Australian Government

Department of Health

Reducing Regulation in the Health Portfolio

POLICY BACKGROUND PAPER

Department of Health Policy Background Paper

The Department of Health is publishing this policy background paper to inform debate on current and future regulatory arrangements in the health portfolio. Observations and descriptions are for discussion purposes only—they do not represent government policy or indicate commitment to a particular course of action

This Policy Background Paper draws upon the approach in the Department of Communications' Background Policy Papers: Paper 1 (Deregulation in the Communications Portfolio) and Paper 2 (Regulating harms in the Australian communications sector). Both papers are available on the Deregulation page of the Department of Communications website.

Context

Reducing the burden of regulation, including red and green tape, is one of the Australian Government's top five priorities, with a stated reduction target of $1 billion per annum.

Regulation is any rule endorsed by government where there is an expectation of compliance, including legislation, regulations, quasi-regulations, such as standards and codes of practice, and any other aspect of regulator behaviour which can influence or compel specific behaviour by business and the community. Red tape burden imposed by the Commonwealth's procurement, grants and the cost recovery frameworks is also included.

The Australian Government's deregulation agenda is guided by the principle that regulation should only be imposed where absolutely necessary, and should not be the default position for dealing with public policy issues. This principle extends to opportunities to reduce duplication between federal and state frameworks.

Identification of reform opportunities are being sought from as wide a range of stakeholders as possible so that the Australian Government will have a broad perspective on how regulation and red tape affect people using or involved with services under the Health portfolio.

Information on opportunities to reform will be considered in the context of the Health portfolio as a whole, taking into account that Health regulation must maintain best practice health interventions, protect public health and safety, and implement effective compliance regimes, whilst reducing unnecessary regulatory and red tape burden on businesses and the community.

This Policy Background Paper—*Reducing Regulation in the Health Portfolio*— is intended to help stakeholders frame their thoughts about reducing regulatory burden in health.

Scope

The introductory sections of this paper focus on the how of regulation rather than what is to be regulated; so necessarily strays into regulatory theory and practice.

However, the regulatory interventions used to deliver public policy outcomes are critical in achieving those outcomes while minimising cost to the health sector. As with policy development itself, the design of regulatory interventions needs to be informed by good analysis, an in-depth understanding of the risks and preferences of, and costs to, consumers, end-users and service providers and the testing and validation of options.

This paper therefore asks the overarching question for consideration:

> ***What is fit-for-purpose regulatory intervention that minimises burden to the health industry while ensuring appropriate protection from harm for health consumers and the public in general?***

The question challenges policy makers, regulators and the health industry to revisit current interventions and ask whether they remain fit-for-purpose in the current environment and how protections can be ensured in the future.

Principles of Regulation – rationale for intervention

As it is the clear objective of the Australian Government to reduce the overall burden of regulation, a commonly-accepted set of principles will help guide the way in which regulation is structured or whether any regulation should be retained in an area.

On a first principles basis, effective and appropriate regulation may embody a number of key elements. It should:

- serve clearly identified public policy objectives, and be effective in achieving those objectives;
- establish rules that are clear, simple and practical for all users and that have a sound legal and empirical basis;
- produce benefits that outweigh the costs, including those imposed on industry (compliance), government (enforcement) and consumers (reduced innovation, fewer services, and higher prices); and
- be consistent with other regulations and policies.

In practice, application of these principles alone are unlikely to be particularly helpful in guiding the development of health regulation given societal expectations and the need to uphold public health and safety outcomes to be delivered by the health sector.

A more practical conversation is needed about regulation that stands the test of time given the rapid movements in technology, services and consumer or citizen expectations.

Public Policy Objectives

The following broad groups of public policy objectives have stood the test of time.

- **Access to services / participation in society.** People should enjoy reasonable and equitable access to health services.
- **Efficient allocation and use of resources.** A minimum level of service should be available to all and public resources should be used efficiently over time.
- **Diversity of voices.** There should be a diversity of major sources of information and perspectives and that this information should be fair, accurate and transparent.
- **Values and safeguards.** Services should reflect community standards, meet community needs and be 'fit-for-purpose'. Users should be provided with effective and accessible avenues of complaint and redress if standards are not met.

Tools

The following provides an outline of the range of 'tools' available to government to deal with the public policy objectives.

- **Black letter law:** primary or subordinate legislation (including regulations and delegated instruments) that requires or prohibits particular actions or behaviours from health sector participants.
- **Administered law:** standards, directions or 'service provider rules' made by the relevant regulator (e.g. the Therapeutic Goods Administration, Office of the Gene Technology Regulator, the Australian Sports Commission) to affect the behaviour of stakeholders.
- **Co-regulation:** a model whereby the health sector is given the opportunity to self-regulate in the first instance, supported by sanctions and a more explicit role for the regulator / legislation if self-regulation is found to fail. Experience suggests that co-regulation is only effective where a sector is clearly defined with small number of participants.
- **Quasi-market instruments:** for example, mandating a particular outcome via black-letter law or regulation (such as Standards).
- **Contestable funding / tax incentives:** relevant for encouraging investment in infrastructure or services. The Australian Government could make available incentives for the provision of particular infrastructure, services or content genres as an alternative to regulation, such as practice incentives to encourage general practitioners or pharmacists to provide particular services.
- **Self-regulation:** allowing the health industry to establish appropriate benchmarks for the provision of services and to assess and respond to consumer complaints and concerns. This approach can work with some sectors, however would need to be very carefully balanced against risk to health and safety.
- **Education and awareness:** informing consumers of their rights and options in relation to health. A consumer education function is likely to continue to have a place in terms of consumer protection initiatives (i.e. obesity prevention).
- **Public sector provision:** government can also directly fund activities required to achieve particular public policy outcomes.

Different tools, or a combination of tools, are required to effectively achieve outcomes. Consideration of the relative merits of the use of these tools is necessary to inform identification of opportunities to reform.

Starting the Discussion

As outlined in the scope of this paper, the overarching question to be addressed is:

> ***What is fit-for-purpose regulatory intervention that minimises burden to the health industry while ensuring appropriate protection from harm for health consumers and the public in general?***

Sitting under this question are concepts that support overall discussion. When considering your responses to these questions, please take into account the principles and public policy objectives outlined on page 4, and how the tools outlined on page 5 would assist in developing your ideas.

In your experience, where is regulation most keenly experienced?

Do you consider the balance between community safety and regulation right for health?

In your opinion is health under-regulated or over-regulated? What aspects of health does this apply to?

Are you aware of particular processes, rules or forms that are causing an unnecessary burden to members of the public, health service providers or organisations? Please briefly outline them.

What do you think could be changed to make these processes or rules work better while assuring protection from harm?

How will your proposed changes reduce the burden?

How will your proposal address the public policy objectives outlined on page 4?

What tools would assist making changes? (Consider, for example, whether education and awareness would be an option in preference to regulation.)

What are the potential harms or risks to consumers or the public that may increase, decrease or be introduced by your proposal? What can be done to mitigate those risks?

Providing a Submission

Please provide your submission through the Deregulation Unit comments form on the Department of Health's website at http://www.health.gov.au/internet/main/publishing.nsf/Content/opportunities-to-reduce-regulation-and-red-tape

OR

Email your submission to dereg@health.gov.au

OR

Mail your submission to:
The Director
Implementation, Compliance and Communication Section
Deregulation Unit
MDP 67
GPO Box 9848
Canberra ACT 2601