

Department of Health and Ageing 2011-2012 Regulatory Plan

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 effect on business, or restrict competition.

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: September 2011

Past changes

Title	<i>Accreditation Grant Principles 2011</i>
Description of issue	The Accreditation Grant Principles 2011 were amended to: <ul style="list-style-type: none"> • remove or amend outdated provisions; • streamline the accreditation process; • make the Accreditation Grant Principles more logical, consistent and more readily understood • enhance consumer engagement; and • provide greater clarity and consistency of administrative processes.
Date of effect	20 May 2011
Contact details	Valerie Spencer Director Residential Care Quality Section Quality and Monitoring Branch Office of Aged Care Quality and Compliance Department of Health and Ageing Ph: (02) 6289 1570 Email: valerie.spencer@health.gov.au

Title	<i>Aged Care Amendment Bill 2011</i>
Description of issue	The Aged Care Amendment Bill 2011 amended the <i>Aged Care Act 1997</i> to strengthen consumer protection for accommodation bonds paid to aged care services and to improve arrangements for the handling of complaints about Commonwealth funded aged care services.
Date of effect	22 June 2011
Contact details	Mike Burns Director Prudential and Approved Provider Standards Section Prudential and Approved Provider Regulation Branch Office of Aged Care Quality and Compliance Department of Health and Ageing Ph: (02) 6289 7294 Email: mike.burns@health.gov.au

Title	<i>Amendments to the Health Insurance (Allied Health Services) Determination 2010</i>
Description of issue	Amendments to the <i>Health Insurance (Allied Health Services) Determination 2010</i> were made to require the completion of ten hours annually of continuing professional development by providers of focussed psychological strategies.
Date of effect	9 June 2011
Contact details	Chris Killick-Moran Director Clinical Services Reform Section Mental Health Reform Branch Mental Health and Chronic Disease Division Department of Health and Ageing Phone: (02) 6289 7329 Email: chris.killick-moran@health.gov.au

Title	<i>Amendments to the Hearing Services (Participants in the Voucher System) Determination 1997</i>
Description of issue	This Determination defines the classes of people eligible for the voucher component of the Hearing Services Program and provides a description of available hearing services. The amendments that were made described the conditions (the level of hearing loss and motivation) under which a hearing aid can be fitted to a voucher client. The benefit of this amendment is that hearing aids fittings are aligned to clinical need for all voucher clients in the Hearing Services Program.
Date of effect	1 July 2010 http://www.comlaw.gov.au/Browse/ByTitle/Acts/Asmade
Contact details	Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au

Title	<i>Health Care Identifiers Act 2010, Healthcare Identifiers (Consequential Amendments) Act 2010 and Healthcare Identifiers Regulations 2010</i>
Description of issue	These Acts and Regulations established the Healthcare Identifiers Service which commenced on 1 July 2010. The Department of Human Services is the Service Operator. Healthcare Identifiers will be assigned by the Healthcare Identifiers Service Operator to individuals and healthcare providers to support the management of health information, reduce errors and mismatching, and improve patient safety. The Acts and Regulations set out the purposes for which Healthcare Identifiers can be used, eligibility criteria for healthcare providers, offences and penalties for associated breaches of the legislation and governance and oversight arrangements.
Date of effect	The Acts commenced on 29 June 2010 (the day after Royal Assent was received). The Regulations came into effect on 1 July 2010.
Contact details	Liz Forman Assistant Secretary eHealth Strategy Branch Primary and Ambulatory Care Division Department of Health and Ageing Ph: (02) 6289 1944 Email: liz.forman@health.gov.au

Title	<i>Health Insurance (Allied Health Services) Amendment Determination 2010 (No 2)</i>
Description of issue	This Determination amends the <i>Health Insurance (Allied Health Services) Determination 2009 (No. 2)</i> to make changes to the eligibility criteria for three allied health professions (podiatry, psychology and mental health nurses) arising from the creation of the National Registration and Accreditation Scheme.
Date of effect	1 July 2010
Contact details	Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au

Title	<i>Health Insurance (Allied Health Services) Determination 2011</i>
Description of issue	This Determination provides new arrangements for audiologists, occupational therapists, optometrists, orthoptists, physiotherapists, psychologists and speech pathologists to provide services under the Helping Children with Autism program and the Better Start for Children with Disability initiative.
Date of effect	1 July 2011
Contact details	Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au

Title	<i>Health Insurance Amendment (Compliance) Act 2011</i>
Description of issue	This Act allows the Chief Executive Medicare to give a notice requiring a person to produce documents to substantiate a Medicare benefit paid in respect of a service; and provides for an administrative penalty if a practitioner is unable to substantiate a Medicare benefit paid in respect of a service.
Date of effect	9 April 2011
Contact details	Penny Shakespeare Assistant Secretary Medicare Benefits Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 6945 Email: penny.shakespeare@health.gov.au

Title	<i>Health Insurance Amendment Regulations 2010 (No. 1)</i>
Description of issue	<p>These regulations are part of the implementation of the <i>Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010</i>. The Act provides for new arrangements to enhance and expand the role of midwives and nurse practitioners, allowing them to take a greater role in providing quality health care.</p> <p>The amendments to the <i>Health Insurance Regulations 1975</i> include details of the collaborative arrangements and eligibility requirements for midwives and nurse practitioners and support the creation of new Medicare arrangements, detail the particulars required on accounts and receipts and facilitate referrals to specialists and consultant physicians and requesting diagnostic imaging and pathology.</p>
Date of effect	1 November 2010
Contact details	<p>Tracy Thompson Director General Practice, Nursing and Midwifery Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 1938 Email: tracy.thompson@health.gov.au</p>

Title	<i>Health Insurance Amendment Regulations 2011 (No. 2)</i>
Description of issue	<p>These amendments to the Health Insurance Regulations 1975 provide for new arrangements to allow orthoptists to provide a health service under the Better Start for Children with Disability initiative.</p>
Date of effect	1 July 2011
Contact details	<p>Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au</p>

Title	<i>Health Insurance (General Medical Services Table) Amendment Regulations 2010 (No. 4)</i>
Description of issue	<p>These regulations make changes to the Better Access to Psychiatrists, Psychologists and General Practitioners through the Medicare Benefits Schedule initiative to enable appropriately qualified General Practitioners to provide focused psychological strategies services regardless of practice setting.</p>
Date of effect	1 July 2010
Contact details	<p>Jacqueline Mitchell Director</p>

	Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au
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Title	<i>Health Insurance (General Medical Services Table) Amendment Regulations 2011 (No 1)</i>
Description of issue	These regulations make changes to the existing medical referral items for the Helping Children with Autism program, and create two new medical referral items to support the Better Start for Children with Disability initiative.
Date of effect	1 July 2011
Contact details	Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au

Title	<i>Health Insurance (Midwifery and Nurse Practitioner) Determination 2010</i>
Description of issue	The <i>Health Insurance (Midwives and Nurse Practitioner) Determination 2010</i> created new Medicare Benefits Schedule items for eligible midwives and nurse practitioners (participating midwives and nurse practitioners) who are working in collaboration with a medical practitioner. <u>Participating Midwives</u> The midwifery item structure includes antenatal, intra-partum (delivery in a hospital setting) and postnatal services for up to six weeks following delivery. <u>Participating Nurse Practitioners</u> The nurse practitioner items include four consultation items. The services provided by the nurse practitioner must be within their scope of practice.
Date of effect	1 November 2010
Contact details	Tracy Thompson Director General Practice, Nursing and Midwifery Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 1938 Email: tracy.thompson@health.gov.au

Title	<i>Health Insurance (Telehealth Services) Determination 2011 and Health Insurance (Extended Medicare Safety Net – Telehealth) Amendment Determination 2011</i>
Description of issue	<p>The <i>Health Insurance (Telehealth Services) Determination 2011</i> introduced new Medicare Benefits Schedule items for specialist and consultant physician video consultations which came into effect on 1 July 2011.</p> <p>Eleven new Medicare Benefits Schedule items are now available for video consultations linking patients located in regional, remote or outer metropolitan Australia, with a medical specialist or consultant physician. New items are also available Australia wide for video consultations with a specialist or consultant physician for care recipients in Residential Aged Care Facilities and patients of Aboriginal Medical Services and Aboriginal Community Controlled Health Services in relation to which a direction made under subsection 19(2) of the <i>Health Insurance Act 1973</i> applies.</p> <p>There are also now twenty three new Medicare items for clinical support provided to the patient by a medical practitioner, practice nurse, Aboriginal health worker, midwife or nurse practitioner at the patient-end of a video consultation with a specialist or consultant physician.</p> <p>The <i>Health Insurance (Extended Medicare Safety Net (EMSN) – Telehealth) Amendment Determination 2011</i> places Extended Medicare Safety Net benefit caps on two of the new specialist items for obstetric and assisted reproductive technology consultations provided via video conference. These caps are consistent with the EMSN caps already in place for the existing face-to-face consultation items for these services.</p>
Date of effect	1 July 2011
Contact details	<p>Jennifer Campain and Veronica Davidson Directors Medicare Eligibility Section Medicare Benefits Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 7015 or (02) 6289 4597 Email: jennifer.campain@health.gov.au or veronica.davidson@health.gov.au</p>

Title	<i>Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act 2010</i>
Description of issue	<p>a) This Act amended the <i>Private Health Insurance Act 2007</i> to address some anomalies that inadvertently advantaged or disadvantaged some people with respect to the application of the lifetime health cover policy provisions.</p> <p>b) This Act also amended the <i>National Health Act 1953</i> to extend the Pharmacy Location Rules and the operation of the Australian Community Pharmacy Authority until 30 June 2015.</p>
Date of effect	28 June 2010
Contact details	<p>a) Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au</p> <p>b) Tony Wynd Director Pharmacy Location Rules Section Community Pharmacy Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7595 Email: tony.wynd@health.gov.au</p>

Title	<i>Health Practitioner Regulation (Consequential Amendments) Act 2010</i>
Description of issue	This Act makes consequential amendments to the <i>Health Insurance Act 1973</i> to recognise and support the implementation of the National Registration and Accreditation Scheme for Health Professions. The <i>Health Practitioner Regulation (Consequential Amendments) Act 2010</i> will also streamline the processes involved in the recognition of doctors for Medicare purposes.
Date of effect	Assented to on 31 May 2010
Contact details	Ruth Maberley A/g Director National Registration and Accreditation Scheme Policy Section Workforce Development Branch Health Workforce Division Department of Health and Ageing Ph: (02) 6289 5484 Email: ruth.maberley@health.gov.au

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010</i>
Description of issue	These Regulations increased all fees and charges for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2010-11 by 3.6% (Consumer Price Index/Wage Cost Index). Available at www.nicnas.gov.au .
Date of effect	1 July 2010
Contact details	Dr Roshini Jayewardene Team Leader Regulatory Strategy Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au

Title	<i>NICNAS Nanomaterials Administrative Changes 2011</i>
Description of issue	Introduction of new procedures and data requirements for new chemicals notification and assessment of industrial nanomaterials.
Date of effect	1 January 2011
Contact details	Dr Matthew Gredley Team Leader Reform Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 E-mail: matthew.gredley@nicnas.gov.au

Title	<i>Private Health Insurance (Benefit Requirements) Rules</i>
Description of issue	These Rules provide for the minimum or default benefits payable for psychiatric, rehabilitation, palliative care and other hospital treatment. Various amendments to the Rules were made in respect of these minimum requirements or benefit levels. In 2010 the Rules were amended to allow insurers and hospitals to contract at rates below the minimum benefit level for treatment that is not psychiatric, rehabilitation or palliative care. Where there is no contract, the default benefit applies.
Date of effect	July 2010, August 2010, September 2010, October 2010, November 2010, December 2010, January 2011, March 2011, June 2011
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au

Title	<i>Private Health Insurance (Complying Product) Rules</i>
Description of issue	<p>These Rules provide that health insurers must comply with a range of requirements and must meet certain obligations to people insured or seeking to be insured under their health insurance products. Consequential amendments to rules, consistent with amendments to the <i>Private Health Insurance (Prostheses) Rules</i>, regarding the payment of a prostheses benefit for an insulin infusion pump, were made in December 2010.</p> <p>These Rules also set out the patient contribution amount payable by nursing-home type patients in each state or territory. Amendments to these amounts were made in January and March 2010.</p>
Date of effect	August 2010, September 2010, November 2010, January 2011, March 2011, May 2011, June 2011
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au

Title	<i>Private Health Insurance (Prostheses) Rules</i>
Description of issue	<p>Various amendments to these Rules were made to update prostheses benefits, as required throughout the year. Amendments to create a new Part C to the Schedule to these Rules, as well as amendments defining insulin infusion pump, implantable cardiac event recorder, and the circumstances in which a prosthesis benefit for an insulin infusion pump is payable, were made in December 2010. The amendments gave effect to legislative changes made by the <i>Private Health Insurance Legislation Amendment Act 2010 (No.1)</i></p>
Date of effect	August 2010, December 2010, February 2011
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au

Title	<i>Quality of Care Amendment Principles 2011</i>
Description of issue	<p>Amendments were made to the <i>Quality of Care Principles 1997</i> to introduce the Community Care Common Standards for Australian Government community care programs, including community care in the form of Community Aged Care Packages, and flexible care in the form of Extended Aged Care at Home and Extended Aged Care at Home – Dementia.</p>
Date of effect	1 March 2011

Contact details	<p>Susan Jones Director Community Care Quality Section Quality and Monitoring Branch Office of Aged Care Quality and Compliance Ph: (02) 6289 3991 Email: susan.jones@health.gov.au</p>
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Title	<i>Security-Sensitive Biological Agents (SSBAs) Regulatory Scheme – Amendments to Part 3 of the National Health Security Act 2007</i>
Description of issue	<p>Part 3 of the <i>National Health Security Act 2007</i> (NHS Act) establishes controls to regulate handling of security-sensitive biological agents (SSBAs).</p> <p>Following amendments to the NHS Act to enable background checks to be conducted by AusCheck, a portfolio of the Attorney-General's Department, Part 3 of the SSBA Standards was amended in July 2010 to include requirements for entities to conduct background checks of 'authorised persons' against a list of disqualifying offences. Before a person can be 'authorised' to handle Tier 1 SSBAs, access the area where Tier 1 SSBAs are handled, or access sensitive information about Tier 1 SSBAs, they will need to hold a current 'eligible' or 'qualified' background check result. The revised Standards came into force on 14 July 2010 and are available on the Department of Health and Ageing's website.</p> <p>The SSBA Standards were further amended in June 2011 to include more clarity regarding the storage of SSBAs, handling a formerly suspected SSBA following a positive confirmatory test and a number of general changes to improve overall clarity. A draft was made available for public consultation during November and December 2010. Over 50 comments from 10 individuals or organisations were received and these comments have been incorporated into the new SSBA Standards, where appropriate.</p>
Date of effect	The National Health Security Amendment (Background Checking) Bill 2009 was introduced into the House of Representatives in November 2009 and received Royal Assent on 3 March 2010. The related SSBA Standards commenced on 14 July 2010.
Contact details	<p>Sandra Gebbie Director Laboratory Capacity and Regulation Section Health Emergency Management Branch Office of Health Protection Department of Health and Ageing Ph: (02) 6289 3428 Email: sandra.gebbie@health.gov.au</p>

Title	<i>Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009</i>
Description of issue	<p>This Act amends the <i>Therapeutic Goods Act 1989</i> to :</p> <ol style="list-style-type: none"> 1. allow the registration or listing of medicines and therapeutic devices to be suspended rather than fully cancelled in certain circumstances; 2. allow the taking of video and other recordings and taking of samples of things related to therapeutic goods on premises; 3. ensure consistency of the powers that can be exercised by an authorised person under the <i>Therapeutic Goods Act 1989</i> in relation to the entry, inspection of, and the taking of samples from specified premises; 4. clarify the definition of accessory to a medical device and require that medicine labels not make claims that are inconsistent with the claims approved for the product; 5. apply technical amendments to existing provisions referring to legislative instruments in the <i>Therapeutic Goods Act 1989</i>; 6. incorporate a new framework for the regulation of homoeopathic and anthroposophic medicines with details in regulations and other subordinate legislation made under the <i>Therapeutic Goods Act 1989</i> after further consultation with industry; 7. clarify that manufacturing licenses cover single sites, except in certain circumstances, and enabling variation and transfer of licenses to another manufacturer; 8. allow the Minister to determine lists of ingredients that are permitted and prohibited to be included in listed medicines and allow applications to be made for a variation to the permitted ingredients list; and 9. include other amendments including clarification of the way conditions are set on registered and listed goods and clarifying the Advertising Code as a legislative instrument. <p>These amendments will also require the making of legislative instruments for the purposes of specified provisions under this Amendment Act.</p>
Date of effect	<p>Items 1, 2, 3, 4 and 5 – 28 August 2009; Item 6 - 1 July 2011; Item 7 –commenced on 25 February 2010; Item 8 –commenced on 8 February 2010; Item 9 – commenced on 25 January 2010.</p>
Contact details	<p>Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: (02) 6232 8230 Email: terry.lee@tga.gov.au</p>

Title	<i>Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011</i>
Description of issue	<p>This Act sets out a small number of changes to the <i>Therapeutic Goods Act 1989</i>, those being:</p> <ol style="list-style-type: none"> 1. an amendment to section 9D of the <i>Therapeutic Goods Act 1989</i> with the effect that a request to vary an existing entry in the Australian Register of Therapeutic Goods under subsection 9D(3) of the <i>Therapeutic Goods Act 1989</i> will not be effective unless the request has been made in accordance with the approved form and manner; it contains the information required and any prescribed application fee has been paid; 2. amendments to sections 24, 24A and 24D of the <i>Therapeutic Goods Act 1989</i> requiring a person who makes an application under section 23 of the <i>Therapeutic Goods Act 1989</i> for registration of therapeutic goods in the Australian Register of Therapeutic Goods to pay the full amount of the relevant evaluation fee when the application is accepted for evaluation. Twenty five per cent of the evaluation fee will be returned to the applicant if the evaluation is not completed within the prescribed period; and 3. amendments to subsections 31(1B) and 31(1C) of the <i>Therapeutic Goods Act 1989</i> to replace references in those provisions to "pre-submission form" with "pre-submission planning form" to reflect the terminology of new processes for the assessment of prescription medicines. <p>In addition to the above, the <i>Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011</i> also sets out transitional provisions relating to the determination instrument to be made by the Minister under subsection 28(2) of the Act setting out conditions of registration or listing.</p>
Date of effect	The <i>Therapeutic Goods Amendment (2011 Measures No. 1) Act 2011</i> received Royal Assent on 25 July 2011. The provisions of the Act commenced on the day after Royal Assent.
Contact details	<p>Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: 02 6232 8230 Email: terry.lee@tga.gov.au</p>

Title	<i>Therapeutic Goods Amendment Regulations 2011 (No.2), the Therapeutic Goods (Charges) Amendment Regulations 2011 (No.2) and the Therapeutic Goods (Medical Devices) Amendment Regulations (No. 2)</i>
Description of issue	<p>These amending regulations set out a number of changes to their respective principal regulations, including in relation to:</p> <ol style="list-style-type: none"> 1. increasing Therapeutic Goods Administration fees and charges by a general composite increase of 3.4 per cent; 2. splitting current evaluation fees for prescription medicines into specified application fees and evaluation fees; 3. increasing the membership of the Advisory Committee on the Safety of Medicines from twelve to fifteen, and the membership of the Advisory Committee on Prescription Medicines from 25 to 32; 4. prescribing the classes of medicines for the purposes of paragraph 3(5)(ca) of the <i>Therapeutic Goods Act 1989</i> which will be unacceptable if the label does not contain an advisory statement specified in the instrument to be made by the Minister under s.3(5A) of the <i>Therapeutic Goods Act 1989</i>; and 5. setting out definitions for "complementary medicine", "designated active ingredients" and "traditional use", which are consistent with the definitions for those terms which were included in the old Part 6-4 of the <i>Therapeutic Goods Act 1989</i> which was removed from the Act by the <i>Therapeutic Goods Amendment (2009 Measures No.1) Act 2009</i> in January 2010.
Date of effect	These amending regulations were registered on the Federal Register of Legislative Instruments on 21 June 2011 and each commenced on 1 July 2011
Contact details	<p>Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: 02 6232 8230 Email: terry.lee@tga.gov.au</p>

Planned changes

Title	<i>Amendment to the Declared Hearing Services Determination 1997</i>
Description of issue	<p>This Determination describes the classes of people eligible for the Community Services Obligations component of the Hearing Services Program and the hearing services to be provided under each class. The amendments would extend eligibility for the Hearing Services Program to Australians between the ages of 21 and 25 inclusive.</p> <p>The purpose of, and the benefits of, the anticipated changes are to increase access to services to young people aged 21-25 inclusive. Young people in this age group who are currently ineligible for free hearing services will be positively affected. These services are provided by the Australian Government hearing service provider, Australian Hearing – no other contracted service providers will be affected.</p>
Consultation opportunities	<p>Consultation regarding these changes commenced in May 2011 with Australian Hearing and will cease November 2011 to enable the finalisation of a renegotiated Memorandum of Understanding by 1 January 2012.</p>
Expected timetable	<p>Date of effect 1 January 2012</p>
Contact details	<p>Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au</p>
Date last modified	<p>September 2011</p>

Title	<i>Amendments to Health Insurance (Accreditation of Podiatric Surgeons) Guidelines</i>
Description of issue	<p>The Health Insurance (Accreditation of Podiatric Surgeons) Guidelines set out the accreditation standards for recognition as a podiatric surgeon for the purpose of health insurance. Following the establishment of the Australian Health Practitioners Regulation Agency and the Health Practitioner Regulation National Law, podiatrists and podiatric surgeons are regulated by the Podiatry Board of Australia, which is part of the Australian Health Practitioners Regulation Agency. The Podiatry Board of Australia is currently reviewing the qualifications for recognition as a Podiatric Surgeon.</p>
Consultation opportunities	<p>The Department of Health and Ageing is consulting with the Australian Health Practitioners Regulation Agency, the Podiatry Board of Australia and the College of Podiatric Surgeons.</p>
Expected timetable	<p>July-September 2011</p>
Contact details	<p>Peter Woodley</p>

	Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to the Health Insurance (Diagnostic Imaging Services Table) Regulations 2011</i>
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 MRI services. The current arrangements for Medicare-eligible MRI providers will also be rationalised.
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.
Expected timetable	Expected completion May 2012.
Contact details	Hilary Metcalf Director DI Quality – MRI Diagnostic Services Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 8675 Email: hilary.metcalf@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to the Health Insurance (Diagnostic Imaging Services Table) Regulations 2011 and the Health Insurance (Pathology Services Table) Regulations 2011</i>
Description of issue	The 2009-10 Budget included a measure to introduce patient choice in provider of pathology and diagnostic imaging services. To give effect to this measure, amendments will be made to the above regulations to ensure that patients are aware that they are free to choose their own provider.
Consultation opportunities	Since the Budget measure was announced, consultation has occurred with the pathology and imaging sectors.
Expected timetable	Expected completion June 2012.
Contact details	Hilary Metcalf Director DI Quality – MRI Diagnostic Services Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 8675 Email: hilary.metcalf@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to Health Insurance Regulations 1975 and other regulations</i>
Description of issue	<p>The amendments to these regulations will support amendments to the <i>Health Insurance Act 1973</i> made through the <i>Health Practitioner Regulation (Consequential Amendments) Act 2010</i>. 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 <i>Health Insurance Act 1973</i> 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.</p> <p>Amendments to the following regulations are required:</p> <ul style="list-style-type: none"> • <i>Health Insurance (General Medical Services Table) Regulations</i>; and • Repeal of <i>Health Insurance (Vocational Registration of General Practitioners) Regulations 1989</i>. <p>Amendments to the following regulations may also be required:</p> <ul style="list-style-type: none"> • <i>Health Insurance (Pathology Services Table) Regulations</i>; • <i>Health Insurance (Diagnostic Imaging Services Table) Regulations</i>; and • <i>National Health Regulations 1954</i>.
Consultation opportunities	<p>A consultation process was conducted within the Department of Health and Ageing to advise on the proposed amendments to the regulations and seek input on any subordinate legislation affected by the proposed changes.</p> <p>A further consultation process is to be undertaken with key external stakeholders to assess the regulatory impacts that the proposed amendments may have on business or individuals.</p>
Expected timetable	<p>The <i>Health Practitioner Regulation (Consequential Amendments) Act 2010</i> is expected to be proclaimed by mid 2012</p>
Contact details	<p>Ruth Maberley A/g Director National Registration and Accreditation Scheme Policy Section Workforce Development Branch Health Workforce Division (02) 6289 5484 Email ruth.maberley@health.gov.au</p>
Date last modified	<p>September 2011</p>

Title	<i>Amendment to the Hearing Services (Participants in the Voucher System) Determination 1997</i>
Description of issue	The Determination defines the classes of people eligible for the voucher component of the Hearing Services Program and provides a description of available hearing services. The proposed amendments would remove all reference to transitional arrangements for clients entering the Hearing Services Program in 1997 and be rewritten in plain English. The transitional arrangements have been irrelevant for a number of years. The purpose and benefits of anticipated changes will be to assist contracted service providers of the voucher component of the Hearing Services Program to better understand their contractual and regulatory obligations. The proposed changes are expected to have a positive effect on compliance with contractual and regulatory obligations.
Consultation opportunities	Consultation regarding these changes commenced in June 2011, to cease September 2011, with Approved Professional Bodies, business representative groups, practitioners and peak bodies representing clients. Information regarding consultation opportunities will be placed on the secure section of the Hearing Services Program website for providers and practitioners – this Determination is primarily relevant only to contracted service providers and practitioners.
Expected timetable	Date of effect 1 January 2012.
Contact details	Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au
Date last modified	September 2011

Title	<i>Amendment to the Hearing Services Providers Accreditation Scheme 1997</i>
Description of issue	<p>The Hearing Services Providers Accreditation Scheme 1997 describes the conditions under which new entities may be accredited prior to contracting with the Department of Health and Ageing for provision of hearing services under the voucher component of the Hearing Services Program. The proposed amendments would see relevant sections of the Rules of Conduct transferred to the Accreditation Scheme. Wording will be simplified and clarified to ensure all powers are expressly stated and that the Department of Health and Ageing is not relying on powers that are implied. A provision will be added to vary or suspend an accreditation in addition to the current ability to approve or revoke.</p> <p>The purpose and benefits of the proposed amendments are anticipated to be the streamlining of departmental administrative processes in the accreditation of new entities.</p>
Consultation opportunities	<p>Consultation regarding these changes commenced in June 2011, ceasing September 2011, with Approved Professional Bodies, business representative groups, practitioners and peak bodies representing clients. Information regarding consultation opportunities will be placed on the secure section of the Hearing Services Program website for providers and practitioners – the proposed amendments relate to applications by new entities to provide services under the Program and are sourced often from current Program providers.</p>
Expected timetable	Date of effect 1 January 2012.
Contact details	<p>Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au</p>
Date last modified	September 2011

Title	<i>Amendment to the Hearing Services Voucher Rules 1997</i>
Description of issue	<p>The Voucher Rules provide the conditions under which vouchers are issued to eligible clients under the Hearing Services Program. The amendments would remove the requirement for ongoing certification by a doctor or hearing services provider before the issuing of a voucher for services to existing clients of the Hearing Services Program.</p> <p>The purpose of, and the benefits of, the anticipated changes are to streamline the conditions around which vouchers are issued to return clients. The changes will positively affect contracted service providers who will have a more streamlined system to assist clients to access services and return clients who will have less red tape to contend with in accessing hearing services.</p>
Consultation opportunities	<p>Consultation regarding these changes commenced in June 2011, ceasing September 2011, with Approved Professional Bodies, business representative groups, practitioners and peak bodies representing clients. Information regarding consultation opportunities will be placed on the secure section of the Hearing Services Program website for providers and practitioners – the proposed amendments relate to the conditions of issuing of vouchers relevant to contracted service provider and practitioners.</p>
Expected timetable	Date of effect 1 January 2012.
Contact details	<p>Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au</p>
Date last modified	September 2011

Title	<i>Amendments to Private Health Insurance (Accreditation) Rules 2008</i>
Description of issue	<p>The Private Health Insurance (Accreditation) Rules 2008 set out the accreditation standards for treatment covered by a health insurance policy, for which a private health insurance benefit may be payable.</p> <p>The Rules will be amended to reflect the national accreditation requirements for health professionals that came into force following the establishment of the Australian Health Practitioners Regulation Agency and the Health Practitioner Regulation National Law.</p>
Consultation opportunities	The Department of Health and Ageing has consulted with the Australian Health Practitioners Regulation Agency.
Expected timetable	July-September 2011
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to Private Health Insurance (Benefit Requirements) Rules 2010</i>
Description of issue	<p>The <i>Private Health Insurance (Benefit Requirements) Rules</i> provide for the minimum benefit requirement for psychiatric, rehabilitation and palliative care and other hospital treatment, and the minimum level of benefits payable for hospital treatment including second tier default benefits. Various amendments to the <i>Private Health Insurance (Benefit Requirements Rules)</i> are planned in respect of these minimum requirements or benefit levels.</p>
Consultation opportunities	<p>The <i>Private Health Insurance (Benefit Requirements) Rules</i> are developed in consultation with state and territory government health departments, and with respect to the second tier default benefits, the Second Tier Advisory Committee which includes equal representation from both private hospital and private health insurance sectors, in addition to relevant state and territory government health departments.</p>
Expected timetable	Amendments will occur at various times throughout 2011-12.
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to Private Health Insurance (Complying Product) Rules 2010 (No 2)</i>
Description of issue	The <i>Private Health Insurance (Complying Product) Rules</i> have and will be amended in respect of the patient contribution payable by nursing-home type patients.
Consultation opportunities	Consultation occurred/occurs with state/territory governments.
Expected timetable	Amendments will occur at various times throughout 2011-2012.
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to Private Health Insurance (National Joint Replacement Register Levy) Rules 2010</i>
Description of issue	The <i>Private Health Insurance (National Joint Replacement Register Levy) Rules</i> specify the two levy days within a financial year on which the levy is imposed on each sponsor for joint replacement prostheses, set the rate of the levy and specify the two census days on which the number of joint replacement prostheses are determined, for purpose of calculating the rate of the levy. The levy amount will be re-calculated in 2011, prior to the first levy date in September 2011. The purpose of the levy is to fund the National Joint Replacement Registry.
Consultation opportunities	The levy is payable by industry sponsors of joint replacement prostheses. Prostheses List benefits are developed in consultation with industry and other stakeholders through Prostheses Listing Advisory Committee processes. The Department of Health and Ageing consults directly with the Australian Orthopaedic Association, which manages the National Joint Replacement Registry regarding the registry's funding.
Expected timetable	Before September 2011
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendments to Private Health Insurance (Prostheses) Rules 2011 (No 1)</i>
Description of issue	Various amendments to the <i>Private Health Insurance (Prostheses) Rules</i> will be made to update prostheses benefits, as required, throughout the year

Consultation opportunities	Prostheses List benefits are developed in consultation with industry and other stakeholders through Prostheses Listing Advisory Committee (PLAC) processes. The PLAC commenced in October 2010, replacing the Prostheses Devices Committee. Before October 2010, consultation occurred through the Prostheses Device Committee processes.
Expected timetable	The Prostheses List is released twice per year, each August and February.
Contact details	Peter Woodley Assistant Secretary Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 9490 Email: peter.woodley@health.gov.au
Date last modified	September 2011

Title	<i>Amendment to the Therapeutic Goods Regulations 1990</i>
Description of issue	<p>Changes to the <i>Therapeutic Goods Regulations 1990</i> are proposed in relation to a number of separate matters, including to:</p> <ol style="list-style-type: none"> 1. amend Regulation 10H of the Regulations (which deals with circumstances in which the person in relation to whom a biological is included in the Australian Register of Therapeutic Goods is taken to have changed) to make it clear that the offence for a failure by a person who is no longer a sponsor of a biological to return their certificate of inclusion is an offence of strict liability; 2. establish a new Advisory Committee on the Safety of Medical Devices (replacing the current Medical Device Incident Review Committee (the MDIRC), which is a subcommittee of the Advisory Committee on Medical Devices); 3. amend the evaluation fee at item 2C of Part 2 of Schedule 9 (which relates to evaluations associated with certain requests to the Secretary under subsections 9D(1), (2) or (3) of the <i>Therapeutic Goods Act 1989</i> for a variation of an entry in the Australian Register of Therapeutic Goods) to reduce that fee by 20 per cent to reflect the fact that an application fee has recently been introduced in the <i>Therapeutic Goods Regulations 1990</i> for such requests (item 2AC). The reduction of the evaluation fee in this regard was inadvertently not included in those recent amendments to the <i>Therapeutic Goods Regulations 1990</i>, and, as an interim measure until the <i>Therapeutic Goods Regulations 1990</i> are amended, applicants will only be required to pay the evaluation fee at the level that will apply once the fee is adjusted.

Consultation opportunities	<p>Relevant sponsors will be informed of the proposed amendment of the fee at item 2C of Part 2 of Schedule 9 described at paragraph 3 above, and of the interim measures mentioned. The changed status of the MDIRC would reinforce the government's response to the 2009 Health Technology Assessment Review, which recommended enhancements to the monitoring of medical devices to improve medical device safety.</p> <p>The Department of Health and Ageing called for submissions to this review from interested individuals and organisations from 27 March 2009 to 29 May 2009.</p> <p>The Therapeutic Goods Administration will consult with its key stakeholders on the specifics of this proposed amendment via its formal consultative forum, the Therapeutic Goods Administration Industry Consultative Committee.</p>
Expected timetable	December 2011 – timeframe within which the changes are expected to be in place.
Contact details	<p>Will Freebairn Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8979 Email: will.freebairn@tga.gov.au</p> <p>Matt Swainson Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8982 Email: matthew.swainson@tga.gov.au</p>
Date last modified	September 2011

Title	<i>Amendment to Therapeutic Goods Regulations 1990 – implementation of a new regulatory framework for biologicals</i>
Description of issue	Changes are required to the <i>Therapeutic Goods Regulations 1990</i> consequential to amendments to the <i>Therapeutic Goods Act 1989</i> through the <i>Therapeutic Goods Amendment (2009 Measures No. 3) Act 2009</i> for the new regulatory framework for biologicals.
Consultation opportunities	There have been a number of public consultations with all States and Territories and key professional groups which have continued to further clarify the development of the proposed framework.
Expected timetable	In November 2006 the Australian Health Ministers' Conference endorsed four classes of biologicals (according to risk level) for the proposed biological regulatory framework. Implementation was planned to coincide with the commencement of the Australia New Zealand Therapeutic Products Authority (ANZTPA), however negotiations to establish ANZTPA were suspended in July 2007. The Australian Government then agreed that the Therapeutic Goods Administration progress the implementation of the Australian Health Ministers' Conference-endorsed biologicals regulatory framework in an Australia-only context. The amended Therapeutic Goods Regulations commenced on the 31 May 2011. Stakeholders have been, and are continuing to be, consulted on specific provisions and details of the regulatory framework for biologicals.
Contact details	Glenn Smith Director Biological Sciences Section Therapeutic Goods Administration Ph: (02) 6232 8291 Email: glenn.smith@tga.gov.au
Date last modified	September 2011

Title	<i>Amendments to the Tobacco Advertising Prohibition Regulations 1993</i>
Description of issue	It is proposed to amend the <i>Tobacco Advertising Prohibition Regulations 1993</i> to prescribe specific requirements as to: <ol style="list-style-type: none"> 1. the size, content, format and location of tobacco advertisements on the internet or other electronic medium; 2. the inclusion of health warnings, warnings about age restrictions on the sale of tobacco products, information about any fees, taxes and charges payable in relation to tobacco products on the internet or other electronic medium; 3. age restricted access systems for access to tobacco advertisements on the internet or other electronic medium; and 4. other minor technical amendments.

Consultation opportunities	There will be a consultation process on the draft regulations in the six month period following passing of the Tobacco Advertising Prohibition Amendment Bill 2010 through Federal Parliament.
Expected timetable	Amendments to the regulations will occur in the six month period after the Tobacco Advertising Prohibition Bill 2010 has received Royal Assent.
Contact details	Simon Cotterell Assistant Secretary Drug Strategy Branch Population Health Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au
Date last modified	September 2011

Title	<i>Complaints Principles</i>
Description of issue	The <i>Complaints Principles</i> are intended to replace the <i>Investigation Principles 2007</i> as consequential amendments to the <i>Aged Care Amendment Bill 2011</i> to improve arrangements for the handling of complaints about Commonwealth funded aged care services.
Consultation opportunities	<p>Reform work is underway to shift the focus of the Aged Care Complaints Scheme from 'investigation' (where the Department of Health and Ageing investigates complaints and determines whether there has been a breach or not) to a more flexible scheme that employs a range of mechanisms to resolve a complaint including early resolution, conciliation, mediation and encouraging the parties to resolve the issue themselves.</p> <p>The Department of Health and Ageing conducted comprehensive consultation in relation to the Aged Care Complaints Scheme. A discussion paper on the proposed reforms to the Aged Care Complaints Scheme was issued and 33 submissions were received.</p>
Expected timetable	The proposed implementation date for the Complaints Principles is 1 September 2011
Contact details	Emily Grayson Director CIS Procedures & Information Management Section Aged Care Complaints Branch Office of Aged Care Quality and Compliance Ph: (02) 6289 7613 Email: emily.grayson@health.gov.au
Date last modified	September 2011

Title	<i>Health Insurance (Allied Health Services) Determination 2011</i>
Description of issue	<p>Amendments made to this Determination will 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).</p> <p>The option of an additional six from allied health services per year under exceptional circumstances will be removed</p>
Consultation opportunities	<p>Providers of Better Access mental health services and consumers will be informed of the changes to the mental health Medicare item numbers prior to 1 November 2011.</p> <p>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 to General Practitioners and Allied Mental Health providers.</p>
Expected timetable	1 November 2011
Contact details	<p>Chris Killick-Moran Director Clinical Services Reform Section Mental Health Reform Branch Mental Health and Chronic Disease Division Department of Health and Ageing Phone: (02) 6289 7329 Email: chris.killick-moran@health.gov.au</p> <p>Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au</p>
Date last modified	September 2011

Title	<i>Health Insurance Amendment (Compliance) Bill 2010 [Compliance Bill]</i>
Description of issue	<p>The purpose of this Bill is to give effect to the second component of the Increased Medicare Benefits Scheme Compliance Audits initiative announced in the 2008-09 Budget by introducing:</p> <ul style="list-style-type: none"> • a requirement for persons (practitioners and specified third parties) to produce information to substantiate a Medicare benefit amount paid in respect of a professional service; • a civil penalty for specified third parties (such as corporate practices) who refuse to produce information relevant to substantiating services provided by a practitioner for which a Medicare benefit has been paid; and • a financial administrative penalty for certain practitioners who are unable to substantiate a Medicare benefit which has been paid in respect of a service.
Consultation opportunities	<p>Significant consultation has been, and continues to be conducted, with a broad range of stakeholders including medical professions, specialist colleges, allied health practitioners, privacy and consumer organisations. An exposure draft of the Compliance Bill and Privacy Impact Assessment was published in April 2009. In addition the Senate Community Affairs Legislation Committee held an Inquiry into Compliance Audits and reported on 17 June 2009. Following stakeholder comments, the initial Bill was amended and introduced into the House of Representatives on 17 September 2009.</p>
Expected timetable	<p>Introduced into the House of Representatives on 17 November 2010.</p>
Contact details	<p>Jennifer Campain A/g Assistant Secretary Medicare Benefits Branch Medical Benefits Division Department of Health and Ageing Ph: (02) 6289 6945 Email: jennifer.campain@health.gov.au</p>
Date last modified	<p>September 2011</p>

Title	<i>Health Insurance Amendment Regulations 2011 (No)</i>
Description of issue	These regulations provide new arrangements for general practitioners under the Better Access to Psychiatrists, Psychologists and General Practitioners through the Medicare Benefits Schedule initiative. Existing general practitioner Medicare Benefits Schedule items for the development of a General Practitioner Mental Health Treatment Plan will be replaced by new time tiered Medicare Benefits Schedule items under these new arrangements.
Consultation opportunities	Providers of Better Access mental health services and consumers will be informed of the changes to the mental health Medicare item numbers prior to 1 November 2011. Fact sheets relating to the changes will be made available on the Department of Health and Ageing's website. The Department will also work with the Department of Human Services to distribute information to General Practitioners and Allied Mental Health providers.
Expected timetable	1 November 2011
Contact details	<p>Chris Killick-Moran Director Clinical Services Reform Section Mental Health Reform Branch Mental Health and Chronic Disease Division Department of Health and Ageing Phone: (02) 6289 7329 Email: chris.killick-moran@health.gov.au</p> <p>Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au</p>
Date last modified	September 2011

Title	<i>Health Insurance (General Medical Services Table) Regulations 2011</i>
Description of issue	Indexation and other changes, including a change to provide new arrangements for general practitioners under the Better Access to Psychiatrists, Psychologists and General Practitioners through the Medicare Benefits Schedule initiative. General practitioner services will be time tiered under these new arrangements.
Consultation opportunities	Providers of Better Access mental health services and consumers will be informed of the changes to the mental health Medicare item numbers prior to 1 November 2011. 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 to General Practitioners and Allied Mental Health providers.
Expected timetable	1 November 2011, July 2012
Contact details	<p>Chris Killick-Moran Director Clinical Services Reform Section Mental Health Reform Branch Mental Health and Chronic Disease Division Department of Health and Ageing Phone: (02) 6289 7329 Email: chris.killick-moran@health.gov.au</p> <p>Jacqueline Mitchell Director Chronic Disease and Allied Health Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 8072 Email: jacqueline.mitchell@health.gov.au</p> <p>Jenny Williams Director Schedule review and Production Section Medicare Benefits Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 5892 Email: jacqueline.mitchell@health.gov.au</p>
Date last modified	September 2011

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment (International Agreements) Regulations 2012</i>
Description of issue	The Regulations would introduce conditions or restrictions to allow the controlled introduction of a chemical subject to s106 of the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> .
Consultation opportunities	Consultation will occur through established mechanisms, including the National Industrial Chemicals Notification and Assessment Scheme Industry Government Consultative Committee. The Department of Sustainability, Environment, Water, Population and Communities will also be consulted.
Expected timetable	Amendments to regulation would be in place by 30 June 2012.
Contact details	Lewis Norman Team Leader Compliance and Enforcement Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8807 E-mail: lewis.norman@nicnas.gov.au
Date last modified	September 2011

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Bill 2011</i>
Description of issue	<p>This Bill will provide for a number of changes to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i>:</p> <ul style="list-style-type: none"> to enable the transfer of responsibility of some chemicals controlled under other regulatory schemes to the National Industrial Chemicals Notification and Assessment Scheme. In the first instance this will be used to transfer chemicals in certain cosmetic products from the Therapeutic Goods Administration to the National Industrial Chemicals Notification and Assessment Scheme; and to enhance administration of the assessment scheme and improve efficiency. <p>Regulatory Impact Analysis for the legislative amendments has been completed and will be made available at www.nicnas.gov.au.</p> <p>Consequential to the measure to enhance administration of the assessment scheme and improve efficiency are changes to the Schedule to the Act regarding data requirements for UV filters in cosmetics applied to the skin. These were included in the Bill.</p> <p>The Bill was reported in the 2010-11 Annual Regulatory Plan as the Industrial Chemicals (Notification and Assessment) Amendment (Existing Chemicals Reforms) Bill 2011. Two measures that were included in this</p>

	originally proposed Bill – the existing chemicals program measure and the measure to amend processes that will facilitate implementation of outcomes from the current NICNAS cost recovery review – are not being progressed via the Bill.
Consultation opportunities	The cosmetic reforms were agreed after extensive consultation between and across government, industry and the community, including the NICNAS Cosmetic Advisory Group, and a draft of the measure was exposed to the Cosmetic Advisory Group in November 2010. The measure to enhance the administration of the assessment scheme and improve efficiency was consulted upon via a public process on two occasions in 2010. A draft of the Inventory Amendment Bill was then exposed to the Cosmetic Advisory Group, as well as to the National Industrial Chemicals Notification and Assessment Scheme Industry Government Consultative Committee and the Community Engagement Forum, in June 2011. The changes to the Schedule to the Act were consulted upon at the same time and using the same mechanisms as the consultations on the amendments to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> .
Expected timetable	The Bill was introduced in Winter 2011 and is expected to be passed in Spring 2011, followed by Royal Assent soon after.
Contact details	<p>Technical: Dr Matthew Gredley Team Leader Reform Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8873 E-mail: matthew.gredley@nicnas.gov.au</p> <p>Policy: Dr Donald Ward Director Scheduling Secretariat Section Office of Chemical Safety and Environmental Health Branch Office of Health Protection Department of Health and Ageing Ph: (02) 6289 2662 E-mail: donald.ward@health.gov.au</p>
Date last modified	September 2011

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment Regulations 2011</i>
Description of issue	Consequential amendments as necessary flowing from the proposed 2011 amendments to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> to enable the transfer of responsibility for some chemicals controlled under other regulatory schemes to NICNAS and enhance administration of the assessment scheme and improve efficiency.
Consultation opportunities	The cosmetic reforms were agreed after extensive consultation between and across government, industry and the community, including exposure of the draft legislation to National Industrial Chemicals Notification and Assessment Scheme consultative committees. The administrative amendments were consulted upon via a public process on two occasions in 2010, and were also exposed as draft legislation to NICNAS consultative committees. The amendments to the Regulations will be the subject of regulatory impact analysis and will be subject to consultation in 2011-12 noting that these are consequential amendments arising from agreed changes to the Act.
Expected timetable	Early 2012, subject to Royal Assent of the Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Bill 2011 following passage through Parliament in Spring 2011.
Contact details	<p>Technical: Dr Matthew Gredley Team Leader Reform Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: matthew.gredley@nicnas.gov.au</p> <p>Policy: Dr Donald Ward Director Scheduling Secretariat Section Office of Chemical Safety and Environmental Health Branch Office of Health Protection Department of Health and Ageing Ph: (02) 6289 2662 E-mail: donald.ward@health.gov.au</p>
Date last modified	September 2011

Title	<i>Legislation to require plain packaging of tobacco products</i>
Description of issue	The legislation will restrict or prohibit: <ul style="list-style-type: none"> • tobacco industry logos • brand imagery • colours • promotional text other than brand and product names in a standard colour, position, font style and size.
Consultation opportunities	Targeted consultation regarding these changes was undertaken with tobacco retailer groups, the tobacco industry and cigar importers during late 2010 and early 2011. A 60 day public consultation period was undertaken between 7 April and 6 June 2011 on the Exposure Draft of this Bill accompanied by a Consultation Paper.
Expected timetable	Legislation to be enacted in 2011, coming into effect on 1 January 2012 with all tobacco products to be sold in plain packaging by 1 July 2012.
Contact details	Simon Cotterell Assistant Secretary Drug Strategy Branch Population Health Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au
Date last modified	September 2011

Title	<i>National Health (Australian Community Pharmacy Authority Rules) Determination 2011</i>
Description of issue	New pharmacy location rules to be determined by the Minister under section 99L of the <i>National Health Act 1953</i> , as part of the Fifth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.
Consultation opportunities	Consultation is to occur with a range of stakeholders, including the Pharmacy Guild of Australia, through an external review of the rules to be undertaken in the first six months of 2010 and detailed discussion of issues and potential changes during the second six months of 2010. The Pharmacy Guild of Australia is a signatory to the Fifth Community Pharmacy Agreement and is working with the Department of Health and Ageing to develop the amendments to the rules.
Expected timetable	The changes to the Ministerial Determinations (Pharmacy Location Rules) are expected to be complete by December 2011.
Contact details	Tony Wynd Director Pharmacy Location Rules Section Community Pharmacy Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7595 Email: tony.wynd@health.gov.au

Date last modified	September 2011
Title	<i>National Health Act 1953</i>
Description of issue	<p>Amendments to the <i>National Health Act 1953</i> and <i>National Health Regulations 1954</i> are required to enable the implementation of the 'Continued Dispensing in Defined Circumstances' and the 'Supply and Pharmaceutical Benefits Scheme Claiming for a Medication Chart in Residential Aged Care Facilities' initiatives agreed to under the Fifth Community Pharmacy Agreement by:</p> <ul style="list-style-type: none"> • extending the existing emergency supply requirements within State and Territory legislation under the <i>National Health Act 1953</i> to enable 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	<p>The Pharmacy Guild of Australia is a signatory to the Fifth Community Pharmacy Agreement and is working with the Department of Health and Ageing to develop and implement these initiatives.</p> <p>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.</p> <p>Consultation for these initiatives will continue throughout their development.</p>
Expected timetable	1 July 2012 – Program implementation
Contact details	<p>Kim Bessell Assistant Secretary Community Pharmacy Branch Principal Pharmacy Adviser Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 8371 Email: kim.bessell@health.gov.au</p>
Date last modified	September 2011

Title	<i>Personally Controlled Electronic Health Record System (PCEHR) Bill</i>
Description of issue	<p>The personally controlled electronic health (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.</p> <p>The PCEHR Bill will support the establishment and implementation of the PCEHR system. It is anticipated that the PCEHR Bill will establish arrangements for operating the PCEHR system and establish processes for participation, enquiry and complaint. It will also recognise existing regulatory frameworks regarding the flow of health information and other associated legislation and quasi-regulation.</p>
Consultation opportunities	The Department of Health and Ageing has developed the proposed legislative framework in consultation with a working group of representatives from Commonwealth, state and territory health departments, as well as with other Commonwealth agencies. The proposed legislative framework is described in a Legislation Issues Paper, which was released in July 2011 for public consultation.
Expected timetable	The PCEHR system will commence from 1 July 2012.
Contact details	<p>Liz Forman Assistant Secretary eHealth Strategy Branch Primary and Ambulatory Care Division Department of Health and Ageing Ph: (02) 6289 1944 Email: liz.forman@health.gov.au</p>
Date last modified	September 2011

Title	<i>Personally Controlled Electronic Health Record System Regulations</i>
Description of issue	<p>The personally controlled electronic health (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.</p> <p>It is anticipated that PCEHR Regulations will be required to support the establishment and implementation of the PCEHR system. Details to be included in the Regulations are currently under consideration.</p>
Consultation opportunities	The Department of Health and Ageing has developed the proposed legislative framework in consultation with a working group of representatives from Commonwealth, state and territory health departments, as well as with other Commonwealth agencies. The proposed legislative

	framework is described in a Legislation Issues Paper, to be released in July 2011 for public consultation.
Expected timetable	The PCEHR system will commence from 1 July 2012. The enabling legislation must therefore be in place by 30 June 2012.
Contact details	Liz Forman Assistant Secretary eHealth Strategy Branch Primary and Ambulatory Care Division Department of Health and Ageing Ph: (02) 6289 1944 Email: liz.forman@health.gov.au
Date last modified	September 2011

Title	<i>Proposed implementation of a new Code of Good Manufacturing Practice for Human Blood and Blood Components, Human Tissues and Human Cellular Therapy Products</i>
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.
Consultation opportunities	Extensive consultation on the draft code has already been undertaken.
Expected timetable	December 2011
Contact details	Bill Turner Head Office of Manufacturing Quality Therapeutic Goods Administration Ph: (02) 6232 6822 Email: bill.turner@tga.gov.au
Date last modified	September 2011

Title	<i>Remaking the Hearing Services Rules of Conduct 2005</i>
Description of issue	These Rules regulate the registration of practitioners working under the voucher component of the Hearing Services Program. The Rules will be rewritten in plain English and grouped more logically. The proposed amendments will cease the registration of student audiometrists by the Department of Health and Ageing and require overseas trained practitioners, new practitioners and current practitioners who are members, to be a member of an Approved Professional Body. Approved Professional Bodies will be responsible for specifying and monitoring professional development requirements of their members rather than the Department of Health and Ageing. For existing qualified practitioners who are not a member of an Approved Professional Body, the Rules will require them to meet equivalent continued professional development standards.

	<p>The educational requirements of an audiometrist will be updated to bring it into line with current practice.</p> <p>The Minister's discretionary powers in relation to applying sanctions to a practitioner will be clarified.</p> <p>Qualified practitioners will have the same responsibility as contracted service providers (businesses) to provide quality services.</p> <p>The purpose and benefits of the anticipated changes is to streamline practitioner registration process for the Department of Health and Ageing, contracted service providers and practitioners. The changes will affect contracted service providers responsible for registering practitioners with the Department of Health and Ageing and new practitioners required to meet Approved Professional Body membership requirements – the registration process will be more streamlined and formalises what currently occurs – all new practitioners currently applying for registration are already Approved Professional Body members.</p>
Consultation opportunities	<p>Consultation regarding these changes has been ongoing since 2009, ceasing in September 2011, with Approved Professional Bodies, business representative groups, practitioners and peak bodies representing clients.</p> <p>Information regarding consultation opportunities has been placed on the secure section of the Hearing Services Program website for providers and practitioners and a series of electronic messages (Service Provider advices and e-Bulletins) to providers will also provide further information.</p>
Expected timetable	Date of effect 1 January 2012.
Contact details	<p>Lynne Clune Director Implementation Team Office of Hearing Services Branch Regulatory Policy and Governance Division Department of Health and Ageing Ph: (02) 6289 5411 Email: lynne.clune@health.gov.au</p>
Date last modified	September 2011

Title	<i>Residential Care Subsidy Amendment Principles</i>
Description of issue	<p>Amendments are intended for the Residential Care Subsidy Principles following a 2011-12 Budget Measure announcing the extension of the aged care viability supplement, currently 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 which suggests that some provider groups are likely to face greater pressures in transition to the Aged Care Funding</p>

	<p>Instrument which was introduced on 20 March 2008.</p> <p>Amendments to the Residential Care Subsidy Principles are required to expand current 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.</p> <p>The purpose of the <i>Residential Care Subsidy Amendment Principles 2011 (No. 1)</i> 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.</p>
Consultation opportunities	The extension of the viability supplement was undertaken following consultation with a range of stakeholders in the aged care sector and members of the Aged Care Funding Instrument expert reference group. The Department of Health and Ageing also consulted with the Prime Minister's Council on Homelessness.
Expected timetable	It is proposed that the amendments will take effect retrospectively from 1 July 2011
Contact details	<p>Dominique Hansen Director Aged Care Policy Section Policy and Evaluation Branch Ageing and Aged Care Division Ph: (02) 6289 7187 Email: dominique.hansen@health.gov.au</p>
Date last modified	September 2011

Title	<i>Review of Guidelines for Certification of Physical Containment Level 3 Laboratories issued by the Gene Technology Regulator</i>
Description of issue	The Gene Technology Regulator intends to review the existing Guidelines for Certification of a Physical Containment Level 3 Laboratories (PC3 Guidelines) issued under the <i>Gene Technology Act 2000</i> to ensure that they remain consistent and up to date with current legislation and other standards and guidelines.
Consultation opportunities	The Office of the Gene Technology Regulator (OGTR) will consult with key stakeholders on any proposed changes, including regulated organisations as well as States/Territories, government agencies and authorities, and the general public including via the OGTR website. Consultation is anticipated to commence in the second half of 2011.
Expected timetable	It is intended that the review be undertaken in 2011-12 and it is anticipated that any revised guidelines would be issued by mid-2012.
Contact details	<p>Rebecca Newton Evaluator Contained Dealings Evaluation Section</p>

	Evaluation Branch Office of the Gene Technology Regulator Ph: (02) 6271 4216 Email: rebecca.newton@health.gov.au
Date last modified	September 2011

Title	<i>Review of licence application form for Dealings Involving Intentional Release of Genetically Modified Organisms into the environment</i>
Description of issue	The <i>Gene Technology Act 2000</i> requires that licence applications must contain information specified by the Gene Technology Regulator. The Gene Technology Regulator intends to review the existing licence application form for 'Dealings involving Intentional Release of genetically modified organisms into the environment'. The aim of the review is to simplify and clarify requirements for applicants and to ensure that information requested is consistent with the legislation and up to date with current scientific knowledge.
Consultation opportunities	The Office of the Gene Technology Regulator (OGTR) will consult with key stakeholders on any proposed changes, including regulated organisations as well as States/Territories, government agencies and authorities. Consultation is anticipated to be undertaken in late 2011 and will also be notified on the OGTR website.
Expected timetable	It is intended that the review be undertaken in 2011-12 and it is anticipated that any revised form(s) will be issued in the first half of 2012.
Contact details	Will Tucker Manager Plant Evaluation Section Evaluation Branch Office of the Gene Technology Regulator Ph: (02) 6271 4234 Email: will.tucker@health.gov.au
Date last modified	September 2011

Title	<i>Revised arrangements for the efficient use of cancer chemotherapy drugs provided in infusion or injection</i>
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 will reduce wastage by ensuring that each prescription is written for an individual dose, and will mandate the use of a dispensing algorithm that will select the most appropriate 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 will

	<p>provide for specific reimbursement for this activity.</p> <p>These arrangements will be made possible through the introduction of a new legislative instrument made under section 100 of the <i>National Health Act 1953</i>.</p>
Consultation opportunities	Consultation on the impacts of this measure has been undertaken with all major stakeholders.
Expected timetable	The arrangements will commence from 1 December 2011.
Contact details	<p>Bruce Griffin Director Hospital Pharmaceuticals Section Access and Systems Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 2340 Email: bruce.griffin@health.gov.au</p>
Date last modified	September 2011

Title	<i>Tobacco Advertising Prohibition Amendment Bill 2010</i>
Description of issue	<p>The Tobacco Advertising Prohibition Amendment Bill 2010 will:</p> <ol style="list-style-type: none"> 1. make it a specific offence to advertise or promote tobacco products on the internet and all other electronic media and future technologies unless compliant with state and territory legislation or Commonwealth regulations; and 2. other minor and technical amendments.
Consultation opportunities	Consultation with the tobacco industry, state and territory governments and non-government organisations was conducted during the development of the Regulation Impact Statement.
Expected timetable	The <i>Tobacco Advertising Prohibition Amendment Bill 2010</i> passed the House of Representatives on 22 March 2011. The Bill was introduced in the Senate on 23 March 2011 and is due to be debated in the Senate during the parliamentary winter sittings period, commencing 4 July 2011.
Contact details	<p>Simon Cotterell Assistant Secretary Drug Strategy Branch Population Health Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au</p>
Date last modified	September 2011

Title	<i>Review of certain guidelines issued by the Gene Technology Regulator</i>
Description of issue	The Gene Technology Regulator intends to review a number of existing guidelines issued under the <i>Gene Technology Act 2000</i> . The objective of the review is to ensure that guidelines remain up to date with current scientific knowledge and consistent with other standards

	<p>and guidelines. The guidelines proposed for review are:</p> <ol style="list-style-type: none"> 1 Guidelines for the Accreditation of Organisations 2 Guidelines for Certification of a Physical Containment Level 2 Laboratory 3 Guidelines for Certification of a Physical Containment Level 2 Animal Facility 4 Guidelines for Certification of a Physical Containment Level 2 Plant Facility 5 Guidelines for Certification of a Physical Containment Level 2 Invertebrate Facility 6 Guidelines for Certification of a Physical Containment Level 2 Aquatic Organism Facility
Consultation opportunities	The Office of the Gene Technology Regulator (OGTR) will consult with key stakeholders on any proposed changes, including regulated organisations as well as States/Territories, government agencies and authorities, and the general public, including via the OGTR website. It is anticipated that consultation will be undertaken in 2011 – 2012.
Expected timetable	It is intended that the reviews be undertaken in 2011-12 and it is anticipated that any revised guidelines will be issued by late 2012.
Contact details	<p>Ian Coleman Manager Application and Licence Management Section Evaluation Branch Office of the Gene Technology Regulator Ph: (02) 6271 4205 Email: ian.coleman@health.gov.au</p>
Date last modified	September 2011

Title	<i>Review of Guidelines for Certification of Physical Containment Level 3 Laboratories issued by the Gene Technology Regulator</i>
Description of issue	The Gene Technology Regulator intends to review the existing Guidelines for Certification of a Physical Containment Level 3 Laboratories (PC3 Guidelines) issued under the <i>Gene Technology Act 2000</i> to ensure that they remain consistent and up to date with current legislation and other standards and guidelines.
Consultation opportunities	The Office of the Gene Technology Regulator (OGTR) will consult with key stakeholders on any proposed changes, including regulated organisations as well as States/Territories, government agencies and authorities, and the general public including via the OGTR website.. Consultation is anticipated to commence in the second half of 2011.
Expected timetable	It is intended that the review be undertaken in 2011-12 and it is anticipated that any revised guidelines would be issued by mid-2012.
Contact details	<p>Rebecca Newton Evaluator Contained Dealings Evaluation Section</p>

	Evaluation Branch Office of the Gene Technology Regulator Ph: (02) 6271 4216 Email: rebecca.newton@health.gov.au
Date last modified	September 2011

Title	<i>User Rights Principles</i>
Description of issue	Amendments are intended for the <i>User Rights Principles 1997</i> , as consequential amendments to the <i>Aged Care Amendment Bill 2011</i> . These amendments would strengthen consumer protection for accommodation bonds paid to aged care services
Consultation opportunities	The Department of Health and Ageing conducted comprehensive consultation with industry, community and government stakeholders in relation to the proposed enhancements to the prudential regulation of accommodation bonds. Consultation on the proposed prudential reforms included the release of an Issues Paper and a Consultation Paper seeking comment on the design of the reforms. In total, 60 submissions were received and the Department of Health and Ageing conducted over 45 consultation meetings. Overall, stakeholders did not support the current regulatory regime (status quo) and broadly agreed that reforms were necessary and appropriate.
Expected timetable	The proposed implementation date for the amendments to the <i>User Rights Principles 1997</i> is 1 August 2011.
Contact details	Mike Burns Director Prudential and Approved Provider Standards Section Prudential and Approved Provider Regulation Branch Office of Aged Care Quality and Compliance Department of Health and Ageing Ph: (02) 6289 7294 Email: mike.burns@health.gov.au
Date last modified	September 2011

Title	<i>Post-Implementation Review – Annotation of the Australian Inventory of Chemical Substances (AICS) in respect of certain lead compounds</i>
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 OBPR requirements, post-implementation review of the impact of the annotation on industry and the community will be conducted.
Consultation opportunities	Consultation with stakeholders will occur 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.
Expected timetable	The review is being progressed with consultations expected to occur in the second half of 2011.

Contact details	Dr Matthew Gredley Team Leader Reform Section National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: matthew.gredley@nicnas.gov.au
Date last modified	September 2011

Title	<i>Post-Implementation Review – Retention of the Pharmacy Location Rules</i>
Description of issue	<p>The <i>Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act 2010</i> provides for amendments to the <i>National Health Act 1953</i> relating to the arrangements for approving pharmacists to supply pharmaceutical benefits to the community.</p> <p>Under the <i>National Health Act 1953</i> 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.</p> <p>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.</p> <p>The <i>National Health Act 1953</i> 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.</p>
Consultation opportunities	Consultation on the impacts of the measures is expected to be conducted in 2011.
Expected timetable	Post Implementation Review to be completed by 1 July 2012.
Contact details	Tony Wynd Director Pharmacy Location Rules Section Community Pharmacy Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7595 Email: tony.wynd@health.gov.au
Date last modified	September 2011

Title	<i>Post-Implementation Review – Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Act (No.2) 2008</i>
Description of issue	The <i>Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Act (No. 2) 2008</i> (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.
Consultation opportunities	<p>Consumers were invited to comment on the changes to the Medicare Levy Surcharge income thresholds via a Consumer's Health Forum newsletter in May 2010. No further consultation has been carried out specifically for the Post-Implementation Review.</p> <p>The Post-Implementation Review draws upon consultations held for the Senate Inquiry into the Medicare Levy Surcharge Thresholds in 2008; consultation undertaken in 2009 for the Review of the impact of the new Medicare Levy Surcharge thresholds on public hospitals; and feedback on the impact of the new Medicare Levy Surcharge thresholds given by insurers for premium increase applications in 2008 and 2009.</p>
Expected timetable	Expected completion end 2011.
Contact details	Alastair Wilson Director Budget and Data Analysis Private Health Insurance Branch Medical Benefits Division Department of Health and Ageing Email: alastair.wilson@health.gov.au Phone: (02) 6289 4078
Date last modified	September 2011