on Business – Social and Economic Infrastructure Services*, March 2009.

The application for the New South Wales Taxi Transport includes the question 'On average how far can the applicant walk before needing to stop and rest?' with a comment 'This question must be answered!'[47]

Table 3.2 provides an illustration of the volume of forms GPs have to contend with.

The area of taxi subsidies provide an example of possible benefits of administrative efficiency in documentation which GPs have to fill out. In Victoria, the substantial taxi subsidy compliance forms have been shifted onto an online processing system. When the new process comes into effect in 2011, the Victorian government estimates that this change will generate an overall administrative saving of $748,000.

Table 3.2: Forms which require the input of GPs in Victoria

Housing	The medical cooling concession form
	Companion card application form
	Application for public housing
	Application for early housing
Child Protection	Protective intervention report form
	Child wellbeing referral form
	Request for information response form
Health	Infectious diseases notification forms
	Victorian Patient Transport Assistance Scheme
	Application to treat an opioid dependent person with methadone or buprenorphine
	Notification of drug dependent person
	Notification of termination of methadone or buprenorphine program
	Pertussis prevention for new parents form
	Government Funded Vaccine Order form
	Adult Refugee Vaccine Order form
	Infectious diseases: notifiable conditions form
	Non-emergency patient transport audit tool
	Victorian Birth Defects notification form
	Better Safer Transfusion Program
	Cleaning Standards Internal Audit form
	Application for a permit to treat a patient with schedule 8 drugs
	Application for a warrant to obtain or use ovulatory stimulants
	Application for a warrant to obtain or use prostaglandins
	Application for a warrant to obtain or use retinoids
	Application for a warrant to obtain or use thalidomide
Mental Health	Recommendation form for a person to receive involuntary treatment from an approved mental health service
	Recommendation form for sedation for the purpose of safely transporting a person to an approved mental health service
	Recommendation form for involuntary treatment order
	Form for informed consent to major non-psychiatric treatment
Worksafe	Independent Medical Examiner

[47] Application for Taxi Transport Subsidy for People with Severe and Permanent Disabilities. (NSW) Available at http://www.transport.nsw.gov.au/sites/default/file/ttss/ttss-application.pdf

	Driver Commercial Health Assessment Medical Certificate
Registry of Deaths, Births and Marriages	Medical Certificate Cause of Death form (of a person aged 28 days or over)
	Medical Certificate Cause of Perinatal Death form
Coroners Court	Medical Deposition Form
Other	Victorian Curriculum Assessment Authority form
	Request form for non-coronial post-mortem examination

Source: AMA Victoria

Some specific areas where GPs facilitate government services are worth briefly discussing.

Disability support pensions

For GPs, the administrative burden of disability pensions is substantial. The Productivity Commission found that while FaCS/Centrelink programs only accounted for a small portion of total administrative cost, they were frequently cited as the most frustrating. Two-thirds of GPs surveyed by the Productivity Commission described the time spend on Disability Support Pension forms as unreasonable.

One doctor has written:

> *'The Centrelink Disability Pension review form needs to be completed repeatedly and often, the patient's condition hasn't changed. If this is the case, it would be good to have the option of saying 'no significant change' on the review.*
>
> *Another concern is the inflexibility of time frames. Patients will present with a note saying that if the review is not completed in the next few days, their payment will be cut off. This is especially frustrating when the patients' regular doctor is unavailable because it makes picking up the load far more onerous. Extensions should be available.'*[48]

Since the Productivity Commission's study, the number of Australians on disability support pensions has increased from 624,000 in 2001 to 736,000 in 2009. Disability Support Pensions, along with other related schemes, such as the Carer Payment, have to be frequently reviewed regardless of any change in status.

The Disabled Support Pension Medical Report is an eight page document to be filled out by the GP, including extensive description of patient history (etiology, precipitating factors, underlying causes, results and dates of investigations/procedures and radiology, pathology, RFTs, specialist reports), past treatment (including frequency, duration, type) and specific details of planned future treatment.

Sick notes

One surprising contributor to GP paper burden is the increasing requests for sick notes by employees who need to provide evidence of sickness to their employer.

[48] Tony Bartone [comment], *AMA War on Red Tape website*, 16 February 2009, available at http://waronredtape.blogspot.com/2009/02/federal-government.html?showComment=1234780980000#c4238155695589153650

While the private sector uses sick notes to assess sick leave, sick notes requirements are also imposed by government services. Sick notes are used for assessing Centrelink Sickness Allowance payments, or exemptions from jury duty. Further documentation – on top of a standard sick form - is required by some state curriculum authorities to prove illness.

According the Australian Institute for Health and Welfare's 'Bettering the Evaluation And Care of Health' data, the number of patient requests for sickness certificates has nearly doubled in the last decade; from 170,000 per year in 1998-2000 to 318,000. Further increases have been seen in requests to fill out workers compensation and carer's leave certificates. Employers' requirements for sick leave certificates also places a burden on the health sector as sick employees require appointments for illnesses that only last a single day.[49]

Social housing support

Applications for social housing can take into account the health circumstances of applicants, and here too general practitioners are the primary means by which the government assesses their suitability for housing.

The Queensland social housing medical report requires practitioners to report to the Queensland Department of Communities (Housing and Homelessness Services) details such as the current medications the patient is receiving, patient history, and how the initial diagnosis was made. Apart from the obvious compliance burden imposed by such a form, the relevance for social housing application is to be questioned.

In many cases, general practitioners are asked lifestyle questions – in the case of New South Wales housing, GPs are asked 'What type of housing does the client/patient require due to their condition?' GPs position in the medical system means that they burdened with the implementation of public policy in a wide array of areas.

Policymakers and general practice

General practice provides the entry point for most users of the medical system in Australia. As a consequence, it is substantially utilised by policymakers to facilitate service delivery, and to coordinate health care. These dual roles expose general practitioners to substantial regulatory burdens as they perform these tasks.

Furthermore, the regulatory structures which govern general practice compensation are being used by policymakers to pursue policy goals – which, while often laudable, exacerbate these pressures.

[49] Shannon McKenzie, 'Rising demand for sick notes a red-tape nightmare' *Medical Observer*, 17 July 2009

4 Pharmaceuticals regulation

Overview

The Australian pharmaceutical industry undertakes the development, production and supply of pharmaceutical and medicinal products.[50]

According to Medicines Australia, the Australian pharmaceutical industry has a turnover of some $17 billion.[51] The industry employs approximately 34,000 people across Australia, including 14,000 directly employed in pharmaceutical manufacturing.

With exports valued at $3.9 billion in 2007-08, pharmaceuticals represent Australia's second largest manufactured export product.

The Australian pharmaceuticals industry comprises a complex chain of biomedical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling, distribution and retail (figure 4.1).

Consumers with medical conditions treatable with pharmaceuticals either seek this treatment from general practitioners or hospitals, or they self-medicate.[52] If the treatment requires a prescription pharmaceutical, the doctor provides the prescription to the patient and this can be filled out at a registered pharmacy. Some pharmaceuticals must be administered within a hospital.

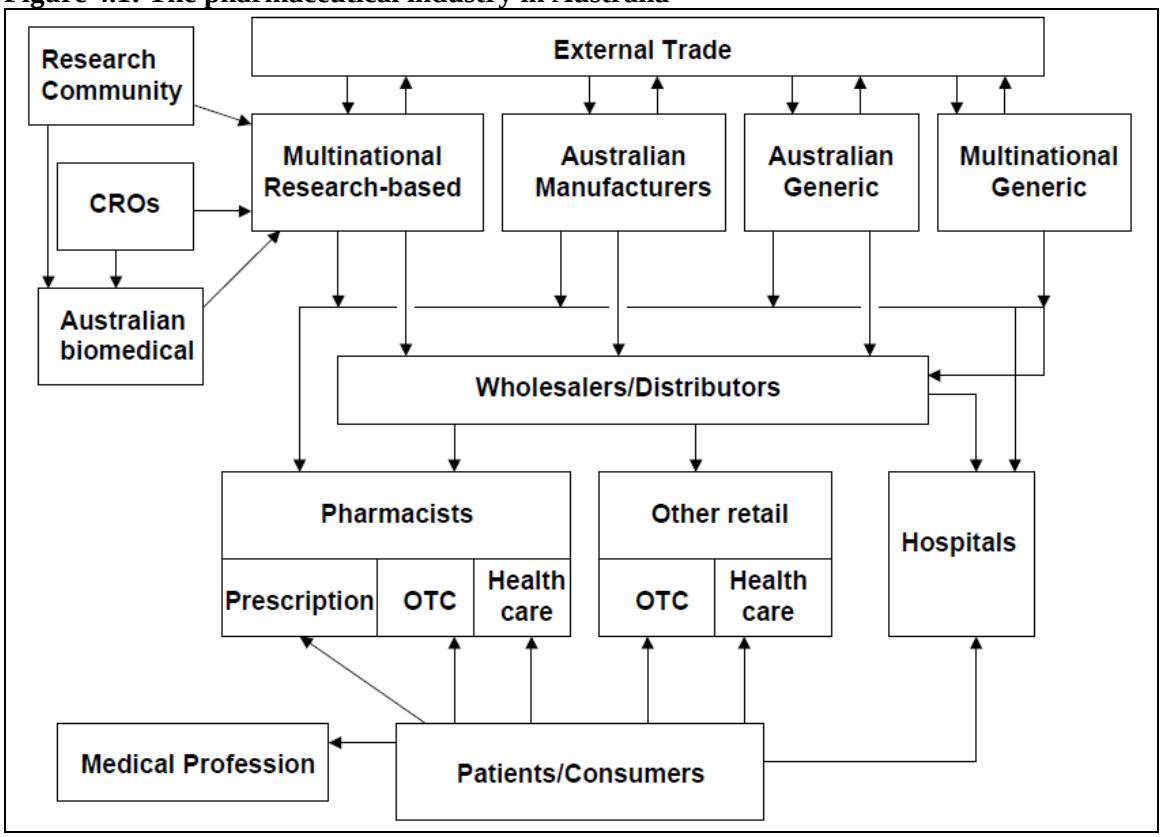
According to state and territory legislation, only hospitals and pharmacists are permitted to dispense prescription medicines in Australia.

Alternatively, if the pharmaceutical treatment does not require a prescription these can be purchased from either a pharmacist or selected other retail outlets.

The supply of pharmaceuticals in Australia is dominated by research-based multinational pharmaceutical companies. Some Australian companies act exclusively as manufacturers, but most combine manufacturing with wholesaling, distribution and other health-related activities.

[50] For the purpose of this Chapter the terms 'pharmaceutical' and 'medicine' will be used interchangeably.
[51] Medicines Australia, http://www.medicinesaustralia.com.au/pages/page4.asp (accessed 24 November 2009).
[52] Kim Sweeny, 2007, 'The Pharmaceutical Industry in Australia', Victoria University of Technology Centre for Strategic Economic Studies, Working Paper No. 34, September.

Figure 4.1: The pharmaceutical industry in Australia



CRO is an abbreviation for clinical research organisation, while OTC is over-the-counter medicines.
Source: Kim Sweeny, 2007, 'The Pharmaceutical Industry in Australia', Victoria University of Technology Centre for Strategic Economic Studies, Working Paper No. 34, September.

The industry makes a significant contribution to the lives of patients by limiting the impacts of illness and to those who incur the costs of health care by reducing rates of hospitalisation or other advanced treatment episodes.

The benefits of pharmaceutical products are also enjoyed financially by the individual, insurance companies and governments since their use contributes to an overall diminution of health care expenditure. While there are no comparable Australian analyses, a Columbia University study found that for every dollar of expenditure on a medicine the expenditure costs of hospitals were reduced by US$7.17.[53]

Despite their significant contribution to health outcomes, pharmaceuticals are heavily regulated from their point of innovation to point of sale. While there are numerous regulations affecting the industry, the principal regulations that affect pharmaceutical production, distribution and retail include the processes of securing:

- clinical trial data required throughout any medicines innovation process to ensure marketing approval

[53] Brian J. Bedkober, 2009, *Problems in Health Care Delivery: Government as Cause, not Cure*, Bookpal.

- marketing approval by the federal Therapeutic Goods Administration (TGA), who assess safety and efficacy for any pharmaceutical to be listed on the Australian Register of Therapeutic Goods (ARTG) as a requirement for sale in Australia
- licenses to manufacture pharmaceuticals in a TGA approved manufacturing facility
- listing on the commonwealth government's Pharmaceutical Benefits Scheme (PBS) that subsidises specific medicines, with the effect of ultimately deciding which medicines are likely to be prescribed by Australian doctors.

Therapeutic Goods Administration

The commonwealth predecessor to the TGA was established in 1963 following the problems associated with the sale of Thalidomide. Prior to 1963 retail sale of therapeutic goods was principally the role of state governments.[54]

The commonwealth assumed the responsibility of state governments following the passage of the *Therapeutic Goods Act 1986*, followed shortly thereafter by the *Therapeutic Goods Act 1989*. The 1989 Act established the current TGA and empowered it to require the compulsory listing of medicines on the Australian Register of Therapeutic Goods (ARTG), the requirement for the submission of safety and efficacy data for medicines and the licensing of manufacturing facilities.[55]

Figure 4.2 illustrates the steps of regulatory approval required by the TGA for a manufacturer to take a medicine to market.

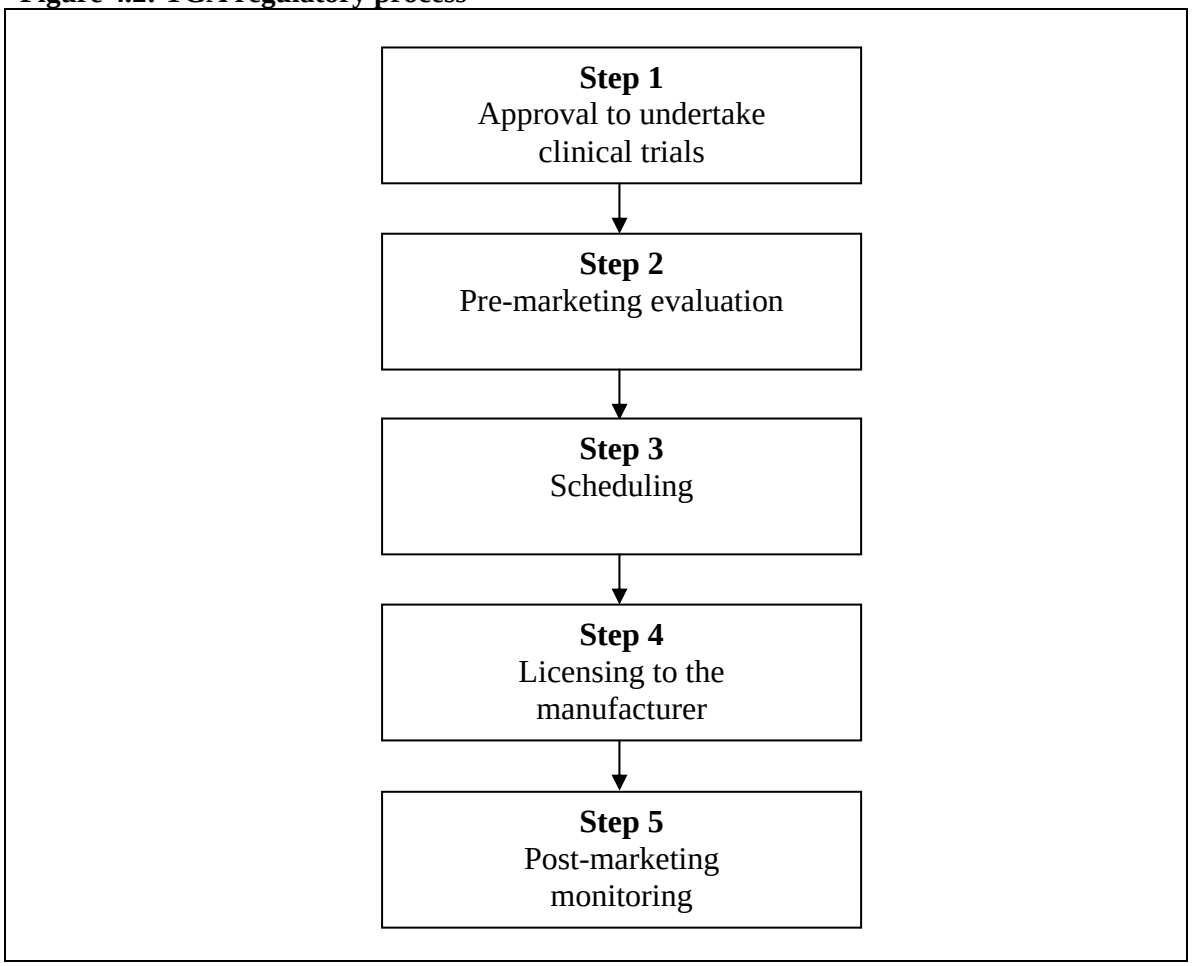
Unlike other regulatory regimes, once a medicine is listed on the ARTG there are limited regulatory compliance obligations enforced by the TGA. The principal post-marketing approval role of the TGA is to license appropriate manufacturers and ensure relevant standards are upheld in the manufacturing of medicines.

The TGA is also responsible for the occasional recall of medicines and also to monitor reports of adverse reactions to medicines. While the TGA is ultimately responsible for the delisting of medicines if they are found to have adverse consequences, because medicines are generally listed on the ARTG after they have received marketing approval from other developed countries, the numbers delisted remain small.

Further, the necessity for the TGA to engage in post-marketing approval clinical analysis is likely to deliver low dividends in comparison to the cost to the agency, and the duplicated cost imposed through the regulation on the innovator and licensed manufacturer.

[54] John McEwen, 2007, *A History of Therapeutic Goods Regulation in Australia*, Department of Health and Ageing, http://www.tga.gov.au/about/tghistory.pdf (accessed 24 November 2009).
[55] Industry Commission, 1996, *The Pharmaceutical Industry*, Inquiry report, p. 42.

Figure 4.2: TGA regulatory process



Source: Adapted from Industry Commission, 1996, *The Pharmaceutical Industry*, Inquiry report, p. 46.

However there is duplication in the activities of the TGA between two common markets – Australia and New Zealand. A 2002 report by Toogoolawa Consulting recommended the establishment of a trans-Tasman therapeutic goods administration.

The principal benefits of a bi-national regulator include the reduction of regulatory compliance obligations on innovator and generic companies seeking marketing approval, reduces the time for a medicine to be given marketing approval and reduces multiple standards for information, and standards of the information, required for marketing approval.[56]

It is also noted that similar bi-national regulators already operate, such as Foods Standards Australia New Zealand.

As a consequence the Australia New Zealand Therapeutic Products Administration was initially supported by both the Australian and New Zealand government, but has since been deferred due to the lack of support in the New Zealand parliament for a new regulatory apparatus.[57]

---

[56] John McEwen, *A History of Therapeutic Goods Regulation in Australia*, p. 154.
[57] Department of Health and Ageing and Medsafe, 2007, 'Postponement of the ANZTPA Establishment Project', http://www.anztpa.org (accessed 2 December 2009).

Clinical trials

A core function of the TGA is to regulate clinical trials for the development of new medicines and also to regulate the clinical trial data required to support an application for a medicine to be listed on the ARTG.

To secure listing on the ARTG applications fall into category 1, 2 and 3 applications. Category 1 applications are for new medicines or chemical compounds that had not previously been granted marketing approval in another country. Category 2 applications are for new medicines or chemical compounds that have received marketing approval and the sponsor can submit approval reports from Canada, the United States, the United Kingdom, Sweden or the Netherlands. Category 3 applications are those to amend already submitted data.

The most burdensome applications are category 1 applications, which require the submission of a Common Technical Document (CTD) including the following modules:

Module 1	Administrative information and prescribing information for Australia
Module 2	Summaries
Module 3	Quality
Module 4	Non-clinical study report
Module 5	Clinical study reports[58]

Assessing the cost of clinical trials to Australian applications is difficult. Clinical trials are an incredibly costly component estimated to cost up to 40 per cent[59] of the final cost of bringing a medicine to market, and can take up to six years of the process of bringing a medicine to the market.[60]

While the cost of bringing a medicine to market is predicted to be as high as $1.5 billion by 2015,[61] because clinical trial data is then used to support marketing approvals all over the world, the cost is diffused through applications by each competent agency. However, because clinical trials are expensive, but also provide economic opportunities in research and development and for the scientific profession, it is a highly sought after industry, with phase I – IV clinical trials worth more than $450 million annually to the Australian economy.[62]

Another regulatory cost component of clinical trials is the steps necessary for ethics approval. In a submission to the Productivity Commission's 2008 *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades* report Medicines Australia argues that the cost of State-based ethics approval applications for clinical trials extends the timeline for completing clinical trials, unnecessarily duplicates existing approvals and with it adds regulatory cost.[63]

---

[58] Department of Health and Ageing, 2004, Australian Regulatory Guidelines for Prescription Medicines, Therapeutic Goods Administration, http://www.tga.gov.au/pmeds/argpm.pdf (accessed 2 December 2009).
[59] Brian J. Bedkober, op. cit, p. 169.
[60] PhRMA, 'Pharmaceutical industry profile 2005, From laboratory to patient: Pathways to biopharmaceutical innovation', cited in Allen Consulting Group, 2006, *Drivers of pharmaceutical industry investment: Understanding Australia's competitive position*, September, p. 13.
[61] Brian J. Bedkober, p. 166
[62] Kim Carr and Nicola Roxon, 2009, 'Boost for clinical trials in Australia', Media statement, 27 October.
[63] Productivity Commission, 2008, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*, http://www.pc.gov.au/projects/study/regulatoryburdens/manufacturing/finalreport (accessed 2 December 2009).

The 2008 PC report found that the government was aware of the duplication and lack of harmonisation of ethics approvals and has allocated $5.6 million to the National Health Ministers Advisory Council to develop a framework for harmonisation to reduce approval times and costs. However, the issue has not been resolved and the NHMRC is currently scheduling the conclusion of its inquiry for 2010.[64]

Australian Register of Therapeutic Goods

To sell a medicine in most economies requires safety and efficacy assessment by a regulator such as the United States' Food and Drug Administration or Australia's TGA.

In Australia a medicine cannot be sold in the marketplace unless it is listed on the ARTG, which is a computer database of all therapeutic goods that have successfully completed safety and efficacy assessments performed by the regulator supported by data provided by the innovator of the medicines from clinical trials.

The ARTG is broken into two categories registered goods and listed goods.

Registered goods are those that contain a high level of risk associated with their consumption, principally including prescription medicines. Listed goods are those that attract a lower level of risk and are generally 'over the counter' medicines.[65]

While applications for listing on the ARTG are generally treated on a 'first come, first served' basis, priority systems are in place for both assessment and listing for medicines for life-threatening illness based on phase two trial data.[66]

The process of listing on the ARTG is about striking the balance between the benefits of ensuring a medicine will deliver clinical benefits to its consumers, against the risks associated with its consumption and potential side effects.

The vast majority of medicines submitted for listing on the ARTG are listed because the cost of submitting an application is a sufficient deterrent to whimsical applications, but also because the clinical trial data requirements expose any issues surrounding the safety and efficacy of the medicine to the applicant.

Similarly, because many medicines have previously been submitted and approved for marketing approval in larger developed markets, such as the United States and Europe, the gap rejections of applications are likely to occur by their competent agency before an application is made to the TGA.

The cost of listing on the ARTG is difficult to assess. While there are standardised costs, not all costs are incurred for all product listings because some applications are more straightforward than others. Table 4.1 provides a summary of listing costs for ARTG listing based on activity.

---

[64] Productivity Commission, p. 58.
[65] Department of Health and Ageing, 'TGA fees and charges explanatory note', http://www.tga.gov.au/fees/fees09exp.htm (accessed 2 December 2009).
[66] Department of Health and Ageing, 'Australian regulation of prescription medical products', http://www.tga.gov.au/docs/html/pmeds_reg.htm (accessed 2 December 2009).

Table 4.1: Maximum possible evaluation fees and charges for ARTG listing

Activity	Cost ($A)
New chemical entity	187,900
Extension of indications	111,700
Major variations	72,800
New generic product	71,700
Additional trade name	11,800
Minor variations	4,290
Changes to product information involving evaluation data	4,290
Changes to product information where no evaluation data required	1,320
Changes to consumer medicines information	1,320

This table is an indicative summary based on full cost recovery for category 1 and 2 submissions.
Source: Department of Health and Ageing, 'Summary of fees and charges', http://www.tga.gov.au/docs/html/feesach.htm (accessed 2 December 2009).

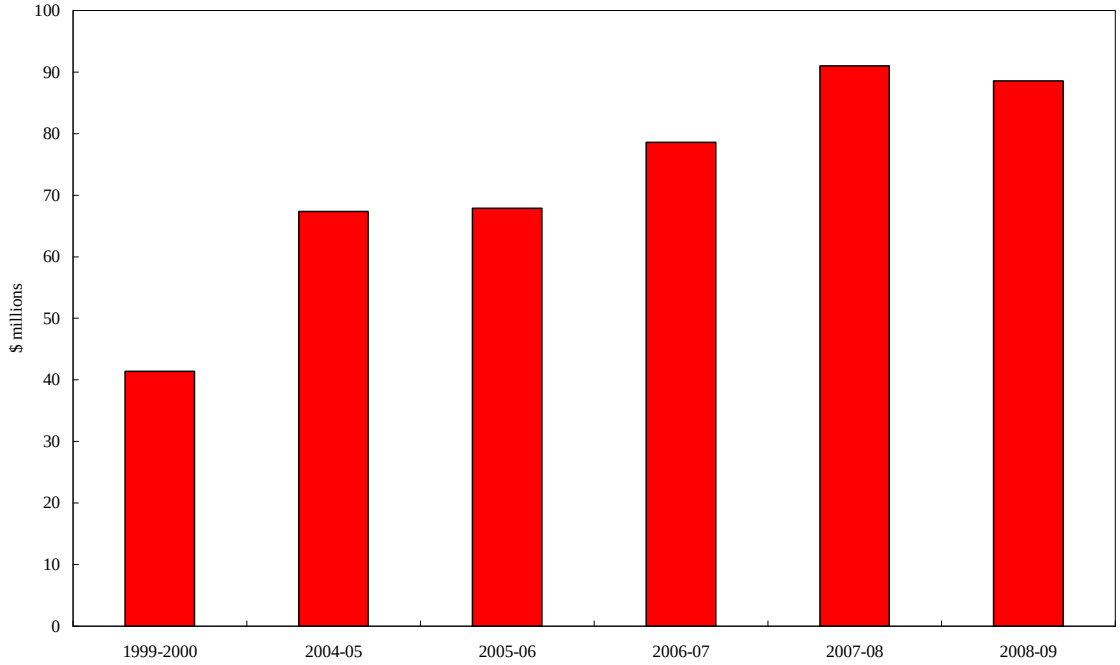
However, we can make some rough assessments on the average cost of product listing. The TGA is one of the few government regulatory agencies that operate on a full cost recovery basis by charging equivalent fees of applicants seeking TGA approval equivalent to their share of operational costs.

While the cost schedule for registration is outlined as Table 4.1, there is no uniform final price for the cost of marketing approval, initial and ongoing listing on the ARTG, or licensing of premises. However, because the TGA delivers these services in a commercial format to industry, there is information available of the TGA's income from goods and services rendered.

According to the 2008/2009 Annual Report for the Department of Health and Ageing, the total income of goods and services rendered was $88.5 million for the 2008-09 financial year[67]. Figure 4.3 outlines the progressive increase in income of TGA goods and services rendered.

[67] The TGA recovers the cost of all activities undertaken within the scope of the *Therapeutic Goods Act 1989* from industry through fees and charges. Annual charges for entries on the Australian Register of Therapeutic Goods and manufacturing license charges are recognised as revenue in the financial year to which the charges relate and are non-refundable, except where exemption is given on the basis of low value/low volume turnover. Application fees and minor evaluation fees (less than $10,000) are recognised as revenue on receipt. Major evaluation and conformity assessment fees are recognised progressively as services are performed.

Figure 4.3: Income from TGA goods and services rendered, $A



Source: Department of Health and Ageing, *Annual Report*, various years; Productivity Commission, 2001, *Cost recovery by government agencies*, Report no. 15, AusInfo, Canberra.

The goods and services rendered for receipt of incomes outlined in Figure 4.3 includes more than just the cost of listing medicines on the ARTG. It also includes other goods and services provided by the TGA including the listing of medical devices, post-marketing monitoring and manufacturing licensing fees.

However, Figure 4.3 does provide an indirect account of the cost of the fees required to be paid to engage in TGA processes, excluding the costs directly incurred by companies in preparation for TGA processes.

The other cost of listing on the ARTG is the cost incurred by companies from time and sales lost while applications are assessed. These costs are also borne by patients who may require medical support. Table 4.2 outlines the maximum allowable timelines for assessment of category 1 and 2 applications, and mean evaluation times taken by the TGA.

Table 4.2: Timelines for consideration and approval of applications

Activity	Timeframe (working days)	
	Category 1	Category 2
Advice to proceed or reject application	40	20
Evaluation of application	225a	175a
Mean evaluation		
New chemical entities	150	
New generic	100	
New indications	160	
Product information changes	90	
Additional trade names	45	
Other category 1 applications	130	

a Maximum allowable timeframe for consideration.

Source: Department of Health and Ageing, 'Australian regulatory guidelines for prescription medicines', http://www.tga.gov.au/pmeds/argpm.pdf (accessed 2 December 2009).

The TGA does occasionally exceed the maximum allowable period for assessment, but in these situations the cost to the sponsor is partially offset through a reduction of application fees by 25 per cent.

Manufacturing licensing

For a manufacturer to produce medicines listed on the ARTG there are also significant regulatory burdens. Manufacturers are heavily regulated for the production of medicines because of the highly complex composition of medicines and the importance of ensuring the exact correct ingredients are included in each medicine consistent with the approval for listing on the ARTG.

To become a licensed manufacturer, facilities must 'demonstrate adherence with internationally recognised manufacturing principles in the Australian Code of Good Manufacturing Practice.'[68] To secure compliance with the Code manufacturers are required to submit data and have their facility assessed by TGA regulators.

With such assessments come delays in approval. In its submission to the Productivity Commission's 2008 Annual Review of Regulatory Burdens Medicines Australia highlighted that 'companies are frequently left waiting for months for such assessments … [and] … finally when clearances are received, they have short expiry times requiring companies to make new applications within a short timeframe. This is time and labour intensive a well as a costly regulatory burden.'[69]

Further, because Australian manufacturing facilities also produce medicines for exports many are also required to undergo equivalent assessments for overseas regulators to ensure they can manufacture for their market. As a consequence facilities are often undergoing duplicate regulatory compliance for manufacturing licensing.

The same PC report highlighted that there is 'insufficient recognition' of equivalent audits and assessments for facilities by other regulatory authorities resulting in unnecessary duplication in regulatory applications for the TGA that may have already been completed by US or EU

[68] Productivity Commission, p. 54.
[69] Productivity Commission, p. 60.

authorities.[70] Australia currently has agreements with American, Canadian, European, Singaporean and Swiss regulators to share information, but there is not sufficient cooperation to remove duplicate assessments.

The trans-national lack of cooperation adds a significant economic burden to medicine manufacturing for little appreciable benefit. To streamline the process the TGA should be seeking to have their assessments for licensing recognised by other national competent agencies to reduce the cost burden for export manufacturing, and require facilities to only complete one assessment.

Pharmaceutical Benefits Scheme

Established in 1950, the Pharmaceutical Benefits Scheme (PBS) is the commonwealth government mandated program to subsidise prescription medicines to increase their access. By having a PBS the government achieves a policy objective of reducing the retail cost of medicines, and also increases its purchasing power against pharmaceutical companies to reduce the price of their medicines because in practice only medicines sold on the PBS are bought by consumers.

While the relationship between government and pharmaceutical companies heavily favours the government because of its monopsony power, the offset for pharmaceutical companies is that they guarantee sales of their medicines to the general public based on the agreed price which is offset from subsidies from the government.

While there is significant cost incurred by pharmaceutical companies because of the government's monopsony power to bulk purchase, such costs will not be assessed here because the benefit is derived to the commonwealth government.

The PBS operates by listing certain medicines for subsidy. Because not all medicines need to be provided with a subsidy, and the cost of operating a broad-based medicines subsidy scheme could require a nearly unlimited budget, the commonwealth divests responsibility for assessment of listing medicines onto the PBS to the independent Pharmaceutical Benefits Advisory Council (PBAC), who assess applications submitted.

Applications are assessed against the effectiveness, cost effectiveness and appropriateness of the applicant medicine against other medicines already listed on the PBS. A new medicine is subject to subsidy if they:

- 'prevent or treat conditions not already covered by pharmaceuticals on the list and are of acceptable cost effectiveness;
- are more effective (in terms of health outcomes), or less toxic (or both) than a pharmaceutical already listed for the same indications and are of acceptable cost effectiveness; or
- they are at least as effective (in terms of health outcomes) and as safe as a pharmaceutical already listed for the same indications and or similar cost.'[71]

Once a medicine is listed on the PBS it is subject to a subsidy that limits the expenses on individuals through their co-payment. The maximum co-payment a PBS listed medicine can

[70] Productivity Commission, Ibid.
[71] Industry Commission, 1996, *The Pharmaceutical Industry*, Inquiry report, p. 81.

require is $33.30, and $5.40 for concession card holders.[72] Co-payments are indexed against the consumer price index on the 1st of January of each year. Pharmacists can also charge an additional fees of up to a total of $4.84 ($3.79 additional fee plus $1.05 dispensing fee), which is also indexed.

A listed PBS medicine can be removed based on an assessment of: its effectiveness against other medicines available; its toxicity exceeds its therapeutic value; it's capable of being purchased without a prescription; it is treating a condition not requiring medical supervision; its removal would not prompt inappropriate prescription of other medicines or the medicine has been superseded by a superior medicine.

While approval for listing on the PBS is afforded to the PBAC, any medicine expected to cost more than $10 million per annum is required to be approved by Cabinet.[73]

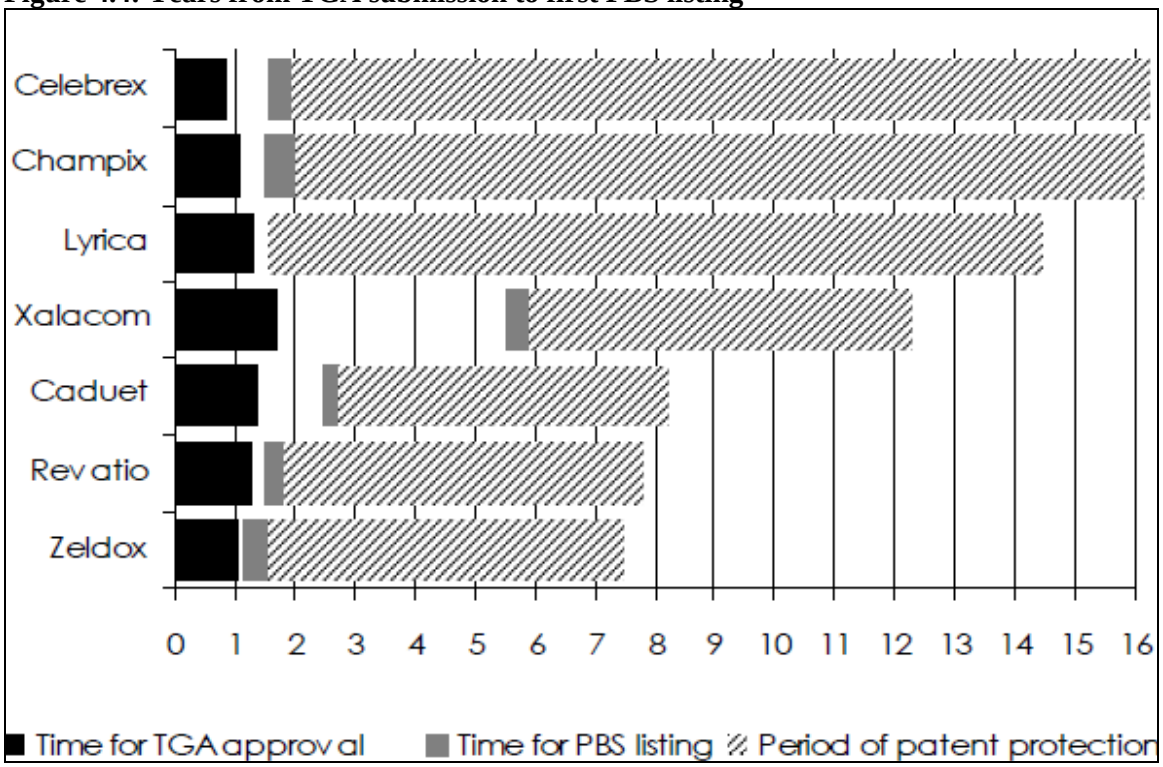
The estimated timeframe for listing on the PBS is approximately eight months.[74] The eight months includes three months from the date of applications to assessment by the PBAC, and then a further five months until it is listed onto the PBS.

However, there are regulatory costs incurred because of a lack of harmonisation between applications for marketing approval through the TGA and applications for listing on the PBS. As a consequence there tends to be a duplication of effort and the timeline from the completion of clinical trials to retail sale is unnecessarily extended.[75]

As Figure 4.4 shows, the timeline can extend by up to two years and has the effect of both delaying market entry and reducing the effective patent life of an innovative medicine.

[72] Australian Department of Health and Ageing, 'About the PBS', http://pbs.gov.au/html/consumer/pbs/about
[73] A summary discussion of the operations of the PBAC is available at Productivity Commission, 2008.
[74] Industry Commission, 1996, *The Pharmaceutical Industry*, Inquiry report, p. 80.
[75] Productivity Commission, 2008, p. 77.

Figure 4.4: Years from TGA submission to first PBS listing



Source: Pfizer Australia submission to the Productivity Commission, 2008, *Annual Review of Regulatory Burdens*, Inquiry Report.

There are also regulatory issues and costs surrounding the transparency and accountability of the PBS listing process. One of the key outcomes of the Australia United States Free Trade Agreement for the pharmaceutical industry was inclusion in Chapter 2 of the agreement for the government to:

- 'disclose procedural rules, methodologies, principles, and guidelines used to assess a proposal;
- afford applicants timely opportunities to provide comments at relevant points in the process;
- provide applicants with detailed written information regarding the basis for recommendations or determinations regarding the listing of new pharmaceuticals or for setting the amount of reimbursement by federal healthcare authorities;
- provide written information to the public regarding its recommendations or determinations, while protecting information considered to be confidential under the Party's law; and
- make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination", among other provisions.'[76]

However, under current regulation the transparency and perceived fairness of PBAC processes remains contentious as industry raises concerns about the limiting responses to evaluations by the applicant to five days, despite the considerable timeframes required to compile submissions, which is further exacerbated by the insistence by the PBAC to send evaluations by post.[77]

[76] Department of Foreign Affairs and Trade, 2005, Australia United Stated Free Trade Agreement, http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/chapter_2.html (accessed 2 December 2009).
[77] Productivity Commission, 2008, p. 71.

As a consequence the PC has recommended that the PBAC should, at least, develop an electronic form of transmission of evaluations considering the necessity for security. In doing so the PBAC would even modestly decrease the considerable resources that need to be discharged in a short timeframe for review by the applicant, but also reduce the possibility of the applicant missing the deadline and being required to resubmit the initial application during the next application period.

5 Private health insurance regulation

Overview

Private health insurance in Australia is a voluntary facility for private funding of hospital care and ancillaries. Insurance funds may cover the costs of treatment for private patients in private or public hospitals and can include some services that Medicare does not cover, such as dental care, optical care, physiotherapy and chiropractic care.

As at 30 June 2008 there were 39 registered private health insurers operating in Australia – 25 insurers were registered as open membership insurers and 13 were restricted access insurers.

Insurers vary markedly in terms of size. Medibank Private was the largest insurer with a share of total policies of about 29 per cent, and the Reserve Bank Health Society was the smallest at 0.04 per cent. The market shares of the BUPA group of private health insurers (operating under the brands of Clearview, HBA, MBF and Mutual Community) comprise the second largest concentration of membership totaling 28 per cent.[78]

Total premium revenue for registered health insurers was about $12.2 billion in 2007-08, an increase of ten per cent from 2006-07. This increase was attributable to an increase in premiums and growth in membership. The industry recorded a profit (or surplus) before tax of $562 million in 2007-08.[79]

In the same financial year, about $10.4 billion in benefits were paid on behalf of policy holders. This included $7.6 billion in hospital benefits and $2.7 billion in general treatment benefits. Benefits payments tend to grow at rates significantly in excess of the general consumer price index.

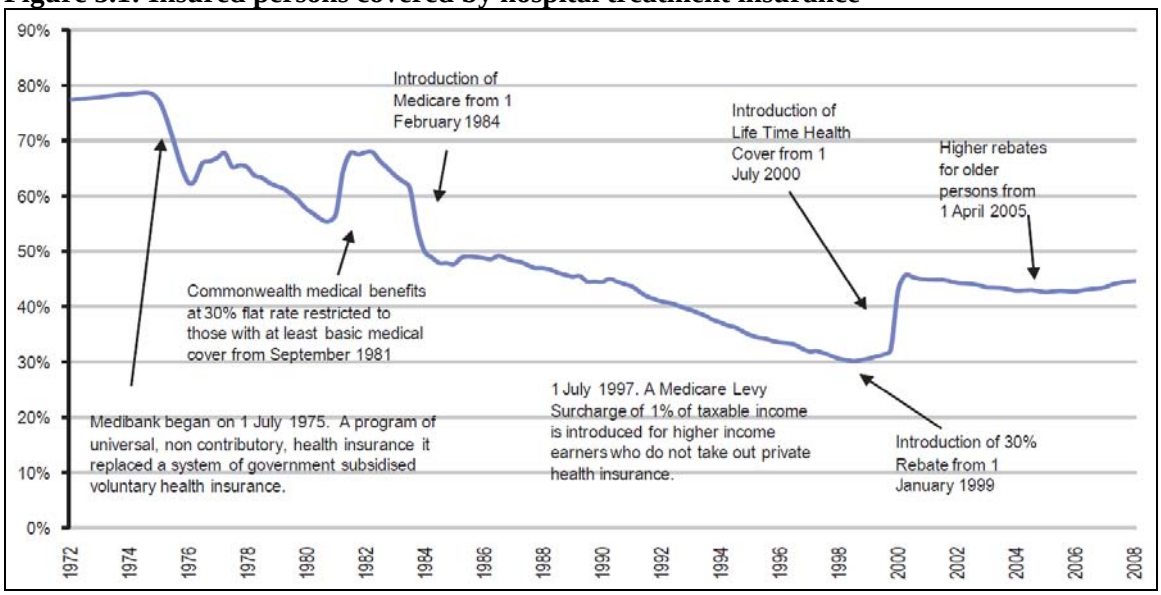
Management expenses in 2007-08 were about $1.3 billion, or 10.5 per cent of total premium revenue.

For a number of years since the introduction of the universal tax-financed insurance scheme Medicare in 1984, the proportion of the Australian population covered by private health insurance had declined (Figure 5.1). This ‘crowding out’ of private health insurance occurred as individuals, particularly of younger and healthier demographic status, ceased their private insurance membership in favour of the ‘free’ (at the point of use) public insurance.

The leakage of private health insurance membership was halted by a range of policy interventions introduced by the former Howard federal government, including a Medicare Levy surcharge on high income earners, a 30 per cent rebate on insurance premiums and the Life Time Health Cover policy to encourage people to take out hospital cover earlier in life and maintain it.

[78] Private Health Insurance Administration Council (PHIAC), 2008, *Operations of the Private Health Insurers Annual Report 2007-08*, PHIAC, Canberra.
[79] PHIAC, Ibid.

Figure 5.1: Insured persons covered by hospital treatment insurance



Source: PHIAC, 2008, *Operations of the Private Health Insurers Annual Report 2007-08*.

It has been stated that 'private health insurance is often referred to as the most heavily regulated industry in the Australian market place.'[80]

According to PHIAC, stipulations surrounding product offering, the nature of business to be conducted by insurers within health benefits funds, government approval of product pricing and minimum capital requirements specific to the conduct of health insurance are all features of the private health insurance regulatory framework.[81] Private health insurance is also required to be offered on a community rated basis.[82]

It has also been observed that this extensive regulation of health insurance is maintained on an implicit basis 'as if it … [the industry] … were an extension of social security rather than part of the financial system.'[83]

Underlining the extent to which regulations impose costs on insurers, an Australian Health Insurance Association (AHIA) industry survey estimated that $46 million was spent on regulatory compliance costs by health funds in 2004-05. According to PHIAC, management expenses of insurers were $892 million for that year. This implies that regulatory compliance costs effectively accounted for about five per cent of administration costs of fund managers.

The following sections examine some of the major regulatory burdens (excluding community rating and reinsurance) imposed on the private health insurance industry by Australian governments.

---

[80] Australian Health Insurance Association (AHIA), Submission to Regulation Taskforce (Banks Review), November 2005.
[81] PHIAC, op cit, p. 7.
[82] In general terms, community rating is a form of premium regulation requiring insurers to charge the same premiums to all members, regardless of age, health status or any other characteristic that may affect medical expenditures.
[83] Peter Carroll, 'Microeconomic reform of the Australian private health insurance industry (a synopsis)', Australian Doctors Fund, http://www.adf.com.au/archive.php?doc_id=106 (accessed 7 October 2009).

Consumer product information disclosure

From 1 April 2007 private health insurers have been required to provide consumers with standard product information in a prescribed form for each product they offer. Information is required to be provided to consumers with respect to the following:

- nature of the cover
- price
- product exclusions
- front-end deductibles
- nature and impacts of gaps in the cost of medical, hospital and ancillary cover
- waiting periods and portability
- other matters as determined by the Minister.

According to the *Private Health Insurance Act 2007*, standard information statements need to be available on request and must be provided to all members at least once each year.

Health insurers are required by law to provide a standard information statement (SIS) in hard copy format, as well as provision online on their own websites or through the http://www.privatehealth.gov.au website. Other notices that must be sent to fund members in hard copy include tax statements and information concerning premium and product changes.

The need to produce hard copy documentation also affects health insurance portability arrangements. When consumers transfer between funds, a Transfer Certificate is required to certify waiting periods served and to protect benefit entitlements. The current paper based system, which is administratively inefficient and confusing/frustrating for consumers, could be enhanced by the introduction of a system which would allow transfer certificates to be transmitted electronically.

In its submission to the 2006 Banks Regulation Taskforce, the AHIA stated that 'in the age of electronic communications and storage, it is untenable that funds are required to produce "hard copy" rebate forms or hard copy anything.'[84]

The Health Insurance Restricted Membership Association of Australia (HIRMAA) has also raised issues concerning the unnecessary expenses, duplication and waste of existing requirements in this area:

'the requirement to send a hard copy to all policyholders annually is onerous, expensive and environmentally insensitive (a minimum of 250,000 sheets of paper for HIRMAA funds alone). HIRMAA believes that, as an alternative, funds should clearly advise their members that a hard copy SIS is readily available on request and that a regularly updated SIS is available on the fund's website and on the website of the Private Health Insurance Ombudsman.'[85]

Indeed, the statutory requirement for hard copy consumer product and other disclosure information adds to the overall cost of providing health insurance products. It is estimated by the AHIA that greater provision of consumer information online would generate potential savings of

[84] AHIA, op cit.
[85] Health Insurance Restricted Membership Association of Australia (HIRMAA), 2007, Submission to government, 22 June.

about $12.5 million across the industry, as well as the greater potential to provide information to consumers in a more precise and user-friendly fashion.

Premium approvals

Under the *Private Health Insurance Act 2007* the Australian government Minister for Health and Ageing has the power to approve applications for changes in private health insurance premiums.

The Minister is obliged to approve all premium increases, unless it is deemed contrary to an (undefined) 'public interest' criterion. If the Minister does not allow an increase the reasons for this have to be publicly disclosed.

An application by a health fund to change its premium must be lodged at least sixty days prior to the proposed change taking effect. The Private Health Insurance Administration Council (PHIAC) provides the Minister with advice on prospective premium rises.[86]

According to the AHIA, the application process is 'arduous, labour intensive and has no certainty for individual funds in forecasting future premium income.'[87] A 2008 study by Carrington, Coelli and Rao suggests that insurers must submit detailed financial information and cost/benefit projections, all certified by an accredited actuary, to justify any premium increases sought.[88]

Similarly, the Institute of Actuaries of Australia stated that 'registered insurers will need to clearly identify their case in applying … for a premium increase. This is a significant area of sovereign risk for health insurers.'[89]

A number of issues impinging on the overall burden of premium approval regulation include:

- the length of the process required to prepare an application and achieve the rate increase
- uncertainty about the rate application approval until the last moment
- the risk that rejection of a rate application will have an adverse impact on the prudential circumstances of a fund
- no advance knowledge of the date of approval which affects the production and distribution of brochures, publications and letters
- duplication of material and potential waste of resources resulting from this lack of certainty.[90]

Consultations with industry suggests that elements of the regulatory process are inherently flawed, creating unreasonably excessive burdens upon industry (Box 5.1).

---

[86] Amanda Biggs, Private health insurance premium increases – an overview, Department of the Parliamentary Library Background Note, http://www.aph.gov.au/Library/pubs/BN/sp/HealthInsurancePremiums.htm (accessed 7 October 2009).
[87] AHIA, op cit.
[88] Roger Carrington, Tim Coelli and D. S. Prasada Rao, 2008, 'Regulation of Private Health Insurance Premiums: Can Performance Assessment Play a Greater Role?', University of Queensland School of Economics Centre for Efficiency and Productivity Analysis, Working Paper 04/2008.
[89] Gayle Ginnane, 2007, 'The new private health insurance environment', Presentation to the Institute of Actuaries of Australia, September.
[90] AHIA, op cit.

Box 5.1: Premium price approval process

A senior executive in the health care sector with longstanding experience in the private health insurance industry outlined the problems associated with the timing of health insurance premium approval processes as follows:

'health funds are restricted to one rate change every twelve months.

… funds were informed in September they were required to submit the usual application for rate changes. This is a process consuming many hours of executive, actuary and board time.

You are required in September 2009 to predict a price for each individual produce you sell in each state jurisdiction you sell that product the price to prevail out until April 2011. It applies from April 2010 through until April 2011. It is to be submitted to the Department for Ministerial approval by 20th November. The process has to have full board certification following advice from the appointed actuary.

You are actually carrying out these predictions after having only four full months of exposure to your last year's approved rates and product changes. … You need to predict variations to the price of … assets you hold because it could well be 5 to 10% of your annual income.

The Department then on the 26th November advised funds that the approval process would be such that those funds whose applications warranted further action would be advised between the 22nd and 23rd of December.

The required action could take two forms:

- *A resubmission of the proposal with further justification for the level of price sought without necessarily being informed which of the products were causing concern*
- *A variation to the price sought which would mean full actuarial certification and full board approval of the changes and the total resubmission, not just the changes.*

All of this to be completed by the 8th of January for re-submission after being informed on the 23rd December.

It is a joke.'

Other concerns have been raised about the impact of the existing premium regulation on price competition and insurers' financial viability. The regulation effectively weakens incentives for insurers to minimise their costs, undertake efficient investments or act in an innovative or competitive manner.[91]

The Carrington-Coelli-Rao study found that 'there is little incentive for funds to improve performance under the current regulatory regime. Eleven of the 18 funds that received above industry average premium increases in 2004-05 had VRS [variable returns to scale] efficiency less than the sample average. … The potential large gains in efficiency underscore the urgency to revamp the regulatory process to approve premiums.'[92]

According to the Industry Commission, price regulations also 'act as a deterrent to entry by new players used to operating in a market in which they don't have to seek government approval for the prices of their services. In this sense, price controls may deter those market oriented firms

[91] Access Economics, 2005, Regulation of Private Health Insurance Pricing, Report for Challenger Financial Services Group, November.
[92] Carrington, Coelli and Rao, op cit, p. 35-37.

most likely to introduce innovative products and to be active in pushing for cost minimisation – thus keeping average premium higher than necessary.'[93]

Winding back price regulation of private health insurance would give funds a greater incentive than at present to compete between each other, improving the efficiency of insurers and moving the market closer to optimal premium levels.

Private health insurance rebate

The commonwealth government maintains a rebate intended to ensure private health insurance remains affordable and sustainable. Most eligible Australians receive a 30 per cent rebate on the cost of their insurance, with people aged 65 to 69 and 70 and over receiving 35 per cent and 40 per cent rebates respectively.

Means tested rebate

The commonwealth government last year introduced the Fairer Private Health Insurance Incentives Bill including provisions to means test the payment of the private health insurance rebate.

For singles and families earning over and above a certain income threshold, the amount of the rebate will be reduced and the Medicare Levy Surcharge will be increased for those on higher incomes who opt out of private health insurance (table 1).

Table 1: Proposed private health insurance rebate and Medicare Levy surcharge rates

	Current threshold	**Proposed Tier 1**	**Proposed Tier 2**	**Proposed Tier 3**
Single	$0-$75,000	$75,001-$90,000	$90,001-$120,000	$120,001+
Families	$0-$150,000	$150,001-$180,000	$180,001-$240,000	$240,000+
Medicare levy surcharge	Nil	1%	1.25%	1.5%
Private health insurance rebate				
Less than 65 years	30%	20%	10%	Nil
65 to 69 years	35%	25%	15%	Nil
70 years and over	40%	30%	20%	Nil

Source: Parliament of Australia, 2009, *Fairer Private Health Insurance Incentives Bill 2009 and two related bills*, Senate Community Affairs Committee, August.

Industry representatives have highlighted the potential effects of these proposed rebate changes on the administrative cost structure of funds.

For example, in its submission to the Senate Community Affairs Committee inquiry into the Bill the Private Health Insurance Intermediaries Association stated that it 'will further complicate an already complex system, and in all likelihood, add a significant administrative burden.'

[93] Industry Commission, 1997, *Private Health Insurance*, Inquiry Report No. 57, AGPS, Canberra, p. 327.

The AHIA submission stated that 'private health funds will be required to request that fund members self-identify which rebate level they are entitled to, before their eligibility is then reconciled by the Australian Taxation Office as part of the individual's annual tax assessment. This process is likely to lead to confusion amongst policy holders as to their entitlement if their income level varies from year to year and will add cost imposts on private health funds as they implement new systems to accommodate the policy change.'

In its submission to the Senate inquiry, iSelect noted that 'continued tampering with Australia's private health insurance system is also facilitating a very confused message about the value and role of private health, serving to ultimately erode the confidence of millions of Australians in a critical element of our healthcare system.'

HIRMAA noted that longer term consequences of the proposed change:

'The introduction of further limitations on the eligibility criteria of the PHI rebate would have a disastrous impact on membership and send a clear (if unintended) signal to the community that the medium term objective is to totally abolish the rebate and ultimately diminish the role of PHI and, as a direct consequence, the private health sector in Australia's health system.

HIRMAA reiterates its contention to the Minister for Health and Ageing and the DoHA that to allow the industry to stabilise its position, after two Federal budgets containing significant changes to PHI, it is imperative that the 2010-11 Federal Budget, and subsequent budgets, not contain further reductions to or diminution of PHI incentives. To do otherwise will create a justifiable belief by consumers that their PHI products are becoming less attractive and affordable.'[94]

In addition to the potential administrative cost burdens associated with the proposed insurance rebate change, market research suggests that up to 240,000 Australians with private health insurance are likely to exit cover as a result of the legislation with a further 730,000 people likely to downgrade their level of hospital cover.[95]

Private Health Insurance Incentives Scheme

The rebate scheme was introduced in 1999, and replaced the Private Health Insurance Incentives Scheme (PHIIS) introduced in 1997. However, people with insurance policies before 1 January 1999 and were eligible to claim a rebate under PHIIS are entitled to compare the PHIIS amount with the tax rebate, and claim whichever is higher.

As noted previously by the AHIA, 'there are real costs for health funds by having to manage two types of rebate and having to issue two types of statements (one for 30% and one for PHIIS).'[96]

An industry survey indicates that there are less than 10 consumers out of 11 million Australians with private health insurance still enrolled under PHIIS. This near-redundant regulatory requirement should be removed to simplify existing health fund operational requirements.

---

[94] HIRMAA, 2009, Submission to Senate Community Affairs Legislation Committee Inquiry on *Fairer Private Health Insurance Incentives Bill 2009* and Related Bills, June.
[95] AHIA, 2009, 'Senate Report Ignores the Facts', Media Release, 5 August.
[96] AHIA, op cit, p. 6.

6 Private hospitals regulation

Overview

The private sector (including not-for-profit entities) is involved in the provision of health care services through hospital settings, making an important contribution to alleviating patient loads faced by public hospitals.

According to data provided by the Australian Institute of Health and Welfare (AIHW), there were 552 private hospitals in Australia in 2007-08 including 272 day surgery facilities. Over three-quarters of private hospitals were located in the three largest states of New South Wales, Victoria and Queensland.[97]

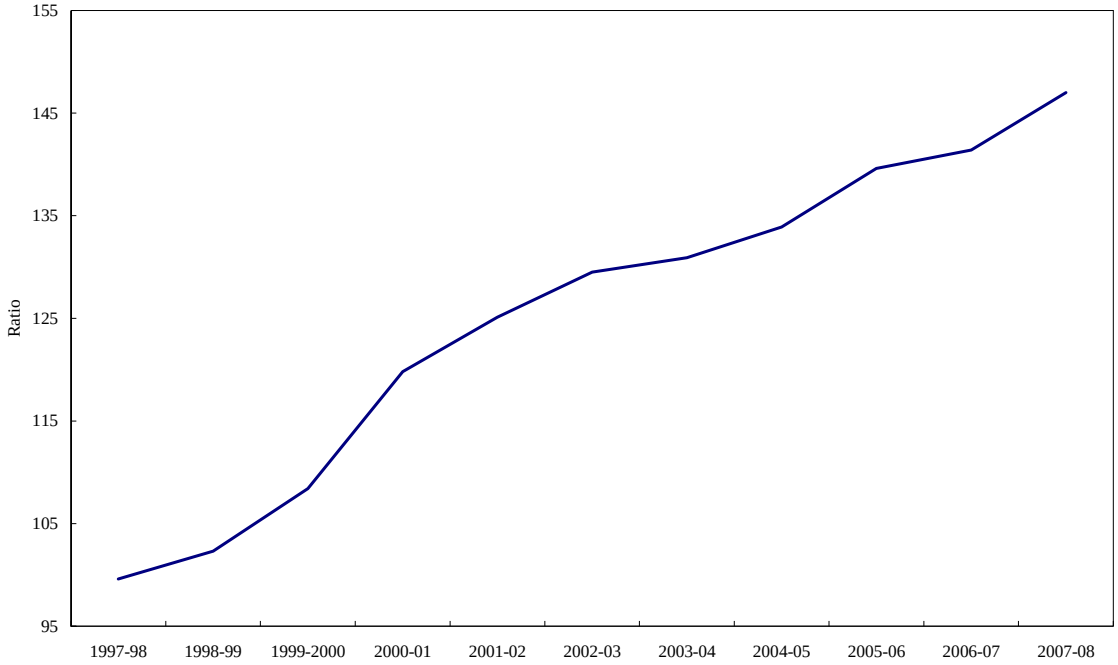
About 57 per cent of private acute and psychiatric hospitals operated on a for-profit basis in 2006-07. Ramsay Healthcare is currently the largest group operator, representing a quarter of the private hospital market. Approximately 28 per cent of hospitals were owned by not-for-profit religious or charitable organisations, with bush nursing, community and memorial hospitals accounting for the remainder.[98]

Private hospitals provided 27,768 beds in 2007-08, representing a third of hospital beds available in Australia. The number of licensed or available beds in the private sector has grown by 21 per cent over the past decade.

The operating environment of the private hospital sector is also characterised by a significant growth in admissions, from 1,793,000 patients in 1997-98 to 3,130,000 in 2007-08. Similarly, the number of admissions per 1,000 population has also grown (Figure 6.1).

[97] Australian Institute of Health and Welfare (AIHW), 2009, Australian hospital statistics 2007-08, Health services series No. 33, Canberra, AIHW.
[98] Australian Bureau of Statistics (ABS), Private Hospitals 2006-07, cat. no. 4390.0.

Figure 6.1: Private hospital separations per 1,000 population



Source: AIHW, Australian hospital statistics, various years.

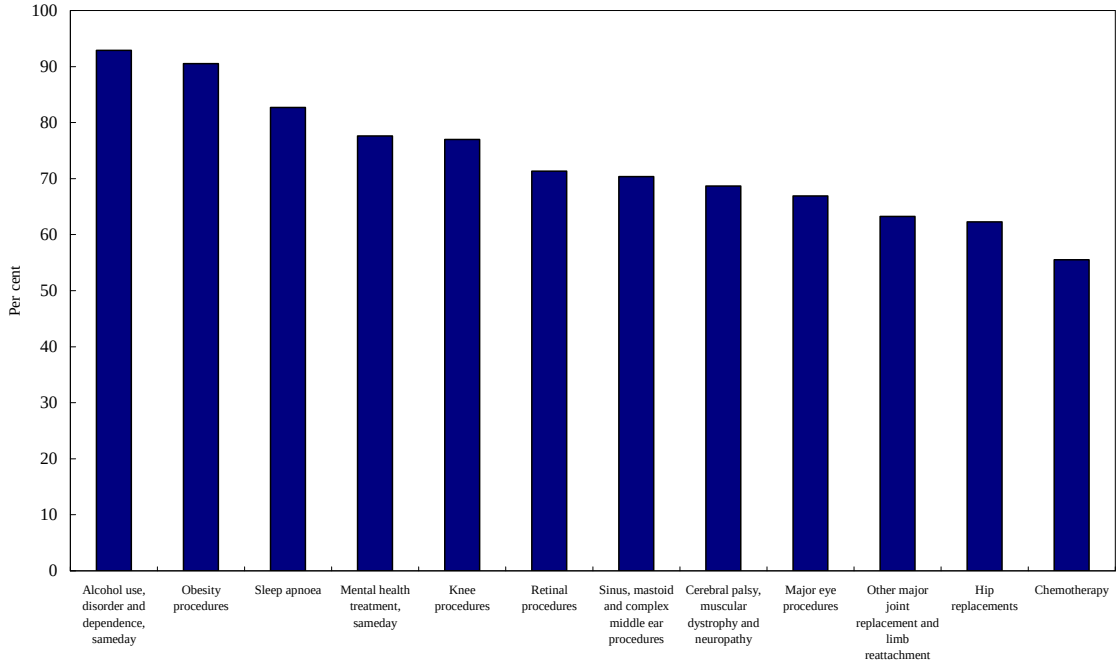
The diversity of treatments provided by private hospitals belies their stereotypical reputation as provider of cosmetic surgeries only. The majority of numerous complex procedures and treatments are performed within private hospitals (Figure 6.2). Private hospitals also performed 48 per cent of all cardiac valve procedures in 2006-07.

Private hospitals are funded by their owners and operators. The services provided to patients treated in private hospitals are (at least) partially subsidised from a variety of sources, including private health insurance funds, Medicare, Department of Veterans' Affairs (DVA), Pharmaceutical Benefits Scheme and third party insurers.

Income received by acute and psychiatric private hospitals in Australia during 2006-07 was approximately $7.1 billion, an increase of 7.5 per cent over the previous year. Patient revenue accounted for 96 per cent of all income generated by hospitals in 2006-07. Recurrent expenditure by acute and psychiatric hospitals across Australia was about $6.6 billion, with wages and salaries representing over half of total expenditures.[99]

[99] ABS, Ibid.

Figure 6.2: Private hospital share of separations for selected treatments, 2006-07



Based on AR-DRG version 5.1.
Source: AIHW, Australian hospital statistics 2006-07, online tables S12.1, S12.2.

The operations of the private hospital sector are influenced by an array of government regulations. These impose a multitude of administrative hurdles for individual private hospitals. Compounding the burden of regulation faced by the sector is the variation of regulatory arrangements across jurisdictions.

Licensing provisions

In order to commence services private hospitals must obtain a license or an approval to operate, and adhere to a range of conditions if they wish to maintain their service provision.

The state and territory governments are responsible for the licensing and approval of private hospitals in their respective jurisdictions in accordance with state legislation.[100]

As noted by the Australian Commission on Safety and Quality in Health Care (ACSQHC) accreditation review, there are significant inconsistencies across jurisdictions in terms of the scope of services subject to licensing.

For example, general private hospitals are required to be licensed in all jurisdictions while some jurisdictions do not cover day hospitals under their licensing regimes (Table 6.1). According to

[100] According to a legislative mapping report prepared as part of the Australian Commission on Safety and Quality in Health Care (ACSQHC) accreditation review, South Australia and the Northern Territory do not maintain licensing provisions for day procedure facilities.

the ACSQHC, 'the inconsistent coverage … adds complexity to the operating environment for organisations operating in multiple jurisdictions.'[101]

Table 6.1: Selected private health facility licensing coverage, 2008

	NSW	Vic	Qld	WA	SA	Tas	ACT	NT
Private hospital	Y	Y	Y	Y	Y	Y	Y	Y
Day hospital	N	np	Y	Y	N	N	Y	np
Day procedure facility	Y	Y	Y	Y	N	N	N	np
Psychiatric day hospital	N	Y	N	Y	N	N	N	np
Private psychiatric hostels	N	np	N	Y	N	Y	N	np
Private nursing post	N	np	N	Y	N	N	N	np

a. State and territory definitions of service providers vary in some cases. np = information not provided.
Source: Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008, *Proposals on an Alternative Model for Safety and Quality Accreditation and Matters relating to Costs and Duplication of Accreditation Processes*, February.

According to a licensing legislation mapping study undertaken as part of the ACSQHC accreditation review, hospitals are obliged to meet a wide range of substantive, largely input-based conditions relating to:

- location, type of patient or service, and the number of patients or beds. For example, the South Australian *Health Care Act 2008* stipulates conditions for the licensing of private hospitals including 'the location of the premises or proposed premises and their proximity to other facilities' and 'whether the prescribed limit of hospital beds for the state, or for the particular region in which the premises or proposed premises are or will be situated, has already been reached or exceeded.'
- the type or character of the licensee. In Western Australia the hospital licensee must be 'a person of good character and repute and a fit and proper person to conduct a private hospital' and must have 'sufficient material and financial resources available.'
- clinical practice and health care quality. In a number of jurisdictions separate regulations apply to specific services provided, including emergency and intensive care, surgical, obstetric, rehabilitation, and psychiatric services in additional to general services provided by a private hospital. Other regulations stipulate the quality of care that must be provided to patients on private hospital premises (see below for further discussion).

[101] Australian Commission on Safety and Quality in Health Care (ACSQHC), 2008, Proposals on an Alternative Model for Safety and Quality Accreditation and Matters Relating to Costs and Duplication of Accreditation Processes, http://www.health.gov.au/internet/safety/publishing.nsf/Content/37088D5E3CFF8205CA2573AF007BC4FF/$File/FINAL_AltModel_Feb08.pdf (accessed 15 February 2010), p. 39.

- premises, facilities and equipment. In New South Wales there are provisions relating to furniture, furnishings and bed linen, kitchens and serveries, and medical, surgical and nursing equipment. The South Australian legislation specifies room sizes that are to apply in the state's private hospital facilities (see below for further discussion).
- management and staffing. In Western Australia and some other states a general private hospital must be staffed by registered general nurses, registered psychiatric nurses and enrolled nurses only.
- registers and records: Most states require private hospitals to maintain records of admitted patients, including medical condition subject to treatment.[102]

Licensing provisions also typically include a range of miscellaneous requirements covering such issues as patient rights, fire safety and emergency evacuation, hospital administrative practices and policies, storage and handling of drugs and chemicals, waste management and disposal, food safety and infection control. They may also specify compliance with other legislation or regulations.[103]

According to the ACSQHC, 'there is reasonable similarity in the standards areas covered by accreditation and licensing.'[104] Nonetheless, for private hospital organisations operating across state borders this duplication would entail potentially significant cost burdens of a substantive nature.

In addition to these formal governmental requirements, numerous standards and guidelines for practices have been developed by colleges and professional associations. Third-party accrediting bodies widely subscribed to by the private hospital industry include the Australian Council on Healthcare Standards (ACHS) (referred to in Chapter 2), International Standards Organisation (ISO) and the Quality Improvement Council (QIC).

Private hospitals also face strong commercial and ethical incentives to ensure that various quality standards are maintained.

Case study: Benchmarking licensing administrative compliance activities

Licenses, permits and registrations are key instruments used by government to ensure compliance by hospitals with regulatory objectives.

One way to establish the indicative burden of regulation is to compare the type and number of administrative compliance activities undertaken by a licensee applying to establish a new (general) private hospital in New South Wales, Victoria and Queensland – as noted above, the base for three-quarters of all private hospital establishments in Australia.[105]

---

[102] ACSQHC, 2008, *Proposals on an Alternative Model for Safety and Quality Accreditation and Matters relating to Costs and Duplication of Accreditation Processes*, February; State and territory government health legislation and regulations; 'State and Territory Private Health Facility Licensing Legislation Mapping', Study for ACSQHC Accreditation Review.

[103] Productivity Commission, 1999, *Private Hospitals in Australia*, Research Paper, AusInfo, Canberra.

[104] ACAQHC, Ibid, p. iii.

[105] The jurisdictional coverage of this case study is limited to those states and territories that provide license application forms and associated guidelines online.

Other things being equal, a jurisdiction that imposes a larger number of administrative compliance activities, due to its licensing regime, than others is likely to impose a greater administrative compliance (or 'paperwork') cost burden upon an applicant.[106]

This case study examines the type and number of administrative compliance activities arising from a private hospital license application. Other license applications that may need to be submitted, for example in relation to business naming rights, taxation or workers' compensation, are excluded from this analysis.

The Business License Information Service (BLIS) and government agency website information were used to identify the license required to open a new hospital. These sources also provided details of the requirements and activities likely to generate administrative compliance costs.

Table 6.2 provides indicative information on the major administrative compliance activities pertaining to a new private hospital with more than 200 beds.

The numbers of activities across the three jurisdictions are similar. However, it is noted that there is sufficient variation of reporting requirements between states.

In addition, Victoria and Queensland require more written statements from the applicant including in relation to proposed clinical standards, infection control procedures, patient complaint systems and staffing structure. These processes are likely to be time-consuming for the applicant and, in some cases, may require external assistance from consultants and other groups to prepare.

[106] Other, 'non-paperwork' costs associated with the license approval process – such as the delay costs in terms of foregone profitability as an applicant awaits approval from a regulatory agency – are excluded.

Table 6.2: Summary of administrative compliance activities for general private hospital license

NSW	Vic	Qld
Application form - Form 1	Application form	Application form (including Attachments A, B and C)
Covering letter including:	Statutory declarations	Application coversheet (incl. written submission)
-contact name	Details of directors / office holders	Statutory declaration
-proposed license class	Professional qualifications and curriculum vitae	Details and experience of directors and senior staff
-item numbers and anticipated procedures	2 x character references for each director / office holder	Certificate of incorporation
-types of anaesthetic	Statement on previous or current proprietary experience in any state or territory	Details of agreements for emergency patient transfer
-listed specialties	Police check certificate	Local authority certificate of occupancy
-paediatric requirements	Certificate of registration of business name	Compliance statement for buildings, fittings and medical equipment
Statutory declarations	Statement on financial viability	Organisational staffing chart
Address of registered office / details of directors and secretaries	Written statement of land ownership	Details of staffing structures including rosters and staff numbers for each service
National Criminal Record Check Consent Form	Certificate of occupancy	Details of quality assurance program
Fitness and Probity Check Form	Compliance statement for buildings, fittings and medical equipment	Details of various policies and procedures
Certificate of incorporation	Confirmation of details of senior staff	Copies of self-assessments against selected health standards
Corporation extract	Details of management and staffing arrangements	Compliance with minimum throuput number and clinical service requirements
Certificate of approval of business name	Terms of reference and membership of medical advisory committee (where applicable)	Details of staff attendance of hospital orientation programs
Signed letter of endorsement from aneasthetist	Details of proposed professional development for clinical staff	Confirmation of selected information and other systems
Development application from local council	Details of health accreditation	Orders / invoices of furnishings and equipment
2 x architectural plans	Information on:	
	-quality improvement	
	-clinical risk management	
	-infection control	
	-patient and staff complaints systems	
	-policy manuals	
	Details of numbers of overnight/day beds and health services provided	

It is assumed that the hospital is structured as a corporation, and that it will own the land upon which the premises are based.
Source: Business License Information Service (BLIS); state government health agency websites.

Once a private hospital receives licensing approval by a state or territory, it is typically required to periodically renew its license. A hospital must also routinely provide a range of performance data to a government:

- In New South Wales, specific requirements to provide routine information are not specified however the *Private Hospitals and Day Procedure Centres Act 1988* refers to the need for a registered facility to provide information as required by the CEO of the health department.
- In Victoria, hospitals are required to provide monthly reports to the state government in relation to the details of, and treatment received by, each patient. In addition, hospitals must report their occupancy information (including numbers of separations and bed days, and average number of available beds) on a monthly basis. Private hospital facilities must also report pregnancy outcome data and statistics, and report on cancer treatments provided.
- The Queensland government requires private hospitals to report, at various time intervals during a license period, on patient identification, diagnosis and activity; clinical indicator data; and provide copies of reviews of hospital quality assurance procedures. Hospitals must also provide information to the government on adverse events and similar incidents.

In a number of submissions to government agencies, the Australian Private Hospitals Association has indicated that interstate variations in licensing regimes have led to multiple measurement and reporting regimes.

Compounding the burdens that result from license requirements is the 'high degree of variability in the amount of feedback provided to private hospitals from … State and Territory Health Departments from these data collections. … This variability is a shortcoming of the present arrangements which … do not enable a systemic approach to promoting organisational learning.'[107]

It is difficult to establish the incremental compliance costs associated with license requirements, particularly when it is understood that private hospitals would normally maintain regulatory standards codified by government as part of normal commercial practices.

Nonetheless, a study of proposed licensing provisions in NSW suggests that the potential compliance costs associated with extending existing license obligations are substantial. The proposed *Private Health Facilities Regulation 2009* includes provisions to:

- ensure regulatory consistency between private hospitals and day procedure centres
- specify requirements in relation to staff numbers and qualifications, general and specialist clinical equipment required and minimum accommodation standards
- increase the reporting regime and review of incidents, including root cause analysis to investigate adverse events
- equip the Director General of Health with the power to approve or reject facility licensing applications on the basis of geographic and/or clinical need
- enhance the powers of the Medical Advisory Committee to oversee clinical service delivery at each facility.

[107] Australian Private Hospitals Association (APHA), 2008, Submission to the National Health and Hospitals Reform Commission, http://www.apha.org.au/wp-content/uploads/2009/04/apha-nhhrc-submission.pdf (accessed 15 February 2010), p. 17.

A regulatory impact statement (RIS) prepared for NSW Health by PricewaterhouseCoopers (PwC) states that 'the proposed regulation is more demanding, and at times more prescriptive, than the existing regulations.'[108]

PwC estimates that compliance costs due to the proposed regulation could total as much as $29 million in the first year, and $13 million per annum after that. These are due to a combination of upfront purchase costs associated with acquiring equipment, building and design works and the costs of adjusting procedural and system requirements, record keeping and providing notifications to government.

The study also refers to other potential costs associated with extending the NSW licensing regulations: 'the regulation will restrict entry to the market via the licensing system and impose certain minimum standards on market participants. Those minimum standards will of necessity involve service providers incurring some expense and may potentially reduce competition, efficiency and profitability within the industry.'[109]

Physical capital requirements

Government regulations and associated guidelines require private hospitals to construct and maintain specialised, and often high-cost, facilities.

General state government hospital legislation, and accompanying regulations, proscribe a range of standards concerning the quality of physical capital and facilities to be provided. Some of these standards tend to be highly prescriptive (Box 6.1), which may increase the cost of capital expenditure than would otherwise be the case.

Recent changes in physical capital requirements by the states have been cited to impede new capital expenditure. For example, a 2005 study by Access Economics stated that facility guidelines in Western Australia had significantly increased costs of hospital redevelopment, specifically when it came to building standard requirements.[110]

The Access Economics study also mentioned that changes to central sterilising supply department (CSSD) regulations were an impediment to the efficient allocation of capital within hospitals. This is because changes to sterilisation standards have resulted in the need for new CSSD equipment, thus leaving less capacity for other capital expenditure.[111]

In consultations with industry, the authors learned of instances of enforcement that led to significant costs on hospitals. For example, one private hospital was forced to remove grab rails in a fire stair area to prevent hangings by potentially suicidal patients even though the rails were about average waist height. In addition, unnecessary changes to building design guidelines applicable to existing, well-functioning hospitals had led to retrofits costing hundreds of thousands of dollars in some cases.

---

[108] PricewaterhouseCoopers (PwC), 2009, *Regulatory Impact Statement for the Private Health Facilities Regulation 2009*, Report for NSW Health, July, p. 15.
[109] Ibid, p. 40.
[110] Access Economics, 2005, Private Hospitals Capital Expenditure, Report prepared for Australian Private Hospitals Association (APHA), March.
[111] Access Economics, Ibid.

Box 6.1 Case study: South Australian private hospital facility standards

The South Australian *Health Care Regulations 2008* outlines the following and other standards of construction:

- Access: all corridors for bed, trolley or barouche traffic must have at least 1,800mm in width clear of handrails and other permanent intrusions; doorways to water closets, bathrooms and shower cubicles intended for access of wheelchairs must have a clear opening of at least 900mm, and if corridors are 1,800mm in width the doorway opening to wards must be at least 1,200mm in width.
- Room sizes: every room to be occupied by one patient must have a floor area of at least 9.3 square metres; every room with more than one patient must have at least 8.4 square metres of floor space for each patient, or at least 7.5 square metres for children aged up to 14 years or 3.9 square metres for each child in a cot.
- Ablution facilities: on each floor a hospital must have a bathroom, containing an island or peninsula plunge bath, with minimum floor dimensions of 3,000mm x 2,400mm or, in the case of a bathroom with a pedestal pan and hand basin, 3,000mm x 3,000mm.
- Maternity facilities: a private maternity hospital must have delivery room with minimum floor dimensions of 4,800mm x 3,900 mm and a minimum ceiling height of 2,70mm, and must be designed so that no person can enter the room from any other part of the hospital except through one door or point of entrance.
- Surgical facilities: a private surgical hospital must have an operating room with minimum floor dimensions of 6,000mm x 5,400mm and a minimum ceiling height of 2,700mm, both soiled and clean utility rooms, and separate change room facilities for staff.

Source: South Australian government legislation website.

Local government regulations have also led to additional capital costs for private hospitals. In particular, variations in regulatory requirements by councils, and attitudes towards development and planning, impose extra costs for private hospital groups operating in more than one location.

Safety and quality regulations

A greater regulatory focus has been accorded to issues of safety and quality in clinical practice as a consequence of high-profile reports highlighting the extent of adverse events in hospitals.[112]

In 1992, the Quality of Australian Health Care study estimated that the prevalence of adverse events as a proportion of total (private and public) hospital admissions was 16.6 per cent (or 13 per cent of 100 admissions).

A more recent estimate, provided by the AIHW, indicates that there were 382,000 hospital separations with an International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM) code for an adverse event (4.8 per 100 separations). There were 268,000 separations with adverse events in the public sector (5.6 per 100 separations) and 115,000 separations in the private sector (3.7 per 100 separations).

According to a 2008 study by Cruikshank and Ferguson, about 200,000 adverse events are caused by health care acquired infections each year.[113] The most important sites of infection are the

[112] Adverse events are defined as incidents in which harm resulted to a person receiving medical care. They include infections, falls and other injuries, and medication and medical device problems and errors. Adverse events can affect the wellbeing and financial situation of patients, and impair the operational efficiency of health care providers.

bloodstream and surgical sites. Infections in such sites, particularly due to methicillin-resistant *Staphylococcus aureus* (MRSA) cause complications, and one in three patients who develop such infections die. Cruikshank and Ferguson state that MRSA is now endemic in most Australian hospitals.

The available evidence suggests that the rate of hospital-acquired infections is lower in private hospitals compared to their public sector counterparts. A Productivity Commission draft study on the comparative efficiency of private and public hospitals found that the rates of MRSA and Vancomycin Resistant Enterococci (VRE) infections were lower in Victorian private hospitals than public hospitals between 2005-06 and 2007-08.[114] Similar results were found in Queensland (based on average infection rates) and Western Australia.

As a growing number of official inquiries, including in relation to the Campbelltown and Camden hospitals (NSW) and Bundaberg hospital (Qld), have highlighted that adverse events have also been associated with human errors, medical team and system failures.

At the federal level, the ACSQHC was established in January 2000 to lead national efforts to improve the safety and quality of health care provision in Australia.

The ACSQHC has been developing an alternative national model for safety and quality accreditation of health care providers, which aims to clarify roles and responsibilities for the safety and quality of care.

Draft standards have been developed for governance of safety and quality, patient identification, health care associated infection and medication safety. It is expected that consultations on the draft set of safety and quality healthcare standards will commence in late 2009.

The agency has also developed an alternative model of accreditation for health care providers as part of the broader safety and quality agenda. However, a number of studies have suggested that a given hospital's accreditation status is a poor predicator of the safety and quality of health care.[115]

State governments have also established bodies dedicated to promote patient safety and quality standards.

For example, the Queensland Health Quality and Complaints Commission (HQCC) develops and endorses health safety and quality standards in that state, and monitors the quality of private and public health service provision against the standards. The HQCC has outlined seven health care standards to assist providers to improve the quality of their services:

- review of hospital-related deaths: reviews must be conducted into the deaths of admitted patients, non-admitted patients who were within the care of a hospital at the time of death (such as in an emergency department), and patients discharged from hospital up to 30 days before death.

---

[113] Marilyn Cruikshank and John Ferguson, eds., 2008, *Reducing Harm to Patients from Health Care Associated Infection: The Role of Surveillance*, Australian Commission on Safety and Quality in Health Care.

[114] Productivity Commission, 2009, *Public and Private Hospitals*, Research Report, Canberra.

[115] A number of these studies are cited in David Greenfield and Jeffrey Braithwaite, 2007, *A Review of Health Sector Accreditation Research Literature*, University of New South Wales, Faculty of Medicine, Centre for Clinical Governance Research in Health.

- care after a heart attack: upon discharge from a hospital a GP should be sent a summary of treatment and medicines, and should confer with the patient about correct medication dosages, cardiac rehabilitation and undertake a review of lifestyle.
- surgical safety: doctors and nurses are obliged to obtain a completed and signed consent form from a patient or representative, check for the correct patient and surgical site, administer antibiotics, assess blood clot risks, and use appropriate medication or devices to ameliorate potential blood clotting.
- clean hands: health providers should have facilities for hand washing, and staff and visitors should clean their hands before approaching a patient.
- credentialing: doctors must be registered and qualified for tasks, must operate within their recognised ability and be re-evaluated every three to five years, and hospitals must have necessary service capability and resources for the treatments they provide.
- complaint management: patients are entitled to make complaints about services provided, including unsatisfactory care, lack of communication, lack of respect, dignity or privacy, negligent or unprofessional behaviour, and privacy of, and access to, medical records.
- duty to improve: health care providers must demonstrate they have made real improvements to patient safety and quality of services.

The enabling legislation for the HQCC imposes on health care providers a duty to put in place procedures to improve service quality, and can obtain from hospitals reports, records or other information relating to the quality of services provided.

In addition to this, states and territories have long imposed regulatory standards to promote hospital settings that are safe and comfortable for patients and that deliver high quality care (Box 6.2).

Box 6.2 Selected state and territory government health safety and quality regulatory requirements

States and territories enforce a range of generic safety and quality provisions affecting the safety and quality of care provided in private hospitals that are likely to impose a range of administrative and substantial compliance burdens. As will be shown below, some of the provisions are vague in their interpretation while others are highly prescriptive or unnecessary.

New South Wales

The *Private Hospitals Regulation 1996* requires a hospital to establish written procedures for evaluating and recording the quality of clinical services and care, and for non-clinical services, and for correcting identified problems.

The regulation also specifies requirements to have a written infection control policy, and specifies hygiene requirements for the hospital building, fixtures and fittings. Further, 'meals at a private hospital must be prepared and served in sufficient variety, quality and quantity to be attractive and palatable to and edible by patients.'

When it comes into force, the *Private Health Facilities Act 2007* will require private hospitals to establish 'root cause analysis' teams to investigate sentinel events. These arrangements will broadly mirror those that presently exist for NSW public hospitals.

Box 6.2 (cont'd): Selected state and territory government health safety and quality regulatory requirements

Victoria

In Victoria, the *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002* prescribes conditions regarding the care of patients. The patient must 'be treated with dignity and respect and with due regard to his or her religious beliefs, and ethnic and cultural practices' and 'is not subjected to unusual routines, particularly with respect to the timing of meals and hygiene procedures.'

The regulations also specify a minimum number of hospital staff to provide care for patients. For example, at least one registered nurse must be on duty for each ten patients during day and evening shifts.

Western Australia

The *Hospitals (Licensing and Conduct of Private Hospitals) Regulations 1987* enunciate a range of safety and quality standards that hospitals must comply with.

According to the regulations, hospitals must adhere to requirements relating to food and beverage provision. Patients must receive fresh fruit or fruit juice daily, and the menu must not be repeated at intervals of less than four weeks. Breakfast must not be served before 7am, the midday meal not before 12 noon and the evening meal not prior to 5pm.

The regulations also specify that animals are not allowed on the premises of a licensed private hospital.

Source: State legislation websites.

The outgrowth in safety and quality regulations applicable to private hospital systems poses significant burdens upon operators.

As recently noted by the APHA, there are 'multiple measurement and reporting regimes around the safety and quality of services in private hospitals which are imposed in differing ways by state and territory licensing regimes, private health insurance fund contracting arrangements, accreditation agencies and state-based safety and quality agencies. This is wasteful and does little, if anything, to actually assure patient safety.'[116]

The APHA has also stated that the regulatory 'duplication and overlap, far from ensuring safer and higher quality health care, actually has the reverse effect by redirecting scarce resources (staff and financial) away from the provision of health care to comply with administrative requirements.'[117]

[116] APHA, Submission to the National Health and Hospitals Reform Commission.
[117] APHA, Submission to Phase 2 of the Australian Commission on Safety and Quality in Health Care Review of Accreditation, October 2007.

7 Regulation quality and governance issues

Introduction

The Australian health care sector is characterised by a labyrinthe network of financing and policy activities designed in an attempt to promote the health status of, and improve the care outcomes for, Australians (Figure 7.1).

One of the consequences of the extensive level of public sector involvement in health has been the rapid growth of regulation over time. As previous Chapters highlighted, a number of key regulations tend to impose substantial compliance costs upon private health care providers.

A key determinant of regulatory performance and outcomes is the extent to which regulations conform to accepted best practices in their design, administration and enforcement. According to a Productivity Commission feasibility study on regulation benchmarking, regulated entities (in this context, within the health care sector) are 'likely to face unnecessary burdens where regulation is not designed, administered or enforced in keeping with best practice principles.'[118]

As noted in Chapter 2, growth in the quantity of regulation can also represent a major source of burden and complexity for many operators in the health system.

Other issues that can affect the overall quality of commonwealth and state government regulations have been raised by health sector stakeholders. These include matters regarding the integrity of regulation making, more rigorous assessments of regulatory proposals, and effective consultation processes with those parties affected by proposed regulations.

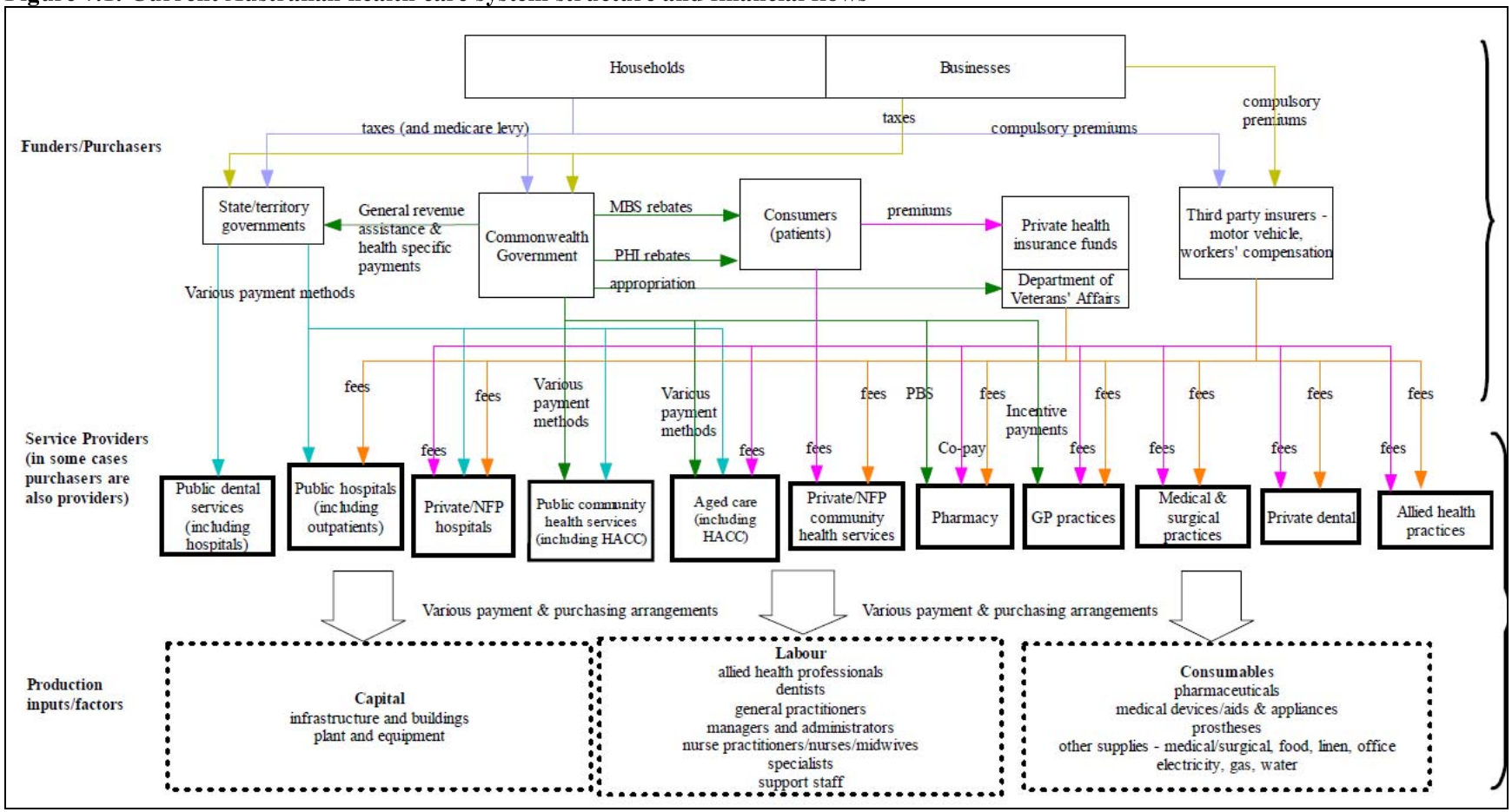
In Australia's federal system with concurrent responsibilities across levels of government, issues of regulatory inconsistency and duplication have been cited as key concerns for health sector operators.

The manner in which existing regulations are enforced by regulators can also be crucial in influencing regulatory burden. For example, issues such as excessive prescriptiveness in interpreting legislation, rigid enforcement actions and elements of regulatory overreach over and beyond the spirit of enacted statutes may effectively increase costs for health care businesses.

The following sections examine some of the major quality and governance issues affecting the design, administration and enforcement of health care legislation.

[118] Productivity Commission, 2007, *Performance Benchmarking of Australian Business Regulation*, Research Report, p. 111.

Figure 7.1: Current Australian health care system structure and financial flows



Source: National Health and Hospitals Reform Commission, 2009, *The Australian Health Care System: The Potential for Efficiency Gains – A Review of the Literature*, Background Paper, June.

Profile of Australian health sector regulations and regulatory administration

As noted above, the stock of regulation can pose as a significant source of burden for many health care sector participants. This is partly due to the fact that operators in the sector need to comprehend the breadth of different regulatory requirements that directly affect their enterprise.

A proxy indicator that is commonly used to quantify the level of regulatory burden is the number of pages of current primary legislation imposed by each relevant jurisdiction. It is important to note that this provides only a general indication of the amount of regulatory activity, and does not necessary indicate the degree of actual regulatory burden on affected parties.[119]

Based on information derived from commonwealth, state and territory legislation websites, the health care sector was subject to over 300 Acts – in turn containing over 22,600 pages of requirements – during the last financial year (Table 7.1).

Table 7.1: Number of Acts and pages administered by Health Ministers

	Cwealth	NSW	Vic	Qld	WA	SA	Tas	ACT	NT	Total
Acts	59	37	27	36	41	30	32	23	20	305
Pages	5,025	1,623	3,732	5,023	2,735	1,023	1,310	1,552	630	22,653
Pages per Act	85	44	138	140	67	34	41	67	32	74

Approximate number of pages of primary legislation for NSW and Tasmania estimated by converting number of bytes in the html-format database.
Source: Commonwealth, state and territory government legislation websites.

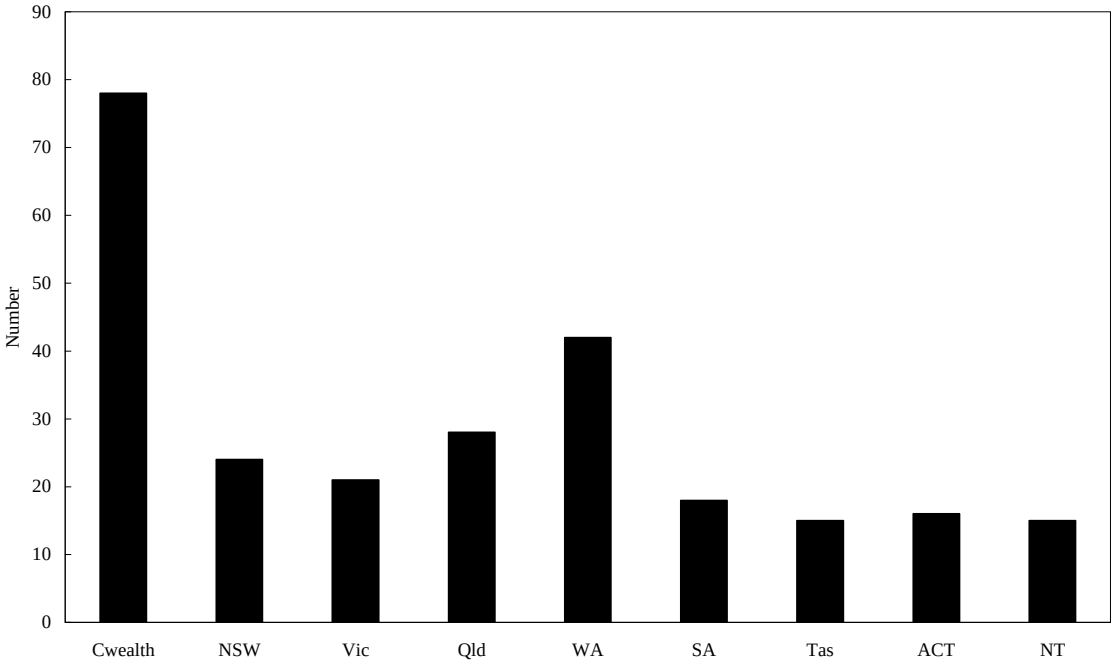
The number of pages per Act could be regarded as an indirect measure of the amount of prescriptive regulation enforced. Queensland has the highest average number of pages per legislation (140 pages), followed by Victoria (138) and the commonwealth government (85). By contrast, the Northern Territory has the lowest average number of pages per Act (32 pages).

The number of regulators responsible for administering and enforcing government regulations provides another indication of the extent to which governments seek to regulate the activities of the health care sector (Figure 7.2).[120]

[119] As explained by Berg, there are a number of other caveats attached to this indicator. Legislation generally is wider in scope and content than subordinate legislation (or regulation) which is not measured in this section. The number of pages of legislation is affected by presentation and style changes affecting the ratio of words to pages. Chris Berg, 2008, *The growth of Australia's regulatory state: ideology, accountability and mega-regulators*, Institute of Public Affairs, Melbourne.

[120] The types of regulators vary across the commonwealth, states and territories, with core government departments complemented by a mix of statutory authorities, offices, commissions, councils and other bodies. In addition, the coverage of regulatory administration may vary appreciably across jurisdictions. Some governments maintain 'super-regulators' responsible for regulating a wide range of health care activities, while others may have smaller, niche regulators covering a limited number of policy areas with, in some cases, only an enforcement or administrative role.

Figure 7.2: Number of health care regulators



Including departments, agencies, statutory authorities, offices, commissions, committees and intergovernmental councils. Excluding state area health services and cemetery trusts. Data for some jurisdictions include bodies responsible for aged care regulatory policy.
Source: Commonwealth, state and territory government health department annual reports and websites.

With the exception of the commonwealth and Western Australian governments, the number of health care sector regulators is broadly comparable across jurisdictions.

There is considerable diversity in terms of the amount of financial and labour resources absorbed by governments to maintain regulatory controls over the health care sector (Table 7.2).

Table 7.2: Appropriations and staffing of selected health care regulators

	Government	Revenue	Staff
Therapeutic Goods Administration	Cwealth	92,340,000	585
Health Quality and Complaints Commission	Qld	10,598,975	80
NSW Medical Board	NSW	8,995,000	52
Queensland Nursing Council	Qld	7,598,018	39
Australian Organ and Tissue Authority	Cwealth	3,724,000	19
Health Care Complaints Commission	NSW	402,000	81

Source: Selected agency websites.

As noted in previous Chapters, the number of health regulators has expanded in recent years – for example, administration and enforcement of health care safety and quality. More recently, the commonwealth government has expressed its intention to enter the preventative health regulatory field effectively duplicating existing state initiatives (Box 7.1).

Box 7.1: Regulatory expansion in health – the Australian National Preventive Health Agency

The Council of Australian Governments (COAG) agreed on 29 November 2008 to establish the Australian National Preventive Health Agency (ANPHA) as one element of the National Partnership Agreement on Preventive Health.

The purpose of the ANPHA will be to support Australian Health Ministers' Conference and COAG in creating a framework for a national approach to preventive health. It is envisaged that the functions of the Agency will be to:

- provide evidence-based advice to Health Ministers on key national-level preventive health issues, either at their direction or by providing sentinel information about emerging challenges and threats
- provide national leadership and stewardship of surveillance and data on preventable chronic diseases and their lifestyle related risk factors in order to improve the availability and comparability of the evidence
- collate evidence available from a range of sources in order to assess and report biennially on the state of preventive health in Australia
- support behavioural change through educational, promotional and community awareness programs relating to preventive health
- provide financial assistance to third parties to support the development and evolution of evidence around preventive health interventions and to achieve preventive health gains, for example through grants supporting research
- form partnerships with relevant groups (industry, non-government and community sectors) to encourage cooperative action leading to preventive health gains
- promulgate national guidelines, standards, codes, charters and other frameworks to guide preventive health initiatives, interventions and activities
- manage schemes rewarding best practice in preventive health interventions and activities.

The commonwealth government has provided a funding allocation of $133.2 million over four years for the ANPHA, including $102 million for national social marketing campaigns targeting obesity and smoking.

Assuming that the legislation will be passed, the likely regulatory activities of the ANPHA are most likely encapsulated in the final report of the National Preventative Health Taskforce released in September 2009. The report advocated a range of regulations that would affect business, including controls over the fat, salt and sugar content of foods, changes to urban planning and building design, and mandated plain packaging of foods and other goods.

Apart from the potentially adverse effects of ANPHA regulatory activities upon the integrity of individual choices, the prospective actions outlined above are likely to impose significant compliance burdens upon the economy in the name of promoting public health.

Source: Department of Health and Ageing, http://www.health.gov.au/internet/main/publishing.nsf/content/phd-anpha (accessed 12 January 2010); Parliament of Australia, 2009, Bills Digest – Australian National Preventive Health Agency Bill 2009, Department of Parliamentary Services, Parliamentary Library, http://aph.gov.au/library/pubs/bd/2009-10/10bd034.pdf (accessed 12 January 2010); Julie Novak, 2009, 'No beer, no pies, no fags – the future of Australia?', The Courier Mail, 7 September; Tim Wilson, 2009, 'Nanny knows best', The Australian, 4 September.

The following sections discuss selected issues raised by health sector representatives in relation to the quality, and governance, of regulation that may play their role in increasing compliance burdens upon health care operators.

Pharmaceuticals regulatory governance

TGA transparency and consultation processes

One aspect of good regulatory process is that decisions made by regulators are transparent at all stages of the regulatory cycle. Specifically, ensuring that the outcomes and bases of regulatory decisions are made apparent to regulated parties and the wider community promotes a sense of accountability by the regulators. This requirement for more transparency assumes greater importance as regulators become equipped with substantial discretionary powers.[121]

In its submission to the Productivity Commission's review of manufacturing and distributive trades regulation, Pfizer Australia raised concerns regarding the level of transparency and communication by the Therapeutic Goods Administration (TGA):

'we are not certain how or why the TGA makes decisions. That is, it lacks transparency. And this creates uncertainty for us. Even if specific TGA processes cannot be changed, we would find our work easier if the TGA explained when and how and why it makes decisions. We would have more time to prepare what the TGA requires, give and get useful advice, and contribute more constructively.'[122]

Pfizer also referred to the lack of advance warning received, and the limited time available, when asked by the TGA to give advice regarding new guidelines.

In another submission to the same PC review, Johnson & Johnson had recounted instances of poor communication by the TGA (including a lack of consultation on personnel changes and reluctance to convene face-to-face meetings), as well as inconsistent and untimely advice which serve to raise the complexities and costs associated with interfacing with the regulatory process.[123]

PBS listing and pricing approval processes

As noted in Chapter 4, most prescription medicines in Australia are supplied and subsidised through the Pharmaceutical Benefits Scheme (PBS). Medicines have to be registered before they can be considered for inclusion on the PBS. The Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the commonwealth health minister about which medicines, medicinal preparations and vaccines should be listed on the PBS.

The Pfizer Australia submission to the Productivity Commission review of manufacturing and distributive trades regulation highlighted a number of deficiencies in PBS listing and pricing approvals. One problem relates to the inconsistency of advice from government:

'A major problem … in the past is the mismatch of early advice on our PBAC submissions and the PBAC's final recommendations. Before Pfizer Australia lodges a major PBAC submission, like all manufacturers, we discuss it with representatives of the Pharmaceutical Benefits Branch of the Department of Health and Ageing. (The Branch provides secretariat and technical support to the PBAC). … There have been times when advice given to us by the Branch at this initial stage is not reflected *at all* in the independent

[121] Chris Berg, 2008, *The growth of Australia's regulatory state: ideology, accountability and mega-regulators*, Institute of Public Affairs, Melbourne, p. 62.
[122] Pfizer Australia, 2008, Submission to Productivity Commission Annual Review of Regulatory Burdens on Business – Manufacturing Sector and Distributive Trades, p. 8.
[123] Johnson & Johnson, 2008, Submission to Productivity Commission Annual Review of Regulatory Burdens on Business – Manufacturing and Distributive Trades, July.

evaluation (upon which the listing decision is based), or in the PBAC's final recommendations to the Minister. We have had submissions rejected or deferred, which we prepared in good faith using the advice provided by the Department.'

Pfizer also referred to a lack of accountability of PBAC evaluations. For example, 'an increasing number of elements in evaluations are either simply wrong or contain major omissions, and consequently the PBAC is being given guidance that may lead them to incorrectly reject our medicines. Pharmaceutical manufacturers currently have only limited opportunities to address errors of fact or omissions.'

Other deficiencies of process were referred to by Pfizer. There was a perceived lack of redress, with companies only allowed ten minutes to address PBAC in relation to their submissions and following receipt of commentary from external academic groups. According to Pfizer, 'this is disproportionate to the amount of time invested in developing a submission, and the complexity that submissions often involve.'

Similarly, pharmaceutical manufacturers are permitted only up to five days to respond to evaluator comments (which often run over 50 pages and are typically highly technical).

This account suggests that improvements could be made to existing consultation processes instituted by the TGA and PBAC in order to improve regulatory efficiency and thereby streamline health business compliance costs.[124]

Private health insurance regulatory governance

Overarching regulatory framework for health insurance

The private health insurance industry operates under arguably the most complex regulatory environment in Australia.

Until 2007, the *National Health Act 1953* (NHA) was the primary legislation governing health funds. As noted by the 2006 Regulation Taskforce, the Act was 'crafted in a different regulatory and health care environment, reflecting a predominantly publicly funded health system, rather than the current mixed public and private system.'[125] There were also a number of provisions in the *Health Insurance Act 1973* (HIA) that governed the conduct of health funds.

Over time there had been numerous additions to this framework, with many of these designed to address *ad hoc* policy issues in a largely reactive fashion. Consistent with the outgrowth in legislative activity, multiple regulatory bodies emerged at the national level.

The Department of Health and Ageing administered the NHA and health fund rules, while the Private Health Insurance Administration Council (PHIAC) was charged with regulating the financial probity of insurers. In addition, the Public Health Insurance Ombudsman (PHIO) was established to manage consumer complaints and the Health Insurance Commission had a role in administering the private health insurance incentives.

---

[124] Productivity Commission, 2008, *Annual Review of Regulatory Burdens on Business: Manufacturing and Distributive Trades*, Research Report, p. 69.

[125] Regulation Taskforce, 2006, *Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business*, Report to the Prime Minister and Treasurer, January, p. 24.

The *Private Health Insurance Act 2007* was introduced by the Rudd government, repealing the health insurance provisions of the NHA and HIA ensuring that the health insurance industry was regulated under its own Act of parliament for the first time.

While this legislative change was accompanied by some positive developments for the sector, including provisions enabling insurers to fund out-of-hospital care treatments, opportunities to rationalise the administration of commonwealth health insurance regulation was largely overlooked.

In other words the industry is subject to regulatory developments by a myriad of agencies, which often operate at cross-purposes to each other. As a result, the overall regulatory regime remains extremely complex and imposes increasingly burdensome compliance requirements on health funds, resulting in higher premiums for fund members and higher government outlays.[126]

Ministerial discretion over health insurance operations

With respect to several other regulations affecting private health funds, direct ministerial discretion over regulation applies. For example, a fund is required to seek regulatory approval from the federal health minister for an increase in premiums above the consumer price index.

There have been some changes to this regulatory stipulation over time.[127] In 1996, the federal government introduced the practice whereby premium increases required approval by the health minister, in consultation with the prime minister and treasurer. In 2003, the process was streamlined with insurers seeking a premium increase below CPI not obliged to submit as much information compared to at- or above-CPI applicants.

With the passage of the *Private Health Insurance Act 2007*, the time required for insurers to submit price increase applications was lengthened. The minister is also obliged to approve all premium increases unless this would be contrary to the 'public interest.' However, the concept of public interest is left undefined in the legislation.

As noted by Access Economics in an assessment of the pricing approval regulatory framework, the result of this regulatory discretion 'is a climate of poor accountability and transparency, which creates considerable uncertainty for existing funds and potential market entrants.'[128] It also introduces 'a political overtone to decisions.'[129]

Biggs has noted that there is the potential for approved premium increases larger than inflation to attract consumer complaints to the Private Health Insurance Ombudsman (PHIO), even if these price movements were approved by the federal minister.[130]

Private hospitals regulatory governance

---

[126] Regulation Taskforce, 2006, p. 25.
[127] Changes to the price approval regulation are discussed in Amanda Biggs, Private health insurance premium increases – an overview, Department of the Parliamentary Library Background Note, http://www.aph.gov.au/Library/pubs/BN/sp/HealthInsurancePremiums.htm (accessed 7 October 2009).
[128] Access Economics, 2005, Regulation of Private Health Insurance Pricing, Report for Challenger Financial Services Group, November, p. i.
[129] Ibid, p. 9.
[130] Amanda Biggs, Private health insurance premium increases – an overview, p. 1. The number of complaints relating to premium increases has declined in recent years.

Role of the Queensland Health Quality and Complaints Commission

The Queensland Health Quality and Complaints Commission (HQCC) were established following inquiries into aspects of the state's public hospitals and health systems respectively. As well as functioning as a complaints management agency, the HQCC was also provided with powers to set and monitor leading practice standards for health care.

A recent assessment of Queensland health care system by retired UK chief medical officer Sir Liam Donaldson highlighted ambiguity between the roles of the HQCC and the Queensland Department of Health: '[there is] no clear agreement on the respective roles of the [HQCC] and Queensland Health in quality improvement.'[131]

Specifically, Donaldson noted that senior management in the Health Department would be unlikely to 'accept a wide-ranging quality improvement and cultural change role for the [HQCC].'[132]

Issues have also been raised about potential conflicts inherent in the internal structure of HQCC. In testimony to a Queensland parliamentary sub-committee hearing in 2007 the Executive Director of the Private Hospitals Association Queensland (PHAQ), Ms Lucy Fisher, referred to the organisational structure of the HQCC:

'the Queensland commission is, to my knowledge, unlike any other entity in Australia in that in other jurisdictions the complaints and investigative units are independent of the standard setting and quality monitoring units. I think there is a real danger where you have an organisation that goes across the spectrum to then put on powers of prosecution. There is a danger I think in that it could be counterproductive to your main aim of quality improvement, because if it is seen to be a punitive organisation you may find that clinicians are less enthusiastic to contribute their time to quality improvement activities.'[133]

The PHAQ has also expressed concern about the prospects of duplication of regulatory effort between the HQCC and the Australian Commission for Safety and Quality in Health Care.[134]

This view was endorsed in a submission by General Practice Queensland, which stated 'there appears to be a structural tension between the HQCC's dual priorities of Quality Improvement and complaints management.'[135]

Other issues

Conflicting interests in health departments

[131] Patrick Lion, 2010, 'Queensland Health a bureaucratic mess: Sir Liam Donaldson', The Courier Mail, 9 February.
[132] Patrick Lion, Ibid.
[133] Queensland Parliament, 2007, Health Quality and Complaints Commission Select Sub-Committee, Public Hearing Transcript of Proceedings, 17 August.
[134] Private Hospitals Association Queensland, 2007, Submission to Queensland Parliament Health Quality and Complaints Commission Select Sub-Committee, 3 August.
[135] General Practice Queensland, 2007, Submission to Queensland Parliament Health Quality and Complaints Commission Select Sub-Committee, 2 August.

A recent report authored by former leading bureaucrat Ken Baxter for the Australian Centre for Health Research revealed the extent of difficulties of policy and regulatory administration within the commonwealth, state and territory health departments. Some of the problems identified by the report include:

- the existence of inherent conflicts of interest between policy, services delivery and regulatory arms of government departments
- an expansive breadth of responsibilities and financial commitments that are typically too large for a single minister, or small number of ministers, to handle effectively
- there remains the need for major changes in the 'culture' of government departments, including in their relationships with other agencies and between levels of government.[136]

With respect to the commonwealth level, it is recommended that the Department of Health and Ageing be structurally separated. The department could be broken into two divisions – national health policy (comprising no more than 250 people) and a 'Services and Operations Division' – with regulatory and research functions transferred to the finance and industry departments respectively.[137]

The need for separation of policy and regulatory responsibilities was described in an illustrative example by Baxter as follows: 'the head of the TGA might need to take a decision inconsistent with health policy or with which the department might not agree, yet the head of the TGA reports to the secretary of the department.'[138]

The report also recommended that timetables should be set for the repeal of outdated, irrelevant or contradictory legislation as well as regulations that do not assist the efficiency of policy development or funding of health services and their delivery.

---

[136] Australian Centre for Health Research, 2009, *Commonwealth-States and Territories Future Relationships, Administrative Arrangements and Implementation of Performance Based Funding for the Australian Public Hospital System*, November.

[137] In the case of professional regulation and accreditation procedures, these could be transferred to the states as part of their health services delivery responsibilities and would, in turn, be governed by mutual recognition arrangements. Australian Centre for Health Research, 2009, *Commonwealth-States and Territories Future Relationships, Administrative Arrangements and Implementation of Performance Based Funding for the Australian Public Hospital System*, November, p. 50.

[138] David Uren, 2010, 'Federal health 'riddled with conflict', The Australian, 15 January.

9 Conclusion

Australia's health regulation nightmare

Every Australian deserves the opportunity to access high quality health care services, to have confidence that those services will improve their standard of living and be to be as affordable as possible.

But despite the efforts of Australia's health care businesses in providing world-class care, the burden of regulation is slowly strangling its capacity to deliver the services expected from it.

Many of the regulations that exist in health serve very little identifiable benefit beyond giving a broad sense of confidence to the public. But in the process costs are raised, impinging on the quality or degree of access to health care services.

The increasingly blurred line of responsibility for the funding and service delivery of health between the states and federal government has resulted in health care service providers grappling with duplicate and overlapping regulation.

New South Wales alone has 37 different Acts of Parliament governing the delivery of health care. Victoria has 27 Acts. The Commonwealth, with no Constitutional responsibility for health care service delivery has 59 relevant Acts. In total there are more than 26,000 pages of legislation governing health care making operations across state boundaries a logistical and compliance nightmare.

Further, the number of health care regulators interpreting and implementing this legislation is on the rise. Each state has between fifteen and twenty different health care regulatory agencies. There are also nearly 80 at a commonwealth level. As a result a single health care facility operating in only one state faces the prospect of having to work with up to nearly one hundred different regulating entities.

As a consequence health care providers are required to invest significant resources toward regulatory compliance, and often duplicating the same material for state and commonwealth regulators.

In private hospitals there is a clear overlap both between commonwealth and state government regulations and a lack of logical consistency between regulations in different states, particularly in the area of licensing.

Regulatory burdens are not just placed on service delivery. Regulatory impositions for medicines and medical devices add further costs to the health system. The regulatory burden for bringing medicines and other equivalently regulated products to market was at least $89 million in 2008-09.

Marketing approval can also be extremely long with average approval times as high as 160 days. Similarly listing of medicines on the Pharmaceutical Benefits Scheme, which is necessary for the medicine to be sold to consumers, can exceed a year.

Australia's medicines regulatory burden is not unique. But there is clearly a need to address over-lapping regulation in the licensing approval for the manufacture of medicines produced for both the domestic and export market.

Considering the global nature of innovation for pharmaceuticals, Australia is incurring costs in regulatory compliance and extending the timeframe for bringing medicines to market despite already successfully jumping safety and efficacy tests overseas.

It is illogical that Australia and New Zealand have not harmonised their approval for medicine sales considering the deep economic integration of the two markets. And further efforts could be taken to fast track medicines given marketing approval in comparable developed country markets like the United States, England and Europe.

Need for reform

From health practitioners there is little argument about the need to alleviate red-tape burdens. There is strong evidence that health care practitioners are spending a significant amount of time on regulatory compliance, with limited benefits at the expense of delivering health care services.

For example, GPs have become a key part in the process of assessing eligibility for a series of welfare payments and programs.

Every dollar spent on employing regulatory compliance officers, paperwork for doctors and nurses and submitting it to regulators means less money spent on improving or extending the lives of Australians.

Regulatory reform in health care cannot be instigated soon enough. As the commonwealth government's Intergenerational Reports have found Australia is facing looming problems in both meeting the cost and delivery of health care required by an ageing population. With the majority of the cost of health care incurred by Australians required near the end of people's lives having a large section of the population demanding high quality health care services at the same time will place a strain on health care infrastructure and finances.

In light of this increase in projected demand, cutting health care regulation will be crucial to ensure private providers can ease demand strain upon health services.

The flexibility and innovation of the private sector is likely to result in a much higher quality of health care services provided. But heavy regulation will limit the flexibility of the private sector to meet the demand for private health care services and increase demand on the public system.

It is for these reasons that governments must reduce the burden of excessive health care regulation with urgency.