Response to the Treasury Discussion Paper:

'Coverage of the *Medical Indemnity (Prudential Supervision and Product Standards) Act 2003*'

Committee of Deans of Australian Medical Schools (CDAMS)

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1. About CDAMS

The Committee of Deans of Australian Medical Schools (CDAMS) represents the Heads of the 17 university-based medical education programs in Australia. CDAMS members have overall responsibility for their university's medical course as at least one of their various roles, and some members also have responsibility for other health professional education programs. CDAMS is represented on a wide range of government and statutory bodies with responsibility for different aspects of medical education and training. CDAMS also has close ties with the medical Deans in New Zealand, Fiji and Papua New Guinea, providing a broad focus to the development of medical education in the Australasian region.

CDAMS has been active on the issue of professional indemnity coverage in universities with medical schools since 2002. CDAMS is pleased to present a brief response to the Treasury's Discussion Paper on the coverage of the *Medical Indemnity (Prudential Supervision and Product Standards) Act 2003* (for the purposes of brevity in our submission, this will be referred to simply as 'the Act'). This submission represents the considered views of the academic and administrative leaders of Australia's 17 medical schools, with additional input from university insurance and risk management staff.

2. Background

One of the main objectives of the Act is to "ensure the stability of medical indemnity insurers …[by continuing to offer] secure and affordable medical indemnity cover" (Treasury Discussion Paper, pp. 1 & 2). The Act explicitly targets insurance cover by traditional medical indemnity providers for individual healthcare professionals. However, as Treasury acknowledges, the Act also unintentionally caught up universities (in their capacity as training institutions for healthcare professionals) in its application.

A range of temporary exemptions from the Act were introduced to address a number of unforeseen applications of the Act that were "potentially reducing the availability of appropriate and affordable medical indemnity insurance for health care professionals" (p. 10). It is now proposed to retain some of these exemptions, and delete others.

Our response is primarily concerned with the sections in the Discussion Paper on training institutions (pp.25-26) and clinical trials (26-27), these sections being directly related to the impact of the proposed deletion of Regulation 4(1)(d). In canvassing the views of our members for this response, the clear consensus amongst medical schools is that the deletion of Regulation 4(1)(d) would have an immediate and negative impact, and that it should be made a permanent exemption. It is CDAMS recommendation that this Regulation should be retained in the Act as a permanent exemption to guarantee the future of medical education and medical research in Australian universities.

3. Training Institutions

It should be made clear that there is no viable, long-term source of medical indemnity insurance available to universities with medical schools that is compliant with the Act's product standards requirements. CDAMS would like to assure Treasury that universities have been assiduous over the last few years in attempting to source commercial insurance or to identify alternative options, including self-insuring. Unfortunately, the options available through the commercial insurance market are extremely limited in Australia.

There is only one reliable source of indemnity coverage in Australia, from a non-APRA regulated discretionary mutual. The main alternative source of commercial insurance is from overseas insurers which are not subject to the Australian legislation. The Discussion Paper states that the reason for the proposal for deletion of Regulation 4(1)(d) is that "training institutions have had sufficient time to put appropriate insurance arrangements in place" (p.26). Clearly, however, in the relatively short period since the introduction of the exemptions in mid-year 2004, appropriate insurance arrangements have proven almost entirely impossible to identify or implement.

The main reasons for making Regulation 4(1)(d) a permanent exemption include:

- The indemnity cover required by universities is to cover its staff and students for both teaching and research-related activities in clinical practice environments, as well as covering the teaching services provided for the University in those environments by health professionals who are primarily employed by health units or are self-employed. This indemnity also covers the direct clinical activities of students with the clients of health units. However, it does not cover the clinical practice activities of university staff or of those providing teaching services for the university.
- There is great variability across universities in their ability to source affordable, reliable, adequate indemnity insurance. Some universities are experiencing few problems sourcing affordable, appropriate coverage, while other universities are unable to source any (see point below).
- Commercial insurers have refused to offer insurance cover to most universities in New South Wales, the ACT and Queensland due a history of litigation and pay-outs. At least 4 universities in these states have had to self-insure, with consequent negative impacts on clinical and overseas placements for students.
- There is no single reliable source of indemnity insurance for all universities in the same way that private practitioners can expect reliable, secure, stable coverage from the national MDOs.
- There is wide disparity between the indemnity coverage offered to university staff and students in public hospitals by State governments. The Victorian and South Australian governments have instituted excellent coverage schemes, but this has not been reflected in all States. The Queensland and Tasmanian State governments do not provide indemnity coverage for university staff or students in public hospitals. The NSW government scheme is minimal and is subject to protracted and difficult annual negotiations, which is not reliable for longer term planning of clinical services or training.
- Some universities have needed to go directly offshore to source appropriate indemnity cover from overseas insurers, usually at a much higher cost. Such insurance providers would not be subject to Australian regulatory provisions.

The implications of removing the current temporary exemption include:

- Limiting the access of universities to obtaining indemnity cover related to their health professional programs only from those companies which meet the regulatory standards of the Act. In effect, and until such time as new commercial providers are established or current insurers offer new insurance products to the university sector, this would force all universities with medical schools to become self-insuring or to take their business off-shore.
- There would be a significant and widespread loss of adequate indemnity cover in some or all universities with medical schools, which would inevitably lead to a major disruption of clinical placement activities for all health professional programs (ie. not solely in medicine) in universities. This would impact on the universities' ability to fulfil their obligations to provide a certain quality standard of education.
- Without adequate coverage for universities, State-based Health Departments would be likely to exclude university staff and students from their indemnity cover for training activities service in public hospitals, leading to a significant impact on the quality of training for students.
- Some universities have questioned the legal ramifications if the provision of education does not meet agreed standards, particularly for fee-paying students or other students in contracts with universities or directly with the Commonwealth government.
- There would be a likely withdrawal by health professionals employed by individual health units or self-employed professionals from the provision of clinical teaching services for universities, impacting negatively on the medical academic workforce.

4. Medical Research and Clinical Trials

There is an internal contradiction in the Discussion Paper which indicates that despite recognising the difficulties affecting indemnity insurance for clinical trials, Treasury remains intent on pursuing the deletion of Regulation 4(1)(d) regardless. The Discussion Paper states that "Treasury has been advised that insurance for clinical trials that complies with the requirements of the Act has *proven impossible to purchase*" (p.26, italics added), and furthermore, that the main insurer in the market (Unimutual) is not APRA-regulated. The paper goes on to state that it "*may* be possible for insurance arrangements to *evolve* to address these difficulties" (p.27, italics added), which in itself suggests that further time is necessary for an appropriate insurance market to develop.

Despite these admissions, Treasury posits the rationale for deleting Regulation 4(1)(d) as "training institutions *have had sufficient time* to put appropriate insurance arrangements in place for their clinical trial and research activity" (p.27, italics added). This is an inconsistent argument. If Treasury accepts that the commercial insurance market for clinical trials is not able to provide appropriate, affordable coverage, then universities should continue to be exempted from the Act.

CDAMS believes that the proposal put forward to delete Regulation 4(1)(d) is unworkable and will be severely detrimental to the conduct of medical research in Australia, and that the Regulation should be made a permanent exemption from the Act. Reasons for maintaining the exemption include:

- There is great variability across universities in their ability to source affordable, reliable, adequate indemnity insurance for clinical trials. Some universities are experiencing few problems sourcing affordable, appropriate coverage, while other universities are unable to source any.
- Commercial insurers have refused to offer clinical trials coverage to most universities in New South Wales, the ACT and Queensland, where at least 4 have been forced to self-insure, with consequent negative impacts on clinical trials, particularly higher risk Phase I to III trials.
- As with training activities, there is no single reliable source of indemnity insurance for clinical trials for all universities.
- The scope of the insurance cover available for clinical trial activities is far more limited than that available to cover teaching-related activities, and has therefore created far more limiting conditions for many university researchers in their planned research.
- In some States indemnity cover for health-related research activities by universities in State-based health units is provided by State Health Departments. Such cover usually only extends to clinical trials involving personnel employed by the health units.
- Some universities have needed to go directly offshore to source appropriate indemnity cover. This has particularly applied to cover for clinical trials. Such insurance providers would not be subject to Australian regulatory provisions.
- The indemnity cover required by universities is to cover its staff and students for clinical trial-related activities in clinical practice environments and does not cover that 'portion of the insurance indemnifying the medical practitioner's provision of health care'.
- The argument that universities should face the same insurance costs as other business enterprises (p.109) ignores the fact that the vast majority of clinical trials in universities are conducted for the public health benefit, and do not have immediate commercial applications, as does that conducted by for-profit businesses like pharmaceutical companies.

The implications for clinical trials and medical research of removing the current exemption include:

- Limiting the access of universities to obtaining indemnity cover related to their clinical trial activities only from those companies that meet the regulatory standards of the Act. Such companies do not provide such cover for clinical trials.
- There would be a significant and widespread loss of adequate indemnity cover in some or all universities for clinical trials, which would lead to a major disruption of clinical trials and medical research in universities, where the majority of Australia's medical research is undertaken. This would also impact negatively on the research education opportunities for research students.
- In turn, this would lead to a negative impact on Australia's excellent reputation as an international leader in medical research, with flow-on effects for our growing biotech industries.
- Losing clinical academics who could no longer maintain professional standing as they would be able to perform medical research.
- Losing substantial income from trial sponsors, grant funding agencies and enrolment of PhD students at a time when universities are being forced to generate as much income from all sources as possible.

5. Employed Medical Practitioners and Public Hospitals

It is our interpretation of the Act that university staff providing health care services in public hospitals should be properly classed as employed medical practitioners, and therefore subject to the proposed exemption as set out in the Discussion Paper, Option A, paragraphs 83-87. In this sense, CDAMS supports the proposal that the "product standards be limited to contracts of medical indemnity purchased by individual medical practitioners" (p.19). If Treasury insists that university staff providing health care services are subject to the Act, then it necessarily follows that those staff are employed medical practitioners subject to the above exemption.

Similarly, CDAMS is interested in a clarification from Treasury as to why Regulation 4(1)(f), exempting public health care providers from the Act, should not apply to university staff providing health care services in public hospitals. It would seem that the rationale behind this exemption applies just as fully to university staff who are public health care providers. Many of the medical school respondents questioned the apparent dichotomy between exempting public health care providers on a permanent basis, and not university staff in public hospitals.

6. Conclusion

The rationale of the Discussion Paper is to ensure continuing "access to adequate insurance provided by stable medical indemnity insurers" (p.8). The consensus amongst medical schools and university insurance managers is that the discontinuation or deletion of the current exemptions for training institutions will have serious and long-lasting deleterious effects on the availability and affordability of adequate coverage for medical education, training and research.

It is CDAMS strong opinion that the Act has not had the intended stabilising effect in the commercial market for indemnity coverage for training institutions. In the policy rationale, the Discussion Paper states that the "scope of the prudential requirements and product standards may need to be reconsidered if they reduce the availability or affordability of appropriate insurance" (p.8). It is clear that against this policy background, the proposals to wind back the current exemptions for universities would do exactly that, reduce the availability and affordability of appropriate insurance for universities.

In order to guarantee the ongoing viability of quality medical education and research in Australia, CDAMS recommends that:

- Regulation 4(1)(d) should be formalised as a permanent exemption to the Act;
- Employers of medical practitioners should be permanently exempted from the Act, and universities should be classified as employers of medical practitioners;
- Where university staff offer public health care services, universities should be considered public health care providers and therefore subject to Regulation 4(1)(f) exempting public health care providers;
- Product standards should be amended to apply only to insurance contracts purchased by individual medical practitioners;
- The Act should be restricted to apply only to medical professionals.