

## Department of Health and Ageing 2012-2013 Regulatory Plan

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### Explanatory Note

The Department of Health and Ageing, like other Australian Government agencies which have responsibility for business regulation, is required to publish a regulatory plan on its web site each financial year.

The regulatory plan deals with changes within the Department of Health and Ageing's area of responsibility and contains information about:

- changes to business regulation which have occurred since the beginning of the previous financial year; and
- activities planned in the current financial year which could lead to changes to business regulation.

### *What regulation does a regulatory plan cover?*

A regulatory plan covers business regulation. This includes primary legislation, subordinate legislation, quasi-regulation or treaties that directly affect business, have a significant indirect impact on business, individuals or the economy.

Quasi-regulation refers to rules or arrangements where governments influence businesses to comply, but which do not form part of explicit government regulation.

A regulatory plan does not include information about the following:

- regulations of a minor or machinery nature that do not substantially alter existing arrangements;
- regulations that involve consideration of specific government purchases;
- regulations of a state or self-governing territory that apply in a non-self-governing territory; and
- anticipated activity about which it would be inappropriate to publish information on grounds of confidentiality.

In addition, there may be regulatory activities that have not been included in the regulatory plan because they could not be foreseen when the plan was prepared at the start of the financial year.

In view of these exclusions, users should not take a regulatory plan to be a comprehensive source of information on past or potential changes to business regulation.

### *How up to date is information in this regulatory plan?*

This plan was last updated: April 2013.

## **Part A**

### **PAST REGULATORY CHANGES**

## Past Changes occurring in 2011 - 2012

### **Aged Care Complaints Scheme**

#### **Description of issue**

The Complaints Principles replaced the Investigation Principles 2007 as consequential amendments to the Aged Care Amendment Bill 2011 to improve arrangements for the handling of complaints about Commonwealth subsidised aged care services.

#### **Date of effect**

1 September 2011

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### **Aged Care Funding Instrument - Amendments to Classification Principles 1997**

#### **Description of issue**

Amendments to the Classification Principles 1997 will improve the Aged Care Funding Instrument (ACFI) and related processes to ensure that residential aged care funding better matches the care needs of residents. In developing these amendments, the Department of Health and Ageing has consulted with the ACFI monitoring group and directly with peak bodies, providers and consumer representatives. The Department of Health and Ageing will also be forming a group with representation from the sector to monitor the impact of the changes.

#### **Date of effect**

1 July 2012

#### **Contact details**

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### **User Rights Principles**

#### **Description of issue**

Amendments were made to the User Rights Principles 1997, as consequential amendments to the *Aged Care Amendment Act 2011*. These amendments strengthened consumer protection for accommodation bonds paid to aged care services.

**Date of effect**

1 October 2011

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**Amendments to Allocation Principles 1997****Description of issue**

Amendments were made to *Allocation Principles 1997* to support training within the aged care sector that is sensitive to the specific needs of older people in the Lesbian, Gay, Bisexual, Transgender and Intersex (LGBTI) community, and help ensure that sexual diversity does not act as a barrier to receiving high quality aged care in either community or residential settings.

This amendment also adds older people in the LGBTI community into the special needs criteria under the *Allocation Principles 1997*, to ensure access to appropriate care suitable to their needs.

**Date of effect**

1 July 2012

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**User Rights Amendment Principles – Introduction of the Basic Daily Fee Supplement****Description of issue**

Amendments were made to the *User Rights Principles 1997*, as part of the implementation of the Basic Daily Fee (BDF) Supplement. The BDF Supplement is part of the Clean Energy Household Assistance Package and is paid to aged care providers on behalf of eligible residential aged care residents.

The BDF supplement was introduced to ensure self-funded retirees are not disadvantaged by the increase to the Basic Daily Fee on 1 July 2012. This supplement offers aged care providers the option of sourcing the difference in the

BDF (84% to 85% of the basic aged pension) from the Government instead of from the resident.

This amendment to the User Rights Principles requires the aged care provider to provide the resident with information about their eligibility for the BDF supplement.

**Date of effect**

1 July 2012

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**Residential Care Subsidy Amendment Principles 2011**

**Description of issue**

Amendments were made to the *Residential Care Subsidy Principles* following a 2011-12 Budget Measure announcing the extension of the aged care viability supplement, previously provided to eligible aged care services operating in rural and remote areas, to certain categories of specialist aged care providers. The measure responds to the findings of the Review of the Aged Care Funding Instrument (ACFI), which suggested that some provider groups were likely to face greater pressures in transitioning to the ACFI which was introduced on 20 March 2008.

Amendments to the *Residential Care Subsidy Principles* were required to expand previous viability supplement arrangements so as to provide additional support for residential care providers who specialise in providing:

- a) low care in rural and remote areas, or
- b) care for homeless people or Indigenous Australians with complex behavioural needs.

The purpose of the *Residential Care Subsidy Amendment Principles 2011 (No.1)* is to specify the method for assessing how small a service is, and the size of the population that it serves and the degree of isolation of the service's location.

**Date of effect**

1 July 2011

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**Residential Care Subsidy Amendment Principles - Introduction of the Basic Daily Fee Supplement**

**Description of issue**

Amendments were made to the *User Rights Principles 1997*, as part of the implementation of the Basic Daily Fee (BDF) Supplement. The BDF Supplement is part of the Clean Energy Household Assistance package and is paid to aged care providers on behalf of eligible residential aged care residents.

The BDF supplement was introduced to ensure self-funded retirees are not disadvantaged by the increase to the Basic Daily Fee on 1 July 2012. This supplement offers aged care providers the option of sourcing the difference in the BDF (84% to 85% of the basic aged pension) from the Government instead of from the resident.

This change to Residential Care Subsidy Principles adds a new division which outlines the eligibility criteria for the BDF supplement.

**Date of effect**

1 July 2012

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**Declared Hearing Services Determination 1997**

**Description of issue**

Amendments to the Determination implemented a 2011-2012 Budget commitment to extend eligibility under the Community Service Obligations for hearing rehabilitation and devices to young adults up until their 26th birthday.

**Date of effect**

1 January 2012

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### **Hearing Services Rules of Conduct 2012**

#### **Description of issue**

The Rules of Conduct 2005 were remade to support the implementation of 2011-12 Budget reforms to the Hearing Services Voucher Program. The 2012 Rules consolidate and clarify service provider responsibilities.

#### **Date of effect**

1 July 2012

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### **Hearing Services (Participants in the Voucher System) Determination 1997**

#### **Description of issue**

Amendments were made consequential to the making of the Rules of Conduct 2012. These amendments clarify the provision of hearing devices under the Hearing Services Voucher Program.

#### **Date of effect**

1 July 2012

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### **Hearing Rehabilitation Outcomes for Voucher Holders**

#### **Description of issue**

The Hearing Rehabilitation Outcomes were revised to support the implementation of 2011-12 Budget reforms to the Hearing Services Voucher Program. It documents the outcomes to be achieved by Contracted Service Providers in delivering services to voucher holders.

#### **Date of effect**

1 July 2012

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### **Eligibility Criteria for Refitting (Hearing Services Voucher Program)**

#### **Description of issue**

Outlines the information a hearing practitioner has to consider when deciding to refit a hearing services voucher client with a new hearing device.

#### **Date of effect**

1 July 2012

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### **Legislation requiring the plain packaging of tobacco products**

#### **Description of issue**

The legislation prohibits tobacco industry logos, brand imagery, colours and promotional text other than brand and variant names in a standard colour, position, font style and size. Tobacco product retail packaging is required to appear in a drab brown colour in matt finish. Additional requirements also apply to the appearance of tobacco products themselves. Plain packaging applies not just to cigarette products but to all tobacco products including loose leaf tobacco, cigars, bidis as well as hookah and shisha products.

#### **Date of effect**

Under the *Tobacco Plain Packaging Act 2011*, all tobacco products manufactured or packaged in Australia for domestic consumption have been required to be in plain packaging from 1 October 2012. All tobacco products for retail sale in Australia have been required to be in plain packaging from 1 December 2012.

The compliance and enforcement framework for plain packaging has been finalised and the Tobacco Plain Packaging Enforcement Policy is available at the [yourhealth.gov.au](http://yourhealth.gov.au) website. Any enforcement action undertaken for offences under the Act will be proportionate to the alleged breach and in accordance with the Enforcement Policy.

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### **Tobacco Advertising Prohibition Amendment Act 2012**

#### **Description of issue**

The *Tobacco Advertising Prohibition Amendment Act 2012* (the Amendment Act) amends the *Tobacco Advertising Prohibition Act 1992* to extend existing restrictions on tobacco advertising to the internet and other electronic media (e.g. mobile phones).

The Amendment Act also provides an exception for internet point-of-sale tobacco advertising that complies with state/territory legislation or, in the absence of such legislation, Commonwealth regulations.

The *Tobacco Advertising Prohibition Amendment Regulation 2012* (the Amendment Regulation) amended the *Tobacco Advertising Prohibition Regulations 1993* to prescribe internet point-of-sale tobacco advertising requirements, and remove some redundant provisions.

#### **Date of effect**

Both the Amendment Act and the Amendment Regulation commenced on 6 September 2012.

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### **Tobacco Advertising Prohibition Amendment Regulation 2012**

#### **Description of issue**

The *Tobacco Advertising Prohibition Amendment Act 2012* (the Amendment Act) extends restrictions on tobacco advertising to the internet and other electronic media. It also provides an exception for internet point-of-sale tobacco advertising that complies with state/territory legislation or advertising that complies with state/territory legislation or, in the absence of such legislation, Commonwealth regulations.

The *Tobacco Advertising Prohibition Amendment Regulation 2012* (the Amendment Regulation) will amend the *Tobacco Advertising Prohibition Regulations 1993* to prescribe internet point-of-sale tobacco advertising requirements, and remove some redundant provisions.

#### **Consultation Opportunities**

A public consultation process on the draft regulations was held from 3 to 30 April 2012, after the Amendment Act received Royal Assent on 6 March 2012.

**Date of effect**

The Amendment Regulation was made on 16 August 2012 and commenced on 6 September 2012, when the Amendment Act commenced.

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**Amendment to the Therapeutic Goods Regulations 1990, the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002****Description of issue**

These changes relate to a small number of separate matters, as follows:

Therapeutic Goods (Medical Devices) Regulations 2002:

- reclassifying implantable medical devices that are total or partial hip, knee or shoulder joint replacements from Class IIb medical devices to Class III medical devices; and
- providing for certain transitional arrangements to apply in relation to such products that are already included in the Australian Register of Therapeutic Goods (the Register) as Class IIb devices as at the commencement of the amendments on 1 July 2012 or that are the subject of an ongoing application for inclusion in the Register as a Class IIb device at that time.

Therapeutic Goods Regulations 1990:

- enabling the Complaints Resolution Panel to deal with a complaint about an advertisement for a therapeutic good if court proceedings begin, or have begun, in relation to the subject matter of the complaint; and
- enabling sponsors of therapeutic goods granted an exemption from paying an annual charge for financial years 2009-10 or 2010-11 in respect of a new entry in the Register because their turnover of the relevant goods was of low value, but who did not provide the Secretary with the information required under the regulations to substantiate the low value of their turnover, to provide that information within a further timeframe.

Therapeutic Goods (Charges) Regulations 1990:

- removing the current liability for manufacturers who manufacture only biologicals to pay an annual charge in relation to their manufacturing licence. This amendment was inadvertently left out of amendments to the Therapeutic Goods (Charges) Regulations 1990 that commenced on 31 May 2011.

**Date of effect**

Amendments to the:

- Therapeutic Goods (Medical Devices) Regulations 2002 commenced on 1 July 2012;
- Therapeutic Goods Regulations 1990 commenced on 30 June 2012; and

- Therapeutic Goods (Charges) Regulations 1990 commenced on 31 May 2011.

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**Amendment to the Therapeutic Goods Regulations 1990, the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002 to increase TGA fees and charges for financial year 2012-13**

**Description of issue**

Amendments to the Therapeutic Goods Regulations 1990, the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002 relate to the increase of TGA fees and charges for financial year 2012-13 by 5.6 per cent.

This increase reflects an increase of 3.6 per cent based on the indexation model agreed with industry, and a further increase of 2 per cent in order to fund the implementing of reforms set out in the document 'TGA Reforms: A blueprint for TGA's future', and to improve the TGA's post market surveillance capacity.

**Date of effect**

1 July 2012

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**Health Insurance (Allied Health Services) Determination 2011**

**Description of issue**

Amendments made to the Allied Health Services Determination provide new arrangements under the *Better Access to Psychiatrists, Psychologists and General Practitioners* through the Medicare Benefits Schedule initiative, regarding the total number of services provided by allied health professionals each calendar year (decreasing from 12 services to 10 services per year). The option of an additional six allied health services per year under exceptional circumstances was removed.

**Date of effect**

1 November 2011

**Contact details**

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**Allied Health Services Determination - additional access to allied health services under exceptional circumstances****Description of issue**

Amendments were made to the Allied Health Services Determination so that from 1 March to 31 December 2012 provision exists for patients to access up to an additional six individual allied mental health services under exceptional circumstances, to a maximum total of 16 services per patient in the 2012 calendar year. From 1 January 2013 the number of individual allied mental health services for which a person can receive a Medicare Rebate will be ten services per calendar year.

**Date of effect**

1 March 2012

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### **Health Insurance (Allied Health Services) Determination 2012**

#### **Description of issue**

As part the 2012-13 Budget, new diagnostic audiology items were introduced to the Medicare Benefits Schedule (MBS) on 1 November 2012 for patients who have been referred to an audiologist by a medical specialist.

The new items are intended to mirror the Otolaryngology (ear, nose and throat) items for services delivered by, or on behalf of, medical practitioners (MBS items 11300 to 11339, excluding 11304).

#### **Consultation Opportunities**

Audiology and medical groups were consulted during the development of the new items.

#### **Date of effect**

1 November 2012

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### **Amendments to the Health Insurance (Diagnostic Imaging Services Table) Regulations 2011**

#### **Description of issue**

From 1 May 2012 the current 95% bulk billing incentive which is paid for all diagnostic imaging services will be extended to 100% in the case of all Magnetic Resonance Imaging (MRI) services. The previous arrangements for Medicare-eligible MRI providers were also rationalised.

#### **Date of effect**

1 May 2012

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**Amendments to the Health Insurance (Diagnostic Imaging Services Table) Regulations 2011 and Health Insurance Act 1973**

**Description of issue**

Part of the Diagnostic Imaging Reform Package to standardise Medicare-eligible operating arrangements for all current Medicare eligible Magnetic Resonance Imaging (MRI) units. All MRI Providers are required to enter into a Deed of Undertaking with the Department and Health and Ageing if providing Medicare rebateable MRI services.

**Date of effect**

1 May 2012

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**National Accreditation Requirements for Podiatric Surgeons**

**Description of issue**

The Health Insurance (Accreditation of Podiatric Surgeons) Guidelines (the Guidelines) set out the accreditation standards for recognition as a podiatric surgeon for the purpose of health insurance.

The Private Health Insurance (Accreditation) Rules 2008 (the Rules) set out the accreditation standards for treatment covered by a health insurance policy, for which a private health insurance benefit may be payable.

Following the establishment of the Australian Health Practitioners Regulation Agency (AHPRA) and the *Health Practitioner Regulation National Law*, podiatrists and podiatric surgeons are regulated by the Podiatry Board of Australia, which is part of AHPRA. With the establishment of AHPRA, the requirement for separate accreditation for the purposes of health insurance was no longer necessary, and was removed from the Guidelines. The Rules were amended to reflect the national accreditation requirements for podiatric surgeons.

**Date of effect**

October 2011

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## **Post-Implementation Review – Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Act (No.2) 2008**

### **Description of issue**

The *Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Act (No. 2) 2008* (the Act) raised the Medicare Levy Surcharge threshold for individuals to \$70,000 per year and for couples and families to \$140,000 per year. These changes applied to income tax returns for the 2008–09 financial year and continue for subsequent years. The Act also indexes the individual Medicare Levy Surcharge income threshold annually against full-time adult Average Weekly Ordinary Time Earnings (AWOTE), and for the family surcharge threshold to equal double the individual surcharge threshold.

### **Date of effect**

Published June 2012

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## **Health Insurance Amendment Regulation 2012**

### **Description of issue**

The amendments to the Health Insurance Regulations are consequential amendments to correct referencing that is necessary due to the passage of the *Health Insurance Amendment (Professional Services Review) Act 2012 (the PSR Act)*.

### **Date of effect**

27 December 2012

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## **Health Insurance (Professional Services Review) Regulations 2012**

### **Description of issue**

The amendments to the Health Insurance (Professional Services Review) Regulations 1999 implement provisions contained in the *Health Insurance Amendment (Professional Services Review) Act 2012 (the PSR Act)*. These changes:

- contain consequential amendments to ensure that the regulations refer to the correct provisions in the *Health Insurance Act 1973*.
- contain a list of appropriate persons or bodies to which the Director may refer a person under review for non-compliance with professional standards or if there is a significant risk to life or health of another person.

**Date of effect**

27 December 2012

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**Health Insurance (Professional Services Review – Allied Health and Others) Determination 2012****Description of issue**

The Health Insurance (Professional Services Review - Allied Health and Others) Determination 2012 (the Determination) lists those health professionals who are practitioners and those vocations that are professions for the purposes of Part VAA of the *Health Insurance Act 1973* (the Act). The Determination adds 12 new practitioner groups to the ambit of the PSR scheme.

**Date of effect**

1 January 2013

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**Health Insurance (General Medical Services Table) Regulation 2012****Description of issue**

Indexation and other changes, including, on 1 November 2012, a new restriction for 20 telehealth items to impose a requirement that the practitioner is located 15 or more kilometres apart (by the most direct route by road) from the patient at the time of a telehealth consultation. On 1 January 2013, six new MBS telehealth items were introduced for short video consultations with specialists. These amendments implemented 2012-13 Budget measures.

### **Consultation Opportunities**

Since the Budget measures were announced, consultation has occurred with relevant provider groups.

#### **Date of effect**

1 November 2012, January 2013, March 2013

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### **National Health (Australian Community Pharmacy Authority Rules) Determination 2011**

#### **Description of issue**

The New Pharmacy Location Rules were determined by the then Minister for Health and Ageing under section 99L of the *National Health Act 1953*, as part of the Fifth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.

#### **Date of effect**

The Ministerial Determination (Pharmacy Location Rules) was signed by the Minister on 13 September 2011 and the new Rules commenced from 18 October 2011.

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### **Revised arrangements for the efficient use of cancer chemotherapy drugs provided in infusion or injection**

#### **Description of issue**

The 2010-11 Federal Budget announced changes to the way cancer chemotherapy drugs administered by infusion or injection will be supplied and claimed as Pharmaceutical Benefits. The changes reduce wastage by ensuring that each prescription is written for an individual dose, and provide remuneration based on the most cost-efficient combination of vial sizes to make up individual doses (that is, the combination that will make up the prescribed patient dose at least cost to the Pharmaceutical Benefits Scheme).

The measure also recognises the specialist requirements of preparing these infusions and injections and provides for specific reimbursement for this activity.

These arrangements have been made possible through the introduction of a legislative instrument made under section 100 of the *National Health Act 1953*.

**Date of effect**

1 December 2011

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***National Health Act 1953 and National Health (Pharmaceutical Benefits) Regulations 1960 – pricing structure for PBS***

**Description of issue**

Amendments to the *National Health Act 1953* (the Act) and *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) have changed the pricing structure for the Pharmaceutical Benefits Scheme (PBS). The main amendments relate to the way prices for medicines on the PBS are approved and derived. PBS prices are currently approved as a ‘price to pharmacy’ amount which includes the ‘ex-manufacturer price’ and wholesale margin. The changes mean that prices at ex-manufacturer level are the common base point for all PBS pricing calculations and payments. One price is agreed for one PBS quantity of each pharmaceutical item, with the same price for all brands of the same item. Prices for other quantities of the same item are calculated proportionally.

The amendments also included technical changes for listing items for supply on the PBS only through prescriber bags (previously known as a ‘doctor’s bag’ or ‘emergency bag’).

The changes to the Regulations ensured that provisions for price disclosure calculations, and ‘prescriber bag’ arrangements, reflect the changes made to the Act.

**Date of effect**

The Bill received Royal Assent on 28 June 2012 and the Regulation was made on 12 July 2012. The Act and related changes to the Regulations commenced on 1 October 2012.

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### **Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Act 2011**

#### **Description of issue**

This Act provides a number of changes to the *Industrial Chemicals (Notification and Assessment) Act 1989* related to implementation of the 2007 reforms to the regulatory responsibility of products at the therapeutic-cosmetic interface, as well as to improve administrative efficiency:

- to enable the listing on the Australian Inventory of Chemical Substances (AICS) of some chemicals controlled under other regulatory schemes to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS); and
- to enhance administration of the assessment scheme and improve efficiency, including changes to the Schedule to the Act regarding data requirements for UV filters in cosmetics applied to the skin.

#### **Date of effect**

The Act commenced on 27 September 2011. In November 2011, NICNAS commenced applying the inventory amendment to the listing of chemicals in certain cosmetic products transferred in 2007 from the Therapeutic Goods Administration to NICNAS.

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### **Industrial Chemicals (Notification and Assessment) Amendment Regulations 2011**

#### **Description of issue**

Consequential amendments made to the *Industrial Chemicals (Notification and Assessment) Regulations 1990* flowing from the *Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Act 2011* to enhance administration of the assessment scheme and improve efficiency.

#### **Date of effect**

10 December 2011

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### **Industrial Chemicals (Notification and Assessment) Amendment Regulations 2012**

#### **Description of issue**

The amendments to the Industrial Chemicals (Notification and Assessment) Regulations 1990:

- increased all fees and charges for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2012-13 in accordance with the *NICNAS Cost Recovery Impact Statement 2012-13 to 2015-16*; and
- made amendments consequential to the new national workplace health and safety laws (Model Regulations) which align the definition of a hazardous chemical and NICNAS new chemicals permit criteria with the Model Regulations.

#### **Date of effect**

The amendments were registered on the Federal Register of Legislative Instruments on 27 May 2012 commenced on 1 July 2012.

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### **Industrial Chemicals (Notification and Assessment) Amendment Bill 2012**

#### **Description of issue**

The Bill amends the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) to:

- implement measures arising from the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) *Cost Recovery Impact Statement 2012-13 to 2015-16* conducted in accordance with the Government's Cost Recovery Guidelines and agreed by Government; and

- make minor consequential technical amendments arising from the new Model Work Health and Safety Regulations 2011 (Model Regulations).

**Date of effect**

The Bill was assented to on 6 November 2012. Changes arising from the Cost Recovery Impact Statement will commence from 1 July 2013, and the minor technical amendments commenced on the day of Royal Assent.

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**Health Insurance (Section 19AB Exemptions) Guidelines 2012****Description of issue**

Section 19AB of the *Health Insurance Act 1973* (the Act) places a restriction on the eligibility of overseas trained doctors (OTDs) and foreign graduates of an accredited medical school (FGAMS) to bill Medicare for their services. This restriction commences on the date that the medical practitioner is first registered in Australia and remains in effect for a minimum period of ten years from this date.

This restriction in terms of eligibility to bill Medicare may be relaxed if the medical practitioner is granted an exemption under section 19AB (3).

Section 19AB (3) exemptions are granted according to the provisions set out within Guidelines, made under section 19AB (4) of the Act.

The Health Insurance (Section 19AB Exemptions) Guidelines 2012 were introduced to replace the former Section 19AB Guidelines. The Health Insurance (Section 19AB Exemptions) Guidelines 2012 were introduced to:

- clarify the full range of conditions under which a section 19AB(3) exemption may be granted to an OTD or FGAMS; and
- ensure all information regarding section 19AB of the Act reflected changes to legislation that were introduced as part of the *Health Insurance Amendment (New Zealand Overseas Trained Doctors) Bill 2010*.

**Date of effect**

The Health Insurance (Section 19AB Exemptions) Guidelines came into effect on 3 September 2012.

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## **Review of the Healthcare Identifiers (HI) Act 2010, HI Regulations and the HI Service**

### **Description of issue**

The *Healthcare Identifiers Act 2010* (the Act) implements a national system for consistently identifying consumers and healthcare providers through assignment of unique 16 digit numbers called healthcare identifiers to each healthcare recipient and healthcare provider. The legislation also sets out clear purposes for which healthcare identifiers may be used.

The HI Act requires that a review be completed and reported on before 30 June 2013. On 30 August 2012 Minister Plibersek appointed an independent reviewer to conduct the review.

During the review process consultation has been undertaken with Commonwealth stakeholders, jurisdictions, healthcare provider groups and consumer groups.

### **Date of effect**

The Review is expected to be completed and tabled in Parliament before 30 June 2013.

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## **Personally Controlled Electronic Health Records (Participation Agreement) Rules 2012**

### **Description of issue**

The personally controlled electronic health record (PCEHR) system is a key element of the Australian Government's national health reform agenda. The purpose of the PCEHR (Participation Agreements) Rules is to prescribe a requirement that healthcare provider organisations, repository operators, portal operators and contracted service providers enter into a participation agreement in order to be, and remain, registered as a participant in the PCEHR system.

Participation agreements deal with a number of matters that are not covered by the Act or related subordinate legislation, including by granting the intellectual property licences necessary for the PCEHR system to operate as intended.

### **Date of effect**

The Rules came into effect on 18 August 2012.

### **Contact details**

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### **Personally Controlled Electronic Health Records (Assisted Registration) Rules 2012**

#### **Description of issue**

The personally controlled electronic health record (PCEHR) system is a key element of the Australian Government's national health reform agenda. The purpose of the *PCEHR (Assisted Registration) Rules 2012* (Assisted Registration Rules) is to prescribe requirements for healthcare provider organisations that choose to assist consumers in applying for registration for a PCEHR, and to ensure the security of this manner of registration. The Assisted Registration Rules also prescribe a requirement of the System Operator to retain certain documents associated with assisted registration.

Consumers can register for a PCEHR using various channels and assisted registration will provide another channel. This manner of registration will encourage registration by a high proportion of vulnerable consumers (such as those in aged care and with chronic illness) who will benefit from having a PCEHR and who would be much more likely to apply to register with the support or assistance of their healthcare provider.

#### **Date of effect**

11 December 2012

#### **Contact details**

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### **Personally Controlled Electronic Health Records (Assisted Registration) Amendment Rules 2013**

#### **Description of issue**

The personally controlled electronic health record (PCEHR) system is a key element of the Australian Government's national health reform agenda. The purpose of the *PCEHR (Assisted Registration) Amendment Rules 2013* is to provide parents with the opportunity to register newborns not listed on the parent's Medicare card through the assisted registration channel.

#### **Date of effect**

The Amendment Rules 2013 will commence by 22 April 2013.

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Part B

**PLANNED REGULATORY CHANGES**

**2012-13**

## Planned changes

### **Amendments to the Aged Care Act 1997**

#### **Description of issue**

Amendments to the *Aged Care Act 1997* to give effect to the Government's *Living Longer Living Better* aged care reform package. The changes fundamentally reform the regulation of aged care by implementing changes in relation to residential care, changes to establish a new type of care (home care), changes relating to governance and administration, and changes that are minor, administrative or consequential.

#### **Consultation Opportunities**

The Department of Health and Ageing conducted comprehensive consultation in relation to the proposed changes. An overview of the proposed legislation changes was publicly released on the *Living Longer Living Better* website and communicated through the Aged Care Reform Update newsletter. Stakeholders and the general community were able to provide written comments on the proposed changes during a four week period. Comments were published on the *Living Longer Living Better* website, unless the author explicitly requested otherwise.

Further industry briefing sessions on the proposed amendments were held during March and April 2013.

#### **Date of effect**

1 July 2013, 1 January 2014, 1 July 2014

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### **Australian Aged Care Quality Agency Bill 2013**

#### **Description of issue**

This Bill will establish a new body, the Australian Aged Care Quality Agency, to accredit and monitor Australia's residential providers from 1 January 2014 and home care providers from 1 July 2014. This will be the sole agency that providers will deal with in relation to the quality assurance of the aged care services that they deliver. It will replace the Aged Care Standards and Accreditation Agency.

#### **Consultation Opportunities**

The Department of Health and Ageing conducted comprehensive consultation in relation to this change to the legislation. An overview of the proposed legislation changes was publicly released on the *Living Longer Living Better* website and communicated through the Aged Care Reform Update newsletter. Stakeholders and the general community were able to provide written comments on the proposed

changes during a four week period. Comments were published on the *Living Longer Living Better* website, unless the author explicitly requested otherwise.

Further industry briefing sessions on the Bills were held during March and April 2013.

**Date of effect**

1 January 2014

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**Australian Aged Care Quality Agency (Transitional Provisions) Bill 2013**

**Description of issue**

This Bill will enable the transition of the existing assets and resources of the Aged Care Standards and Accreditation Agency to the new body, the Australian Aged Care Quality Agency.

**Consultation Opportunities**

The Department of Health and Ageing conducted comprehensive consultation in relation to this change to the legislation. An overview of the proposed legislation changes was publicly released on the *Living Longer Living Better* website and communicated through the Aged Care Reform Update newsletter. Stakeholders and the general community were able to provide written comments on the proposed changes during a four week period. Comments were published on the *Living Longer Living Better* website, unless the author explicitly requested otherwise.

Further industry briefing sessions on the Bills were held during March and April 2013.

**Date of effect**

1 January 2014

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## **Amendments to the Aged Care (Bond Security) Amendment Bill 2013**

### **Description of issue**

This Bill amends the existing bond security legislation to extend the guarantee scheme for accommodation bonds to refundable accommodation deposits and refundable accommodation contributions, which will be new types of accommodation payments existing from 1 July 2014.

### **Consultation Opportunities**

The Department of Health and Ageing conducted comprehensive consultation in relation to this change to the legislation. An overview of the proposed legislation changes was publicly released on the *Living Longer Living Better* website and communicated through the Aged Care Reform Update newsletter. Stakeholders and the general community were able to provide written comments on the proposed changes during a four week period. Comments were published on the *Living Longer Living Better* website, unless the author explicitly requested otherwise.

Further industry briefing sessions on the Bills were held during March and April 2013.

### **Date of effect**

1 July 2014

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## **Amendments to the Aged Care (Bond Security) Levy Amendment Bill 2013**

### **Description of issue**

This Bill extends the existing levy provisions under the bond security legislation to ensure that if the guarantee scheme is triggered and the Commonwealth repays accommodation bonds or the new types of accommodation payments existing from 1 July 2014, the Commonwealth is able to recover its costs, via a levy, from approved providers.

### **Consultation Opportunities**

The Department of Health and Ageing conducted comprehensive consultation in relation to this change to the legislation. An overview of the proposed legislation changes was publicly released on the *Living Longer Living Better* website and communicated through the Aged Care Reform Update newsletter. Stakeholders and the general community were able to provide written comments on the proposed changes during a four week period. Comments were published on the *Living Longer Living Better* website, unless the author explicitly requested otherwise.

Further industry briefing sessions on the Bills were held during March and April 2013.

**Date of effect**

1 July 2014

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**Amendments to Aged Care Principles**

**Description of issue**

Currently there are 22 sets of Principles made under the *Aged Care Act 1997* that contribute to the operation of Aged Care programs. Nineteen sets of Principles will be amended with effect from 1 July 2013. In most cases the changes are consequential (e.g. community care to home care) or machinery in nature (e.g. updating outdated references to documents and repealing redundant provisions).

Some more substantive changes are however being made to enable three new supplements to be paid; to implement new home care arrangements; and to strengthen powers of the Aged Care Commissioner.

**Consultation Opportunities**

As part of the '*Living Longer Living Better*' aged care reform package, extensive consultation was undertaken with relevant Commonwealth Departments, the aged care industry, consumer groups, unions, older Australians their families and carers, and the broader community. Given the nature of the changes to the Principles is to give effect to the policy decisions, targeted consultation will be undertaken in respect of consequential and machinery changes. Consultation on substantive changes will be undertaken through relevant stakeholder working groups.

**Date of effect**

1 July 2013

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## **Amendments to Residential Care Subsidy Principles 1997 the Community Care Subsidy Principles 1997**

### **Description of issue**

Amendments to the *Residential Care Subsidy Principles 1997* and the *Community Care Subsidy Principles 1997*, will introduce a Conditional Adjustment Payment for service providers complying with the Aged Care Workforce Compact.

The Compact will ensure that an appropriately skilled and well-qualified workforce is available to care for older Australians who need aged care by linking workforce reforms to improvements in services, attraction, retention, education and training, and career development.

### **Consultation Opportunities**

In developing the Aged Care Workforce Compact, there has been extensive consultation with relevant Commonwealth Departments, the aged care industry and unions, including through a Strategic Workforce Advisory Group, comprising Government, service providers and unions. This Group will also provide advice on its implementation.

### **Date of effect**

To take effect from 1 July 2013.

### **Contact details**

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## **Amendments to the Health Insurance (Diagnostic Imaging Capital Sensitivity) Amendment Determination 2012**

### **Description of issue**

The *Health Insurance (Diagnostic Imaging Capital Sensitivity) Amendment Determination 2012* (the Amendment Determination) amends the Principal Determination to give effect to the second phase of the Capital Sensitivity 2009-10 Budget Measure from 1 July 2012. This Determination revokes some of the transitional provisions in the Principal Determination that are now obsolete and sets out the eligibility criteria for practices wishing to seek an exemption for inner regional areas.

### **Consultation Opportunities**

Consultation has already occurred as part of the recently completed review of diagnostic imaging, the outcomes of which were announced in the 2011-12 Budget.

### **Date of effect**

(unknown at this point)

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**Health Insurance (Diagnostic Imaging Services Table (Regulations 2012****Description of Issue**

As part of the Diagnostic Imaging Reform Package, in the 2011-12 Budget, the Australian Government allocated \$104.4 million over four years to expand patient access to magnetic resonance imaging (MRI) services. This includes the introduction of GP MRI requesting items for select indications for patients 16 years and over.

**Consultation Opportunities**

The Department has established an Expert Working Group of representatives from the Royal College of General Practitioners, the Royal College of Radiologists and the Australian College of Rural and Remote Medicine to provide input to the development of these Medicare funded MRI items.

**Date of effect**

The regulations are proposed to be made in November 2013.

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**Health Insurance Regulations 1975****Description of issue**

Amendments will be made to the *Health Insurance Regulations 1975* to enable Medicare eligible midwives to have collaborative arrangements with hospitals and health services, as announced by Minister Pliibersek in August 2012. This is to address the ongoing difficulties midwives have had in establishing collaborative arrangements with individual medical practitioners.

**Consultation Opportunities**

Consultation is underway with key stakeholder groups to develop these changes. Fact sheets relating to the changes will be made available on the Department of Health and Ageing's website. The Department of Health and Ageing will also work with the Department of Human Services to distribute information.

**Date of effect**

1 July 2013

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**National Health Act 1953 and National Health (Pharmaceutical Benefits) Regulations 1960 – continued dispensing in defined circumstances and supply of PBS claiming for medication charts in residential aged care facilities**

**Description of issue**

A suite of legislative and regulatory changes were made to enable the implementation of the 'Continued Dispensing of Pharmaceutical Benefits Scheme (PBS) Medicines in 'Defined Circumstances' and 'Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities' initiatives, which were agreed to as part of the Fifth Community Pharmacy Agreement.

Amendments were made to the *National Health Act 1953*, *National Health (Pharmaceutical Benefits) Regulations 1960* and the *National Health (claims and under co-payment data) Rules 2012*. New instruments were determined under section 89A and section 93A of the *National Health Act 1953* and under regulation 37AA of the *National Health (Pharmaceutical Benefits) Regulations 1960*.

These changes provide the framework for supply and claiming of pharmaceutical benefits under these new arrangements, including the conditions for supply and eligible pharmaceutical benefits. This includes:

- enabling pharmacists to supply and claim the standard quantity of a Pharmaceutical Benefits Scheme medication to a patient in the absence of a valid prescription in limited circumstances to ensure the continuity of the patient's long term therapy; and
- enabling pharmacists to supply and claim for Pharmaceutical Benefits Scheme medications from a medication chart within a Residential Aged Care Facility without the need for a separate prescription.

**Consultation Opportunities**

The Department of Health and Ageing worked with the Pharmacy Guild of Australia as co-signatories to the Fifth Community Pharmacy Agreement to develop and implement these initiatives.

Consultation with a range of stakeholders has been undertaken to inform the development of the initiatives and the legislative amendments required. Consultation activities included meetings with peak organisations and key stakeholders such as the Pharmacy Guild of Australia, the Australian Medical Association, the Australian Commission on Safety and Quality in Health Care, the Department of Human

Services, state and territory departments of health and all relevant Divisions in the Department of Health and Ageing. Furthermore, a formal written consultation was conducted.

**Date of effect**

National implementation in 2013 dependent on state and territory legislative change.

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**National Health (Pharmaceutical Benefits) Regulations 1960 – price disclosure method**

**Description of issue**

Amendments to the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) are required following a December 2012 Federal Court decision concerning the treatment of brands of pharmaceutical items that have been delisted from the Pharmaceutical Benefits Scheme (PBS) when undertaking calculations for potential price disclosure reductions.

Previous practice has been not to require data to be disclosed to the Department once a brand delists from the PBS. Following the December 2012 court decision the amendments would make provision for collection and use of delisted brand data. Related amendments would also be made concerning the data to be used in the price disclosure calculation method. This would include the use of sales volume data disclosed by companies throughout the calculation (rather than the use of PBS volume data at one point), and that a required set of continuous data may be provided by more than one listed or delisted brand. In addition, the amendments would allow there to be more than one reduction day for each price disclosure cycle, and provide a technical clarification for calculations where the disclosed sales volume is zero or less.

**Consultation Opportunities**

The Department has corresponded with all companies with PBS listed medicines about the December 2012 court case outcome and the need for consequential changes to price disclosure data collection and the method for calculating potential reductions. Further, discussions have occurred with peak industry, consumer, pharmacy and wholesaler bodies regarding the amendments.

**Date of effect**

It is intended that the amending Regulation be considered in April 2013 for commencement as soon as possible after consideration.

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**Post Implementation Review – Retention of the Pharmacy Location Rules****Description of issue**

The *Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act 2010* provides for amendments to the *National Health Act 1953* relating to the arrangements for approving pharmacists to supply pharmaceutical benefits to the community.

Under the *National Health Act 1953* a pharmacist is approved by the Secretary to supply pharmaceutical benefits at particular premises. If approved, the pharmacist may provide pharmaceutical benefits at or from those premises.

The amendments were the result of agreed negotiations of the Fifth Community Pharmacy Agreement (the Fifth Agreement) between the Minister for Health and Ageing and the Pharmacy Guild of Australia to retain the Pharmacy Location Rules. The Fifth Agreement commenced on 1 July 2010 and expires on 30 June 2015.

The *National Health Act 1953* previously gave effect to the Pharmacy Location Rules and the operation of the Australian Community Pharmacy Authority (ACPA) until 30 June 2010. The amendments were required to extend the Pharmacy Location Rules and the operation of the ACPA for the term of the Fifth Agreement to end 30 June 2015.

**Consultation Opportunities**

The Department consulted with the Pharmacy Guild of Australia in developing the Fifth Community Pharmacy Agreement. An independent review of the Pharmacy Location Rules, conducted in 2010, consulted with more than 10 stakeholder organisations and more than 20 individual stakeholders.

**Date of effect**

The Department is currently working in consultation with OBPR to complete the Post Implementation Review.

**Contact details**

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## **Amendments to the Cosmetic Standard 2007**

### **Description of issue**

The Cosmetic Standard 2007 is proposed to be amended to reference the *AS/NZS 2604:2012 Sunscreen products - Evaluation and classification* standard, which was revised from the *AS/NZS 2604:1998 Sunscreen products - Evaluation and classification* standard in May 2012. This change will give legal effect to the revised standard in the context of cosmetic sunscreen products.

### **Consultation Opportunities**

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) has consulted with peak industry and consumer groups in accordance with its Community Engagement Charter. NICNAS has also consulted with the Therapeutic Goods Administration which regulates therapeutic goods covered by the *AS/NZS 2604:2012 Sunscreen products - Evaluation and classification* standard.

### **Date of effect**

Following completion of consultations, Government will consider amendment of the Cosmetic Standard 2007 before the end of 2012-13. It is expected that transitional arrangements will be put in place should Government decide to amend the Cosmetic Standard.

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## **Industrial Chemicals (Notification and Assessment) Amendment Regulation 2013**

### **Description of issue**

The Regulation will realise amendments to the *Industrial Chemicals (Notification and Assessment) Regulations 1990* consequential to the *Industrial Chemicals (Notification and Assessment) Amendment Bill 2012*. The Regulation will:

- make minor consequential technical amendments to the term “Material Safety Data Sheet” to become “Safety Data Sheet”
- adjust fees and for 2013-14 in accordance with the *NICNAS Cost Recovery Impact Statement 2012-13 to 2015-16* and
- bring the application of regulation 4J into line with current practice.

### **Consultation Opportunities**

Consultation is complete. NICNAS undertook two public consultations on the Cost Recovery Impact Statement measures as part of its Cost Recovery Review during the period 2010-12, and undertook further consultation on the draft legislation in 2012. The changes arising from the Work Health and Safety Model Regulations were consulted upon by Safe Work Australia and the resulting changes to the Act are consequential. Also, the adjustments to the fees and charges for 2013-14 are specified in the CRIS statement. Finally, NICNAS published a notice of intention to amend regulation 4J in the February 2013 edition of the *Chemical Gazette*. NICNAS

will inform stakeholders on the progress of these amendments through its normal consultative mechanisms.

#### **Date of effect**

NICNAS will seek to introduce the Regulation in time for changes to take effect from 1 July 2013, noting the *Industrial Chemicals (Notification and Assessment) Amendment Bill 2012* was assented to in November 2012.

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#### **Post-Implementation Review – Annotation of the Australian Inventory of Chemical Substances (AICS) in respect of certain lead compounds**

##### **Description of issue**

The AICS was annotated to restrict the use of certain lead compounds in industrial surface coatings and inks. The annotation was fully effective from 1 January 2009. In accordance with Office of Best Practice Regulation (OBPR) requirements, a post-implementation review of the impact of the annotation on industry and the community, as well as the future need for the annotations, has been conducted.

##### **Consultation Opportunities**

Consultation with stakeholders occurred during February to April 2012 in accordance with the protocols and principles in the National Industrial Chemicals Notification and Assessment Scheme Community Engagement Charter, and the Australian Government's Best Practice Regulation requirements.

##### **Date of effect**

A Post Implementation Review report has been completed and certified by the OBPR as being compliant with the Government's best practice regulatory requirements. Publication of the Review is expected before 30 June 2013, when NICNAS will also communicate the future of the annotations.

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#### **Amendment to the Industrial Chemicals (Notification and Assessment) Act 1989 – implementation of regulatory reforms**

##### **Description of issue**

Reform of the *Industrial Chemicals (Notification and Assessment) Act 1989* under the Better Regulation Ministerial Partnership (Partnership) between the Minister for Finance and Deregulation and the Minister for Health.

## **Consultation Opportunities**

There have been two public consultation rounds that commenced in November 2011 and June 2012 seeking stakeholder input into the development of reform options.

### **Date of effect**

The Partnership is expected to bring forward proposed changes during 2013.

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## **Review of Part 6-3 of the Therapeutic Goods Act 1989 – Scheduling of substances**

### **Description of issue**

Part 6-3 of the *Therapeutic Goods Act 1989 (TG Act)* provides for a uniform system of access controls for goods containing scheduled substances (medicines and chemicals). The scheduling of substances allows restrictions to be placed on their supply to the public, in the interests of public health and safety. This is aimed at minimising the risks of poisoning from, and the misuse and abuse of, scheduled substances.

Section 52EC of the *TG Act* requires that an independent panel review the operation of this part and report to the Minister for Health on:

- the system of access controls for goods containing scheduled substances established by this Part
- the outcomes of the administration of scheduled substances by the Secretary and by the committees established by this Part
- the effect of the amendments [which were passed in 2009] on the therapeutic goods industry and on individual parties within the industry
- whether there are adequate avenues for review of decisions made by the Secretary and by the committees established by this Part

and may make recommendations for further changes to the scheduling regime.

The Minister must cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of that House after the day on which the Minister receives the report.

### **Consultation Opportunities**

The panel must invite and consider public submissions. Submissions were required to be lodged with the Department of Health and Ageing between 2 and 29 April 2013.

**Date of effect**

The review commenced on 12 March 2013 and must be completed within six months. It is expected to be completed by late August 2013.

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**Amendments to Health Insurance Regulations 1975 and other regulations****Description of issue**

The amendments to these regulations will support amendments to the *Health Insurance Act 1973* made through the *Health Practitioner Regulation (Consequential Amendments) Act 2010*. The purpose of the amendments is to support the implementation of the National Registration and Accreditation Scheme for health professions by updating definitions in the *Health Insurance Act 1973* and subordinate legislation made under it and streamlining processes for the recognition of medical practitioners for the purposes of Medicare, including removing the current Vocational Register for general practitioners.

Amendments to the following regulations are required:

- Health Insurance (General Medical Services Table) Regulations; and
- Repeal of Health Insurance (Vocational Registration of General Practitioners) Regulations 1989.

Amendments to the following regulations may also be required:

- Health Insurance (Pathology Services Table) Regulations;
- Health Insurance (Diagnostic Imaging Services Table) Regulations; and
- National Health Regulations 1954.

**Consultation Opportunities**

Key stakeholders were consulted during the development of amendments to the *Health Insurance Act 1973*. Further consultation with stakeholders is expected to be undertaken in 2013.

**Date of effect**

The *Health Practitioner Regulation (Consequential Amendments) Act 2010* is expected to be proclaimed at time of passing associated regulations.

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### **Personally Controlled Electronic Health Record System — Designated Privacy Laws**

#### **Description of issue**

The personally controlled electronic health record (PCEHR) system is a key element of the Australian Government's national health reform agenda. The purpose of the PCEHR system is to address information fragmentation by allowing a person to more easily access their own health information and make their own health information securely accessible to different healthcare providers involved in their care.

A determination was required to specify the state and territory privacy laws that will apply to state or territory authorities or instrumentalities that seek to register as a repository operator or portal operator for the PCEHR system.

#### **Consultation Opportunities**

The Department of Health and Ageing consulted with a working group of representatives from Commonwealth, state and territory health departments, as well as with other Commonwealth agencies, and the sector.

#### **Date of effect**

The PCEHR system commenced on 1 July 2012. The determination of designated privacy laws is expected to be developed concurrently with negotiations with state and territory public sector repository operators or portal operators to participate in the PCEHR system.

#### **Contact details**

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### **Amendments to the *Healthcare Identifiers (HI) Act 2010*, HI Regulations and the HI Service**

#### **Description of issue**

To make amendments arising from the review of the *Healthcare Identifiers Act 2010*, HI Regulations and the HI Service undertaken in 2012–13 financial year

#### **Consultation opportunities**

The Department of Health and Ageing will consult with representatives from Commonwealth, state and territory health departments, as well as with other Commonwealth agencies, and the sector.

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**Healthcare Identifiers Amendment Regulation****Description of issue**

The personally controlled electronic health (PCEHR) system is a key element of the Australian Government's national health reform agenda.

The Healthcare Identifiers (HI) Service was established as a foundation element for electronic transmission of health records, enabling unique identifiers to be assigned to consumers, individual healthcare providers and healthcare provider organisations.

The Healthcare Identifiers Amendment Regulation will support the role of authorised representatives in the PCEHR system. It does this by making clear certain entities can collect, use and disclose the identifying information and healthcare identifier of a prospective authorised representative. The Regulation will also ensure that all Department of Veterans' Affairs health information can be included in a consumer's PCEHR.

The Department of Health and Ageing is developing the proposed regulation in consultation with the Departments of Veterans' Affairs and Human Services, and a working group of representatives from Commonwealth, state and territory health departments.

**Date of effect**

The regulations are proposed to be made in April 2013.

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**New Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products and Therapeutic Goods Order – Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products**

**Description of issue**

The Australian Code of Good Manufacturing Practice for Human Blood and Tissues was first published on 24 August 2000. It has not been updated since that time. International and industry standards have improved considerably since. It is proposed to implement a new code to better reflect contemporary standards and to clarify areas of current expectation.

The proposed Therapeutic Goods Order – ‘Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products’ would specify minimum technical requirements with which such products must comply regarding reducing the risk of the transmission of infectious disease, particularly in relation to donor selection, donor testing and the collection of such products from donors.

**Consultation Opportunities**

Extensive consultations on the draft code and order have already been undertaken.

**Date of effect**

These instruments are being prepared in the expectation of commencement in mid-2013 (May-July). Each of these instruments will commence the day after they are registered on the Federal Register of Legislative Instruments, and registration will be arranged to occur at the same time for both instruments.

**Contact details**

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## **Therapeutic Goods Amendment (2013 Measures No.1) Bill 2013**

### **Description of issue**

This Bill amends the *Therapeutic Goods Act 1989* (the Act), principally to clarify the operation of a number of provisions in the Act and align various requirements in the Act to ensure consistency in the regulation of different types of therapeutic goods.

The Bill also amends the Act to, in particular:

- include a new power to allow the Minister to make a legislative instrument to exclude products identified in the instrument from the definition of ‘therapeutic goods’, or to exclude products identified in the instrument from that definition when used, advertised or presented for supply in a manner specified in the instrument;
- include a power for the Secretary to remove products from the Australian Register of Therapeutic Goods (the Register) that are not, in fact, therapeutic goods;
- introduce an offence and civil penalty provision relating to the making of statements that are false or misleading in a material particular in or in connection with a request under section 9D of the Act to vary an entry of therapeutic goods in the Register; and
- include a power for the Secretary to (with notice) suspend or cancel the registration or listing of registered or listed therapeutic goods where (in the case of registered goods) the presentation of the goods is not acceptable or where (in the case of listed goods) the presentation of the goods is unacceptable.

### **Consultation Opportunities**

As the measures set out in the Bill are considered to be minor or machinery in nature, they have largely not been the subject of consultation.

However, a briefing on the amendments was provided to representatives of industry peak bodies, consumers and other stakeholders on 22 and 26 March 2013.

This Bill was introduced into Parliament on 20 March 2013. On 21 March the Bill was referred to the Senate Community Affairs Legislation Committee for report on 17 June 2013. The Committee have invited submissions to be made on the Bill by 3 May 2013.

### **Date of effect**

It is anticipated that the Bill will be passed by both Houses of Parliament before the end of the Winter 2013 Sittings (by 27 June 2013).

The majority of its provisions are to commence upon Royal Assent. A small number of measures, set out in Schedule 16 of the Bill (relating to amendments to sections 9D and 23 of the Act to clarify what information the Secretary can require applicants to provide), will commence on a day to be fixed by Proclamation or, if not proclaimed, the day after 6 months from the date of Royal Assent.

### **Contact details**

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**Amendments to the Therapeutic Goods Regulations 1990, the Therapeutic Goods (Charges) Regulations 1990 and the Therapeutic Goods (Medical Devices) Regulations 2002**

**Description of issue**

These amendments will principally amend the regulations mentioned above in order to implement a general increase of 2.9 per cent of TGA fees and charges relating to the regulation of therapeutic goods for financial year 2013-14.

**Consultation Opportunities**

The TGA held meetings with representatives of industry peak bodies between 19 and 21 February 2013, in relation to the proposed increase of TGA fees and charges.

**Date of effect**

These amendments are intended to be in place in time to commence on 1 July 2013, to coincide with the start of the new 2013-14 financial year.

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