



# The Impact and Cost of Health Sector Regulation

An Executive Summary of the report prepared for the  
Australian Centre for Health Research

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## 1. Introduction

Every Australian deserves the opportunity to access high quality health care services. Those services should improve quality of life while remaining affordable.

*The regulatory burden on the health sector is overwhelming*

Increasingly however, Australia's health system is bowing under the weight of a regulatory pile-up. A poorly constructed regulatory framework and a reactive approach to policy making has created a haphazard growth in regulatory requirements, a muddle of duplication, a lack of accountability, and inadequate regulator transparency.

The need to address this problem is made all the more crucial by Australia's demographics. Our ageing population will mean that in 40 years relatively fewer Australians will be of working age and more Australians will be dependent on the health system.

*Our ageing population will increase the pressure on Australia's health system*

The federal government's intergenerational report projects that the ageing population will lead to significant expenditure and service delivery pressures on the future health care system. It is expected that spending on healthcare will increase from four per cent of GDP in 2009-10 to 7.1 per cent in 2049-50.<sup>1</sup>

An inefficient health system is most detrimental to the people who use it. Increased time and money spent on regulatory compliance by health care professionals means less time spent on providing the best possible care for patients.

## 2. Options for the Future of Health

The increased strain on the health sector from an ageing Australia produces two options for the future.

*Higher taxes will be needed to cope with the demands on the future public health system*

The first is to increase taxes. In order to provide a public health system that can cope with the forecast uplift in demand, more public money will be needed. Considering that there is predicted to also be a proportionally smaller work force, this will put substantial pressure on the public purse. In addition, funds would most likely be diverted away from other fundamental public services in order to provide adequate health care.

The second, and preferable option, would be to build up the private health system.

*Australians already trust the private health sector to deliver quality health care*

According to data published by the OECD, the proportion of health care expenditure attributable to the private sector was 32.3 per cent. This figure was significantly above the average of 27 per cent for nearly 30 OECD countries.<sup>2</sup> It is clear that the Australian public have confidence in the private health system to deliver affordable and reliable medical services.

With no reliance on public money, the private health sector is in the perfect position to take on a greater role. Yet the capacity of the private sector to do so is dependent on the regulatory environment within which it operates. As it stands, red tape inefficiencies can be seen across the board of the private sector health system. This is particularly evident in the four areas of private health that the public are most frequently in contact with: general practice, pharmaceuticals, private health insurance and private hospitals.

### 3. Governance: the overarching framework

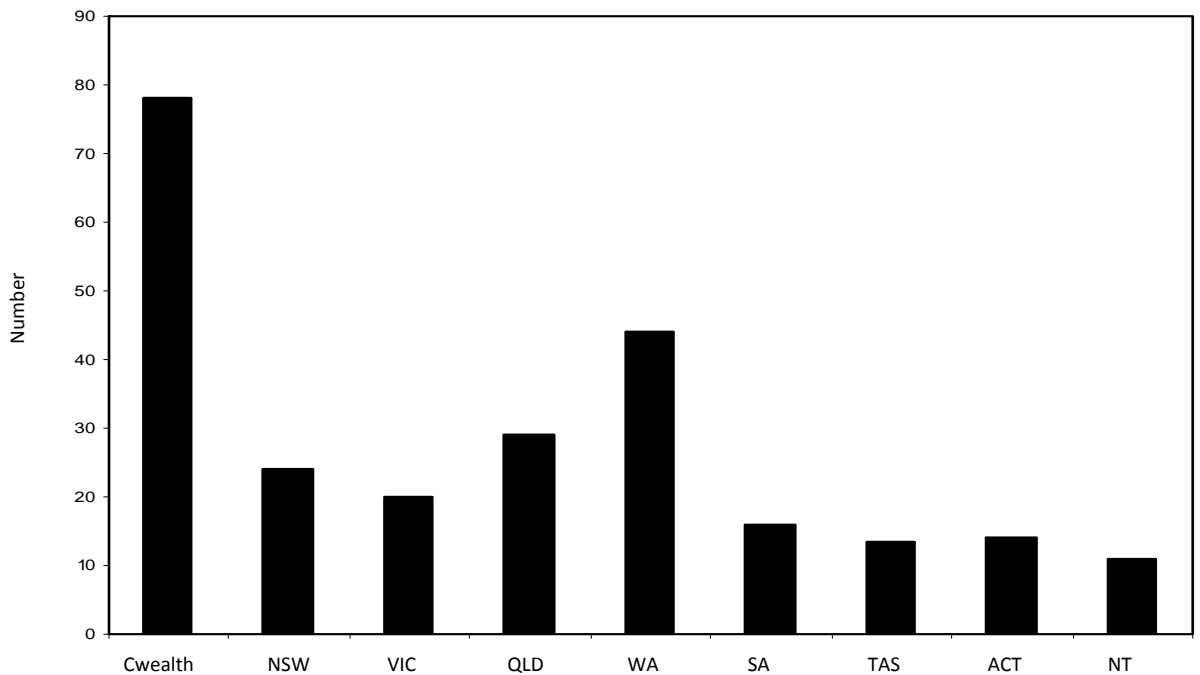
*The overarching framework of Australia's health system is the underlying cause of inefficiency*

The current regulatory framework is a major driving force of inefficiency within Australia's health system.

The structure and financial flows within the health sector is extremely confusing and unnecessarily complex.

When concerns arise in the health sector, it appears that policy makers' first reaction is to stick a regulatory band aid over the problem. The emergence of numerous regulatory bodies and legislation are a testament to this.

**Figure 1: Number of health care regulators**



Source: Commonwealth, state & territory government health department annual reports & websites

The need for a streamlined and integrated regulatory framework was identified in the recent report by Ken Baxter for the Australian Centre for Health Research.<sup>3</sup>

The report found that there remain conflicts of interest between policy, service delivery and the regulatory arms of government departments; that the relationships that government departments have with other agencies can be greatly improved; and that better cooperation between levels of government should be implemented.

Finally, the report raised management concerns regarding the expansive breadth of responsibilities and financial commitments that are typically too large for a single minister to manage.

*A lack of integration between regulators creates a dysfunctional health system*

This lack of integration creates dysfunction throughout the health system. Duplication of requirements from different regulators, and inadequate transparency and accountability procedures, cripples health professionals at the expense of their patients.

The pharmaceutical industry is particularly prone to these symptoms. Industry complaints about the Therapeutic Goods Administration and the Pharmaceutical Benefits Advisory Committee are well documented. Both bodies give inconsistent advice regarding their decisions and both allow very limited timeframes in which pharmaceutical companies can respond to agency requests.<sup>4</sup>

Health insurance is another example where the existing regulatory framework fails the system. The two pillars of health insurance legislation are the 1953 *National Health Act* and the 1973 *Health Insurance Act*. However since their creation more than 40 years ago, any addition to health fund legislation has been largely to address *ad hoc* policy issues in a reactive fashion.

Furthermore, health insurance premium changes are subject to ambiguous ministerial discretion. While this aspect of health insurance regulation was improved in 2007, the federal health minister can reject the premium increase if it is contrary to the ‘public interest’. What public interest means is unclear and transparency is compromised.<sup>5</sup>

In addition to a lack of integration, over-regulation burdens the Australian health system. The regulatory health framework is affected by a phenomenon called to ‘loopholemining’.<sup>6</sup> In order to get the maximum benefit possible within the regulatory framework, medical professionals find ways around regulatory policy. The government then introduces incentive payment readjust the framework and swing the balance back towards their policy objective. The consequence of this is that regulatory complexity usually grows because with regulatory avoidance comes re-regulation.

**Table 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	30	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

Source: Commonwealth, state and territory government legislation websites

As can be seen in Table 1, the amount of legislation that applies to the health profession is extensive.

The Medicare Benefits Schedule (MBS) is an obvious example of over-regulation. The MBS is a list of the Medicare services that are subsidised by the federal government and currently it comprises of 4400 items.<sup>7</sup> It is so large that a hard copy is no longer produced. According to the Australian Medical Association, the requirements stipulated in the MBS 'often disturb existing systems and processes that operate effectively'.<sup>8</sup>

*Australia needs an  
integrated and productive  
health system*

For the health system to be most effective Australia needs an integrated regulatory framework. It needs fewer regulators, less regulation and less time and money wasted on red tape. Doctors and the private health sector should be spending their time providing the best possible care to their patients and not complying with a mass of regulation.

## 4. The Private Health Sector

*Four of the most important private health areas are suffering from extensive red tape burdens*

The private health sector will need to increasingly play a bigger role in Australia's health system. To avoid a reduction in Australia's health standards, four vital areas of the private health system need to be seriously examined to reduce the burdensome regulatory environment in which they run. These areas were chosen because they are the sections of the private system which the public most frequently interact with.

### 4.1 General Practice

*GP's are the gatekeepers of the health system*

General Practitioners are the gatekeepers to the health sector. Around 85 per cent of the Australian population visit a GP at least once a year. Of those only 12.5 per cent are referred on to a specialist.<sup>9</sup> Therefore, for most of us, our main encounter with the health system is our GP.

As their title suggests, general practitioners are generalist doctors. They must be able to identify and diagnose a vast array of medical conditions. In order to do this effectively they must keep on top of new medical developments and technologies and constantly update their skills and knowledge.

*Government welfare programs are proving to be very demanding on GPs*

On top of these demands, the welfare system has evolved in such a way that general practitioners now bear the brunt of administrative duties in welfare approval processes. Some programs which require GP involvement include:

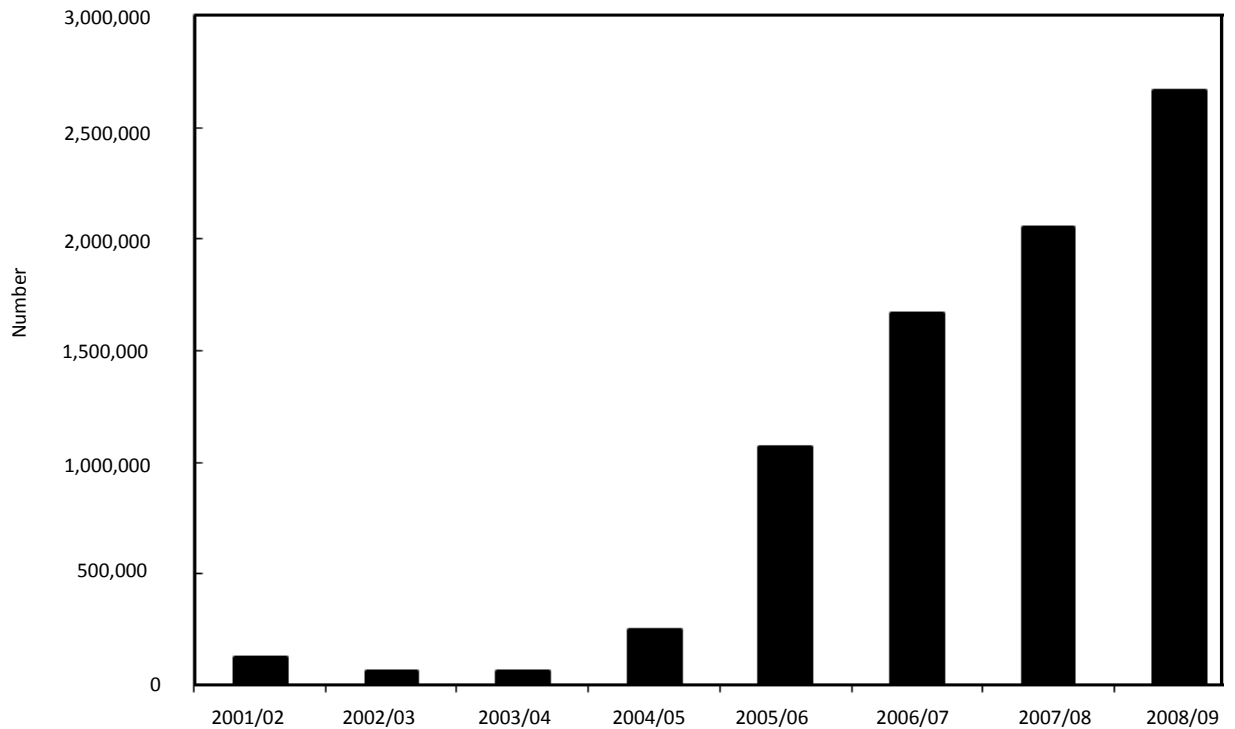
- The Disability Support Pension Sickness Allowance
- Newstart Allowance
- Youth Allowance
- Mobility Allowance
- Carer Payment & Carer Allowance
- Mobility / Disabled Parking Permits
- Telstra Priority Assistance
- Workcover
- Social housing support forms
- Taxi subsidy schemes

Unsurprisingly, in the 2009 *Medical Observer Stress Test* report paperwork was nominated as the second largest contributor to negative health consequences for general practitioners.<sup>10</sup>

Perhaps more shockingly, GPs generally spend up to nine hours a week complying with red tape. Every hour roughly equates to four patient appointments.<sup>11</sup>

It seems that instead of encouraging welfare programs, the paperwork involved actually acts as a disincentive for the uptake of schemes.

**Figure 2: The use of Enhanced Primary Care Medicare Items**



Source: Medicare Australia statistics

In the case of the Enhanced Primary Care (EPC) package, a 2003 Productivity Commission report found that the program was the third highest administrative cost incurred by GPs.<sup>12</sup> In 2005 the EPC program was modified so that the regulatory burden was reduced. Since then participation has dramatically increased.

General practitioners are fundamental to our health system. They are the first port of call for most Australians when health problems arise. Their role is extensive and demanding. Regulation that unnecessarily increases the difficulty of this profession should be immediately reformed.

## 4.2 Pharmaceuticals

The Australian pharmaceuticals industry has a \$17 billion turnover. The industry employs 34,000 people.<sup>13</sup> However, the Economic input of the industry is secondary to its enormous contribution to the health of the nation.

*Pharmaceuticals eradicate the need for further medical treatment*

Pharmaceuticals can reduce or eradicate the need for further medical treatment. They therefore contribute to an overall diminution of health care expenditure and reduce the pressure on the health system.

While no similar study has been undertaken in Australia, it was estimated that every dollar spent on medicines in the US saved hospitals US\$7.17.<sup>14</sup>

In order for pharmaceuticals to play this vital part of a health system, obviously there is a need to test that products are designed and manufactured to have the desired effect.

However, the duplication of assessment in Australia's approvals processes demonstrates an unnecessary amount of regulation imposed on the pharmaceutical industry. As a result, there are significant delays in the availability of essential medicines to the Australian market.

*Duplication in approval processes delays the availability of essential medicines to the Australian market*

Many medicines enter Australia from international markets that have already undertaken rigorous and reliable testing. The US and EU have agreements with Australia to recognise mutual standards of pharmaceutical testing. Despite this Australian regulators, such as the federally run Therapeutic Goods Administration (TGA), do not sufficiently recognise these international audits. Specifically this is seen in TGA's approvals of manufacturing licenses and listings on the Australian Register of Therapeutic Goods (ARTG).

On a national level there are also duplications in approvals processes. In order for a medicine to be sold and marketed in Australia it must be listed on the Australian Register of Therapeutic Goods. For a medicine to be subsidised by government it must be listed on the Pharmaceutical Benefits Scheme (PBS) database. Approvals for listing on the PBS are very similar requirements. More integration between assessed by the Pharmaceutical Benefits Advisory Council which does not take the TGA ruling into consideration despite these two bodies and processes could substantially reduce the time and money spent on pharmaceutical approvals.

After all of these long and arduous approvals processes have been met (including manufacturing licensing, listing on the ARTG, and listing on the PBS) expiry dates for licenses are short and post-marketing monitoring is still required.

Considering their invaluable role in the health system, significant improvements should be made to reduce the regulatory burden on the pharmaceutical industry.

### 4.3 Private Health Insurance

*Private health insurance is crucial for the private health system*

At June 30 2009 there were 37 registered private health insurers operating in Australia. In 2008-09, the industry recorded a surplus (before tax) of \$404 million.<sup>15</sup> Despite these impressive statistics, since the introduction of Medicare in 1984, private health insurance membership has declined.<sup>16</sup>

Private health insurance is so important to the effective operation of the private health system. In general, to be admitted into many private medical facilities private health insurance is required. Considering the importance of the private health system to the future of Australia, private health insurance is an essential component of the sector.

*The Fairer Private Health Insurance Incentives Bill will significantly diminish private health insurance*

In addition, insurance is crucial to the system more broadly due to its financial contribution to the health sector. A reduction in health insurance membership will lead to an absolute reduction in money available for health in Australia. Yet the Fairer Private Health Insurance Incentives Bill was introduced by the federal government last year. The bill is predicted to cause up to 240,000 Australians to exit their private health insurance and 730,000 to downgrade their cover.<sup>17</sup>

The commonwealth government maintains a rebate of between 30 to 40 per cent intended to ensure private health insurance remains affordable and sustainable. However the new bill will mean that singles or families earning over a certain income threshold will have reduced rebate amounts and increased Medicare Levy Surcharges.<sup>18</sup>

This is expected to create more work for private insurers who will have to cross check with the Australian Tax Office that fund members are in the correct threshold category. Furthermore, if incomes vary from year to year a person's threshold eligibility is likely to be confusing.

*The regulations affecting funds act as a disincentive for competitive premium prices*

The regulatory load that the new bill will produce for private insurers is just one more encumbrance to add to the pile. The current regulatory regime is so burdensome for private health insurers that a Carrington-Coelli-Rao study found 'there is little incentive for funds to improve performance.'<sup>19</sup> Consumer product disclosure information requirements and premium approvals are the two most significant burdens.

Private insurers are required to provide hard copies of standard product disclosure information to consumers. These include product statements, tax statements, information concerning premium and/or product changes and 'Transfer Certificates'. Insurers are also required to provide this information online.<sup>20</sup>

Changing to a solely online system is estimated to generate savings of up to \$12.5 million across the industry.<sup>21</sup> This saving will have the flow on effect of reducing the cost of insurance products for consumers. The potential to provide information to consumers in a more precise and user-friendly fashion will also be ameliorated.

As for changes to private health insurance premiums, approval must be sought from the Minister for Health and Ageing. The application process requires the submissions of detailed financial information and cost/benefit projections all certified by an accredited actuary, to justify any premium increases sought. This creates a regulatory burden which effectively creates uncertainty about the rate application until the last moment. Uncertainty affects the production and distribution of consumer information by funds and potentially causes duplication and waste of materials and resources.

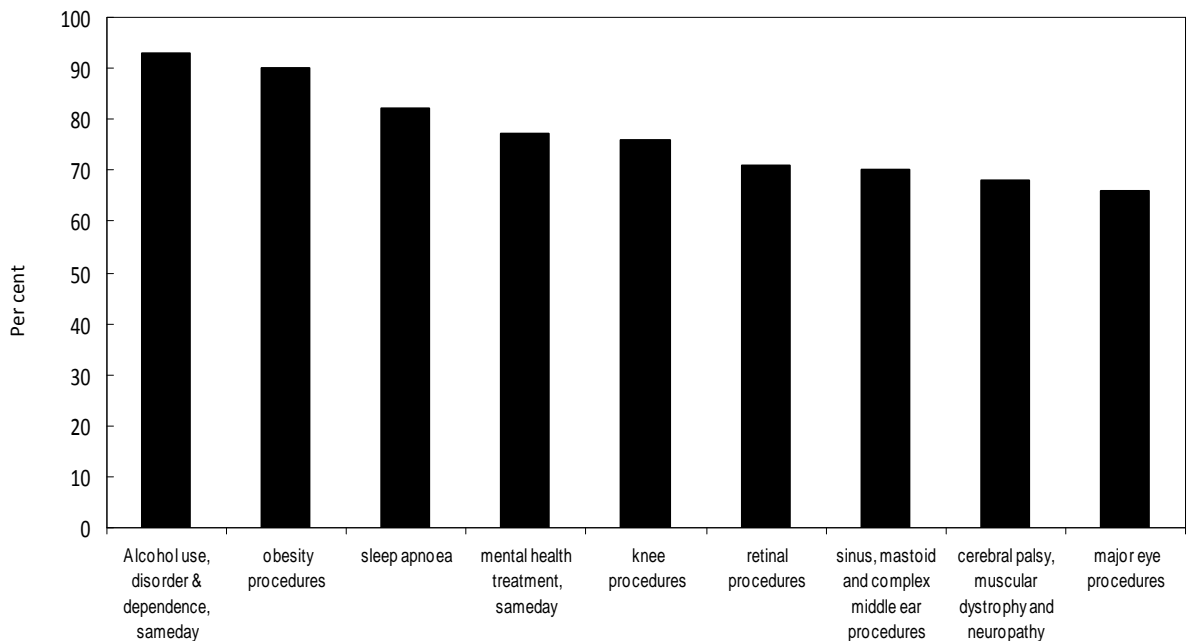
These regulations effectively weaken incentives for insurers to minimise their costs and to act in an innovative or competitive manner. Furthermore, these regulations may deter market oriented firms from introducing innovative products and cost minimisation schemes to the Australian health sector.

#### 4.4 Private Hospitals

*Private hospitals contribute a significant amount to health*

In the year 2008-09 Australia had 561 private hospitals which included 285 day surgery facilities. Those hospitals provided 27,466 beds, accounting for a third of all hospital beds available across the country.<sup>22</sup> Private hospitals provide a diverse range of treatments and procedures catering to the health needs of millions of Australians.

**Figure 3: Private Hospital Share of separations for selected treatments, 2006-07**



Source: AIHW, 2006, *Australian Hospital Statistics, 2006-07*, online tables S12.1, S12.2

*Private hospitals have their own regulatory practices*

Private hospitals, in order to ensure the best standards possible, have adopted their own regulatory procedures. These regulations ensure efficiency and productivity as well as providing the best service possible to their customers, the patients.

Indeed it has been shown that in Victoria, rates of infection in private hospitals were much lower than in public ones in the years 2005-06 and 2007-08. Similar results were seen in Western Australia and Queensland.<sup>23</sup>

Unfortunately, good private hospital self regulatory practice is buried underneath a mound of government regulations. And often, it is not just the one level of government regulation that applies.

*Licensing duplication causes an unnecessary waste of time and money*

Licensing again appears as an impediment to the effective operation of the private health sector. A major problem with private hospital licensing is that they differ between jurisdictions. Private hospitals that operate across jurisdictions then must apply for two or more separate licenses.

**Table 2: 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	na	Y	Y	N	N	Y	na
Day procedure facility	Y	Y	Y	Y	N	N	N	na
Psychiatric day hospital	N	Y	N	Y	N	N	N	na
Private psychiatric hostels	N	na	N	Y	N	Y	N	na
Private nursing post	N	na	N	Y	N	N	N	na

Y= yes; N= no; na= information not available

Source: ACSQHC, 2008, *Proposals on an alternative model for safety and quality accreditation and matters relating to Costs and Duplication of Accreditation Process*, February

Overly prescriptive licensing regulation has been shown to have significant negative consequences. In 2009 a study by PricewaterhouseCoopers investigated the effect of a NSW government's proposal which would effectively extend the licensing obligations. The report found that the total compliance cost associated with the regulation could be as much as \$29 million in the first year, and \$13 million every subsequent year.<sup>24</sup> A cost increase of this amount would surely be felt by consumers as well as the hospitals.

*Physical capital requirements are a large source of red tape*

Physical capital requirements are another source of regulatory burden for private hospitals. The standards enforced by government are often highly prescriptive which unnecessarily increases the cost of capital expenditure than need be the case. For example in South Australia regulation outlines the minimum size of rooms by millimetre.<sup>25</sup>

While state government physical capital requirements have been noted as causing significant compliance costs, local governments add to these requirements. This is particularly relevant in the

development plans of hospitals, which again impinges on the hospitals ability to build a facility which fits patients' needs.

*Safety and quality  
regulation is excessively  
prescriptive*

Finally safety and quality regulations cause enormous compliance headaches for private hospitals. Both state and national regulators exist and both have been found to enforce excessively prescriptive regulation.

The Australian Private Hospital Association expressed their concern for safety and quality regulations in their 2007 submission to the National Health and Hospitals Reform Commission. '[M]ultiple measurement and reporting regimes around the safety and quality services in private hospitals', imposed by state and federal agencies, 'does little to actually assure public safety'.<sup>26</sup>

In order to reduce the strain already felt by the public health system in Australia, private hospitals need to be able to maintain high quality standards that ensure patients are treated well and at a reasonable price. As such, the regulatory environment in which they operate must allow this. The evidence suggests this is not the case. Regulation is enforced by regulators from all tiers of government causing frustrating duplication and high compliance costs. This merely puts patients at a disadvantage. Not only do their medical costs increase but their health services are not as efficient or effective as they should be.

*Australia's health  
regulation needs to be  
reformed and streamlined*

## **5. Conclusions**

The emergence of so much health legislation and so many health regulators has created a complex and frustrating regulatory environment for health professionals to wade through. The lack of integration between regulators that do not have accountable and transparent processes, adds to the confusion.

From health practitioners there is little argument about the need to alleviate red-tape. Strong evidence suggests that health care professionals are spending a significant amount of time on regulatory compliance that has limited benefits, at the expense of time with their patients.

Considering the problems an ageing Australia is facing in regards to meeting the cost and delivery of health care in the future, it is imperative that regulation affecting the health sector is streamlined. Minimum benchmarks that effectively achieve their policy goals need to be set. Inconsistencies, unnecessary duplication, and delays in approval and application processes should also be eliminated.

The regulatory burdens that exist in the current system are merely diverting health care professionals away from what they do best – delivering the best possible care for their patients.

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