



Medical Practice Regulation 2008

Regulatory Impact Statement



REGULATORY IMPACT STATEMENT

TITLE OF REGULATORY PROPOSAL: **Medical Practice Regulation 2008**

PROPONENT: **NSW Department of Health**

RESPONSIBLE MINISTER: **The Hon Reba Meagher MP
Minister for Health**

RELEVANT ACT: **Medical Practice Act 1992**

Table of contents

- 1. WHY IS THE REGULATION BEING REVIEWED?.....4**
- 2. APPROACH TAKEN IN THIS REGULATORY IMPACT STATEMENT4**
- 3. OPERATION OF THE LEGISLATION.....5**
 - 3.1 THE MEDICAL PRACTICE ACT AND THE REGULATION-MAKING POWER5
 - 3.2 ADMINISTRATION OF THE MEDICAL PRACTICE ACT AND REGULATION5
- 4. THE OBJECTIVE OF CLAUSE 11 OF THE REGULATION5**
 - 4.2 THE ALTERNATIVES6
 - 4.2.1 Continuing to rely on the existing Regulation.....6*
 - 4.2.2 The existing Regulation with a practice direction from the Medical Board.....7*
 - 4.2.3 The proposed Regulation7*
- 5. COSTS AND BENEFITS OF THE PROPOSED REGULATION.....7**
 - 5.1 COSTS7
 - 5.2 BENEFITS.....7
- 6. CONCLUSION8**
- APPENDIX A: ORGANISATIONS TO BE CONSULTED.....9**

1. Why is the regulation being reviewed?

The *Medical Practice Regulation 2003* (the 2003 Regulation) facilitates the operation of the *Medical Practice Act 1992* (the Act). The Regulation thereby contributes to the overall regulation of the Medical Profession and the regulation of the provision of medical services in New South Wales.

The *Subordinate Legislation Act 1989* provides for regulations to have a limited life. In most cases, regulations are automatically repealed after 5 years. When a regulation is due for repeal, the responsible agency must review the regulation, its social and economic impacts, and the need for the regulation. The agency must then make a decision about whether the regulation should be remade. The results of this review are required to be published in a Regulatory Impact Statement (RIS) and submissions invited from the public.

This RIS proposes that the existing Regulation be remade.

2. Approach taken in this regulatory impact statement

The Parliamentary Counsel has certified that the proposed *Medical Practice Regulation 2008* (the proposed Regulation), with the exception of clause 11 which concerns the advertising of medical services, deals with matters addressed by schedule 3 of the Subordinate Legislation Act and is therefore exempt from the requirement to prepare a RIS. Accordingly this RIS only addresses clause 11 of the proposed Regulation.

The RIS first considers the objectives of clause 11 of the proposed Regulation and then considers the rationale for clause 11 of the proposed Regulation. The RIS also examines the following options:

- Remaking the Medical Practice Regulation without clause 11; and
- Remaking the Medical Practice Regulation without substantive amendments.

Submissions about the proposed Regulation can be made to:

Legal and Legislative Services Branch
NSW Department of Health
Locked Bag 961
NORTH SYDNEY 2059

Submissions may also be made via email to legalmail@doh.health.nsw.gov.au

3. Operation of the Legislation

3.1 The Medical Practice Act and the Regulation-Making Power

The Medical Practice Act was enacted to provide for the regulation of the medical profession in the interests of the health and safety of the public. The medical profession is similarly regulated worldwide. Mechanisms used to regulate the profession include by imposing certain qualification and character requirements for registration, establishing disciplinary, impairment and performance assessment mechanisms, and establishing the NSW Medical Board to administer the Act and promulgate standards and guidelines to be observed by the profession.

The Medical Practice Act provides for the making of regulation to support the operation of the Act, including in sections 114 (advertising) and section 194 (the general regulation making power). The Medical Practice Regulation supports the operation of the Act by establishing certain additional standards to be observed by medical practitioners including in the areas of infection control, record keeping and advertising of medical services.

3.2 Administration of the Medical Practice Act and Regulation

The Medical Practice Act and its Regulation are administered by the NSW Medical Board. The Medical Board is an independent statutory entity that is self-funding by way of registration fees collected from medical practitioners. The Medical Board's budget for 2006/7 was \$8.236 million.

The Medical Board promotes compliance with the Act and Regulation through education of medical practitioners and the public, the provision of advice, performance assessment, impairment and disciplinary action in respect of medical practitioners and as a last resort prosecution of individuals for breaches of the legislation.

Offences against the Act or Regulation generally carry a monetary penalty (up to 800 penalty units for offences under the Act and no more than 10 penalty units for an offence under the Regulation) although a term of imprisonment of up to 12 months may be imposed where a person unlawfully holds themselves out to be a registered medical practitioner,

Where a medical practitioner has breached the Act or Regulation that matter may also be dealt with as a complaint of unsatisfactory professional conduct or professional misconduct.

4. The Objective of Clause 11 of the Regulation

4.1 The objective of clause 11

Clause 11 in its current form was originally included in the Regulation (as clause 10) on 1 July 2008.

The objective of clause 11 of the Regulation is to establish, in conjunction with the Act, a statutory framework that will ensure that medical services are advertised in a manner that:

- (a) Is not false, misleading or deceptive,
- (b) Does not create an unjustified expectation of beneficial treatment, and
- (c) Does not promote the unnecessary or inappropriate use of medical services.

In seeking to achieve these aims the Regulation expressly addresses the use of photographs, particularly before and after photographs, and the use of statistical or scientific information in the promotion of medical services.

Neither the Health Care Complaints Commission nor the Medical Board report specific data on the number of complaints that are received about advertising of medical services. However, the Health Care Complaints Commission's Annual Report for 2006/7 indicates that there were 183 complaints about medical practitioners that concerned communication issues and of these approximately 17 concerned the provision of inadequate or misleading information.

Members of the medical profession have on a number of occasions also expressed concern about the advertising of medical services using before and after photographs and photographs that may have been manipulated in a manner that may lead consumers to expect an unrealistic result from a procedure. There has also been significant media comment on these matters and on a number of occasions concerns have been expressed by members of Parliament about the advertising of medical services by the use of potentially misleading photographs.

4.2 The Alternatives

Three alternatives have been considered as a means to achieve the objective of clause 11 of the Regulation. These are:

1. Reverting to the previous wording of clause 11.
2. The previous wording of clause 11 combined with a practice guideline from the Medical Board.
3. Making the regulation with the proposed clause 11.

4.2.1 Continuing to rely on the existing Regulation

The provisions of the previous Regulation dealing with advertising are consistent with the consumer protection provisions of section 52 of the Trade Practices Act 1975 (Cth) and section 42 of the Fair Trading Act 1987 (NSW).

In general terms the relevant provisions of the Trade Practices and Fair Trading Acts prohibit conduct, including advertising, in trade or commerce that is misleading and deceptive. The practice of medicine is activity in the course of trade or commerce and therefore any misleading or deceptive conduct by medical practitioners, or their practice companies, may breach either the Trade Practices Act or the Fair Trading Act.

The degree of concern that has been expressed over the last 5 years about the advertising of medical services indicates that the previous wording of the Regulation did not deliver the expected result.

4.2.2 The existing Regulation with a practice direction from the Medical Board

This option delivers little, if any, additional benefit over the previous wording of the Regulation alone. While a practice direction from the Medical Board is highly persuasive and would be treated by the vast majority of medical practitioners as binding, there will continue to be a number of medical practitioners and corporations providing medical services that choose to advertise to the letter of the law rather than in compliance with its spirit and the broad expectations of the community and profession. It is not anticipated that this option would deliver any greater benefits that rely solely on the previous wording of the Regulation.

4.2.3 The proposed Regulation

The proposed clause 11 of the Regulation recognises the difficulties associated with enforcing the previous Regulation in terms of the prevention of advertising that is false, misleading or deceptive or that creates an unjustified expectation of beneficial treatment. While the previous Regulation prohibited advertising that is false, misleading or deceptive or creates an unjustified expectation of beneficial treatment the fact that concerns about advertising continue to be expressed indicates that parts of the community and the medical profession continue to be concerned about the advertising of medical services.

5. Costs and Benefits of the Proposed Regulation

5.1 Costs

In the first instance breaches of the Regulation, other than egregious or flagrant breaches, may be dealt with by way of warning with inconsequential cost to the Board. It is therefore not possible to estimate the number of complaints that may proceed to prosecution and it is therefore impossible to estimate the costs associated with the Board undertaking that action. However, the experience of the Board suggests that the number of complaints dealt with by formal processes is likely to be small.

Those sections of the medical profession that advertise by way of before and after photographs may incur certain costs associated with reformatting their advertising to ensure that it complies with the proposed Regulation and that appropriate disclaimers are included in those advertisements. However these costs are expected to be one-off costs and, in the context of an overall advertising campaign, reasonably insignificant.

5.2 Benefits

The proposed Regulation will help to ensure that consumers are not misled or deceived by the advertising of medical services. This may deliver some small cost savings to the Board by way of having fewer complaints to address. Most importantly the regulation would be expected to deliver benefits to consumers who will not be misled by advertising and to the medical professionals involved who will not have to defend complaints before the Board or in court. These costs are not quantifiable.

6. Conclusion

The analysis in the preceding two sections shows that, of the three alternatives, the proposed Regulation has the highest net present value and will therefore benefit society the most. Both the self-regulation and do nothing options have negative net present values. Clearly the proposed Regulation is the best method by which to achieve the objectives.

Appendix A: Organisations to be consulted

Australasian College of Cosmetic Surgery
Australasian College of Dermatologists
Australasian Society of Aesthetic Plastic Surgery
Australasian Society of Cosmetic Medicine
Australian and New Zealand Association of Oral and Maxillofacial Surgery
Australian Medical Association (NSW Branch)
Australian Society of Plastic Surgeons
Cosmetic Physicians Society of Australasia Inc
Health Care Complaints Commission
Medical Services Committee
NSW Medical Board
Royal Australian College of General Practitioners