Department of Health and Ageing
2010-11 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'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: February 2011

Past changes

Title	***Allocation Amendment Principles 2009 (No.2)***
Description of issue	The Allocation Principles 1997, made under subsection 96-1(1) of the *Aged Care Act 1997*, were amended to specify care-leavers as a class of people with special needs. The amendment is intended to ensure that approved providers are assisted to provide care that is appropriate and responsive to the care needs of people who experienced childhood in an institution or out-of-home care environment.
Date of effect	1 December 2009
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	**Amendment to *Therapeutic Goods (Medical Devices) Regulations 2002; Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 1)*; *Therapeutic Goods Amendment Regulations 2010 (No. 1)***
Description of issue	These Regulations amend the *Therapeutic Goods Regulations 1990*, *Therapeutic Goods (Medical Devices) Regulations 2002*, and *Therapeutic Goods (Charges) Regulations 1990* to increase by 2.4% most annual charges and fees payable in relation to therapeutic goods and manufacturing licences regulated under the *Therapeutic Goods Act 1989*.
Date of effect	1 July 2010
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Classification Amendment Principles 2009 (No.1)***
Description of issue	The *Classification Principles 1997* were amended to adjust the definition of high and low-level care under the Aged Care Funding Instrument to rectify an anomaly which was causing some permanent care recipients to be incorrectly classified as high care when they do not require high care.
Date of effect	1 January 2010
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Flexible Care Subsidy Amendment Principles 2010 (No.1)***
Description of issue	The *Flexible Care Subsidy Principles 1997* were amended to extend their operation to a new kind of care for which flexible care may be payable and makes a minor technical amendment to update the definition of 'Aged Care Assessment Team'.
Date of effect	1 July 2010
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Health Care Identifiers Act 2010*, *Healthcare Identifiers (Consequential Amendments) Act 2010* and *Healthcare Identifiers Regulations 2010***
Description of issue	These Acts and Regulations established the Healthcare Identifiers (HI) Service which commenced on 1 July 2010. Medicare Australia is the Service Operator. Healthcare identifiers will be assigned by the HI 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	***Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act 2010***
Description of issue	a) This Act amended the Private Health Insurance Act 2007, to address some anomalies that inadvertently advantaged or disadvantaged some people with respect to the application of the lifetime health cover policy provisions. b) This Act also amended the National Health Act 1953 to extend the Pharmacy Location Rules and the operation of the Australian Community Pharmacy Authority (ACPA) until 30 June 2015.
Date of effect	28 June 2010

Contact details	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 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

Title	***Health Insurance Amendment Regulations 2010 (No. 1)***
Description of issue	The regulations are part of the implementation of the *Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010* (the Amendment Act). The Amended 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. The amendments to the *Health Insurance Regulations 1975*, 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 services.
Date of effect	1 November 2010
Contact details	Janette Dunn Director Nursing Midwifery and Mental Health Finance Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 4101 Email: janette.dunn@health.gov.au

Title	**Health Insurance Amendment (Extended Medicare Safety Net) Act 2009 and Health Insurance (Extended Medicare Safety Net) Determination 2009**
Description of issue	The Act amends the *Health Insurance Act 1973* to allow the Minister for Health and Ageing to determine, by legislative instrument, the Medicare items that will be subject to an EMSN benefit cap and the level of the EMSN benefit cap. The 'EMSN benefit cap' is the upper limit on the amount of benefit payable under the EMSN for a Medicare item. The Determination sets out the Medicare items that have an EMSN benefit cap and the cap amount applying to each item.
Date of effect	1 January 2010
Contact details	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

Title	**Health Insurance (Allied Health Services) Amendment Determination 2010 (No 2)**
Description of issue	This Determination amends the Health Insurance (Allied Health Services) Determination 2009 (No. 2) 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	Janette Dunn Director Nursing Midwifery and Mental Health Finance Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 4101 Email: janette.dunn@health.gov.au

Title	***Health Insurance (General Medical Services Table Amendment Regulations 2010) No. 4***
Description of issue	These regulations make changes to the 'Better Access to Psychiatrists, Psychologists and General Practitioners through the Medicare Benefits Schedule initiative' to enable appropriately qualified GPs to provide focused psychological strategies services regardless of practice setting.
Date of effect	1 July 2010
Contact details	Janette Dunn Director Nursing Midwifery and Mental Health Finance Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 4101 Email: janette.dunn@health.gov.au

Title	**Health Legislation Amendment (Midwives and Nurse Practitioners) Act 2010**
Description of issue	The Act amends the *Health Insurance Act 1973* and the *National Health Act 1953* to enable nurse practitioners and appropriately qualified and experienced midwives to request appropriate diagnostic imaging and pathology services for which Medicare benefits may be paid. It will also allow these health professionals to prescribe certain medicines under the Pharmaceutical Benefits Scheme (PBS).
Date of effect	The Act was passed by Parliament on 16 March 2010 and was granted royal assent 12 April 2010.
Contact details	Mark Booth Assistant Secretary Policy and Development Branch Primary and Ambulatory Care Division Department of Health and Ageing Phone: (02) 6289 8594 Email: mark.booth@health.gov.au

Title	**Health Insurance (Midwifery and Nurse Practitioner) Determination 2010**
Description of issue	The Health Insurance (Midwives and Nurse Practitioner) Determination 2010 will provide for the creation of new Medicare Benefits Schedule (MBS) items for eligible midwives and nurse practitioners (participating midwives and nurse practitioners) who are working in collaboration with a medical practitioner. Participating Midwives The midwifery item structure includes antenatal, intra-partum (delivery in a hospital setting) and postnatal services for up to six weeks following delivery. Participating Nurse Practitioners The nurse practitioner items will 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	Janette Dunn Director Nursing Midwifery and Mental Health Finance Section Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Phone: (02) 6289 4101 Email: janette.dunn@health.gov.au

Title	***Health Practitioner Regulation (Consequential Amendments) Act 2010***
Description of issue	This Act makes consequential amendments to the *Health Insurance Act 1973* to recognise and support the implementation of the National Registration and Accreditation Scheme for Health Professions. The *Health Practitioner Regulation (Consequential Amendments) Act 2010* 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	Kerri Kellett Director Registration and Accreditation Section Workforce Development Branch Health Workforce Division (02) 6232 3907 Email: kerri.kellett@health.gov.au

Title	**Import, export and monitoring arrangements for controlled drug substances**
Description of issue	The Office of Chemical Safety and Environmental Health has reviewed the relevant parts of the *Customs (Prohibited Imports) Regulations 1956* that relate to narcotic, psychotropic and precursor substances. This process has identified several substances that are controlled under domestic poisons legislation but not under import regulations. An amendment to the *Customs (Prohibited Imports) Regulations 1956* is proposed to ensure consistency with border and domestic poisons controls.
Date of effect	14 December 2010
Contact details	Darren Jones Director Treaties and Compliance Section Office of Chemical Safety and Environmental Health Branch Office of Health Protection Department of Health and Ageing Ph: (02) 6289 2686 Email: darren.jones@health.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2010**
Description of issue	The 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	**National Health (Collaborative arrangements for midwives) Determination 2010 and National Health (Collaborative arrangements for nurse practitioners) Determination 2010**
Description of issue	These determinations describe what constitutes *collaborative arrangements* for the purposes of the writing of prescriptions by *authorised midwives* and *authorised nurse practitioners* for supply of pharmaceutical benefits under the Pharmaceutical Benefits Scheme (PBS). Having a collaborative arrangement with a medical practitioner is a requirement for authorised midwives and authorised nurse practitioners as PBS prescribers.
Date of effect	17 July 2010
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	***National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010***
Description of issue	This Act amended the *National Health Act 1953*: • giving effect to the Further Pharmaceutical Benefits Scheme Pricing Reforms announced in the 2010-11 Budget (including expanded and accelerated price disclosure, and new statutory price reductions); • changing the approach to listing medicines for special supply arrangements and powers to make those arrangements; and • providing for collection of data related to supply of medicines where the price falls under the PBS co-payment.
Expected timetable	Most of the Further PBS Pricing Reform amendments, and changes for medicines supplied under special arrangements, commenced on 1 December 2010. Other amendments commence on 1 February 2011 and 1 April 2012.
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	***National Health Amendment (Pharmaceutical and Other Benefits – Cost Recovery) Act 2009***
Description of issue	The amendments in this Act were required to implement a 2008-09 Budget measure to cost recover processes relating to evaluating and pricing medicines, vaccines and other products for listing on the Pharmaceutical Benefits Scheme and National Immunisation Programme. Fees will be charged to sponsors (generally, the pharmaceutical industry) who bring submissions for listing products to the Pharmaceutical Benefits Advisory Committee for consideration. Details of the cost recovery scheme, including a schedule of fees, are specified in Regulations. Amendments to the Bill, accepted by the Government, provide for an independent review of the impact of PBS cost recovery measure after two years of the passage of the Bill (i.e. in the latter half of 2011).
Date of effect	Cost Recovery commenced on 1 January 2010 as specified in the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009*.
Contact details	Adriana Platona A/g Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	**National Health (Eligible midwives) Determination 2010**
Description of issue	This determination specifies the requirements for a midwife to be an *eligible midwife* for the purposes of Part VII of the *National Health Act 1953.* This Act provides the legislative basis for supply of pharmaceutical benefits under the Pharmaceutical Benefits Scheme (PBS), and includes who may prescribe pharmaceutical benefits.
Date of effect	1 July 2010
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	***National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009***
Description of issue	These Regulations establish the requirements and conditions for cost recovery fees to be applied to the evaluation, pricing and listing medicines and vaccines on the Schedule of Pharmaceutical Benefits and National Immunisation Programme.
Date of effect	1 January 2010.
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	***National Health (Pharmaceutical Benefits) Amendment Regulations 2010* (PBS Reforms)**
Description of issue	These amendments give effect to changes to the price disclosure arrangements flowing from further Pharmaceutical Benefits Scheme Pricing Reforms announced in the 2010-11 Budget, and revoke formulary allocations for PBS listing drugs because they are no longer required in the Regulations.
Date of effect	1 December 2010

Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	***National Health (Pharmaceutical Benefits) Amendment Regulations 2010***
Description of issue	The *National Health (Pharmaceutical Benefits) Regulations 1960* were amended to extend the requirements and conditions for the writing of prescriptions for supply of pharmaceutical benefits under the Pharmaceutical Benefits Scheme (PBS) to include *authorised midwives* and *authorised nurse practitioners* as PBS prescribers.
Date of effect	8 June 2010 for matters relating to approval of midwives and nurse practitioners as authorised PBS prescribers. 1 November 2010 for writing of PBS prescriptions by these prescribers.
Contact details	Adriana Platona A/g Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au

Title	**NICNAS Nanomaterials Administrative Changes 2011**
Description of issue	Introduction of new procedures and data requirements for new chemicals notification and assessment of industrial nanomaterials.
Date of effect	Changes for notification and assessment procedures are in place from 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	***Private Health Insurance (Benefit Requirement) Rules***
Description of issue	These Rules provide for the minimum 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.
Date of effect	July 2009, March 2010, April 2010, June 2010
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	***Private Health Insurance (Complying Product) Rules***
Description of issue	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. The Rules were amended in September 2009 to remove temporary provisions for extended family policies that were no longer required following amendments to the *Private Health Insurance Act 2007* which introduced permanent provisions for such policies. The amendments were consequential to the amendments to the *Private Health Insurance Act 2007,* contained in the *Private Health Insurance Legislation Amendment Act 2009*. Consultation occurred with the private health insurance industry. The 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.
Date of effect	September 2009, January 2010, March 2010
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	***Private Health Insurance (Levy Administration) Rules 2010***
Description of issue	These Rules specify the payment days for various private health insurance levies. With the commencement of the Private Health Insurance (National Joint Replacement Register) Levy, consequential amendments were made to these rules, to specify the payment days for that levy.
Date of effect	23 June 2010
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	***Private Health Insurance (National Joint Replacement Register Levy) Rules 2010***
Description of issue	The Rules give effect to the *Private Health Insurance (National Joint Replacement Register Levy) Act* 2009 by specifying the two levy days within a financial year on which the levy is imposed on each sponsor for joint replacement prostheses. The Rules also 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.
Date of effect	12 March 2010
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	***Private Health Insurance (Prostheses) Rules***
Description of issue	Various amendments to the Rules were made to update prostheses benefits, as required throughout the year.
Date of effect	August 2009, February 2010
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	***Private Health Insurance Legislation Amendment Act 2009***
Description of issue	The *Private Health Insurance Act 2007* was amended to enable private health insurers to allow insurers to permanently offer extended family policies that cover 'dependent child non-students'. 'Dependent child non-students' are people aged from 18 to 24 with no partner where defined in a private health insurer's fund rules. Family policies, or policies with more than one person including a 'dependent child non-student', may be offered at an additional premium cost. Consequential amendments were also made that were consistent with the introduction of the *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*, which imposes a levy to fund the National Joint Replacement Registry. In addition, amendments were made to the *Age Discrimination Act 2004* to provide that compliance with provisions concerning 'dependent child non-students' does not breach age discrimination requirements.
Date of effect	1 July 2009
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	***Private Health Insurance Legislation Amendment Act 2010 (No 1)***
Description of issue	The *Private Health Insurance Act 2007* was amended to enable the Minister for Health and Ageing to: a) specify the clinical conditions for which a benefit would be payable for particular prostheses listed on the Commonwealth Prostheses List ("the list"); and b) specify criteria in the Private Health Insurance (Prostheses) Rules for listing particular prostheses on the list.
Date of effect	13 April 2010
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	Review of the Medicare Benefits Schedule (MBS) Primary Care Items
Description of issue	Amendments to the Health Insurance (General Medical Services Table) Regulations 2009 on 1 May 2010, implemented the recommendations of the MBS Review. They are aimed at simplifying the Schedule and encouraging prevention activities. MBS item numbers were reduced from 85 to 33 – a total reduction of 52 items. The item descriptors for MBS primary care items were clarified; after hours items were simplified; the structures of health assessments and fees were rationalised; and chronic disease management items were simplified.
Date of effect	1 May 2010
Contact details	Chris Wall Assistant Secretary (A/g) Medicare Financing and Analysis Branch Medical Benefits Division Department of Health and Ageing Ph (02) 6289 8642 Email: chris.wall@health.gov.au

Title	***Residential Care Subsidy Amendment Principles 2009 (No.1)***
Description of issue	The *Residential Care Subsidy Principles 1997* were amended in line with changes to the *Aged Care Act* 1997 and *Social Security Act 1997* to ensure that people in receipt of pensions are not charged higher aged care fees than intended and there is an equitable and appropriate flow of the 20 September 2009 pension increase to both the care recipient and approved providers.
Date of effect	20 September 2009
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Residential Care Subsidy Amendment Principles 2009 (No.2)***
Description of issue	The *Residential Care Subsidy Principles 1997* were amended to implement the 2009 -10 Budget Measure – *Measures to Support Older Australians* designed to rectify income testing arrangements for residential aged care are aligned with those applying to other types of aged care.
Date of effect	1 January 2010
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Residential Care Subsidy Amendment Principles 2010 (No.1)***
Description of issue	The *Residential Care Subsidy Principles 1997* were amended to reduce regulatory burden on Commonwealth funded aged care providers by implementing changes to reporting requirements for the Conditional Adjustment Payment, as agreed by the Government response to the Productivity Commission's Annual Review of Regulatory Burdens on Business: Social and Economic Infrastructure Service.
Date of effect	1 July 2010

Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	***Social Security and other Legislation Amendment (Pension Reform)* and *Other 2009 Budget Measures) Act 2009* (Schedule 17)**
Description of issue	Amendments to *Aged Care Act 1997* and the Aged Care Principles ensured that the increase in the pension flowed appropriately and equitably to both the care recipient and the approved provider.
Date of effect	20 September 2009
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	**SSBA Regulatory Scheme – Amendments to Part 3 of the** *National Health Security Act 2007*
Description of issue	Part 3 of the *National Health Security Act 2007* establishes controls to regulate handling of security-sensitive biological agents (SSBAs). The National Health Security Amendment Bill 2009 (the Bill), introduced: 1. provisions to address emergency disease situations; 2. regulation of a presumed or suspected SSBA; 3. provisions for additional search and seizure powers for inspectors and enabling them to seek police assistance; 4. reporting of certain SSBA related events to law enforcement agencies, in addition to the requirement to report those events to the Secretary; 5. enabling the Secretary to decide that an entity need not continue to be a 'registered entity'; and 6. minor and technical amendments to clarify the definitions of 'biological agents' and to enable 'nil' reports of reportable events. The Bill enabled the SSBA Standards and the regulations to provide further operational detail. The SSBA Standards were revised in January 2010 to include requirements relating to handling suspected SSBAs and the *National Health Security Amendment Regulations 2009* prescribed the events when an entity must report to police and the reporting of events for which there are no changes ('nil' reports). In early 2010 the *National Health Security Amendment Regulations 2010 (No 1)* amended the *National Health Security Regulations 2008* to provide for additional exempt entities, make minor changes to streamline the terminology used and to update legislative references. The National Health Security Amendment (Background Checking) Bill 2009 (the Background Checking Bill) received Royal Assent in May 2010 and amended the NHS Act to enable background checks to be conducted by AusCheck, a portfolio of the Attorney General's Department. The SSBA Standards were amended in July 2010 to include requirements for entities to conduct background checks against a list of disqualifying offences.

	Although requirements for background checking had been included in an earlier version of the SSBA Standards, those requirements were removed and the background checking requirements were subsequently included in a revised version of the SSBA Standards of 14 July 2010.
Date of effect	The National Health Security Amendment Bill 2009 was introduced into the House of Representatives on 24 June 2009 and received Royal Assent on 7 October 2009 and the related *National Health Security Amendment Regulations 2009* commenced on 16 December 2009. The *National Health Security Amendment Regulations 2010 (No 1)* commenced on 18 June 2010. 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	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

Title	***Therapeutic Goods Amendment (Medical Devices and Other Measures) Act 2009***
Description of issue	This Act amended the *Therapeutic Goods Act 1989* to: 1. exempt medical devices in certain circumstances from provisions in the Act. This will allow medical devices to be stockpiled to deal with possible national emergencies or be made available quickly in the case of actual emergencies; 2. allow for a wider range of therapeutic goods information to be provided to the public and for the Therapeutic Goods Administration to release information to Commonwealth agencies or international authorities under a wider range of circumstances to support safety and quality in therapeutic goods; 3. apply the same requirements to both pre-approved and other advertisements that contain restricted representations about therapeutic goods; 4. allow for medicines and other therapeutic goods that are not medical devices to meet the requirements of the European Pharmacopoeia or the United States Pharmacopoeia as alternatives to the British Pharmacopoeia; 5. revise the existing 'fit and proper person' test (for the granting of licences for the manufacturing of therapeutic goods other than medical devices and for issuing conformity assessment certificates for the manufacture of medical devices) with a test that is narrower and more transparent and will be easier to administer.
Date of effect	Items 1, 2 and 3 - 18 June 2009; item 4 - 1 July 2009; item 5 - 1 December 2009.
Contact details	Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: (02) 6232 8230 Email: terry.lee@tga.gov.au

Title	***Therapeutic Goods Amendment (2009 Measures No. 1) Act 2009***
Description of issue	This Act amends the *Therapeutic Goods Act 1989* to: 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 Act 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 Act; 6. incorporate a new framework for the regulation of homoeopathic and anthroposophic medicines with details in regulations and other subordinate legislation made under the Act 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. These amendments will also require the making of legislative instruments for the purposes of specified provisions under this Amendment Act.
Date of effect	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.
Contact details	Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: (02) 6232 8230 Email: terry.lee@tga.gov.au

Title	***Therapeutic Goods Amendment (2009 Measures No. 2) Act 2010***
Description of issue	This Act amended the *Therapeutic Goods Act 1989* to: 1. implement separate scheduling arrangements for medicines and chemicals; 2. enable the Secretary of the Department of Health and Ageing to declare specified purposes for which a kind of medical device if used for those purposes cannot be included in the Australian Register of Therapeutic Goods (eg: home-use test kits for serious illnesses) making them unlawful to be supplied to the public; 3. extend the circumstances in which consultation can occur with the Gene Technology Regulator in relation to therapeutic goods that are or contain genetically modified organisms (in addition to genetically modified products currently provided for under the Act); 4. amend the advertising provisions to provide that it is an offence for any person to advertise a therapeutic good inappropriately for an indication that has not been accepted in relation to the product; 5. amend the delegation provisions to enable the regulations to specify relevant persons for the purposes of exercising delegation under section 19A of the Act; and 6. introduce provisions to enable the Minister to specify, by legislative instrument, advisory statements required to be included on the labels of specified medicines. These amendments will also require the making of regulations and legislative instruments for the purposes of specified provisions under this amending Act, e.g. items 1, 2 and 6. For Item 2, a legislative instrument entitled Therapeutic Goods (Excluded

	Purposes) Specification 2010 has been registered in the Federal Register of Legislative Instruments and came into effect on 1 July 2010.
Date of effect	Item 1 commenced 1 July 2010; items 2 to 5 –commenced 30 September 2009; item 6 – commenced on 29 March 2010.
Contact details	Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: 02 6232 8230 Email: terry.lee@tga.gov.au

Title	***Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010* and associated *Therapeutic Goods (Charges) Amendment Act 2010***
Description of issue	The first of these Acts amended the *Therapeutic Goods Act 1989* to: 1. implement a new regulatory framework for the regulation of biologicals (human cellular and tissue based therapy products); 2. include a provision according the Commonwealth, the Secretary of the Department of Health and Ageing, their delegates and other specified persons immunity from civil action when exercising powers, duties or functions under the *Therapeutic Goods Act 1989* except when they do so in bad faith; 3. allow for the recall of goods that are entered in the Australian Register of Therapeutic Goods if it appears that the quality, safety, efficacy or presentation is unacceptable; 4. expand information gathering powers to enable information to be sought from sponsors whose therapeutic goods have been previously registered or listed; 5. clarify that unpaid annual charges are a debt owed to the Commonwealth to provide that they can be recovered; 6. make other minor technical amendments including by clarifying what is meant by 'new information' in relation to a review of decisions under section 60A of the Act. The amendments will also require the making of regulations and legislative instruments for the purposes of specified provisions under this Amendment Act. The *Therapeutic Goods (Charges) Amendment Act 2010* amended the *Therapeutic Goods (Charges) Act 1989* to: 1. enable relevant charges to be set in relation to the inclusion of biologicals in the Register (consequent to the new biologicals framework); 2. provide that the annual charge remains payable where a good is suspended from the Register.
Date of effect	*Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010* Item 1 is to commence on 31 May 2011; items 2 to 6 commenced on 1 June 2010. *Therapeutic Goods (Charges) Amendment Act 2010* Items 1 and 2 are to commence at the same time as item 1 of the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2010.*
Contact details	Terry Lee Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: 02 6232 8230 Email: terry.lee@tga.gov.au

Title	**Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010**
Description of issue	This Act amended the *Therapeutic Goods Act 1989* to: 1. introduce a scheme to allow for the supply of unapproved medical devices to substitute for approved devices that are in short supply or unavailable, similar to section 19A of the Act applying to medicines; 2. enable the listing of export-only variants of registered or listed medicines under section 26 of the Act; 3. provide stronger information gathering powers under section 31 of the Act; 4. amend the process for ministerial reconsideration of initial decisions by the TGA to require that any supporting information be provided with the request; 5. clarify the circumstances when a medical device application either for inclusion of the device in the Register or for a conformity assessment certificate can lapse to provide that this occurs where the relevant fee remains unpaid; 6. clarify the provisions that allow the Minister to determine a list of permitted and prohibited ingredients applying to medicines that are required to be listed under section 26A; and 7. formalise the process for the submission and approval of product information for certain medicines. The amendments will also require the making of legislative instruments for the purposes of specified provisions under this Act including under items 2, 6 and 7.
Date of effect	Item 1 commenced the day the Act received Royal Assent (15 December 2010), items 2 to 5 commenced the day after Royal Assent (16 December 2010), and items 6 and 7 commenced 28 days after Royal Assent (12 January 2011).
Contact details	Philippa Horner Principal Legal Adviser Therapeutic Goods Administration Ph: 02 6232 8881 Email: philippa.horner@tga.gov.au
Date last modified	February 2011

Title	***Therapeutic Goods Amendment Regulations 2010 (No. 3)*; *Therapeutic Goods (Medical Devices) Amendment Regulations 2010 (No. 2)*; and *Therapeutic Goods (Charges) Amendment Regulations 2010 (No. 1)***
Description of issue	These Regulations amend the *Therapeutic Goods Regulations 1990*, *Therapeutic Goods (Medical Devices) Regulations 2002*, and *Therapeutic Goods (Charges) Regulations 1990* to increase by 2.4% most annual charges and fees payable in relation to therapeutic goods and manufacturing licences regulated under the *Therapeutic Goods Act 1989*.
Date of effect	1 July 2010
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2009 (No. 5)***
Description of issue	These Regulations amend the *Therapeutic Goods Regulations 1990* to include a new part to administer and implement an infringement notice scheme. This scheme was incorporated into the *Therapeutic Goods Act 1989* in 2006 but its implementation was delayed due to Australia New Zealand Therapeutic Products Authority reforms.
Date of effect	11 September 2009
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2010 (No. 2)* – revised scheduling framework**
Description of issue	Changes were made to the *Therapeutic Goods Regulations 1990* to implement separate arrangements for the scheduling of medicines and chemicals and administrative arrangements applying to the advisory committees on scheduling.
Date of effect	1 July 2010
Contact details	Mick O'Connor Team Leader Recalls and Advertising Section Monitoring and Compliance Group Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au

Title	***Therapeutic Goods Amendment Regulations 2009 (No. 6)* – Advisory Committees**
Description of issue	Changes were made to the *Therapeutic Goods Regulations 1990* regarding membership, terms of reference and processes of committees that advise the Therapeutic Goods Administration in carrying out its regulatory functions.
Date of effect	1 January 2010, except for provisions relating to the Advisory Committee on Complementary Medicines which commenced on 25 January 2010.
Contact details	Mick O'Connor Team Leader Recalls and Advertising Section Monitoring and Compliance Group Therapeutic Goods Administration Ph: (02) 6232 8197 Email: mick.o'connor@tga.gov.au

Title	**User Rights Amendment Principles 2009 (No.2)**
Description of issue	The *User Rights Principles 1997* was amended to include a new Charter of Rights and Responsibilities for Community Care for people receiving community care, or flexible care in the form of Extended Aged Care at Home or Extended Aged Care at Home (Dementia).
Date of effect	1 October 2009
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au

Title	**Amendments to Therapeutic Goods (Medical Devices) Regulations 2002 and the Therapeutic Goods Regulations 1990**
Description of issue	Changes were made to the Therapeutic Goods (Medical Devices) Regulations 2002 to provide for the disposal of unused emergency medical devices which are no longer the subject of an exemption under section 41GS of the Therapeutic Goods Act 1989 (the Act) and to allow for the reduction of applicable assessment fees where an abridgement assessment of an IVD medical device application for a conformity assessment certificate or inclusion in the Register, is possible. Changes were also made to the Therapeutic Goods Regulations 1990 as a consequence of the introduction of subsection 18A(9B) in the Act and to make minor changes to other requirements relating to the disposal of unused emergency therapeutic goods that are no longer the subject of an exemption under section 18A of the Act. The introduction of subsection 18A(9B) in the Act made the notification requirements to specified persons in relation to emergency therapeutic goods redundant.
Date of effect	28 October 2010
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au

Title	**Development and implementation of *Private Health Insurance (National Joint Replacement Register Levy) Rules 2009***
Description of issue	Rules will be developed to enable the operating costs of the National Joint Replacement Registry to be recovered on each day specified (expected to be twice per year). The Rules will impose the levy on each joint replacement prostheses sponsor according to the number of prostheses they sponsor, at specified rates.
Consultation opportunities	The Department consulted with sponsors of joint replacement prostheses sponsors and with the National Joint Replacement Registry, to develop implementation models for the imposition of the levy.
Expected timetable	October-November 2009 (development), February 2010 (collection).
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	February 2011

Planned activities

Title	Amendments to *Health Insurance Regulations 1975* and other regulations
Description of issue	The amendments to the regulations will support amendments to the *Health Insurance Act 1973* made through the *Health Practitioner Regulation (Consequential Amendments) Act 2010*. The purpose of the amendments to the *Health Insurance Act 1973* together with the amendments to the regulations is to support the implementation of the National Registration and Accreditation Scheme (NRAS) for health professions by updating definitions in the HIA and subordinate legislation made under it and streamlining processes for the recognition of medical practitioners for the purposes of Medicare, including removing the current Vocational Register for general practitioners. Amendments to the following regulations are required: • *Health Insurance (General Medical Services Table) Regulations*; and • Repeal of *Health Insurance (Vocational Registration of General Practitioners) Regulations 1989*. Amendments to the following regulations may also be required: • *Health Insurance (Pathology Services Table) Regulations*; • *Health Insurance (Diagnostic Imaging Services Table) Regulations;* and • *National Health Regulations 1954*.
Consultation opportunities	A consultation process was conducted within the Department to advise on the proposed amendments to the regulations and seek input on any subordinate legislation affected by the proposed changes. 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.
Expected timetable	The *Health Practitioner Regulation (Consequential Amendments*) *Act 2010* is expected to be proclaimed in early 2011.
Contact details	Kerri Kellett Director Registration and Accreditation Section Workforce Development Branch Health Workforce Division (02) 6232 3907 Email: kerri.kellett@health.gov.au
Date last modified	February 2011

Title	Amendment to Hearing Services Rules of Conduct 2005
Description of issue	The *Hearing Services Rules of Conduct 2005* will be reviewed to achieve greater alignment of registration and approval requirements of practitioners under the Hearing Services Program with hearing industry professional body requirements.
Consultation opportunities	Consultation regarding these changes commenced in 2009 with approved professional bodies and industry representative groups representing hearing service providers.
Expected timetable	Expected date of effect 1 July 2011.
Contact details	Lynne Clune Director Quality Assurance Section 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	February 2011

Title	Amendments to ***Private Health Insurance (Benefit Requirement) Rules 2010***
Description of issue	The Rules 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 Rules are planned in respect of these minimum requirements or benefit levels.
Consultation opportunities	The Rules 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.
Expected timetable	Amendments occurred in July 2010, August 2010, September 2010, October 2010. Further amendments will occur at various times during 2010-11.
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	February 2011

Title	**Amendments to *Private Health Insurance (Complying Product) Rules 2010***
Description of issue	The Rules 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 occurred in July 2010, August 2010, September 2010. Further amendments will occur at various times in 2010-11.
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	February 2011

Title	**Amendments to *Private Health Insurance (Prostheses) Rules 2009***
Description of issue	The amendments will give effect to *Private Health Insurance Legislation Amendment Act 2010 (No 1)* by specifying criteria for listing identified prostheses on the Commonwealth Prostheses List (the List) which is contained in the Schedule of the Rules. The identified prostheses will be included in a new Part C of the List. Additionally, various amendments to the Rules are planned to update prostheses benefits, as required through 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 (PDC). Before October 2010, consultation occurred through the PDC processes.
Expected timetable	The Prostheses List is released twice per year. The most current is the August 2010 Prostheses List and the next release will be February 2011. (Part C will be in the February amendments).
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	February 2011

Title	**Amendment to *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations)**
Description of issue	Changes are required to the *Therapeutic Goods (Medical Devices) Regulations 2002* to add a new classification rule to Schedule 2 of the Regulations to reclassify all hip, knee and shoulder joint replacement implants from Class IIb to Class III medical devices.
Consultation opportunities	Consultation about this subject matter first occurred at the end of 2009. A discussion paper is proposed to be circulated in November 2010 to stakeholders which summarises the feedback from the previous consultation and proposes that the changes be implemented next year.
Expected timetable	June 2011 – Expected date legislative changes are to be in force.

Contact details	Anthony Millgate Director Market Authorisation Group Therapeutic Goods Administration Ph: (02) 6232 8520 Email: anthony.millgate@tga.gov.au
Date last modified	February 2011

Title	**Amendment to *Therapeutic Goods Regulations 1990* – implementation of a new regulatory framework for homoeopathic and anthroposophic medicines**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* to incorporate the detail of the regulatory framework for homoeopathic and anthroposophic medicines making therapeutic claims, to ensure they meet appropriate standards of safety, quality and efficacy.
Consultation opportunities	Consultation took place as part of the broader Australia New Zealand Therapeutic Products Authority process. Consultation with key Australian stakeholders on implementation in an Australia-only context is continuing.
Expected timetable	July 2011 – Expected date legislative changes are to be in force.
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au
Date last modified	February 2011

Title	***Amendments to the Tobacco Advertising Prohibition Regulations 1993***
Description of issue	It is proposed to amend the *Tobacco Advertising Prohibition Regulations 1993* to prescribe specific requirements as to: 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.
Expected timetable	Amendments to the regulations will occur in the six month period after the *Tobacco Advertising Prohibition Bill 2010* has been passed.
Contact details	Simon Cotterell Assistant Secretary Drug Strategy Branch Mental Health and Chronic Disease Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au
Date last modified	February 2011

Title	**Biosecurity legislation to replace the *Quarantine Act 1908***
Description of issue	The (Beale) Review of Australia's Quarantine and Biosecurity Arrangements proposed significant changes to the current quarantine system. One of the major recommendations of the Review was to replace the *Quarantine Act 1908* with modern legislation. The current Act is co-administered by the Department of Agriculture, Fisheries and Forestry (DAFF) and this Department. The new legislation is being developed primarily by DAFF, but all aspects affecting human biosecurity are being either co-developed or led by this Department. Specifically, the Bill seeks to: 1. Develop a new framework for managing biosecurity risks, providing flexibility to manage risks pre-border, at the border and post-border. 2. Update and modernise legislation to address biosecurity risks, including expanding and improving information gathering powers and the range and flexibility of biosecurity measures that can be used to address risks relating to human, animal and plant health. 3. Establish any new institutional arrangements required by DAFF to better administer the biosecurity system.
Consultation opportunities	An exposure draft of the proposed Bill will be released for public comment. It is proposed to invite submissions on the draft and to hold a series of meetings with stakeholders to discuss the Bill once it is released. The Department of Agriculture, Fisheries and Forestry (DAFF) is the lead agency for this Bill. DAFF has set up two small groups of industry stakeholders to aid it in the development of the legislation. Consultation will also occur on the development of subordinate legislation.
Expected timetable	Bill expected to be introduced to Parliament in 2012.
Contact details	Greg Flaherty Director Biosecurity Legislation Section Health Protection Policy Branch Office of Health Protection Department of Health and Ageing (02) 6289 2603 Email: greg.flaherty@health.gov.au
Date last modified	February 2011

Title	**Changes to the Cosmetics Standard 2007**
Description of issue	The management of UV filters used in certain cosmetic products, along with associated conditions and restrictions of use to maintain equivalency with current TGA requirements.
Consultation opportunities	Established consultative mechanisms including the NICNAS Cosmetic Advisory Group and wider stakeholder consultation.
Expected timetable	To be undertaken through 2010-11.
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
Date last modified	February 2011

Title	Health Insurance Amendment (Compliance) Bill 2010 [Compliance Bill]
Description of issue	To give effect to the second component of the Increased MBS Compliance Audits initiative announced in the 2008-09 Budget by introducing: • 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	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 were 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.
Expected timetable	Introduced into the House of Representatives on 17 November 2010.
Contact details	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
Date last modified	February 2011

Title	Industrial Chemicals (Notification and Assessment) Amendment (Existing Chemicals Reforms) Bill 2011
Description of issue	The amendments will provide for a number of changes to the *Industrial Chemicals (Notification and Assessment) Act 1989*: – to enable the transfer of responsibility of some chemicals controlled under other regulatory schemes to NICNAS. In the first instance this will be used to transfer chemicals in certain cosmetic products from the TGA to NICNAS – to streamline the secondary notification process and the development of new existing chemicals assessment products to reflect first tranche of agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program – to implement minor amendments of a machinery nature to facilitate implementation of outcomes from the NICNAS cost recovery review – to enhance administration of the assessment scheme and improve efficiency. A Regulatory Impact Analysis for the legislative amendments regarding the NICNAS Existing Chemicals Program will form part of the process and will be made available at www.nicnas.gov.au.
Consultation	The cosmetic reforms were agreed after extensive consultation between and

opportunities	across government, industry and the community, with current implementation in consultation with the NICNAS Cosmetic Advisory Group. Proposed changes to the Existing Chemicals Program were arrived at after broad consultation as part of the overall review of the Program. Implementation of recommendations arising from the review is being undertaken in consultation with the Implementation Steering Group (ISG). The ISG comprises government, industry and community representatives. For implementation of recommendations from the review of the Existing Chemicals Program, stakeholders will be consulted through a range of mechanisms. These will include NICNAS' established consultative mechanisms (the Industry Government Consultative Committee, the Community Engagement Forum, the State/Territory Memorandum of Understanding Group), and other state and territory consultative mechanisms in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation continuing in 2010-11.
Expected timetable	Bill expected to be introduced in Autumn 2011
Contact details	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 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
Date last modified	February 2011

Title	***Industrial Chemicals (Notification and Assessment) Amendment Regulations 2011***
Description of issue	Consequential amendments as necessary flowing from the proposed 2011 amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* to enable the transfer of responsibility of some chemicals controlled under other regulatory schemes to NICNAS and streamlining the secondary notification process and the development of new assessment products.
Consultation opportunities	The cosmetic reforms were agreed after extensive consultation between and across government, industry and the community, with current implementation in consultation with the NICNAS Cosmetic Advisory Group. Proposed changes to the Existing Chemicals Program were arrived at after broad consultation as part of the overall review of the Program. Implementation of recommendations arising from the review is being undertaken in consultation with the Implementation Steering Group (ISG). The ISG comprises government, industry and community representatives. For implementation of recommendations from the review of the Existing Chemicals Program, stakeholders will be consulted through a range of mechanisms. These will include NICNAS' established consultative mechanisms (the Industry Government Consultative Committee, the Community Engagement Forum, the State/Territory Memorandum of Understanding Group), and other state and territory consultative mechanisms in accordance with the protocols and principles in the NICNAS Community Engagement Charter, with consultation continuing in 2010-11.
Expected timetable	Mid-2011

Contact details	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 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
Date last modified	February 2011

Title	***Industrial Chemicals (Notification and Assessment) Amendment Regulations 2011***
Description of issue	The Regulations will introduce conditions or restrictions to allow the controlled introduction of a chemical subject to s106 of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Minor amendment of regulation 11C is required to clarify the conditions relating to the *Fuel Quality Standards Act 2000.*
Consultation opportunities	Established consultative mechanisms, including the NICNAS Industry Government Consultative Committee. The Australian Government Department of Sustainability, Environment, Water, Population and Communities (DSEWPAC) will also be consulted.
Expected timetable	Amendments to regulation expected to be in place by 30 June 2011.
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	February 2011

Title	**Legislative change to implement a revised framework for the advertising of therapeutic products**
Description of issue	Changes to the *Therapeutic Goods Act 1989* and *Therapeutic Goods Regulations 1990* are proposed to improve the existing arrangements for the advertising of therapeutic products.
Consultation opportunities	Extensive consultation was undertaken with the development of the advertising arrangements for implementation as part of the now suspended Australia New Zealand Therapeutic Products Authority. Further consultation on revised arrangements that will improve the existing advertising scheme for therapeutic goods by streamlining requirements and reducing regulatory burdens took place in the middle of 2010.
Expected timetable	July 2011 – Expected date legislative changes are to be in force.
Contact details	Terry Lee Assistant Secretary Office of Legal Services Regulatory Support Group Therapeutic Goods Administration Ph: (02) 6232 8230 Email: terry.lee@tga.gov.au
Date last modified	February 2011

Title	**National Health (Australian Community Pharmacy Authority Rules) Determination 2011**
Description of issue	New pharmacy location rules to be determined by the Minister under section 99L of the *National Health Act 1953*, as part of the Fifth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.
Consultation opportunities	Consultation 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 Commonwealth 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.
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	February 2011

Title	***National Health Act 1953***
Description of issue	Amendments to the National Health Act and National Health Regulations are likely to be required to enable the implementation of the 'Medication Continuance' and the 'Supply and Pharmaceutical Benefits Scheme Claiming for a Medication Chart in Residential Aged Care Facilities' programs agreed to under the Fifth Community Pharmacy Agreement by: • extending the existing emergency supply requirements within State and Territory legislation under the Act to enable pharmacists to supply and claim the

	maximum quantity of a Pharmaceutical Benefits Scheme (PBS) 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; • enabling pharmacists to supply and claim for PBS medications from a medication chart within a Residential Aged Care Facility without the need for a separate prescription; and • removing obsolete references to Nursing Homes within the Act.
Consultation Opportunities	The Pharmacy Guild of Australia is a signatory to the Fifth Agreement and is working with the Commonwealth Department of Health and Ageing to develop and implement these programs. Consultation with a range of stakeholders is underway to inform the development of the components, protocols and standards of the programs and this will in turn inform the legislative amendments required. Consultation will be carried out in a two phased approach: Phase 1: This phase will focus on consultations 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, Medicare Australia, state and territory Departments of Health and all relevant Divisions in the Department of Health and Ageing. Phase 2: Will focus on consultations with service providers and service consumers/users, including, but not limited to, prescribers, pharmacists, aged care industry groups and consumer groups.
Expected timetable	1 July 2012 – Program implementation
Contact details	Kim Bessell Principal Pharmaceutical Adviser Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 8371 Email: kim.bessell@health.gov.au
Date last modified	February 2011

Title	***National Health (Pharmaceuticals and Vaccines – Cost Recovery) Amendment Regulations 2010***
Description of issue	These minor consequential amendments were required as a result of legislative changes affecting drugs made available under section 100 programs. Specifically, repeated reference to section 100 drugs in the principal Regulations were updated, along with some other references to the *National Health Act 1953*.
Consultation opportunities	None, as these are minor administrative changes which do not affect the interpretation of fees and categories.
Expected timetable	Amendments commenced on 1 December 2010 to co-incide with commencement of the relevant amendments in Schedule 6 of the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010.*
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au
Date last modified	February 2011

Title	**National Health (Pharmaceutical Benefits authorised midwife criteria) Determination 2010** **National Health (authorised nurse practitioner criteria) Determination 2010**
Description of issue	These determinations will specify the requirements for an eligible midwife or nurse practitioner to be approved as an *authorised midwife* or *authorised nurse practitioner* for the purposes of Part VII of the *National Health Act 1953.* This Act provides the legislative basis for supply of pharmaceutical benefits under the Pharmaceutical Benefits Scheme (PBS), including who may prescribe pharmaceutical benefits.
Consultation opportunities	Consultation on implementation of arrangements for prescribing under the PBS by midwives and nurse practitioners has occurred with medical, midwifery, nursing, education and consumer representatives, and the Pharmaceutical Benefits Advisory Committee, between September 2009 and June 2010.
Expected timetable	The determinations are expected to be made in the first quarter of 2011.
Contact details	Adriana Platona Assistant Secretary Pharmaceutical Evaluation Branch Pharmaceutical Benefits Division Department of Health and Ageing Ph: (02) 6289 7585 Email: adriana.platona@health.gov.au
Date last modified	February 2011

Title	**NICNAS Data Requirements for new sunscreens- Changes to the Schedule to the *Industrial Chemicals (Notification and Assessment) Act 1989***
Description of issue	Revised data requirements and procedures for new chemicals notification and assessment of UV filters in cosmetics to align with the requirements of the TGA for these UV filters in sunscreen products.
Consultation opportunities	Established consultative mechanisms including the NICNAS Cosmetic Advisory Group, as well as broader stakeholder consultations.
Expected timetable	Mid-2011.
Contact details	Ms Hana Hamdan Team Leader Notification and Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 88 E-mail: hana.hamdan@nicnas.gov.au
Date last modified	February 2011

Title	**Quality of Care Amendment Principles 2010 (No.2)**
Description of issue	Amendments are intended for the *Quality of Care Principles 1997* to introduce the Community Care Common Standards for Australian Government community care programs, including community care in the form of Community Aged Care Packages (CACPs), and flexible care in the form of Extended Aged Care at Home (EACH) and Extended Aged Care at Home – Dementia (EACH-D).
Consultation opportunities	In 2004, following consultation with the sector an Australian Government review report identified there was need to streamline administrative arrangements for community care programs, including the standards and quality reporting processes required by these programs. Following a range of consultations with the community care sector, a draft set of Common Standards was jointly developed by the cross-jurisdictional Community Aged Care Officials (CACO) group. The draft Common Standards and associated common reporting arrangements were piloted nationally and further developed by

	a CACO working group. An external stakeholder reference group with membership from industry and consumer peak bodies, individual service providers and the Aged Care Standards and Accreditation Agency has been consulted throughout the process. In November 2009, CACO endorsed the new Community Care Common Standards Framework to establish a more streamlined quality reporting system for all community care programs.
Expected timetable	Prior to the proposed implementation of the Common Standards on 1 March 2011, further sector communication activities are planned in each state and territory to facilitate introduction of the Common Standards.
Contact details	Debbie Miller Director Legislation and Reform Unit Ageing and Aged Care Division Department of Health and Ageing Ph: (02) 6289 1044 Email: debbie.miller@health.gov.au
Date last modified	February 2011

Title	**Legislation to require plain packaging of tobacco products**
Description of issue	The legislation will restrict or prohibit: - 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	Consultation regarding these changes commenced in late November 2010 with tobacco retailer groups, and the tobacco industry. Broader public consultation, including with tobacco control advocacy groups will be finalised in 2011.
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 Mental Health and Chronic Disease Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au
Date last modified	February 2011

Title	**Post Implementation Review – Annotation of the Australian Inventory of Chemical Substances (AICS) in respect of certain lead compounds – post implementation review**
Description of issue	NICNAS annotated the AICS 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, NICNAS plans to conduct a post-implementation review of the impact of the annotation on industry and the community.
Consultation opportunities	Consultation with stakeholders will occur in accordance with the protocols and principles in the NICNAS Community Engagement Charter, and the Australian Government's Best Practice Regulation requirements.
Expected timetable	It is intended that the review will commence in 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	February 2011

Title	**Post-Implementation Review – Retention of the Pharmacy Location Rules**
Description of issue	The *Health Legislation Amendment (Australian Community Pharmacy Authority and Private Health Insurance) Act* 2010 provides for amendments to the *National Health Act* 1953 relating to the arrangements for approving pharmacists to supply pharmaceutical benefits to the community. Under the *National Health Act* 1953 a pharmacist is approved by the Secretary to supply pharmaceutical benefits at particular premises. If approved, the pharmacist may provide pharmaceutical benefits at or from those premises. The amendments were the result of agreed negotiations of the Fifth Community Pharmacy Agreement (the Fifth Agreement) between the Minister for Health and Ageing and the Pharmacy Guild of Australia to retain the Pharmacy Location Rules. The Fifth Agreement commenced on 1 July 2010 and expires on 30 June 2015. The National Health Act 1953 previously gave effect to the Pharmacy Location Rules and the operation of the Australian Community Pharmacy Authority (ACPA) until 30 June 2010. The amendments were required to extend the Pharmacy Location Rules and the operation of the ACPA for the term of the Fifth Agreement to end 30 June 2015.
Consultation opportunities	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 Pharmacy Location Rules Section Community Pharmacy Branch Pharmaceutical Benefits Division Ph: (02) 6289 7595 Email: tony.wynd@health.gov.au
Date last modified	February 2011

Title	**Post-Implementation Review – Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Bill 2008**
Description of issue	The *Tax Laws Amendment (Medicare Levy Surcharge Thresholds) Act (No. 2) 2008* (the Act) raised the Medicare Levy Surcharge threshold for individuals to $70,000 per year and for couples and families to $140,000 per year. These changes applied to income tax returns for the 2008–09 financial year and continue for subsequent years. The Act also indexes the individual Medicare Levy Surcharge income threshold annually against full-time adult Average Weekly Ordinary Time Earnings (AWOTE), and for the family surcharge threshold to equal double the individual surcharge threshold.
Consultation opportunities	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 PIR. The PIR 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.
Expected timetable	Expected completion June 2011.
Contact details	Alastair Wilson Director Budget and Data Analysis Private Health Insurance Branch Email: alastair.wilson@health.gov.au Phone: (02) 6289 4078
Date last modified	February 2011

Title	**Amendment to Therapeutic Goods Regulations 1990 – implementation of a new regulatory framework for biologicals**
Description of issue	Changes are required to the *Therapeutic Goods Regulations 1990* consequential to amendments to the Act through the *Therapeutic Goods Amendment (2009 Measures No. 3) Act 2009* for the new regulatory framework for biologicals.
Consultation opportunities	There have been a number of public consultations with all States and Territories, Acute Care Division of the Department of Health and Ageing 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 (AHMC) endorsed 4 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 Government has agreed that the Therapeutic Goods Administration progress the implementation of the AHMC-endorsed biologicals regulatory framework in an Australia-only context. The Regulations will commence on the day the amendments to the Act giving effect to the framework commence which is expected to be 31 May 2011. Stakeholders are being consulted on specific provisions and details of the regulatory framework for biological.
Contact details	Marlene Keese Legal Officer Office of Legal Services Therapeutic Goods Administration Ph: (02) 6232 8398 Email: marlene.keese@tga.gov.au
Date last modified	February 2011

Title	**Tobacco Advertising Prohibition Amendment Bill 2010**
Description of issue	The Tobacco Advertising Prohibition Amendment Bill 2010 will: 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	Introduced in the House of Representatives on 17 November 2010.
Contact details	Simon Cotterell Assistant Secretary Drug Strategy Branch Mental Health and Chronic Disease Division Department of Health and Ageing Ph: (02) 6289 8771 Email: simon.cotterell@health.gov.au
Date last modified	February 2011

Title	**Updates to guidelines for the transport, storage and disposal of genetically modified organisms**
Description of issue	The Gene Technology Regulator intends to consolidate two existing guidelines: the transport guidelines for genetically modified organisms (GMOs); and the storage and disposal guidelines for GMOs. During the consolidation process, the content will be reviewed and updated to ensure consistency with the legislation

	and other guidelines.
Consultation opportunities	The Office of the Gene Technology Regulator (OGTR) will consult on the proposed changes with key stakeholders including States/Territories, government agencies and authorities, and regulated organisations as well as the public. Consultation commenced in January 2011 and draft guidelines are publicly available on the OGTR website.
Expected timetable	It is anticipated that the new guidelines will be issued by 1 July 2011.
Contact details	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
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