Department of Health and Ageing
2006-07 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 early in 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 (1 July 2005 to 30 June 2006); and
- activities planned in the current financial year (1 July 2006 to 30 June 2007) 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 on 30 June 2006.

Past Regulatory Activity

Department of Health and Ageing

Title	**Conditions of registration pursuant to subsection 73B(1) of the *National Health Act 1953***
Description of issue	Prevented health funds importing benefit limitation periods on transferred or transferring contributors.
Date of effect	19 November 2005
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9420 E-mail: veronica.hancock@health.gov.au

Title	***Health Legislation Amendment (Private Health Insurance) Act 2006***
Description of issue	The Act enhanced the powers of the Private Health Insurance Ombudsman (PHIO) from 1 July 2006, to increase the effectiveness of the PHIO in dealing with complaints and conducting investigations involving health insurers, health care providers and brokers. The Act also amended the *Private Health Insurance Incentives Act 1998* to extend the time Medicare Australia has to provide annual data to the Australian Taxation Office on the Private Health Insurance Rebates from 90 to 120 days.
Date of effect	1 July 2006
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9420 E-mail: veronica.hancock@health.gov.au

Title	**Medical Indemnity (Run-off Cover Claims and Administration) Protocol 2006 (No.1)**
Description of issue	The Medical Indemnity (Run-off Cover Claims and Administration) Protocol 2006 (the Protocol) allowed for the reimbursement of costs incurred by insurers as a result of administering the run-off cover indemnity scheme (ROCS). There are two aspects to this administration cost: the implementation cost and the annual compliance cost. The Protocol establishes eligibility criteria for the payment of both the implementation and compliance costs.
Date of effect	21 June 2006
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au

Title	***Aged Care Amendment (2005 Measures No. 1) Act 2006***

Description of issue	This amends the *Aged Care Act 1997* (the Act) to establish prudential regulatory arrangements and strengthen protection of residents' accommodation bonds. This Act enables the making of Prudential Standards to ensure stronger prudential regulation of approved providers of both residential and flexible care services and to reduce the risk of an approved provider holding accommodation bonds becoming insolvent. This Act also sets new timeframes for refunding bonds and new provisions which require interest to be paid on resident's accommodation bond refunds.
Date of effect	31 May 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 E-mail: iain.scott@health.gov.au

Title	***Aged Care (Bond Security) Act 2006***
Description of issue	This Act enables the Commonwealth to repay accommodation bond balances and interest owing to residents in the event that their Approved Provider becomes insolvent or bankrupt. In exchange for the payment, the Act provides that any rights that a person paid such an amount by the Commonwealth had to recover the amount from an approved provider are transferred to the Commonwealth.
Date of effect	31 May 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 E-mail: iain.scott@health.gov.au

Title	***Aged Care (Bond Security) Levy Act 2006***
Description of issue	This Act operates in conjunction with the *Aged Care (Bond Security) Act 2006* and enables the imposition of levies on approved providers holding accommodation bonds in order to recover any costs incurred by the Australian Government as a result of repaying accommodation bond balances to residents in the event that an approved provider becomes insolvent or bankrupt.
Date of effect	31 May 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 E-mail: iain.scott@health.gov.au

Title	**User Rights Amendment Principles 2006 (No 1)**

Description of issue	The main purpose of these consequential amendments to the User Rights Principles 1997 is to provide additional detail about the prudential arrangements (provided for in the *Aged Care Amendment (2005 Measures No. 1) Act 2006*) for the protection of accommodation bonds and the new interest requirements on bond repayments. The amendments to the Principles also: • remove inoperable prudential requirements; • formally terminate the Aged Care Accommodation Bond Trust Fund which has not had the capacity to accept accommodation bonds since 23 December 1997; • provide that the only types of flexible care services that may charge bonds are multi-purpose services (residential aged care services are also able to charge bonds); and • extend the rules relating to accommodation bonds to flexible care services that hold accommodation bonds (multi-purpose services).
Date of effect	31 May 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 E-mail: iain.scott@health.gov.au

Title	**Residential Care Subsidy Amendment Principles 2006 (No 1)**
Description of issue	This amendment made a number of technical amendments to the Residential Care Subsidy Principles to ensure the efficient operation of the Conditional Adjustment Payment (CAP). This amendment also extends the 2006 financial reporting date for CAP by one month. The extra reporting time is provided in recognition of the need for providers to adopt the Australian Equivalents to International Financial Reporting Standards in their 2005-06 General Purpose Financial Reports.
Date of effect	7 July 2006
Contact details	Iain Scott Office of the Prudential Regulator Department of Health and Ageing Ph: (02) 6289 4145 E-mail: iain.scott@health.gov.au

Title	**Continuation of pharmacy location arrangements (*Health Legislation Amendment Act 2005*) (previously referred to as 'Amendment to Division 4B of the *National Health Act 1953*')**
Description of issue	An **omnibus** Act that included amending the *National Health Act 1953* to provide for the continuation of the pharmacy location rules, and their administration by the Australian Community Pharmacy Authority, until 30 June 2006.
Date of effect	Component relating to pharmacy location commenced on 19 December 2005
Contact details	Brenda White Pharmaceutical Access & Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	***Health Legislation Amendment (Pharmacy Location Arrangements) Act***

	***2006* (previously titled the *National Health Amendment (Fourth Community Pharmacy Agreement) Bill*)**
Description of issue	To amend the *National Health Act 1953* to implement measures contained in the Fourth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia, including: • extension of pharmacy location rules and their administration by the Australian Community Pharmacy Authority until 30 June 2010; • change to membership of the Australian Community Pharmacy Authority; • introduction of discretionary power for the Minister for Health and Ageing to approve a pharmacist to supply pharmaceutical benefits.
Date of effect	1 July 2006
Contact details	Brenda White Pharmaceutical Access & Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**National Health (Pharmaceutical Benefits) Amendment Regulations 2006 (No.1)**
Description of issue	To amend the National Health (Pharmaceutical Benefits) Regulations 1960 to provide for a number to be allocated to an approval granted by the Minister to a pharmacist to supply pharmaceutical benefits.
Date of effect	1 July 2006
Contact details	Brenda White Pharmaceutical Access & Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**Pharmaceutical Benefits Determination under subsection 99L(1) – pharmacy location rules**
Description of issue	To extend the effect of the existing pharmacy location rules until 30 July 2006.
Date of effect	30 December 2005
Contact details	Brenda White Pharmaceutical Access & Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	**National Health (Australian Community Pharmacy Authority Rules) Determination 2006**
Description of issue	To give effect to new pharmacy location rules agreed as part of the Fourth Community Pharmacy Agreement between the Commonwealth and the Pharmacy Guild of Australia.
Date of effect	1 July 2006
Contact details	Brenda White Pharmaceutical Access & Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: brenda.white@health.gov.au

Title	***National Health (Immunisation Program) Act 2005***
Description of issue	Amended the *National Health Act 1953* to allow the Pharmaceutical Benefits Advisory Committee to undertake the role of recommending vaccines for funding

	under the National Immunisation Program to the Minister for Health and Ageing.
Date of effect	1 January 2006
Contact details	Letitia Toms Targeted Prevention Programs Branch Department of Health and Ageing Ph: (02) 6289 8572 E-mail: letitia.toms@health.gov.au

Title	**Review of health warnings on tobacco products in Australia as specified under the Trade Practices (Consumer Product Information Standards) (Tobacco) Regulations**
Description of issue	Minor amendments to the regulations were drafted by the ACCC, in consultation with the Department. The legislative instrument: Trade Practices (Consumer Product Information Standards) (Tobacco) Amendment Regulations 2005 (No. 1) F2005L02919 (SLI 2005 No. 229)
Date of effect	11 October 2005
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688 E-mail: penny.marshall@health.gov.au

Title	**Amendment to Health Insurance (General Medical Services Table - GMST) Regulations 2005**
Description of issue	Creation of a new Medicare item under the Medicare Benefits Schedule to allow benefits to be payable for an Aboriginal and Torres Strait Islander Child Health Check.
Date of Effect	1 May 2006
Contact details	David Braggett Primary Care Financing Branch Department of Health and Ageing Ph: (02) 6289 4919 E-mail: david.braggett@health.gov.au

Title	**Amendment to Health Insurance (General Medical Services Table - GMST) Regulations 2005**
Description of issue	Creation of new Medicare items under the Medicare Benefits Schedule to allow benefits to be payable for Health Assessments for Refugees and Other Humanitarian Entrants.
Date of Effect	1 May 2006
Contact details	David Braggett Primary Care Financing Branch Department of Health and Ageing Ph: (02) 6289 4919 E-mail: david.braggett@health.gov.au

Title	**Amendment to the Health Insurance Regulations 1975 and Ministerial Determination (under section 3C of the *Health Insurance Act 1973).***
Description of issue	Regulation and Determination were required to create a new Medicare item under the Medicare Benefits Schedule to allow benefits to be paid for exercise physiology services provided by eligible exercise physiologists.
Date of Effect	1 January 2006

Contact details	David Braggett Primary Care Financing Branch Department of Health and Ageing Ph: (02) 6289 4919 E-mail: david.braggett@health.gov.au

Title	**Conformity Assessment Standards Order No 1 of 2005**
Description of issue	Revokes Conformity Assessment Standards Order No 1 of 2003. Specifies the quality management standards for manufacturing medical devices requiring conformity assessment and in particular, quality assurance techniques for medical devices supplied in a sterile state. This Standards Order includes references to the new ISO 13485-2003 which replaces the previous ISO 13485-1996.
Date of effect	29 September 2005
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	**Therapeutic Goods Order No. 74 - Standards for Blood Components. (TGO74).**
Description of Issue	TGO74 replaces TGO72 in prescribing the 11th edition of the Council of Europe document titled "Guide to preparation, use and quality assurance of blood components" as the standard for requirements that must be met for the manufacture of blood components with the exception of tropical areas within Australia and measures to mitigate the risk of variant CJD.
Date of effect	13 January 2006
Contact details	Rita Maclachlan Office of Devices Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No 2]**
Description of issue	The Regulations increase NICNAS Registration charges for the National Industrial Chemicals Notification and Assessment Scheme for 2006-07 by 3.9% rounded to the nearest dollar. Registration charges only apply to those importers or manufacturers of relevant industrial chemicals to a value exceeding $500,000 in a registrable year. A Regulatory Impact Statement (RIS) was not required as the amendments were of a minor or machinery nature and did not substantially alter existing arrangements
Date of effect	1 July 2006
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No 1]
Description of issue	The Regulations: (a) increased the New Chemical assessment fees and charges and registration fees for the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for 2006-07 by 3.9% rounded to the nearest dollar (b) introduced application and renewal fees for NICNAS controlled use permits (c) specified prescribed information required on application for one type of controlled use permits, export only permits A Regulatory Impact Statement (RIS) was not required for (a) above, as the amendments were of a minor or machinery nature and did not substantially alter existing arrangements. No specific Regulatory Impact Statement (RIS) was required for (b) and (c) above, as they were included in the RIS prepared for the Low Regulatory Concern Chemicals (LRCC) amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989.*
Date of effect	(a) was effective on 01 July 2006 (b) and (c) above were effective 20 April 2006
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2005 [No 2]
Description of issue	The purpose of the Regulation is to list tetraethyl lead and tetramethyl lead in regulations relating to s106 of the *Industrial Chemicals (Notification and Assessment) Act 1989* and to amend the current regulation for octabromobiphenyl and decabromobiphenyl in order to give effect to Australia's obligations under the Rotterdam Convention. No specific Regulatory Impact Statement (RIS) for regulations as changes to the *Industrial Chemicals (Notification and Assessment) Act* and regulations to be made under "the Act" were covered in the RIS prepared during the ratification process.
Date of effect	17 November 2005
Contact details	Sneha Satya Review and Treaties National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au

Planned Regulatory Activity

Department of Health and Ageing

Title	**Private Health Insurance Bill 2006**
Description of issue	This Bill will reduce and simplify existing regulations of the private health insurance industry consistent with the government's objectives and protect the public interest.
Consultation opportunities	Industry consultation through the release of a discussion paper (15 June 2006), consultation forums (June and July 2006), proposed release of a directions paper (mid August 2006) and pending approval, and the release of an exposure draft of legislation (October 2006).
Expected timetable	Introduction at the end of November 2006.
Contact details	Charles Maskell-Knight Acute Care Division Department of Health and Ageing Ph: (02) 6289 3151 E-mail: charles.maskell-knight@health.gov.au Louise Clarke Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9490 E-mail: louise.clarke@health.gov.au
Date last modified	17 July 2006

Title	**Private Health Insurance Complaints Levy Regulations 1995**
Description of issue	The Regulations will provide for a levy payable by registered organisations conducting health insurance business for the funding of the Private Health Insurance Ombudsman (PHIO). The amendments will provide for an increase of $200,000 in levy collected to compensate for additional costs to the PHIO to undertake expanded powers as a result of the *Health Legislation Amendment (Private Health Insurance) Act 2006* (HLA(PHI)) Act 2006.
Consultation opportunities	Extensive consultation was undertaken with stakeholders in the development of the (HLA (PHI)) Act 2006.
Expected timetable	Regulations made by November 2006.
Contact details	Veronica Hancock Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9420 E-mail: veronica.hancock@health.gov.au
Date last modified	17 July 2006

Title	**Strengthening offence and enforcement provisions of the *Health Insurance Act 1973* in relation to pathology and diagnostic imaging**
Description of issue	This proposed legislation is in response to the Phillips Fox Review of Enforcement and Offence Provisions of the *Health Insurance Act 1973* (the Act) as they relate to the provision of Pathology Services under Medicare. Commensurate changes for diagnostic imaging will also be introduced. The changes will clarify the existing intent of the Act to prohibit any arrangements for fee splitting or paying other benefits in return for requesting pathology or diagnostic imaging services.

Consultation opportunities	The Phillips Fox Review, (which included consultation with stakeholders), the government response, and other relevant material, including material about subsequent consultations, are all available on the Department's website at: http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pathology-leg-index.htm; and http://www.health.gov.au/internet/wcms/publishing.nsf/Content/diagnosticimaging-practiceprov.htm
Expected timetable	Legislation is expected to be introduced before the end of 2006.
Contact details	Fifine Cahill Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 4038 E-mail: fifine.cahill@health.gov.au
Date last modified	19 July 2006

Title	**Changes to the *Health Insurance Act 1973* and associated subordinate legislation to introduce an accreditation scheme linked to Medicare Benefits for practices providing radiology services**
Description of issue	The Radiology Quality and Outlays Memorandum of Understanding (MoU), which is jointly managed by the Department of Health and Ageing (DoHA), the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australian Diagnostic Imaging Association (ADIA), calls for the accreditation of radiology practices, linked to the payment of Medicare benefits. The ultimate aim of the program is the development of minimum standards of accreditation for all radiology services under the MoU.
Consultation opportunities	The Department expects to release a consultation paper followed by workshops. Stakeholders will be kept well informed about the timeframe for implementation. Information and updates will be regularly posted to the Department of Health's website at www.diagnosticimaging.health.gov.au
Expected timetable	The regulation impact statement is being prepared. The expected schedule will be in place in early 2007.
Contact details	Margaret Curran Diagnostic and Technology Branch Department of Health and Ageing Phone: (02) 6289 7315 Email: margaret.curran@health.gov.au
Date last modified	19 July 2006

Title	**Medical Indemnity Amendment Bill 2006**
Description of issue	The Bill will amend the Run-Off Cover Scheme (ROCS) in order to provide certainty for doctors who leave the medical workforce (either permanently or on maternity leave) as to the range of incidents that will be covered by the ROCS. Essentially, this will allow insurers to clarify indemnity arrangements and provide cover under the ROCS for eligible doctors based on the doctors' last contract of insurance and remove the requirement for the doctors to have had medical indemnity cover at the time of the incident. The amendments also simplify the administration of the scheme for the medical indemnity insurers and Medicare Australia.
Consultation	Key stakeholders have been consulted and given in-principle approval for the

opportunities	amendments. There will be on-going consultation with stakeholders including affected government agencies, industry and professional bodies.
Expected timetable	The Bill is expected to be tabled in Parliament in the Spring sitting of parliament 2006.
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au
Date last modified	25 July 2006

Title	**Medical Indemnity (Run-off Cover Claims and Administration) Protocol 2006 (No.2)**
Description of issue	The current Run-off Cover Claims and Administration Protocol 2006 were designed to pay insurers for administration for the first years of operation only. A new Protocol will be developed to allow for insurers to be reimbursed for future Run-Off Cover Scheme administration costs, a claims handling fees and legal costs associated with run-off cover scheme under the *Medical Indemnity Act 2002.*
Consultation opportunities	Key stakeholders have given in principle approval. There will be on-going consultation with stakeholders including affected government agencies and industry.
Expected timetable	The Protocol is expected to be made and registered on the Federal Register of Legislative Instruments by February 2007.
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au
Date last modified	25 July 2006

Title	**Medical Indemnity (IBNR Claims) Protocol 2006**
Description of issue	The purpose of the Incurred But Not Reported Claims (IBNR) Protocol is to set out the matters relating to the making of payments to the medical indemnity providers, by the Commonwealth, for fees and costs incurred by the IBNR indemnity scheme established under the *Medical Indemnity Act 2002*.
Consultation opportunities	There will be on-going consultation with stakeholders including affected government agencies and industry.
Expected timetable	The Protocol is expected to be made and registered on the Federal Register of Legislative Instruments by February 2007.
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au
Date last modified	25 July 2006

Title	**Medical Indemnity (High Cost Claims) Protocol 2006**

Description of issue	The purpose of the High Cost Claims Protocol is to set out the matters relating to the making of payments to the medical indemnity providers, by the Commonwealth, for fees and costs incurred by the high cost claims indemnity scheme established under the *Medical Indemnity Act 2002.*
Consultation opportunities	Key stakeholders will be consulted.
Expected timetable	The Protocol is expected to be made and registered on the Federal Register of Legislative Instruments by April 2007.
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au
Date last modified	25 July 2006

Title	**Medical Indemnity (Prudential Supervision and Product Standards – Notice of Provision of Run-off Cover) Determination 2006 (No.1)**
Description of issue	The purpose of the determination is to set out other matters that medical indemnity insurers must provide to Medicare Australia in a written notice, in addition to the information required in paragraph 26D(2)(b)(i) and (ii) of the *Medical Indemnity (Prudential Supervision and Product Standards) Act 2003.* Information gathered under this instrument will be used by the Australian Government in the management of this scheme and in the annual preparation of the reports on this scheme which the minister is required to table in Parliament under 34ZW of the *Medical Indemnity Act 2002.*
Consultation opportunities	Key stakeholders have been consulted. On-going consultation will occur.
Expected timetable	The determination is expected to be made and registered on the Federal Register of Legislative Instruments by February 2007.
Contact details	Sonya Kelly Medical Indemnity Branch Department of Health and Ageing Ph: (02) 6289 9213 E-mail: sonya.kelly@health.gov.au
Date last modified	25 July 2006

Title	**Aged Care Amendment Bill**
Description of issue	This Bill will align Extended Aged Care at Home (EACH) and EACH Dementia (EACHD) (flexible care) under community legislation. It will also align legislation and programs in the Indian Ocean Territories with those of comparable mainland communities.

Consultation Opportunities	The amendments to the *Aged Care Act 1997* (the Act) and the Aged Care Principles 1997 (the Principles) arose from actions proposed in the Way Forward – a New Strategy for Community Care. Action point 4.2 of The Way Forward strategy states that the Department of Health and Ageing, in consultation with EACH service providers, will consider development of the Act and the Principles, to align EACH within Community Care. It is intended that once the Bill has been introduced in the Spring 2006 sittings of Parliament, EACH and EACHD providers, peak organisations and other interested parties will be informed by way of direct written communication of the amendments, and the intention of the amendments. The communication will emphasise that the amendments will have no impact on approved provider service delivery methods, and will not require any additional cost in the delivery of the EACH and EACHD programs. The Office of Regulation Review has provided exemption reference RIS ID 8236 for these amendments. In addition, the communication will identify the commencement dates for the amendments, will clearly identify the substantive amendments made to the Act and Principles, and any transitional provisions required for the amendments to take effect. The language to be used in the communication will be plain language, and will provide an opportunity for providers to contact the Department to query any aspect of the amendments. The Department's website will also be updated to include the amendments.
Expected timetable	The Amendment Bill is expected to be introduced into Parliament in the Spring 2006 sitting.
Contact details	Mary McDonald Community Care Branch Department of Health and Ageing Ph: (02) 6289 5182 E-mail: mary.mcdonald@health.gov.au
Date last modified	July 2006

Title	**Aged Care Amendment (Residential Care) Bill 2006**
Description of issue	Amendments to the *Aged Care Act 1997* to give effect to the implementation of the new aged care funding instrument; further harmonisation of aged care and pension assets assessments; and changes in respect of delegations for approvals of care needs assessments conducted by Aged Care Assessment Teams (ACAT).
Consultation Opportunities	The Minister formed an Industry Reference Group in 2004 to assist in the development of the new funding model. This Group, which consists of industry peak bodies, industry professionals, aged care providers and consumer representatives, meets at least quarterly. Consultation was not required for the amendment concerning ACAT delegations as this is a small administrative change to clarify current delegation practices. The amendments relating to harmonisation stem from an option proposed in Professor Warren Hogan's *Review of Pricing Arrangements in Residential Aged Care* that the aged care means testing arrangements should be brought into line with those that apply for the age pension.

	These changes were also discussed with the Ministerial Implementation Taskforce established to implement the recommendations of the Hogan Review and announced in the 2006-07 Budget.	
Expected timetable	Implementation of the new assets assessment arrangements is expected on 1 January 2007 but will also affect gifts made from 10 May 2006. The new funding instrument will be implemented from 1 July 2007. Exemptions from Regulation Impact Statements have been issued by the Office of Regulation Review	
Contact details	Aged care funding instrument	Keith Tracey-Patte Funding Model Implementation Department of Health and Ageing Ph: (02) 6289 1578 keith.tracey-patte@health.gov.au
	Harmonisation of assets assessments	Jacquie Maycock Resident Liaison Department of Health and Ageing Ph: (02) 6289 7909 jacquie.maycock@health.gov.au
	Aged care approvals delegations	Judy Bartholemew Assessment Section Department of Health and Ageing Ph: (02) 6289 5200 judy.bartholemew@health.gov.au
Date last modified	July 2006	

Title	**Amendments to Medicare provider number restrictions - Health Insurance Amendment Bill (No. 2)**
Description of issue	This legislation is administered by the Health Workforce Branch in the Department of Health and Ageing and affects overseas trained doctors and permanent resident/Australian graduates, restricting their access to the Medicare Benefits Scheme. Proposed amendments to sections 19AA, 19AB and 19AD of the Health Insurance Act 1973 to: • introduce a new category of medical practitioner (foreign graduates of Australian medical schools) subject to Medicare provider number restrictions under s19AA of the Act; • introduce a new category of medical practitioner (graduates of offshore campuses of Australian medical schools or non-AMC accredited medical schools operating in Australia) who are subject to Medicare provider number restrictions under s19AB of the Act; and • change the period of review of the Medicare provider number legislation from 2 to 5 years. A regulation impact statement has been obtained for section 19AA (7099) and Section 19AB (5966 and 5961). A regulation impact statement has not been sought for the change to section 19AD

Consultation Opportunities	Consultation that has taken place: "introduce a new category of medical practitioner (foreign graduates of Australian medical schools) subject to Medicare provider number restrictions under s19AA of the Act." – This proposal is the result of comments and discussions between the Royal Australian College of General Practitioners, the Minister and the Department. The Minister had previously approved a proposal to place limitations on these doctors. "introduce a new category of medical practitioner (graduates of offshore campuses of Australian medical schools or non-AMC accredited medical schools operating in Australia) who are subject to Medicare provider number restrictions under s19AB of the Act." – The Australian Medical Council raised the issue which underlies the amendment. The Department's Legal Services Branch was consulted prior to the proposed amendments being submitted to the Minister for approval. "change the period of review of the Medicare provider number legislation from 2 to 5 years." – The change in the period of review was discussed and supported by some stakeholders during the 2005 Biennial Review process. The change was suggested by the Minister when he approved the report being tabled in Parliament.
Expected timetable	The change to section 19AB must be implemented by 2009. The change to Section 19AD needs to be implemented no later than April 2007.
Contact details	Jennifer Chynoweth Health Workforce Branch Department of Health and Ageing Ph: (02) 6289 5636 email: jennifer.chynoweth@health.gov.au
Date last modified	23 August 2006

Title	**Health Legislation Amendment (Pharmaceutical Benefits Entitlement) Bill 2006/07 - relating to arrangements for approving a pharmacist to supply pharmaceutical benefits**
Description of issue	Make various minor, technical and consequential amendments identified during the development of the new pharmacy location rules, including: • providing for special supply arrangements for private hospitals; • enabling the Secretary and Minister to attach conditions to particular approvals; • ensuring flexibility in the recovery of payment for pharmaceutical benefits in certain circumstances.
Consultation opportunities	Ongoing consultation (discussions, meetings and workshops) with Medicare Australia and the Pharmacy Guild of Australia. Potential for consultation (meetings and discussions) with private hospital authorities in August-December 2006.
Expected timetable	Consultation with private hospital authorities (if undertaken) to be completed by December 2006. Development of Bill to be completed by mid-January in time for introduction during the Autumn program.
Contact details	Brenda White Pharmaceutical Access & Quality Branch Ph: (02) 6289 8984

	E-mail: brenda.white@health.gov.au
Date last modified	17 July 2006

Title	**Notification of amendments to the Hearing Services Rules of Conduct 2000**
Description of issue	The Rules of Conduct under the *Hearing Services Administration Act 1997* set out the requirements for contracted providers of hearing services in their dealings with voucher holders under the Commonwealth Hearing Services Voucher System. They include the qualification requirements of persons registered to practice in the Voucher System. There may be changes to Part 3 of the Hearing Services Rules of Conduct 2000 concerning the rules about qualifications for hearing health practitioners who provide services to eligible clients under the Hearing Services Voucher System. The changes will be necessitated by the outcome of a review of the regulation professional qualification requirements of the Hearing Services Program.
Consultation opportunities	The review has been conducted by an independent organisation and included two rounds of consultation with all stakeholder groups.
Expected timetable	The review was completed in July 2006. The timing of changes will be dependent on Ministerial approval of a revised framework.
Contact details	Judi Sutton Office of Hearing Services Department of Health and Ageing Ph: (02) 6289 5411 E-mail: judi.sutton@health.gov.au
Date last modified	20 July 2006

Title	**Health Emergency Planning and Response Branch – COAG Review of Hazardous Materials**
Description of issue	During 2005-06, it is expected that the Council of Australian Governments (COAG) Review of Hazardous Materials will be finalised and that work will commence on implementing the recommendations. The COAG Review is being managed by the Department of Prime Minister and Cabinet (PM&C) with the involvement of a number of Health portfolio agencies and consists of four parts: Ammonium Nitrate, Chemicals, Biologicals and Radiological materials. States and territories are implementing the recommendations of the Ammonium Nitrate report. One of the major recommendations of the Chemical, Biological and Radiological Review is for the strengthening and/or establishment of regulatory regimes for controlling and monitoring the storage, handling and transport of hazardous materials that could potentially be used by terrorists or for other malicious purposes. A National Authority or National Authorities are proposed to administer these regulatory regimes. Regulatory Impact Statements will form part of the proposal to Government to support implementation. In accordance with the Australian Government's policy of reducing the burden to business and the community of regulation, regulatory and accreditation schemes will be harmonised wherever possible with existing schemes.
Consultation Opportunities	The COAG Review is being managed by PM&C with the involvement of a number of Health portfolio agencies and consists of four parts: Ammonium Nitrate, Chemicals, Biologicals and Radiological materials. States and

	territories are implementing the recommendations of the Ammonium Nitrate report.
Expected timetable	Completion of the regulatory change for Chemical and Radiologicals is expected in 2006-07; Biologicals to be rolled out during 2006-07 for possible completion in 2007-08.
Contact details	Director Biosecurity Section Health Emergency Planning and Response Branch Department of Health and Ageing Ph: (02) 6289 1555
Date last modified	July 2006

Title	**Proposed amendments to regulate advertising of tobacco products on the internet**
Description of issue	Proposed amendments to the *Tobacco Advertising Prohibition Act 1992* and the Tobacco Advertising Prohibition Regulations, Statutory Rules 1993 No. 129 to clarify the legislation's intent in respect of advertising on the internet. Amendments will clarify that the prohibition on the advertising of tobacco products applies to advertisements on the internet. These changes will impact upon businesses selling tobacco products over the internet.
Consultation opportunities	There will be opportunity for public comment during the preparation of a Regulation Impact Statement.
Expected timetable	Preparation of a Regulation Impact Statement is estimated to occur in early 2007.
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688 Email: penny.marshall@health.gov.au
Date last modified	4 September 2006

Title	**Proposed amendments to the *Tobacco Advertising Prohibition Act 1992* and the Tobacco Advertising Prohibition Regulations, Statutory Rules 1993 No. 129 to regulate tobacco product covers**
Description of issue	Through amendments to the *Tobacco Advertising Prohibition Act 1992* and the Tobacco Advertising Prohibition Regulations, Statutory Rules 1993 No. 129, the Australian Government intends to regulate cigarette packet covers and stickers/adhesive labels so that they do not undermine current health policy objectives by concealing or subverting health warnings. These changes will impact upon businesses manufacturing and selling cigarette covers and stickers.
Consultation opportunities	There will be opportunity for public comment during Regulation Impact Statement process.
Expected timetable	The Department aims to introduce the bill into Parliament in the Spring 2006 sitting.
Contact details	Penny Marshall Drug Strategy Branch Department of Health and Ageing Ph: (02) 6289 7688

	Email: penny.marshall@health.gov.au
Date last modified	20 July 2006

Title	***Food Standards Australia New Zealand Act 1991* Amendment Bill**
Description of issue	Since the implementation of the new bi-national food regulatory system in 2001, it has become apparent that there are a number of areas in which the food regulatory process may be streamlined and clarified, while protecting public health and safety. In order to address the areas of concern, it is necessary to amend the *Food Standards Australian New Zealand Act 1991* (FSANZ Act). The proposed amendments to the FSANZ Act will seek to: • eliminate unnecessary duplication of regulations; • streamline the food regulatory process; and • improve the clarity and consistency of the operations of Food Standards Australia New Zealand (FSANZ). A significant part of the amendments are intended to streamline and reform the legislative framework relating to the food standards development process which will assist business. Specific improvements include: • prescribing the form of an application, including full substantiation requirements, in order to cut down on the number of times additional information is requested from applicants; • reforming the assessment and consultation process. This will mean that the majority of applications to FSANZ will now be subject to one round of public consultation, instead of two. Two rounds of public consultation will only be required for the development of new Food Standards or major revisions to existing Food Standards; • removing unnecessary process steps in relation to the role of the Ministerial Council in the food standard development; and • enabling additional protection of commercially valuable information, to give an incentive for both large and small companies to capture the commercial benefit of innovation.
Consultation opportunities	Public consultation was undertaken during March and April 2006. Consultation forums were also conducted in Sydney, Melbourne and Wellington.
Expected timetable	It is expected that the amendment bill will be introduced to Parliament in the Spring 2006 sitting.
Contact details	Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au
Date last modified	July 2006

Title	**Ministerial Determination (under section 3C of the *Health Insurance Act 1973)***
Description of issue	It is proposed that new Medicare items will be created under the Medicare Benefits Schedule to allow benefits to be payable for group intervention services for people with type 2 diabetes provided by exercise physiologists, dieticians and diabetes educators on referral by a general practitioner (GP).
Consultation opportunities	Relevant allied health professional and GP groups will be consulted on the development of the new items.
Expected timetable	New items will be introduced in 2007.

Contact details	David Braggett Primary Care Financing Branch Department of Health and Ageing Ph: (02) 6289 4919 E-mail: david.braggett@health.gov.au
Date last modified	September 2006

Title	**Amendment to Health Insurance (General Medical Services Table - GMST) Regulations 2005**
Description of issue	An amendment to the GMST will be required to add a new GP item to the Medicare Schedule for a health check for people around 45 years of age who are at risk of developing a chronic disease.
Consultation opportunities	The item is being developed in consultation with the medical profession and state and territory governments.
Expected timetable	The item is expected to commence on 1 November 2006.
Contact details	David Braggett Primary Care Financing Branch Department of Health and Ageing Ph: (02) 6289 4919 E-mail: david.braggett@health.gov.au
Date last modified	September 2006

Title	**Amendments to Health Insurance Regulations – (Vocational Registration of General Practitioners) 1975 – Recognition of the Australian College of Rural and Remote Medicine**
Description of issue	The proposed amendment will provide for Fellows of the Australian College of Rural and Remote Medicine (ACRRM) to be vocationally recognised and therefore be able to access the higher A1 Medicare rebate. Vocational recognition is administered by Medicare Australia. Medicare Australia will maintain a List of ACCRM Fellows similar to the List of Fellows of the Royal Australian College of General Practice (RACGP). Changes to the Health Insurance Regulations are also required to amend the ongoing eligibility requirements for the Vocational Register; to abolish the General Practice Recognition Eligibility Committee and the General Practice Recognition Appeal Committee; to allow ACRRM to report directly to Medicare Australia; and to remove the requirement for general practitioners (GP) services to be predominantly in general practice for a doctor to be on the vocational register.
Consultation opportunities	The General Practice Branch in the Department of Health and Ageing has consulted with the industry including the ACRRM, the RACGP and the Australian Medical Association. There will be further opportunities to consult with the industry in the implementation of this initiative.
Expected timetable	It is anticipated that the proposed regulations will be operational by the end of 2006.
Contact details	Alan Singh GP Training and Incentives Department of Health and Ageing Ph: (02) 6289 7860 E-mail: alan.singh@health.gov.au
Date created	July 2006

Title	**Proposed Therapeutic Goods Order (TGO) No. 71 – Tamper-Evident Packaging of Therapeutic Goods**

Description of issue	TGO 71 will adopt the document *Code of Practice for the Tamper-evident Packaging (TEP) of Therapeutic Goods* (Edition 1, June 2003), published by the Therapeutic Goods Administration on behalf of the Industry Government Crisis Management Committee, as a standard for therapeutic goods in Australia.
Consultation opportunities	Consultation has occurred with peak industry bodies including the Australian Self-Medication Industry; Medicines Australia and the Complementary Healthcare Council.
Expected timetable	This Order was expected to come into effect in Australia from 1 July 2006, with a one-year transition period during which sponsors should ensure full compliance. The decision on whether to implement TGO 71 is being reconsidered in the context of the Australia New Zealand Therapeutic Products Authority.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Medical Device Standards Order – Sterilants and Disinfectants for Medical Devices**
Description of issue	Proposed standards for sterilants and disinfectants for medical devices.
Consultation opportunities	Prior to implementation consultation will be undertaken with key industry stakeholder groups.
Expected timetable	Initially due for completion by December 2005. Further consultation undertaken. Revised completion date December 2006.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Medical Devices Standards Order No.4 – Natural Latex Condoms**
Description of Issue	Proposed medical device standard for natural latex condoms.
Consultation opportunities	Prior to implementation consultation will be undertaken with key industry stakeholder groups.
Expected Timetable	Due to be completed by March 2007.
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Medical Devices Standards Order No. 5 – Sterile Hypodermic Syringes for Single Use**
Description of Issue	Proposed medical device standard for sterile hypodermic syringes for single use.
Consultation opportunities	Prior to implementation consultation will be undertaken with key industry stakeholder groups.
Expected Timetable	Due to be completed by March 2007.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700

	E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Medical Device Standards Order No.6 – Gloves for General Medical and Dental Use**
Description of Issue	Proposed medical device standard for gloves for general medical and dental use.
Consultation opportunities	Prior to implementation consultation will be undertaken with key industry stakeholder groups.
Expected Timetable	Due to be completed by March 2007.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Medical Devices Standards Order No.7 – Single use sterile surgical rubber gloves**
Description of Issue	Proposed medical device standard for single use sterile surgical rubber gloves.
Consultation opportunities	Prior to implementation consultation will be undertaken with key industry stakeholder groups.
Expected Timetable	Due to be completed by March 2007
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Amendment to the Therapeutic Goods (Medical Devices) Regulations 2002**
Description of issue	An amendment to the Medical Devices regulations to implement the new regulatory framework for *In vitro* diagnostic devices.
Consultation opportunities	This proposal has been agreed to by the Australian Health Ministers' Conference and the Australian Health Ministers' Advisory Council. There has been ongoing consultation with stakeholders including industry, professional bodies and consumers since 2003.
Expected timetable	Initial date of implementation of early 2006. Drafting of the amendment regulations commenced in March 2006. Revised date of implementation dependent upon industry consultation, no later than commencement of Australia New Zealand Therapeutic Products Authority.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Good Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Amendments to Quarantine Proclamation to require permits for commercial quantities of human blood and blood components**
Description of issue	This measure involves removing the current exemption under the Quarantine Proclamation for human blood and blood products intended for human therapeutic use. The effect of the amendment will be to make human blood or

	blood products in commercial quantities prohibited biological materials unless a permit to import them has been granted under s28 of the Quarantine Proclamation. A new permit will be required for each act of importation. The purpose of this requirement will be to ensure that the source of each shipment of blood is checked before permission is granted for its importation.
Consultation opportunities	Consultation has occurred with relevant stakeholders, including CSL Limited, the Australian Red Cross Blood Service, peak industry associations, the Australian Medical Association, the Society of Hospital Pharmacists of Australia, the Fertility Society of Australia and the Australian Bone Marrow Registry.
Expected timetable	Implementation by early to mid 2007.
Contact details	Glenn Smith Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8291 E-mail: glenn.smith@health.gov.au
Date last modified	July 2006

Title	**Implementation of a new regulatory framework for human cellular and tissue therapies, included as part of the Trans Tasman Joint Agency legislation**
Description of issue	A new regulatory framework for Human Cellular and Tissue Therapies.
Consultation opportunities	Two additional rounds of public consultation with all States, Territories, Acute Care Division of the Department of Health and Ageing, New Zealand Ministry of Health and Medsafe, and key Professional groups have continued to further clarify the development of the proposed framework.
Expected timetable	Dependent upon coordination of AHMAC and AHMC. No earlier than commencement of the Australia New Zealand Therapeutic Products Authority.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Implementation of a new framework for the regulation of Blood, included as part of the trans Tasman Joint Agency legislation**
Description of Issue	Development of a separate regulatory scheme for blood, to include blood components and blood products. Drafting instructions have been prepared and were provided to the drafter in July 2006.
Consultation opportunities	The Acute Care Division of the Department of Health and Ageing, the Jurisdictional Blood Committee, the National Blood Authority and New Zealand's Medsafe and Ministry of Health have been consulted.
Expected Timetable	Implementation no later than commencement of the Australia New Zealand Therapeutic Products Authority.
Contact details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8700 E-mail: rita.maclachlan@health.gov.au
Date last modified	July 2006

Title	**Development and implementation of a Trans-Tasman regulatory scheme for**

	therapeutic products
Description of issue	Therapeutic goods have a special exemption under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA seeks to lessen regulatory and trade barriers between Australia and New Zealand. To resolve the special exemption, which must be renewed each year, the Australian and New Zealand Governments have agreed by means of a treaty to establish the Australia New Zealand Therapeutic Products Authority (ANZTPA) to harmonise therapeutic goods regulation between both countries. The move towards a single market for therapeutic goods, with a common regulatory system, will facilitate trade and reduce compliance costs for industry. The Authority will assume the role of the Therapeutic Goods Administration in Australia and Medsafe in New Zealand for ensuring the quality, safety, efficacy and timely availability of therapeutic products manufactured or supplied in Australia and/or New Zealand or exported from the Australian/New Zealand market. The regulatory activities of the Authority will include pre-market assessment or evaluation, product licensing, post-market surveillance, licensing of manufacturers, setting of standards and communicating decisions and information.
Consultation opportunities	Australian and New Zealand officials have been developing the proposed joint regulatory scheme in consultation with stakeholders (including industry and consumer representatives and professional associations). A discussion paper, 'A Proposal for a Trans-Tasman Agency to Regulate Therapeutic Products' was issued in June 2002 for comment. Further meetings followed with major interest groups to refine the proposals and to develop the operational detail. Public consultation also occurred on the Treaty. The legal instruments required to establish the Authority and the joint regulatory scheme are an Australian Bill and a New Zealand Bill (each going through the respective country's parliamentary process), a common set of Ministerial Council Rules for the detail of the regulatory framework, and a set of Managing Director's Orders to define specific technical standards. During 2006/07 there will be a phased release of draft Ministerial Council Rules and draft Managing Director's Orders relating to the joint regulatory scheme for therapeutic products. An exposure draft of the legislation that establishes the Authority will be released for consultation before legislation is introduced. As part of a communication strategy for the project, a web site http://www.anztpa.org keeps stakeholders informed of progress. Details of the Stakeholder Consultation Programme 2006/07 are published on the ANZTPA website: http://www.anztpa.org/consult/programme0607.htm
Expected timetable	Exposure draft of Australian legislation – second half of 2006 Legislation introduced in Australia – early 2007 Legislation passed in Australia – mid 2007 Authority commences operations – second half of 2007
Contact details	Alice Creelman

	Joint Agency Establishment Group Therapeutic Goods Administration Ph: (02) 6232 8189 E-mail: alice.creelman@health.gov.au
Date last modified	July 2006

Title	**Therapeutic Goods (Charges) Amendment Regulations 2006**
Description of issue	An amendment to the Therapeutic Goods (Charges) Regulations to implement fees for a new regulatory framework for *In vitro* diagnostic (IVD) devices. Amends schedules of charges applying to therapeutic goods, listed, registered and included medical devices, to include charges for IVDs.
Consultation opportunities	The IVD fees and charges model has been developed in close consultation with industry and in accordance with the Australian Government's cost recovery policy. TGA consultation on IVD fees and charges included: • Ongoing stakeholder consultation on cost recovery proposals undertaken through a TGA/industry working group involving representatives from the Medical Industries Association of Australia (MIAA) and members from the IVD industry who represent both large and smaller IVD suppliers; and • A Cost Recovery Impact Statement (CRIS) identifying the changes and incorporating stakeholder views was completed in March 2006 in accordance with Australian Government Cost Recovery Guidelines and has been published on the TGA's website.
Expected timetable	The drafting of legislation for the new IVD regulatory framework commenced in March 2006. The Therapeutic Goods (Charges) Amendment Regulations 2006 will coincide with implementation of the IVD regulatory framework. Both are proposed to have effect by no later than the start date of the Australia New Zealand Therapeutic Products Authority.
Contact details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au
Date last modified	July 2006

Title	**Therapeutic Goods (Medical Devices) Amendment Regulations 2006**
Description of issue	An amendment to the Therapeutic Goods (Medical Devices) Regulations to implement fees for a new regulatory framework for *In vitro* diagnostic (IVD) devices. Amends schedules of fees applying to therapeutic goods, listed, registered and included medical devices, to include fees for IVDs.
Consultation opportunities	The IVD fees and charges model has been developed in close consultation with industry and in accordance with the Australian Government's cost recovery policy. TGA consultation on IVD fees and charges included: • Ongoing stakeholder consultation on cost recovery proposals undertaken through a TGA/industry working group involving representatives from the Medical Industries Association of Australia (MIAA) and members from the IVD industry who represent both large and smaller IVD suppliers; and • A Cost Recovery Impact Statement (CRIS) identifying the changes and incorporating stakeholder views was completed in March 2006 in accordance with Australian Government Cost Recovery Guidelines and

	has been published on the TGA's website.
Expected timetable	The drafting of legislation for the new IVD regulatory framework commenced in March 2006. The Therapeutic Goods (Medical Devices) Amendment Regulations 2006 will coincide with implementation of the IVD regulatory framework. Both are proposed to have effect by no later than the start date of the Australia New Zealand Therapeutic Products Authority.
Contact details	Michel Lok Business and Services Branch Therapeutic Goods Administration Ph: (02) 6232 8216 E-mail: michel.lok@health.gov.au
Date last modified	July 2006

Title	***Industrial Chemicals (Notification and Assessment) Amendment Act 2007***
Description of issue	Amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989* to revise current penalty provisions consistent with other similar Commonwealth legislation, including the development of a penalty infringement notice system. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	Consistent with the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Community Engagement Charter, established consultative mechanisms include the NICNAS Industry Government Consultative Committee and Community Engagement Forum. In addition, public consultation on the proposed changes is expected to occur in Quarter 2 and Quarter 3 of 2006/07.
Expected timetable	Amendments to be made by March 2007.
Contact details	Nick Walton Compliance and Reporting National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8807 E-mail: nick.walton@nicnas.gov.au
Date last modified	July 2006

Title	***Industrial Chemicals (Notification and Assessment) Amendment Act 2007***
Description of issue	Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	Consistent with the NICNAS Community Engagement Charter established consultative mechanisms include the NICNAS Industry Government Consultative Committee and Community Engagement Forum. In addition, public consultation on the proposed changes is expected to occur in Quarter 2 and Quarter 3 of 2006/07.
Expected timetable	Amendments to be made by March 2007.
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2006

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2007 [No _]**
Description of issue	Amendments to reflect any agreed outcomes of the Review of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Existing Chemicals Program. A Regulatory Impact Statement will form part of the process
Consultation opportunities	Consistent with the NICNAS Community Engagement Charter established consultative mechanisms include the NICNAS Industry Government Consultative Committee and Community Engagement Forum. In addition, public consultation on the proposed changes is expected to occur in Quarter 2 and Quarter 3 of 2006/07.
Expected timetable	Amendments to be made by March 2007.
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2006

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2007 [No _]**
Description of issue	The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) new chemicals – approved foreign schemes. The *Industrial Chemicals (Notification and Assessment) Act 1989* provides for recognition of approved foreign schemes (section 43) and use of an assessment report generated under the approved foreign scheme (section 44). NICNAS participates in the OECD New Chemicals program which includes work-sharing activities designed to assist in harmonisation of assessments and new chemicals notification procedures and reporting. The work aims to reduce regulatory burden for industry and governments, while maintaining health and environmental standards. Bilateral arrangements between national new chemicals regulators are encouraged under the program. NICNAS is finalising such an arrangement with Environment Canada and is working towards recognition of the Canadian scheme as an approved foreign scheme under the legislation.
Consultation opportunities	Through the Industry Government Consultative Committee and with key industry stakeholders initially during 2002-03 and the Low Regulatory Concern Chemicals (LRCC) consultation process in 2003-04.
Expected timetable	Bilateral Arrangement with Canada – signed late 2002. Recognition of Canadian Scheme – estimated November 2006. Other foreign scheme activities ongoing.
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2006

Title	***Industrial Chemicals (Notification and Assessment) Amendment Act 2006***
Description of issue	To enable legislative underpinning of the National Industrial Chemicals

	Notification and Assessment Scheme (NICNAS) Cosmetic Guidelines arising from the cosmetic reform activities. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	An implementation Working Group consisting of industry community and government developed the NICNAS Cosmetic Guidelines. A Cosmetic Advisory Group will provide advice to NICNAS on maintaining the guidelines. Consistent with the NICNAS Community Engagement Charter, established consultative mechanisms include the NICNAS Industry Government Consultative Committee and Community Engagement Forum.
Expected timetable	December 2006.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au
Date last modified	July 2006

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No _]**
Description of issue	To enable legislative underpinning of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) Cosmetic Guidelines arising from the cosmetic reform activities. A Regulatory Impact Statement will form part of the process.
Consultation opportunities	An implementation Working Group consisting of industry community and government developed the NICNAS Cosmetic Guidelines. A Cosmetic Advisory Group will provide advice to NICNAS on maintaining the guidelines. Consistent with the NICNAS Community Engagement Charter established consultative mechanisms include the NICNAS Industry Government Consultative Committee and Community Engagement Forum.
Expected timetable	December 2006.
Contact details	Roshini Jayewardene Regulatory Strategy & Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8860 E-mail: roshini.jayewardene@nicnas.gov.au
Date last modified	July 2006

Title	**Industrial Chemicals (Notification and Assessment) Amendment Regulations 2006 [No _]**
Description of issue	A number of regulations are required for implementing outstanding Low Regulatory Concern Chemicals (LRCC) reforms. No specific Regulatory Impact Statement (RIS) for regulations is required as it is covered in the RIS prepared for the LRCC amendments to the *Industrial Chemicals (Notification and Assessment) Act 1989.*
Consultation opportunities	Consistent with the NICNAS Community Engagement Charter, established consultative mechanisms include the NICNAS Industry Government Consultative Committee and the Community Engagement Forum. In addition, public consultation on the proposed changes is expected to occur in August – October 2006.

Expected timetable	November 2006.
Contact details	Bob Graf Reform National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	July 2006