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Health Alert
July 2010

This alert contains information on the following topics:

- New taskforce to investigate practices involving pathology and diagnostic imaging
- Stage II of the diagnostic imaging accreditation scheme begins
- Draft operating procedures for undertakings given to the Private Health Insurance Administration Council released
- National Registration and Accreditation Scheme begins
- Legislation update – National Registration and Accreditation Scheme
- Legislation update

New taskforce to investigate practices involving pathology and diagnostic imaging

The Minister for Human Services, Chris Bowen MP announced at the end of May a Medicare Australia taskforce to investigate 'collusion between health professionals and pathology and diagnostic imaging providers'. A copy of the announcement can be found on the Minister's website.

This audit program is consistent with Medicare Australia's National Compliance Program for 2009-2010 (**Program**), which states that 2009-2010 will involve an audit approach focuses on practices who structure their commercial arrangements to encourages unnecessary referrals to pathology and diagnostic imaging providers.

The following examples of arrangements to be investigated are quoted in the Program documentation located on the Medicare website:

- Company structures designed to create payments and incentives to requesting providers through distribution of profits;
- Lease arrangements set outside proper market value; and
- Corporate practice owners placing restrictions on requesting providers to limit their referrals to only providers associated with practice owners.

The penalties for prohibited practice include up to five years in prison for an individual, the loss of access to Medicare and fines of up to $660,000 for companies.

This is a timely reminder for providers of diagnostic imaging and pathology services, as well as requesters of such services (such doctors and hospital operators who employ doctors) to look closely at their existing arrangements.

You should not assume that your existing arrangements comply with the current legislation, because the laws were introduced in 2008 (and subsequent regulations in 2009) and although they apply retrospectively they may not have been in existence at the time your existing arrangements were put in place.

Stage II of the diagnostic imaging accreditation scheme begins

The Health Insurance Act 1973 (Cth) was amended in June 2007 to establish a mandatory diagnostic imaging accreditation scheme (**Scheme**). Accreditation under the Scheme is linked to the payment of Medicare benefits for the provision of diagnostic imaging services.

Stage I of the Scheme, which was introduced in 2008, only provided for accreditation of practices providing radiology services. From 1 July 2010, Stage II of the Scheme commences. Under Stage II, the accreditation arrangements for practices providing radiology services will continue, and practices providing non-radiology services such as cardiac ultrasound and angiography, obstetric and gynaecological ultrasound, and nuclear medicine imaging services will now also need to be accredited.

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Draft operating procedures for undertakings given to the Private Health Insurance Administration Council released

The Act constituting the Private Health Insurance Administration Council (**PHIAC**) enables it to obtain enforceable undertakings from private health insurers. PHIAC has released a draft operating procedure for accepting written undertakings from insurers where there are concerns about an insurer's ability to meet the requirements of a PHIAC supervised obligation. The draft includes the proposed form of undertaking. The full draft operating procedure is available on the PHIAC website.

PHIAC has also released a draft discussion paper on a draft disclosure standard for insurers outlining new information requirements to be reported to PHIAC. It covers routine disclosures such as changes to company details as well as unusual governance events such as proposals to remove a director or a major legal action being taken against an insurer.

National Registration and Accreditation Scheme begins

You may have noticed from our legislation updates that the State jurisdictions have been passing legislation in relation to the regulation and accreditation of health practitioners.

The purpose of this new legislation is to implement a national registration and accreditation scheme (**NRAS**) in accordance with the Intergovernmental Agreement entered into by the Commonwealth and the States in March 2008. All States and Territories except Western Australia have now enacted the National Law.

From 1 July 2010, the NRAS will cover ten health professions - chiropractors, dental care practitioners, medical practitioners, nurses and midwives, optometrists, osteopaths, pharmacists, physiotherapists, podiatrists, and psychologists.

The National Law provides for four more health professions to be included in the national scheme from 1 July 2012 – Aboriginal and Torres Strait Islander health practitioners, Chinese medicine practitioners, medical radiation practitioners (including radiographers), and occupational therapists.

Given the large volume of legislation which was introduced or passed in June, in this edition of health alert we have covered the legislation dealing with the introduction of the NRAS in a separate section.

Legislation update – National Registration and Accreditation Scheme

This section of health alert covers the legislative developments in relation to the introduction of the National Registration and Accreditation Scheme (**NRAS**).

Health Practitioner Regulation Amendment Act 2010 (NSW)

This Act was assented to on 15 June 2010. It makes various consequential amendments which are required as a result of the commencement of the NRAS in New South Wales, and repeals the legislation which previously dealt with some of the health professionals now covered by the NRAS.

Health Practitioner Regulation (New South Wales) Regulation 2010 (NSW)

This Regulation, which was made under the *Health Practitioner Regulation (Adoption of National Law) Act 2009* (NSW), commenced on 1 July 2010.

It includes provisions which:

- set out the composition of certain Councils, including the Chiropractic Council, Optometry Council, Osteopathy Council and Podiatry Council;
- prescribe infection control standards;
- cover certain matters relating to the medical profession, such as requirements for medical practitioners to keep medical records;
- prescribe standards for the approval of pharmacy premises and professional services room premises.

Health Practitioner Regulation National Law Regulation 2010 (VIC)

This Regulation, which was made under the *Health Practitioner Regulation National Law (Victoria) Act 2009* (Vic), commenced on 1 July 2010.

It includes provisions which cover the application of the *Privacy Act 1988* (Cth), *Freedom of Information Act 1982* (Cth) and the *Ombudsman Act 1976* (Cth), including in relation to the National Agency and National Boards.

Health Practitioner Regulation National Law (Tasmania) Act 2010 (TAS)

This Act received assent on 25 June 2010.

The object of the Act is to implement the NRAS in Tasmania.

The *Health Practitioner Regulation National Law (Tasmania) (Consequential Amendments) Act 2010* (TAS) also received assent on 25 June 2010. This Act makes consequential amendments to legislation to ensure consistency with the adoption of the NRAS.

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Health Practitioner Regulation National Law (South Australia) Act 2010 (SA)

This Act received assent on 1 July 2010.

The object of the Act is to implement the NRAS, in South Australia.

Health Practitioner Regulation National Law (South Australia) Regulations 2010 (SA)

These Regulations, which were made under the authority of the Health Practitioner Regulation National Law (South Australia) Act 2010 (SA) (Act), commenced on 1 July 2010.

The Regulations prescribe:

- 'representative bodies' and 'restricted pharmacy services' for the purposes of the Act;
- matters in relation to premises proposed to be registered as a pharmacy and those to be registered as a pharmacy depot;
- matters in relation to pharmacy service providers, including the information relating to a claim against a pharmacy services provider.

Health Practitioner Regulation National Law (ACT) Act 2010 (ACT)

This Act, except for Part 2.16 (Mental Health (Treatment and Care) Act 1994) of Schedule 2 (Consequential amendments), commenced on 1 July 2010 by way of forced commencement.

The object of the Act is to implement the NRAS in the ACT.

Health Practitioner Regulation (Consequential Amendments) Act 2010 (Cth)

This Act, which was assented to on 31 May 2010, amends the *Health Insurance Act 1973* (Cth).

The Act make consequential and transitional amendments required to recognise and support the NRAS.

Legislation update

Aged Care Act 1997 (Cth) (amendments to Principles)

The *Flexible Care Subsidy Amendment Principles 2010* (Cth) amend the *Flexible Care Subsidy Principles 1997* (Cth) to prescribe 'consumer directed care' as a new kind of innovative care service for which a flexible care subsidy may be payable. 'Consumer directed care' is defined as care provided by an approved provider that enables care recipients to exercise flexibility, choice and control over the type of care services they access and the delivery of those services.

The *Quality of Care Amendment Principles 2010 (No. 1) 2010* (Cth) amend the *Quality of Care Principles 1997* (Cth) to remove the obligation on approved aged care providers to make an annual fire safety declaration, and instead only require approved providers to advise the Secretary, by written notice, in the event of non-compliance with relevant state, territory and local government authority fire standards.

The *Residential Care Subsidy Amendment Principles 2010 (No. 1) 2010* (Cth) amend the *Residential Care Subsidy Principles 1997* (Cth) to:

- remove the requirement on Commonwealth funded aged care providers to lodge a separate written notice with the Secretary to demonstrate compliance with financial reporting and workforce survey requirements for the purposes of qualifying for the Conditional Adjustment Payment;
- prescribe the lodgment of audited financial reports as the appropriate means of demonstrating compliance with Conditional Adjustment Payment requirements.

The amended Principles commenced on 1 July 2010.

Freedom of Information Amendment (Reform) Act 2010 (Cth)

This Act received assent on 31 May 2010.

It makes amendments to *Privacy Act 1988* (Cth) which are consequential on the establishment of the Office of the Information Commissioner under the *Information Commissioner Bill 2009* (Cth). It also amends the *Freedom of Information Act 1982* (Cth) to provide that the right to neither confirm nor deny the existence or non-existence of certain exempt documents does not apply to the existing exemption for documents affecting relations with states.

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 (Cth)

This Bill was introduced into the House of Representatives and received its second reading speech on 2 June 2010.

The objective of the Bill is to reform the Pharmaceutical Benefits Scheme pricing arrangements for multiple brand medicines that are subject to competition in the market place, at no additional cost to patients, by:

- applying further statutory price reductions;
- prescribing matters relating to price disclosure;
- clarifying matters on outstanding 25 percent staged price reductions; and
- amending various matters relating to special arrangements for the supply of drugs.

Health and Other Legislation Amendment Regulation (No. 1) 2010 (Qld)

This Regulation, which commenced on 1 July 2010, amended the *Health (Drugs and Poisons) Regulation 1996* (Qld) to:

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- omit an exemption allowing nurses to possess controlled drugs in a rural hospital or 'at a place in the isolated practice area where the person practices nursing';
- clarify that a psychiatrist may prescribe specified condition drugs for the treatment of brain damage or attention deficit disorder in a child without needing to be a child psychiatrist;
- prohibit a dispenser from dispensing a controlled or restricted drug unless he or she reasonably believes that the prescription was made by a person endorsed to do so, and with specific restricted drugs, that the address of the prescriber (as stated on the prescription) is in Queensland;
- allow oral health therapists to authorise certain restricted drugs, and enable them to administer fluorides that are S3 poisons and certain S2 poisons;
- remove the section which provided that a purchase order or an approval was not needed for sale of certain restricted drugs to a dentist, doctor, pharmacist or veterinary surgeon;
- prohibit the sale of specified restricted drugs, by someone other than a restricted drug wholesaler, to authorised persons unless the address of that person (as stated on the purchase order) is in Queensland; and
- update various references, including replacing references to assorted health professional registration legislation with the NRAS.

Health Insurance Amendment (Professional Services Review) Bill 2010 (Cth)

This Bill was introduced into the House of Representatives and received its second reading speech on 17 June 2010. It proposes to amend the *Health Insurance Act 1973* (Cth) to:

- provide for a determination to be made that a health professional is a practitioner for the purposes of the Professional Services Review (**PSR**) Scheme and the Medicare Participation Review Committee (**MPRC**);
- remove the requirement for the Director of PSR to refer practitioners, who have been found to have engaged in inappropriate practice on two or more occasions, to the MPRC;
- provide for the Director and the Determining Authority to apply a disqualification period of up to five years to those practitioners;
- streamline the administration of the PSR Scheme; and
- require persons who are disqualified due to a PSR or MPRC process to display a notice to inform patients that services will not attract Medicare benefits.

Healthcare Identifiers Act 2010 (Cth)

This Act received assent on 28 June 2010.

The objective of the Act is to implement a national system for consistently identifying consumers and healthcare providers and to set out clear purposes for which healthcare identifiers can be used. It is a key part of the Commonwealth's health reform agenda, which will result in the creation of a person controlled electronic health record by July 2012.

The Act:

- establishes arrangements for operating and maintaining the Healthcare Identifiers Service;
- sets out permitted purposes for which healthcare identifiers may be used or disclosed and the offences relating to the misuse of healthcare identifiers and penalties for breaches of the legislation;
- provides that the Federal Privacy Commissioner will provide independent regulation of how healthcare identifiers are handled and the operation of the Healthcare Identifiers Service; and
- provides that annual reports must also be provided to the Ministerial Council by the Privacy Commissioner and Medicare Australia.

The *Healthcare Identifiers (Consequential Amendments) Act 2010* (Cth), which makes consequential amendments to the *Health Insurance Act 1973* (Cth) and the *Privacy Act 1988* (Cth), also received assent on 28 June 2010.

Healthcare Identifiers Regulations 2010 (Cth)

The *Healthcare Identifiers Regulations 2010* (Cth), made under the *Healthcare Identifiers Act 2010* (Cth), commenced on 1 July 2010.

The Regulations set out provisions relating to the assignment, collection, use, adoption and disclosure of healthcare identifiers.

Human Tissue Regulation 2010 (NSW)

This Regulation, which has been made under the *Human Tissue Act 1983* (NSW), repeals and replaces the *Human Tissue Regulation 2005* (NSW).

It prescribes:

- the organisms and substances that are 'prescribed contaminants';
- the classes of medical practitioners who are eligible for appointment as designated specialists;
- the certificate required to be completed before making a donation of blood;
- the amount of blood that will give rise to a presumption that a person is carrying on a business of supplying blood; and
- the means by which consent may be given to the removal of certain tissue after death.

National Health and Hospitals Network Bill 2010 (Cth)

This Bill was introduced into the House of Representatives and received its second reading speech on 23 June 2010.

The objective of the Bill is to establish the Australian Commission on Safety and Quality in Health Care (Commission) as a permanent, independent statutory authority.

The establishment of this body forms part of the implementation of the National Health and Hospitals Network Agreement between the Commonwealth and the States and Territories, with the exception of Western Australia, endorsed on 20 April 2010.

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Pharmacy Regulation Act 2010 (Vic)

This Act received assent on 30 June 2010. It provides for the regulation of pharmacy businesses, pharmacy departments and pharmacy depots.

The Act:

- establishes the Victorian Pharmacy Authority;
- introduces new requirements for pharmacy business ownership, including caps on the growth of pharmacy ownership and requirements of establishment and operation;
- provides for licensing for carrying on a pharmacy business or department, and for the registration of premises.

Therapeutic Goods (Charges) Amendment Act 2010 (Cth)

This Act was assented to on 31 May 2010. It amends the *Therapeutic Goods (Charges) Act 1989* (Cth) to:

- enable annual charges to be levied in respect of the inclusion of biologicals as separate therapeutic goods in the Australian Register of Therapeutic Goods (**Register**); and
- provide that where a registered or listed good or a biological is suspended from the Register, that good can continue to be taken to be included in the Register for the purposes of the Act.

Therapeutic Goods Act 1989 (Cth)

The *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010* (Cth) was assented to on 31 May 2010. It amends the *Therapeutic Goods Act 1989* (Cth) to:

- create a new framework for the regulation of biological therapeutic goods;
- provide individuals employed by or acting for the Commonwealth with immunity from legal proceedings, where their actions are in accordance with the Act;
- provide for the recall of therapeutic goods without requiring that the entry of the good in the Australian Register of Therapeutic Goods be suspended or cancelled;
- allow the Secretary to seek information from past sponsors of medicines and therapeutic devices in relation to the time that they were the sponsor, over the five years prior to the information request.

Therapeutic Goods Amendment Regulations 2010 (No. 2) 2010 (Cth)

These Regulations amend the *Therapeutic Goods Regulations 1990* (Cth).

The Regulations:

- repeal the current scheduling of medicines and chemicals arrangements including those relating to the constitution and meeting procedures for the National Drugs and Poisons Schedule Committee;
- substitute new scheduling arrangements for medicines and chemicals; and
- set out new procedures to support these new scheduling arrangements.

The amending Regulations commenced on 1 July 2010.

Therapeutic Goods (Victoria) Act 2010 (Vic)

This Act received assent on 1 June 2010.

It provides for the application of the national scheme for the regulation of therapeutic goods by applying the *Therapeutic Goods Act 1989* (Cth) as laws of Victoria, and provides for the regulation of therapeutic goods in Victoria in limited circumstances where the Commonwealth Act does not apply.

Voluntary Euthanasia Bill 2010 (SA)

This Bill is a private member's Bill, sponsored by Bob Such MP. It was introduced into the House of Assembly and received its second reading speech on 24 June 2010.

The objective of the Bill is to provide for "the administration of medical procedures to assist the death of a limited number of patients who are in the terminal phase of a terminal illness, who are suffering unbearable pain and who have expressed a desire for the procedures subject to appropriate safeguards".

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