

Department of Health and Ageing 2004-05 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 2003 to 30 June 2004); and
- activities planned in the current financial year (1 July 2004 to 30 June 2005) 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 19 October 2004.

Past Regulatory Activity

Department of Health and Ageing

Title	Policy guidance for the regulation of Novel Foods.
Description of issue	<p>Novel foods are those foods that are non-traditional to Australia and New Zealand, and/or foods for which there has been no safety evaluation.</p> <p>Regulations concerning novel foods have been incorporated into the Australia New Zealand Food Standards Code since June 2001. However, a number of concerns with the existing standard have been identified.</p> <p>Accordingly, Ministers have asked Food Standards Australia New Zealand (FSANZ) to review the standard and the associated user guide and to consider issues raised by stakeholders during the policy consultation process. The Ministerial Council has also specified that industry, government and consumer groups be included in the review process.</p> <p>The revised standard will provide greater clarity for all stakeholders about the process FSANZ undertakes in determining if a food is novel.</p>
Date of Effect	The Australia and New Zealand Food Regulation Ministerial Council adopted the policy guideline on 12 December 2003. The policy guideline has been forwarded to Food Standards Australia New Zealand to assist in the review of the existing novel food standard.
Contact details	<p>Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au</p>

Title	Policy guidance for the Fortification of Foods with Vitamins and Minerals
Description of issue	<p>In May 2002, the Australia and New Zealand Food Regulation Ministerial Council agreed to the addition of policy guidelines on the fortification of foods to the Food Regulation Standing Committee (FRSC) program. In December 2002, FRSC agreed to the addition of food-type dietary supplements to its work plan and the formation of separate working groups to progress the development of policy guidance on fortification and food-type dietary supplements.</p> <p>A discussion paper on the regulation of food-type dietary supplements was released in July 2003 for public consultation. It raised a number of complex issues which brought into question the separation of policy guidance on food-type dietary supplements, fortification and the related issues of health claims and novel foods.</p> <p>In November 2003 FRSC suspended work on Food Type Dietary Supplements pending further work on Fortification. It is expected that continuing work on Fortification of Foods with Other Things will supersede the need for any further work on Food Type Dietary Supplements.</p> <p>In December 2003, a consultation paper on draft policy options for fortification of food with vitamins and minerals was released.</p>

	<p>The consultation drew many comments about the addition to food of substances other than vitamins and minerals. The FRSC working group determined it was not possible to address the issues raised by stakeholders in one policy guideline.</p> <p>The draft policy guideline for the fortification of food with vitamins and minerals was developed based on the submissions received from both the food-type dietary supplements and fortification consultations.</p> <p>The Australia New Zealand Food Regulation Ministerial Council agreed to further work being undertaken with a view to developing a policy guideline with respect to the addition of substances other than vitamins and minerals to food.</p>
Date of Effect	The Australia New Zealand Food Regulation Ministerial Council adopted the policy guideline on 28 May 2004. The policy guideline has been forwarded to Food Standards Australia New Zealand to assist in the assessment of new applications or proposals.
Contact details	<p>Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au</p>

Title	Policy Guideline on Nutrition, Health and Related Claims on foods
Description of issue	<p>A policy guideline was developed by the Australia and New Zealand Food Regulation Ministerial Council to guide Food Standards Australia New Zealand in the development of a food standard on Nutrition, Health and Related Claims on foods.</p> <p>The policy guideline provides a framework that will allow manufacturers of foods to make claims in advertising and labelling that their products contain certain nutritional substances and thereby provide health benefits to consumers.</p> <p>The policy aims to ensure that the health and safety of the public is protected, whilst still allowing for food industry innovation and trade. It does this by incorporating a number of elements designed to ensure that claims made on foods or in advertising are true, scientifically substantiated and not misleading.</p>
Date of effect	<p>The Australia and New Zealand Food Regulation Ministerial Council adopted the policy guideline on 12 December 2003. The policy guideline has been forwarded to Food Standards Australia New Zealand to assist in the development of a draft standard for the Food Standards Code.</p> <p>The food standard on Nutrition, Health and Related Claims is expected to be implemented in early 2006.</p>
Contact details	<p>Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au</p>

Title	Health Insurance Commission New Simplified Claiming Model Contained in the Health and Ageing Portfolio Act 2004
Description of Issue	Among other things the Act provides for a new Health Insurance Commission (HIC) simplified billing claiming model. The model will enhance informed Financial Consent and facilitate increased simplified billing.
Consultation Opportunities	The HIC is responsible for the consultation in relation to this matter.
Expected Timetable	Received Royal Assent Wednesday, 21 April 2004
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	9 June 2004

Title	Health Legislation Amendment (Private Health Insurance Reform) Act 2004
Description of Issue	The legislation implements reforms to the regulation of the private health insurance industry. The legislation aims to produce increased value for money in private health insurance products by allowing funds to be more efficient and responsive to members' needs, through: decreasing the current regulatory burden on health funds; strengthening consumer protection as a result of increased powers for the Private Health Insurance Ombudsman and; improving the effectiveness of Lifetime Health Cover arrangements. Regulations detailing performance indicators for monitoring the performance of health funds are expected to be in place by 1 July 2004.
Consultation Opportunities	The Department has undertaken consultation with key stakeholders, in particular with the industry participants who will be affected by the proposed reforms. The Regulation Impact Statement was made available with the introduction of the draft legislation.
Date of Effect	This legislation received Royal Assent on 27 February 2004, with all provisions commencing by 1 July 2004.
Contact Details	Neil Smith Private Health Industry Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date last modified	9 June 2004

Title	Health Insurance (Billing Agents – Conditions of Approval) Determination (No.1) 2004
Description of Issue	The guidelines were amended to reflect a transfer of responsibility for registration of Billing agents from the Private Health Insurance Administration Council to the Health Insurance Commission.
Date of Effect	The revised guidelines took effect from 18 February 2004.
Contact Details	Veronica Hancock Insurance Industry Section Department of Health and Ageing Ph: (02) 6289 9420

Title	Amendment to Regulation 48 of the National Health Regulations 1954
Description of Issue	Regulation 48 was amended to allow general insurers to offer cover for out-of-hospital medical expenses that do not attract a Medicare rebate, for Australians and other eligible person on cruise ships in Australian waters.
Date of Effect	The amendment took effect from 19 December 2003.
Contact Details	Veronica Hancock Insurance Industry Section Department of Health and Ageing Ph: (02) 6289 9420

Title	Removal of lifestyle benefits from ancillary products Additional conditions of registration
Description of Issue	Determination made under paragraph 73B(1) of the National Health Act 1953 establishes additional conditions of registration for registered health benefits organisations.
Date of Effect	Changes took effect from 1 September 2003
Contact Details	Geoffrey Smedley Insurance Industry Section Department of Health and Ageing Ph (02) 6289 9435

Title	Health Legislation Amendment (Podiatric Surgery and Other Matters Bill) 2004	
Description of Issue	This Bill would enable registered health benefits organisations to pay benefits for accommodation and nursing associated with procedures performed on admitted patients by accredited podiatrists from their hospital tables. It enables a person who is, or is likely to become, an executor or administrator of the estate of a deceased approved pharmacist to supply medicines subsidised under the pharmaceutical benefits scheme at or from the deceased pharmacist's approved premises, and receive payment for that supply. It includes a provision for day surgeries to provide Hospital Casemix Protocol data to the Department of Health and Ageing. It also makes some minor updates and technical amendments.	
Consultation Opportunities	The action regarding podiatric surgeons was taken in response to concerns raised by the National Competition Council after consultation with key medical and podiatric stakeholders as well as State Government.	
Expected Timetable	The bill was introduced on 12 May 2004 its passage is subject to parliamentary processes.	
Contact Details	Peter Callanan Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9840 E-mail: peter.callanan@health.gov.au	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: Catherine.farrell@health.gov.au
Date Last Modified	18 June 2004	

Title	Medical Indemnity (IBNR Indemnity) Contribution Regulations 2003
Description of Issue	Changes the imposition day for IBNR Contribution (later named UMP Support Payment) from 1 August 2003 to 15 August 2003.
Consultation Opportunities	Consultation included HIC – an administrative decision due to system delays.
Date of Effect	30 July 2003
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246
Date Last Modified	The imposition day was later changed by legislation to 1 March 2004 then 1 May 2004.

	Last modified March 2004.
--	---------------------------

Title	Medical Indemnity (Unfunded Incurred But Not Reported Liabilities Factor – United Medical Protection)	
Description of Issue	Determines the Incurred But Not Reported factor as 50% for United Medical Protection.	
Consultation Opportunities	Incurred But Not Reported factor was already included in early policy announcements.	
Date of Effect	14 August 2003	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Date Last Modified	August 2003	

Title	Medical Indemnity (Non-participating MDOs) Determination 2003	
Description of Issue	Determines the MDOs that will not participate in IBNR Contribution.	
Date of Effect	14 August 2003	
Consultation Opportunities	Consultation included Australian Government Actuary and Health Insurance Commission.	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Date Last Modified	August 2003	

Title	Medical Indemnity Amendment Bill 2003	
Description of Issue	<p>Implements the Exceptional Claims Scheme (ECS) to indemnify doctors for claims over their contract limit (generally \$20 million or \$25 million).</p> <p>Clarifies IBNR contribution (later named UMP Support Payment) exemptions for doctors who die and doctors with retroactive cover.</p> <p>Allows refunds of IBNR contributions already paid during 2003-04 (the refunds were later made during December 2004).</p> <p>Sets imposition day as 1 March 2004.</p>	
Consultation Opportunities	AMA and medical indemnity insurers. Regulation Impact Statement available with the introduction of the Bill.	
Date of Effect	ECS provisions 1 January 2003. IBNR provisions 1 July 2003.	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Date Last Modified	December 2003	

Title	Medical Indemnity (IBNR Indemnity) Contribution Amendment Bill 2003	
Description of Issue	Implements the 18 month moratorium on IBNR contributions by doctors.	
Consultation Opportunities	AMA and medical indemnity insurers. Regulation Impact Statement available with the introduction of the Bill.	
Date of Effect	1 July 2003	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Date Last Modified	December 2003	

Title	Medical Indemnity Regulations 2003, Medical Indemnity Amendment Regulations 2003 (No. 1) Medical Indemnity Amendment Regulations 2003 (No. 2)	
Description of Issue	Exemptions from IBNR contribution: members of MDASA and MDAV from IBNR contribution; public sector specialists; persons with retroactive cover; persons aged over 65; persons with a disability; persons who die before imposition day; and salaried medical practitioners Sets payment day as 1 February 2004 then amends to 1 June 2004. Sets High Cost Claims Scheme (HCCS) threshold at \$500,000.	
Consultation Opportunities		
Date of Effect	Exemptions 15 August 2003 – consistent with IBNR imposition day HCCS upon gazettal in October 2003.	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Dates Last Modified	14 August 2003, 9 October 2003 and 21 October 2003	

Title	Medical Indemnity Amendment Bill 2004 Medical Indemnity (IBNR Indemnity) Contribution Amendment Bill 2004	
Description of Issue	Replaces the IBNR Contribution with the new UMP Support Payment, with new criteria which limits the amounts doctors have to pay, and the number of years they have to pay. Enables a single financial transaction for doctors to pay their insurance premiums and UMP Support Payment and receive the Premium Support Scheme (PSS). Enables the PSS to be implemented through legislative instrument.	
Consultation Opportunities	AMA and medical indemnity insurers. Regulation Impact Statement available with the introduction of the Bill.	
Date of Effect	23 March 2004	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246	
Date Last Modified	March 2004	

Title	Medical Indemnity Legislation Amendment (Run-off Cover Indemnity and Other Measures) Bill 2004 Medical Indemnity (Run-off Cover Support Payment) Bill 2004	
Description of Issue	Implements Run-off Cover Scheme (ROCS) to indemnify doctors when they cease private medical practice and expand Exceptional Claims Scheme to include some overseas treatment. Imposes Run-off Cover Support Payment on medical indemnity insurers to fund the ROCS. Expands the ECS to include some overseas treatment.	
Date of Effect	ROCS provisions 1 July 2004. ECS provisions 5 December 2003 consistent with commencement of ECS legislation.	
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02)	

	6289 9246
--	-----------

Title	Medical Indemnity Amendment Regulations 2004 Medical Indemnity (Run-off Cover Support Payment) Regulations 2004
Description of Issue	Implements aspects of the Run-off cover scheme which provides indemnity to cover claims against doctors when they cease private medical practice, and to expand the Exceptional Claims Scheme indemnity to some overseas events. Implements the Run-off cover Support Payment which imposes 8.5% tax on medical indemnity insurers of a proportion of premium income to fund the ROCS (9.5625% for UMP). Sets UMP Support Payment imposition day of 1 November each year for UMP members as UMP operates on a calendar year basis.
Date of Effect	ROCS provisions 1 July 2004. ECS provisions 5 December 2003 consistent with commencement of ECS legislation.
Contact Details	Susan Rogers, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9246

Title	Medical Indemnity Subsidy Amendment Scheme 2004
Description of Issue	Amends the Medical Indemnity Subsidy Scheme 2003 (MISS) to bring procedural general practitioner registrars into the categories of medical practitioners assisted under the MISS (as per earlier media statements) and provides for the repeal of the MISS from midnight on 30 June 2004 when it will be replaced by the Premium Support Scheme 2004.
Consultation Opportunities	Was developed in consultation with the AMA, HIC and independent legal counsel.
Date of Effect	17 June 2004
Contact Details	Paul Currall, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9200
Date Last Modified	

Title	Premium Support Scheme 2004
Description of Issue	Provides for: medical indemnity insurers and medical defence organisations on behalf of medical practitioners where the medical indemnity insurer or medical defence organisation agree to administer the Scheme by entering into a Premium Support Scheme contract for the purposes of the Scheme; and contracted insurers and contracted medical defence organisations to help them meet the cost of administering the Scheme, including implementation costs
Consultation Opportunities	Was developed in consultation with the AMA, HIC, medical indemnity insurers, APRA, and independent legal consul.
Date of Effect	17 June 2004
Contact Details	Paul Currall, Medical Indemnity Branch, Department of Health and Ageing (02) 6289 9200
Date Last Modified	

Title	The Metropolitan Workforce Support Program was included as an amendment to the Health Insurance Regulations 1975 as Schedule 5, Part 2, item 19 and gazetted on 23 December 2003 (2003 No. 356).
Description of issue	<p>The outer metropolitan areas of Australia's cities have undergone considerable growth over recent years, putting additional pressure on services provided by medical practitioners.</p> <p>Consultations have shown that the utilisation of a select group of permanent-resident, overseas-trained doctors, who are currently living in metropolitan areas, could further increase the number of doctors working in outer metropolitan areas of workforce shortage.</p> <p>The Metropolitan Workforce Support Program is a pilot conducted in outer metropolitan areas of workforce shortage in Perth WA. This pilot consists of the recruitment, assessment and placement of a select group of permanent resident overseas trained doctors to work in eligible general practice settings in outer metropolitan Perth. This pilot will allow those overseas trained doctors without vocational registration to access Medicare rebates whilst undertaking training to achieve fellowship of the Royal Australian College of General Practitioners.</p> <p>The Metropolitan Workforce Support Program will provide a snapshot of the overseas trained doctor general practice workforce in outer metropolitan areas of workforce shortage and will be used for further policy development in this area.</p> <p>An amendment to Part 2 of Schedule 5 of the Health Insurance Regulations 1975 was obtained to enable the Metropolitan Workforce Support Program to become an approved program under section 3GA of the Health Insurance Act 1973.</p>
Date of effect	The Metropolitan Workforce Support Program was included as an amendment to the Health Insurance Regulations 1975 as Schedule 5, Part 2, item 19 and gazetted on 23 December 2003 (2003 No. 356).
Contact details	<p>Juleen Browning Overseas Trained Doctors Taskforce Health Workforce Branch Department of Health and Ageing</p> <p>Telephone: (02) 6289 5373 Facsimile: (02) 6289 7333 E-mail: juleen.browning@health.gov.au</p>

Title	Amendments to referral arrangements for diagnostic imaging services funded through Medicare
Description of Issue	<p>Amendments to the <i>Health Insurance Act 1973</i> have implemented the recommendations arising from the Diagnostic Imaging Referral Arrangements Review.</p> <p>Specifically, the amendments have:</p> <ul style="list-style-type: none"> • introduced an accountable substitution model for diagnostic imaging services, which enables the imaging service provider to substitute a more appropriate imaging service when a patient is referred to the service provider for an inappropriate diagnostic imaging service; • excluded services requiring referral by a specialist from being performed

	<p>without a referral, by radiologists as an additional necessary service;</p> <ul style="list-style-type: none"> • extended to all service providers prohibitions against stationing diagnostic imaging equipment or employees at the premises of another practitioner so that diagnostic imaging services may be rendered (these measures only previously applied to radiologists); and • exempted the above prohibition for services in defined areas of need as defined in the regulations.
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003, and the new requirements took effect on 1 July 2003.
Contact Details	<p>Harold Lomas Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail: harold.lomas@health.gov.au</p>
Date Last Modified	14 August 2003

Title	Introduction of registration requirements for diagnostic imaging and radiation oncology premises and mobile facilities
Description of Issue	<p>Amendments to the <i>Health Insurance Act 1973</i> require the registration of premises that render diagnostic imaging procedures and radiation oncology services for Medicare benefits to be payable and the allocation of Location Specific Practice Numbers (LSPNs) to registered sites.</p> <p>The information collected through registration and the use of LSPNs will assist the Government, in conjunction with the diagnostic imaging and radiation oncology professions, to better manage and monitor the provision of these services under Medicare.</p> <p>The requirement to apply and maintain registration lies with the proprietor operating the diagnostic imaging or radiation oncology services at the premises or mobile facility. Medical practitioners are responsible for including a LSPN on accounts, receipts and direct billing assignment forms so that patients can claim Medicare benefits.</p> <p>The detail of information included under the registration requirements is included in the Health Insurance Regulations 1975.</p>
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003, and the new requirements took effect on 1 July 2003.
Contact Details	<p>Harold Lomas Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail Harold.Lomas@health.gov.au</p>
Date Last Modified	14 August 2003

Title	Recognition of osteopaths as a professional group under the <i>Health Insurance Act 1973</i>
Description of Issue	Amendments to the <i>Health Insurance Act 1973</i> now recognise osteopaths as a separate professional group to chiropractors and have the effect of allowing osteopaths to request diagnostic imaging services.
Date of Effect	Legislation was introduced into Parliament on 11 December 2002. The Bill received Royal Assent on 15 April 2003.
Contact Details	Harold Lomas Diagnostics and Technology Branch Department of Health and Ageing Ph: (02) 6289 7315 E-mail: Harold.lomas@health.gov.au
Date Last Modified	14 August 2003

Title	Health and Ageing Legislation Amendment Bill 2003
Description of Issue	The Bill includes the following measures: <ul style="list-style-type: none"> • gives express power to the Secretary to suspend, rather than cancel, an approval to supply pharmaceutical benefits; and • makes explicit the Minister's discretion to suspend, rather than cancel, an approval to supply pharmaceutical benefits by dispensing doctors and hospital authorities.
Date of Effect	May 2004
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Changes to the Health Insurance (General Medical Services Table) Regulations 2001
Description of Issue	<p>The changes are associated with the implementation of the Outer Metropolitan (Other Medical Practitioners) Relocation Incentive Program (Program). This Program was announced as part of the More Doctors for Outer Metropolitan Areas Measure in the 2002-03 Budget.</p> <p>The area of the regulation affected is Schedule 1 of the Health Insurance (General Medical Services Table) Regulations 2001. The specific amendment is to the definition of 'eligible non-vocationally recognised medical practitioner'.</p> <p>The purpose of the regulatory change is to allow doctors in the Program to claim Medicare A1 rebates once they have relocated from an inner metropolitan area to an outer metropolitan area of workforce shortage. The Program is also applicable to eligible doctors already practising in outer metropolitan areas of workforce shortage.</p>
Date of Effect	4 November 2002

Contact Details	Bronwen Dowse Workforce and Quality Branch Department of Health and Ageing Ph: (02) 6289 3120 E-mail: bronwen.dowse@health.gov.au
Date Last Modified	15 August 2003

Title	Private Health Insurance Levy Bills 2003 and National Health Amendment (Private Health Insurance Levies) Bill 2002
Description of Issue	These Bills removes any constitutional doubt in relation to four extant private health insurance industry levies by re-imposing them in compliance with section 55 of the Constitution.
Consultation Opportunities	The action was taken in response to concerns raised by the Australian Nation Audit Office Report 'Management of Commonwealth Non-Primary Levies'. Industry and key stakeholders have already been consulted in relation to this proposed legislation.
Expected Timetable	This package of legislation was passed by Parliament on 26 June 2003 and received Royal Assent on 15 July 2003. The Regulations to these Acts commenced on 1 July 2004.
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	18 August 2003

Title	Review of <i>Health Legislation Amendment Act (No 1) 2001</i> as specified under Section 5E of the <i>National Health Act 1953</i>
Description of Issue	Section 5E of the <i>National Health Act 1953</i> (the Act), inserted by the outreach services legislation (<i>Health Legislation Amendment Act (No 1) 2001</i>) requires that an independent review of the operation of the outreach legislation be undertaken and a report has been tabled in both Houses of Parliament on 30 June 2003.
Consultation Opportunities	Industry and key stakeholders were consulted as part of the review.
Expected Timetable	The report was tabled in both Houses of Parliament on 30 June 2003.
Contact Details	Julie Marr Hospitals Branch Department of Health and Ageing Ph: (02) 6289 9825 E-mail: julie.marr@health.gov.au
Date Last Modified	18 August 2003

Title	Establishment of the National Blood Authority to provide a national management framework for the Australian blood and blood products sector
Description of Issue	Establishment of the National Blood Authority to coordinate and manage Australia's blood supply to ensure that supply levels are sufficient to meet Australian demand.
Consultation Opportunities	<p>Extensive consultations with stakeholders were conducted by the Review of the Australian Blood Banking and Plasma Product Sector, completed on 3 June 2001.</p> <p>Stakeholders consulted included:</p> <ul style="list-style-type: none"> • Australian Red Cross Blood Service; • Therapeutic Goods Administration; • CSL Limited; • National Health and Medical Research Council; • National Institute of Clinical Studies; • Pharmaceutical Benefits Advisory Committee • Australian Council for Safety and Quality in Health Care • Pharmaceutical Benefits Pricing Authority; • Medical Services Advisory Committee; • Haemophilia Foundation Australia; and • other pharmaceutical industry players. <p>In developing an implementation strategy for the Review's recommendations, including the establishment of a National Blood Authority, consultations have been held with relevant stakeholders.</p>
Date of Effect	<p>Legislation to establish the National Blood Authority was introduced into Parliament on 11 December 2002 and received Royal Assent on 15th April 2003.</p> <p>The National Blood Authority was established on 1 July 2003.</p>
Contact Details	<p>Robin Boyce Blood Organ and Tissue Policy and Financing Department of Health and Ageing Ph: (02) 6289 8888 E-mail: robin.boyce@health.gov.au</p>
Date Last Modified	18 August 2003

Therapeutic Goods Administration

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment Act (No 1) 2003</i>
Description of Issue	Reform of the commercial evaluation permit category will ensure that all sectors in the chemical industry can access a fast, low-cost permit to commercially evaluate new industrial chemicals.
Consultation Opportunities	Consultation with industry stakeholders took place in 2000-01, with a period of public comment and consultation in 2001-02. A Regulation Impact Statement was prepared in 2002. The final report was released in February 2003.
Date of Effect	The Bill received Royal Assent on 15 July 2003.
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date Last Modified	22 June 2004

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment Act (No 1) 2003</i>
Description of Issue	Proposals were developed in response to the formal evaluation of the company registration program in 2000, with the aim of streamlining administration and delivering reform. Areas of change include: <ul style="list-style-type: none"> • introduction of late fees into the Act and regulations and the alignment of the annual renewal deadline with the registration expiry date; and • moving the fee setting power from the Act into the regulations to take into account consumer price indexing and allow greater flexibility in adjusting fees to fully recover costs in administering the Act and regulations. <p>Costing arrangements under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) were reviewed with an activity based costing model using 2001-02 data. It was determined that New Chemical activities were under-recovered, Australian Inventory of Chemical Substances (AICS) searches were a significant cost burden on NICNAS and there was insufficient company registration funding for remaining activities.</p>
Consultation Opportunities	Extensive consultations took place in relation to the proposed changes. All key stakeholders, including industry associations and registered companies, were consulted. Results of the activity-based costing model were presented to the Industry Government Consultative Committee (IGCC) in the form of a proposal for increased fees and charges at the November 2002 meeting. Subsequently a draft Regulation Impact Statement was prepared and presented to IGCC for comment in January.
Date of Effect	The Bill received Royal Assent on 15 July 2003.
Contact Details	Nick Miller Business Management and Communication National Industrial Chemicals Notification and Assessment Scheme

	Ph: (02) 8577 8810 E-mail: nick.miller@nicnas.gov.au
--	--

Title	Therapeutic Goods Order No 72
Description of Issue	Therapeutic Goods Order No. 72 – Standards for Blood Components – revokes the existing Therapeutic Goods Orders No 66 and No 66A and updates the edition of a key reference document that prescribes the minimum standard to be met by blood and blood components in Australia. Specifically, it requires that blood and blood components must meet the requirements of the Council of Europe document titled 'Guide to the preparation, use and quality assurance of blood components 9 th edition.
Date of Effect	21 April 2004
Contact Details	Albert Farrugia Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8539 E-mail: albert.farrugia@health.gov.au

Title	Therapeutic Goods Order (TGO) No. 61A Contraceptive Devices – Rubber Condoms
Description of Issue	An amendment to TGO 61 to adopt ISO 4047:2002 Natural Latex Rubber Condoms which replaces ISO 4047:1996 Rubber Condoms. Also amendments to limit the labelling claims relating to reducing the risk of pregnancy, reducing the risk of the transmission of HIV/AIDS and other sexually transmitted infections, and claims relating to the additional of nonoxinol 9.
Date of Effect	24 March 2004
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@health.gov.au

Title	Proposed Therapeutic Goods Order (TGO) No. 71 – Tamper-Evident Packaging of Therapeutic Goods
Description of Issue	TGO 71 will adopt the document <i>Code of Practice for the Tamper-evident Packaging (TEP) of Therapeutic Goods</i> (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.
Date of Effect	This Order is effective from 1 January 2004, with a one-year transition period during which sponsors should ensure full compliance.
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@health.gov.au

Title	Therapeutic Goods Order (TGO) No. 70A – Standards for Export Only Medicines
Description of	Amends TGO 70 – Standards for Export Only Medicines to update referenced

Issue	pharmaceutical standards: British Pharmacopoeia (2002 edition) and United States Pharmacopoeia (26 th edition).
Date of Effect	17 December 2003
Contact Details	Pio Cesarin Non Prescription Medicines Branch Therapeutic Goods Administration Phone: (02) 6232 8660 Email: pio.cesarin@health.gov.au

Title	Therapeutic Goods (Articles that are not Medical Devices) Order No. 1 of 2004
Description of Issue	Further to the Therapeutic Goods (Medical Devices) regulations 2002, this Order declares certain articles not to be medical devices for the purpose of section 41BD(3) of the <i>Therapeutic Goods Act 1989</i> .
Date of Effect	21 April 2004
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@health.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2003 (No 3) – Statutory Rule No. 192
Description of Issue	The <i>Industrial Chemicals (Notification and Assessment) Amendment Act 2003</i> (the Act) made a number of changes to the company registration provisions in Part 3 of the Act. Consequent changes to the regulations included removing the provision for the urgent handling of applications for initial registration, the alignment for the deadline for the renewal of company registration with the expiry date of registration and the introduction of a late renewal penalty for renewals of company registration received after the renewal deadline. Company registration fees and charges were also transferred from the Act to the Industrial Chemicals (Notification and Assessment) Regulations 1990.
Date of Effect	31 July 2003
Contact Details	Nick Miller Business Management and Communication National Industrial Chemicals Notification and Assessment Scheme Phone: (02) 8577 8810 Email: nick.miller @nicnas.gov.au

Title	Therapeutic Goods Amendment Regulations 2003 (No 3) – Statutory Rule No. 257
Description of Issue	These regulations require that where a medicine is manufactured using human embryos or human embryonic stem cells (or material sourced from human embryos or embryonic stem cells), notification to this effect must be included in the Patient Information and the Product Information documentation that accompany the supply of medicines that are, in the main, prescription medicines.
Date of Effect	16 October 2003
Contact Details	Leonie Hunt Drug Safety and Evaluation Branch Therapeutic Goods Administration Phone: (02) 6232 8100 Email: leonie.hunt@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2003 (No 4) – Statutory Rule No.
-------	--

	258
Description of Issue	These regulations provide for the better identification of therapeutic goods for the purposes of recall; enhance compliance with guidelines issued by the TGA for the reporting of adverse drug reactions to the use of medicines; and ensure that the Principal Regulations are consistent with expanded public notification and recovery requirements recently introduced into the <i>Therapeutic Goods Act 1989</i> .
Date of Effect	Regulations 1 to 3 and Schedule 1: 16 October 2003 Schedule 2; 1 October 2004
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2003 (No 5) – Statutory Rule No. 301
Description of Issue	Amends the Principal Regulations as a consequence of the changes made to the <i>Therapeutic Goods Act 1989</i> (the Act) by the <i>Therapeutic Goods Amendment Act (No.1) 2003</i> . All advertising offence provisions have been removed from the Principal Regulations and transferred to the Act. Pre-approval of advertisements about medicines that are intended for broadcast in the broadcast media (previously provided for in the <i>Broadcasting Services Act 1992</i>) is now provided for in the principal Regulations. Other amendments allow individual Therapeutic Goods Advertising Code Council members to refer matters to the Council and amend the requirements for the number of persons constituting a quorum at meetings of the Complaints Resolution Panel.
Date of Effect	5 December 2003
Contact Details	Pio Cesarin Non Prescription Medicines Branch Therapeutic Goods Administration Phone: (02) 6232 8660 Email: pio.cesarin@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2003 (No 6) – Statutory Rule No. 361
Description of Issue	These regulations make a number of minor changes to the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002: <ul style="list-style-type: none"> • Regularise the appointment of authorised officers and authorised persons under the two sets of regulations; • Recognise the Tasmanian Therapeutic Goods Act 2001 as corresponding State law; • Increase the permissible number of consecutive terms for members of the Therapeutic Goods Advertising Code Council and the Complaints Resolution Panel; and • Correct typographical errors.
Date of Effect	23 December 2003
Contact Details	Pio Cesarin Non Prescription Medicines Branch Therapeutic Goods Administration Phone: (02) 6232 8660 Email: pio.cesarin@health.gov.au

Title	Therapeutic Goods Amendment Regulations 2004 (No 1) – Statutory Rule No. 78
Description of Issue	These regulations make a number of changes to the Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002:

	<ul style="list-style-type: none"> • Amend Schedule 4 to the Therapeutic Goods Regulations 1990 to include certain therapeutic goods that have been subject to listing notices; • Include additional exemptions from Part 3-2 (Registration and listing of therapeutic goods) and Division 3 of Part 4-11 (Offences relating to medical devices not on the Register) of the <i>Therapeutic Goods Act 1989</i> in specified limited circumstances; and • Makes amendments to reflect a change in policy that certain products will be treated as medical devices rather than medicines.
Date of Effect	30 April 2004
Contact Details	Rita Maclachlan Office of Devices, Blood and Tissues Therapeutic Goods Administration Phone: (02) 6232 8700 Email: rita.maclachlan@health.gov.au

Title	Industrial Chemicals (Notification and Assessment) Amendment Regulations 2004 (No 1) – Statutory Rule No. 158
Description of Issue	The purpose of the Regulations is to increase the Company Registration and New Chemical assessment fees and charges for the National Industrial Chemicals Notification and Assessment Scheme for 2004-05 by 5.1% rounded to the nearest dollar.
Consultation Opportunities	Results of the activity-based costing model were presented to the Industry Government Consultative Committee (IGCC) in the form of a proposal for increased fees and charges at the May 2003 meeting, accompanied by a draft Regulation Impact Statement.
Date of Effect	1 July 2004
Contact Details	Nick Miller Business Management and Communication National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8810 E-mail: nick.miller@nicnas.gov.au
Date Last Modified	22 June 2004

Title	Office of Gene Technology Regulator - introduction of new guidelines for certification of facilities/physical containment requirements (certain PC2 facilities) and constant temperature room guidelines
Description of Issue	<p>Certain dealings with genetically modified organisms (GMOs) may be conducted in laboratories and other facilities if those facilities comply with containment conditions that are set out in guidelines issued by the Regulator. The containment conditions in the guidelines manage risks to human health and safety and the environment associated with the performance of dealings with GMOs inside laboratories and other facilities.</p> <p>The Regulator has issued new Guidelines for Certification of Facilities/Physical Containment Requirements. The new guidelines affect certification of PC2 animal houses, PC2 plant houses and PC2 laboratories.</p>
Date of Effect	7 August 2003

Contact Details	Ian Coleman Licence And Application Management Section Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date Last Modified	June 2004

Title	Health Insurance (General Medical Services Table) Amendment Regulations 2003 – No.2 Health Insurance (Diagnostic Imaging Services Table) Amendment Regulations 2003 – No.3 Health Insurance (Pathology Services Table) Amendment Regulations 2003 – No.4
Description of Issue	The Regulations introduce new Medicare items to enable GPs to claim an additional payment of \$5 for bulk billing concessional patients and children under the age of 16.
Date of Effect	1 February 2004
Contact Details	Kathy Trembath General Practice Programs Branch Department of Health and Ageing Ph: (02) 6289 7829 E-mail: kathy.trembath@health.gov.au

Title	Health Insurance (General Medical Services Table) Amendment Regulations 2004 – No.1 Health Insurance (Diagnostic Imaging Services Table) Amendment Regulations 2004 – No.1 Health Insurance (Pathology Services Table) Amendment Regulations 2004 – No.1
Description of Issue	The Regulations introduce new Medicare items to enable GPs, in regional, rural and remote areas, and all of Tasmania, to claim an additional payment of \$7.50 for bulk billing concessional patients and children under the age of 16.
Date of Effect	1 May 2004
Contact Details	Kathy Trembath General Practice Programs Branch Department of Health and Ageing Ph: (02) 6289 7829 E-mail: kathy.trembath@health.gov.au

Title	Food Safety Management in Australia – Food Safety Programs
Description of Issue	The Australia and New Zealand Food Regulation Ministerial Council has adopted policy guidelines on <i>Food Safety Management in Australia – Food Safety Programs</i> . The guidelines include recommendations on which food business sectors should develop and implement mandatory food safety programs. It was agreed that the following sectors be required to introduce Food Safety Standard

	<p>3.2.1 <i>Food Safety Programs:</i></p> <ul style="list-style-type: none"> ▪ Food service in which potentially hazardous food is served to vulnerable populations (eg hospitals, nursing homes); ▪ Producing, harvesting, processing and distributing raw oysters and other bivalves; ▪ Catering operations serving food to the general public; and ▪ Producing manufactured and fermented meat.
Date of Effect	The Australia and New Zealand Food Regulation Ministerial Council adopted the policy guidelines on 12 December 2003. The policy guidelines have been forwarded to Food Standards Australia New Zealand to assist in the development of a draft standard for the Food Standards Code. This is not expected to be completed until early 2006.
Contact Details	Ian McKay Food Safety and Surveillance Section Department of Health and Ageing Ph: (02) 6289 5155 E-mail: ian.mckay@health.gov.au
Date Last Modified	16 June 2004

Title	Changes to <i>Health Insurance Act 1973</i> to restore restrictions on access to Medicare for assistance at operations for overseas-trained doctors
Description of Issue	<p>Changes that came into effect on 18 October 2001 varied the <i>Health Insurance Act 1973</i> to allow all overseas-trained doctors to access Medicare for assistance at operations. This included procedures in metropolitan areas.</p> <p>Overseas-trained doctors are normally required under restrictions in the <i>Health Insurance Act 1973</i> to work in rural and remote districts of workforce shortage if they wish to access Medicare benefits for services provided.</p> <p>Prior to this change, the only overseas-trained doctors able to access Medicare benefits were those on occupational trainee visas who were required as part of their training courses to assist at operations.</p> <p>However, a number of doctors on ordinary medical practitioner visas have taken advantage of this change to work in metropolitan areas.</p> <p>The changes, which came into effect in 2001, allowed this anomaly to occur. The legislative change will benefit rural and remote communities by requiring those doctors who have taken advantage of the anomaly to relocate from metropolitan areas.</p>
Consultation Opportunities	<p>Consultation has not been considered necessary on this matter.</p> <p>The intention was to restore arrangements that had been in place prior to the introduction of regulatory changes in October 2001. These changes inadvertently allowed some overseas-trained doctors to access Medicare for assistance at operations in metropolitan areas. The Government intention was that overseas-trained doctors only be able to access Medicare in rural and remote districts of workforce shortage, not metropolitan areas.</p>
Expected Timetable	The legislation received Royal Assent on 21/4/2004 and commenced on that day.

Contact Details	Barny Lee Workforce Distribution Programs Department of Health and Ageing Ph: (02)6289 5632 E-mail: barny.lee@health.gov.au
Date Last Modified	27 September 2004

Title	<i>Amendments to Health Insurance (General Medical Services Table) Regulations 2002 - MedicarePlus for Other Medical Practitioners (OMPs) Program</i>
Description of Issue	<p>On 18 November 2003, the Australian Government announced changes to Medicare.</p> <p>One of the initiatives included in the announcement is the MedicarePlus for Other Medical Practitioners (OMPs) Program, which provides access to the higher Medicare rebate for services provided in areas of workforce shortage by eligible pre 1996 non-vocationally recognised medical practitioners.</p> <p><i>Amendments to the Health Insurance (General Medical Services Table) Regulations 2002</i> were made to allow services provided by an eligible non-vocationally recognised medical practitioner under the MedicarePlus for OMPs Program to attract the full Medicare rebate. This amendment is in line with the Government's intent to recognise the value of services provided by non-vocationally recognised medical practitioners in areas of workforce shortage.</p> <p>The amendments to the Regulations also included the definition of "general practitioner" in Schedule 1, Part 1 of the Rules of Interpretation of the Principal Regulations, to expand the current definition of eligible non-vocationally recognised medical practitioners to include participants in the Program, and also insert a definition of the Program.</p>
Consultation Opportunities	Consultation occurred with relevant stakeholders and included the HIC, the Royal Australian College of General Practitioners (RACGP), and other general practice peak bodies
Date of Effect	Amendments to the Regulations were approved at the EXCO meeting on 18 December 2003. The Regulations commenced on 1 February 2004.
Contact Details	Ms Tuija Uotila Department of Health and Ageing GP Programs Branch Ph: (02) 6289 3645 Email: tuija.uotila@health.gov.au

Planned Regulatory Activity

Department of Health and Ageing

Title	Health Insurance Commission New Simplified Claiming Model – Contained in a Health and Ageing Portfolio Bill
Description of Issue	The Bill provides for a new Health Insurance Commission (HIC) simplified billing claiming model. The model will enhance Informed Financial Consent and facilitate increased simplified billing.
Consultation Opportunities	The HIC is responsible for the consultation in relation to this matter.
Expected Timetable	Introduced in the Senate 27 March 2003, and passed by the Senate on 26 June 2003. Was considered by the House of Representatives and passed in April 2004.
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	18 August 2003

Title	Health Legislation Amendment (Private Health Insurance Reform) Bill 2003
Description of Issue	The proposed legislation will implement reforms to the regulation of the private health insurance industry. The legislation will aim to produce increased value for money in private health insurance products by allowing funds to be more efficient and responsive to members' needs, through: <ul style="list-style-type: none"> • decreasing the current regulatory burden on health funds; • strengthening consumer protection as a result of increased powers for the Private Health Insurance Ombudsman and better information on the relative performance of funds; and • improving the effectiveness of Lifetime Health Cover arrangements.
Consultation Opportunities	The Department has undertaken consultation with key stakeholders, in particular with the industry participants who will be affected by the proposed reforms. The Regulation Impact Statement has been made available with the introduction of the draft legislation. The Senate Community Affairs Legislation Committee inquiry into this Bill enabled both public hearings and submission in relation to the Bill. The Report of the Committee recommended that the Bill proceed.
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au

Date Last Modified	18 August 2003
--------------------	----------------

Title	Amendment to <i>User Rights Principles 1997</i> to remove cap on maximum amount of daily resident fees for approved care recipients in unfunded places
Description of Issue	<p>An amendment to the <i>User Rights Principles 1997</i> made under the <i>Aged Care Act 1997</i> was made to remove the cap on the maximum daily amount of resident fees that an approved provider can charge an approved care recipient in an unfunded place. This allows the approved provider to charge an amount agreed beforehand with the care recipient.</p> <p>An approved provider wishing to charge such an amount is required to notify the care recipient of certain prescribed matters. An approved provider was not able to ask a care recipient who was already receiving care in an unfunded place on 1 September 2003 to leave the residential care service simply because the care recipient did not agree to pay an additional amount.</p> <p>The amendment allows an approved provider with spare capacity to offer places that may have otherwise been unavailable to approved care recipients. The amendment also offers an incentive for approved providers to build spare capacity before they receive an allocation of places. This will decrease the time lag between the allocation of places and those places becoming available for the provision of funded care.</p> <p>Except for this amendment, an approved provider continues to have the same responsibilities towards approved care recipients, regardless of whether they are receiving care in funded or unfunded places.</p>
Consultation Opportunities	<p>Extensive consultation was carried out with industry representatives. The Department also wrote to consumer representatives on the Aged Care Advisory Committee, inviting comments on the proposed legislative amendment.</p> <p>The results of this consultation contributed to the development of a Regulation Impact Statement (RIS) in relation to the proposal.</p>
Date of Effect	1 September 2003.
Contact Details	<p>Jane Bailey Quality Outcomes Branch Department of Health and Ageing Ph: (02) 6213 4800 E-mail: jane.bailey@health.gov.au</p>
Date last modified	21 June 2004

Title	<i>Aged Care Amendment Act 2004</i>
-------	-------------------------------------

Description of Issue	<p>This Act incorporates two amendments to the <i>Aged Care Act 1997</i> (“the Act”). The first repeals s28-1(3)(b) of the Act which had the effect of requiring another assessment by an Aged Care Assessment Team (“ACAT”) before a person’s classification level could move into the high care range of classifications while the person continues to live in the same aged care home. This simplifies the process involved in changing the classification of persons who are receiving care in residential aged care services.</p> <p>Persons in residential aged care services have differing needs for care. In order for an appropriate level of subsidy to be paid, the care needs of persons are assessed and broken into one of eight groups. This is known as applying a classification under the Act. As people age, it is common for their care needs to increase and therefore for their classification to change.</p> <p>Before persons can enter a residential aged care service, they have to be approved by an ACAT as needing care under the Act. The ACAT approval may be limited to low care, which corresponds with care being provided at the classification levels 5, 6, 7 or 8, or high care, which corresponds with classification levels 1, 2, 3 or 4.</p> <p>This Act also amended Division 57A which deals with accommodation charges. When persons enter high care residential aged care services, some people are assessed as being eligible to pay an accommodation charge to the approved provider of the service. The Act formerly limited the period during which the resident could be charged to a maximum of five years. The amendments allow the provider to levy an accommodation charge for the whole period that a person who is eligible to pay the charge remains in that facility. This amendment applies only to people who enter the system on or after 1 July 2004.</p> <p>The amendments do not impose a new requirement on persons assessed as being concessional residents. These persons are still protected from having to pay a charge.</p>
Consultation Opportunities	<p>Extensive consultation was carried out with industry representatives as part of the Review of Pricing Arrangements in Residential Aged Care conducted by Professor Warren Hogan.</p> <p>The Office of Regulation Review (ORR) approved the Regulation Impact Statement for the residential classification status measure and issued the Identification Number 6089 for that measure.</p> <p>ORR provided an exemption for the preparation of a Regulation Impact Statement for the accommodation charge measure and the Identification Number for that measure is 6214.</p>
Date of Effect	1 July 2004.
Contact Details	<p>Stephen Dellar Residential Program Management Branch Department of Health and Ageing Ph: (02) 6289 5500 E-mail: stephen.dellar@health.gov.au</p>
Date Last Modified	25 June 2004.

Title	Amendment to the Health Insurance Regulations 1975 to allow the creation of a new workforce program under section 3GA of the <i>Health Insurance Act 1973</i>
Description of Issue	<p>The outer metropolitan areas of Australia's cities have undergone considerable growth over recent years, putting additional pressure on services provided by medical practitioners. In the 2002-2003 Federal Budget the Government announced the More Doctors for Outer Metropolitan Areas Measure to improve access to medical services in outer metropolitan areas. The measure was implemented in January 2003.</p> <p>Consultations with key stakeholders have continued since the implementation of the measure to determine how the measure can be further enhanced. Consultations have shown that the utilisation of a select group of permanent-resident, overseas-trained doctors, who are currently living in metropolitan areas, could further increase the number of doctors working in outer metropolitan areas of workforce shortage.</p> <p>An amendment to Part 2 of Schedule 5 of the Health Insurance Regulations 1975 is required in order for this new component of the More Doctors for Outer Metropolitan Areas Measure to become an approved program under section 3GA of the <i>Health Insurance Act 1973</i>.</p>
Consultation Opportunities	<p>The Outer Metropolitan Workforce Working Group will develop and implement a pilot program in Perth, on the Department's behalf. The Outer Metropolitan Workforce Working Group will undertake consultations with a number of key stakeholders including:</p> <ul style="list-style-type: none"> • Western Australian Centre for Rural and Remote Medicine; • WA Medical Registration Board; • General Practice Divisions of Western Australia; • General Practice Department of the University of Western Australia; • WA Department of Health; and • general practice training bodies. <p>Consultation has been undertaken with the Office of Regulation Review and it has advised that a Regulation Impact Statement is not required.</p>
Date of effect	The Metropolitan Workforce Support Program was included as an amendment to the Health Insurance Regulations 1975 as Schedule 5, Part 2, item 19 and gazetted on 23 December 2003 (2003 No. 356).
Contact Details	<p>Caragh Cassoni Workforce and Quality Branch Department of Health and Ageing Ph: (02) 6289 3122 E-mail: caragh.cassoni@health.gov.au</p>
Date Last Modified	15 August 2003

Title	The Health Legislation Amendment Bill (No 1) 2003 (Part relates to the <i>Health and Other Services (Compensation) Act 1995</i>)
Description of Issue	<p>Proposed amendments to the <i>Health and Other Services (Compensation) Act 1995</i> (HOSC Act) to clarify the legislation's original intent.</p> <p>This program is administered by the Health Insurance Commission (HIC) and</p>

	<p>recovers all Medicare and residential care benefits paid to a claimant in the event of a successful compensation settlement from a personal injury case.</p> <p>The proposed amendment to the legislation follows a Federal Court ruling which questioned the capacity of the HOSC Act's ability to recover Medicare and Residential Care moneys paid to compensation claimants in certain circumstances.</p>
Date of Effect	The Amendment received Royal Assent on 23 September 2003 and commenced on that date.
Contact Details	<p>Mark Burness Financing and Analysis Branch Department of Health and Ageing Ph: (02) 6289 7015 E-mail: mark.burness@health.gov.au</p>

Title	Notification of amendments to the Hearing Services Rules of Conduct 2000
Description of Issue	<p>The Rules of Conduct under the <i>Hearing Services Administration Act 1997</i> 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.</p> <p>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 may require mandatory professional association membership and specify the requirements for a professional association to become an approved professional body under the Rules of Conduct.</p>
Consultation Opportunities	<p>Comment has been invited from all contracted service providers and practitioners who currently provide services under the Hearing Services Voucher System, as well as with the Audiological Society of Australia (ASA), the Australian College of Audiology (ACAud), the Hearing Aid Audiometrists Society of Australia (HAASA) and consumer representatives.</p> <p>Comment will again be sought from the above groups on the revised proposal.</p>
Expected Timetable	<p>Submission of proposed changes for Ministerial approval –August 2004 Tabling of proposed changes –October 2004</p>
Contact Details	<p>Judi Sutton Office of Hearing Services Ph: (02) 6289 5411 E-mail: judi.sutton@health.gov.au</p>
Date Last Modified	2 June 2004

Title	Future of the Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes
Description of Issue	A Voluntary Agreement for the Disclosure of the Ingredients of Cigarettes was signed by the former Minister for Health and Aged Care, Dr Michael Wooldridge,

	<p>and the three tobacco companies - Philip Morris Ltd, British American Tobacco Australia Ltd and Imperial Tobacco Australia Ltd - on 20 December 2000. The initial Agreement expired on 21 December 2003.</p> <p>Under a variation to the Voluntary Agreement, the Agreement has been extended by 12 months to 21 December 2004. Manufacturers will submit final ingredients reports to the Department 60 days from that expiry date. Four rounds of public disclosure have occurred to date, with data posted on the Department's web site in 2000, 2001, 2002 and 2003.</p> <p>Under the auspices of the Agreement, companies also provided one-off cigarette emissions data that were posted on the Department's web site in early 2002.</p>
Consultation Opportunities	Consultations between the Department and stakeholders are currently occurring regarding the 2004 data, which will be posted on the web-site in the near future.
Expected Timetable	May 2004 – final disclosure under extended Voluntary Agreement. December 2004 – extended Voluntary Agreement expires.
Contact Details	Penny Marshall Tobacco, Drug Prevention and Youth Policy Section Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	07 June 2004

Title	Review of the <i>Tobacco Advertising Prohibition Act 1992</i>
Description of Issue	<p>The review will consider whether <i>Tobacco Advertising Prohibition Act 1992</i> (the Act) has met its objective of limiting the exposure of the public to messages and images that may persuade them to start or continue smoking, and whether the objectives of the Act should be expanded to take into account new and emerging advertising and sponsorship practices. After ten years of administration, the review will also consider areas of the Act that are not effective and whether corrective action is necessary.</p> <p>A panel comprising legal, public policy, public health, broadcasting and tobacco control expertise has been established to provide the Department with advice throughout the course of the review.</p>
Consultation Opportunities	<p>An Issues Paper for public consultation was developed by the Department in collaboration with the Expert Advisory Panel and was released on 30 August 2003.</p> <p>The Issues Paper's availability was advertised in all major national newspapers, published on the Department's website, and distributed to relevant individuals and organisations.</p> <p>If amendments to the Act are considered necessary, all relevant stakeholders, including State and Territory Governments, will be consulted and a Regulatory Impact Statement will be prepared.</p>
Expected Timetable	An Issues Paper was released for public consultation on 30 August 2003. Submissions closed on 17 October 2003 and have been analysed and considered by the Expert Advisory Panel.

	Recommendations on options arising from these submissions will be provided to the Parliamentary Secretary.
Contact Details	Penny Marshall Tobacco, Drug Prevention and Youth Policy Section Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	07 June 2004

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	A review of health warnings on tobacco products commenced in 2000. The review is an action identified under the National Tobacco Strategy as a measure to strengthen public awareness of the harm caused by tobacco use. The review of health warnings is being conducted jointly by the Department of Treasury and the Department of Health and Ageing, with the assistance of a technical advisory group.
Consultation Opportunities	The general public and key stakeholders, including the public health lobby and the tobacco industry, have been consulted at various stages of the review. Consultation to date includes: <ul style="list-style-type: none"> • the release in May 2001 of a discussion paper for public comment; • a meeting in August 2003 with tobacco industry representatives; outlining the Government proposal for new health warnings; • meetings in late 2003 involving the Department and industry representatives; • meetings in late 2003 involving the Parliamentary Secretary and industry representatives; • the release in Feb 2004 of an initial Regulation Impact Statement; and • the release in May 2004 of a revised Regulation Impact Statement.
Expected Timetable	All tobacco products are expected to display the new health warnings from early 2006.
Contact Details	Penny Marshall Tobacco, Drug Prevention and Youth Policy Section Department of Health and Ageing Ph: (02) 6289 9321 E-mail: penny.marshall@health.gov.au
Date Last Modified	07 June 2004

Title	World Health Organisation proposed Framework Convention on Tobacco Control
Description of Issue	The World Health Organisation (WHO) has developed a Framework Convention on Tobacco Control (FCTC) which aims at developing international consensus on measures to contain the health, social and economic costs of tobacco use. Australia was actively involved in negotiations on the convention and attended all six negotiating sessions, with the final session held in February 2003.
Consultation Opportunities	Consultation during the FCTC negotiations occurred with other Federal agencies, State and Territory Governments, non-government organisations and industry

	groups.
Expected Timetable	<p>The World Assembly unanimously adopted the FCTC text in May 2003. Australia signed the FCTC at the United Nations Headquarters in New York on 5 December 2003.</p> <p>The Joint Standing Committee on Treaties tabled its report on the World Health Organization's Framework Convention on Tobacco Control (FCTC) on 5 August 2004, recommending that Australia ratify the Convention. The Executive Council gave approval for ratification on 31 August 2004, and Australia became the 34th member nation to ratify on 27 October 2004. The FCTC will come into force 90 days after 40 member nations have become party to it.</p>
Contact Details	<p>Klaus Klaucke Tobacco, Drug Prevention and Youth Policy Section Department of Health and Ageing Ph: (02) 6289 7688 E-mail: klaus.klaucke@health.gov.au</p>
Date Last Modified	15 June 2004

Title	<i>Amendments to Health Insurance (General Medical Services Table) Regulations 2003 – Rural Other Medical Practitioners (ROMPs) Program</i>
Description of Issue	<p>The Rural Other Medical Practitioners (ROMPs) Program was introduced in January 2001. The Program is implemented through Schedule 1, Part 2, paragraph 3(3)(a) and paragraph 3(4)(a) of the <i>Health Insurance (General Medical Services Table) Regulations 2003</i>.</p> <p>This Program currently provides patients with access to the higher A1 Medicare rebate for services provided in rural or remote areas under the Rural, Remote and Metropolitan Areas classification by non-vocationally recognised medical practitioners who express an interest in achieving vocational recognition.</p> <p>Through the enhancements to the Medicare package, announced on 10 March 2004, the Government agreed to extend certain general practice workforce programs, including the Rural OMPs Program, to 'areas of consideration'. The areas of consideration are likely to include RRMA 1-2 locations. The current Regulations restrict eligibility of areas under the Program to RRMA 3-7 locations.</p>
Consultation Opportunities	Consultation occurred with relevant stakeholders and included the HIC and general practice peak bodies.
Date of Effect	Documents were tabled at the ExCo meeting of 24 June 2004 and implemented on 1 July 2004.
Contact Details	<p>Ms Tuija Uotila Department of Health and Ageing GP Programs Branch Ph: (02) 6289 3645 Email: tuija.uotila@health.gov.au</p>

Title	<i>Amendments to Health Insurance (General Medical Services Table) Regulations 2003 – The Pre-vocational General Practice Placements Program</i>
Description of Issue	On 18 November 2003, the Australian Government announced changes to Medicare.

	<p>One of the initiatives included in the announcement is the <i>Pre-vocational General Practice Placements Program</i> (the Program) which is designed to provide junior doctors an opportunity to undertake a supervised general practice placement in outer metropolitan, regional, rural and remote areas. The Program aims to encourage doctors to take up general practice, particularly in these areas.</p> <p>The proposed Regulations will amend the definition of “general practitioner” in the Rules of Interpretation contained in Part 2 of Schedule 1 to the Principal Regulations, in order to expand the current definition of “general practitioner” to include medical practitioners in the Program.</p> <p>The purpose of the proposed Regulations is to allow services provided by a medical practitioner who is undertaking a placement in general practice as part of the Program, to attract the full Medicare rebate, being the same rate as that for services provided by practitioners who are vocationally registered under Section 3F of the Act.</p>
Consultation Opportunities	Consultations occurred with key medical and general practice organisations, State and Territory health departments, and Postgraduate Medical Education Councils.
Date of Effect	Documents were tabled at the ExCo meeting of 24 June 2004 and implemented on 1 July 2004.
Contact Details	Ms Tuija Uotila Department of Health and Ageing GP Programs Branch Ph: (02) 6289 3645 Email: tuija.uotila@health.gov.au

Title	<i>Amendments to Health Insurance Regulations 1975 – The Pre-vocational General Practice Placements Program</i>
Description of Issue	<p>On 18 November 2003, the Australian Government announced changes to Medicare.</p> <p>One of the initiatives included in the announcement is the <i>Pre-vocational General Practice Placements Program</i> (the Program) which is designed to provide junior doctors an opportunity to undertake a supervised general practice placement in outer metropolitan, regional, rural and remote areas. The Program aims to encourage doctors to take up general practice, particularly in these areas.</p> <p>The proposed Regulations will include the Program in Part 2 of Schedule 5 to the Principal Regulations and would hence specify the Program for the purposes of the Register of Approved Placements.</p> <p>The proposed Regulations will also include three bodies in Part 2 of Schedule 5 to the Principal Regulations for the purpose of separately administering approved placements under the Program. The administering bodies will be the Australian College of Rural and Remote Medicine, the Royal Australian College of General Practitioners and General Practice Education and Training Ltd.</p>
Consultation Opportunities	Consultations occurred with key general practice and medical organisations, State and Territory health departments, and Postgraduate Medical Education Councils
Date of Effect	Documents were tabled at the ExCo meeting of 24 June 2004 and implemented on 1 July 2004.
Contact Details	Ms Tuija Uotila Department of Health and Ageing GP Programs Branch

	Ph: (02) 6289 3645 Email: tuija.uotila@health.gov.au
--	---

Title	Fortification of Foods with Substances other than Vitamins and Minerals
Description of Issue	Policy guidance will be developed to articulate overarching principles for dealing with the addition of substances other than vitamins and minerals to food, considering the need to protect consumer health and safety, the requirement for flexibility to allow industry innovation and the need to clarify the food-drug interface.
Consultation Opportunities	Stakeholder consultation has occurred on both food-type dietary supplements and fortification. Public comment was invited via the Food Regulation Standing Committee (FRSC) secretariat web site. Stakeholders were asked to make a submission commenting on the principles and options in both papers, including a preferred option and any related considerations.
Expected Timetable	It is anticipated that the FRSC will provide policy advice on this issue to the Australia and New Zealand Food Regulation Ministerial Council in late 2005 or early 2006.
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

Title	Review of the Effectiveness of the Food Regulation Agreement
Description of Issue	The Council of Australian Governments (COAG) signed the intergovernmental Food Regulation Agreement (FRA) in November 2000 to implement a new food regulatory system to provide for a more coordinated and effective approach to food safety in Australia and New Zealand. It was amended in December 2002. There is a requirement to review the effectiveness of the Food FRA. Although the review is not due for consideration by Council of Australian Governments (COAG) until December 2006, planning work needs to commence during 2005.
Consultation Opportunities	The proposed process for undertaking the review is to engage a consultant through a tender process. It is expected that the consultant will liaise with a broad range of stakeholders including the parties to the Agreement, consumers, industry and public health professionals.
Expected Timetable	It is anticipated that a consultant will be appointed and consultation will commence during 2005. COAG will consider the review report in December 2006.
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

Title	Review of the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System (the
-------	---

	Treaty)
Description of Issue	<p>The exchange of notes for the Treaty between Australia and New Zealand in 2002 signalled the start, in earnest, of full implementation of the Council of Australian Government's (COAG) Food Regulatory Reforms and the commencement of the <i>Australia New Zealand Food Authority Amendment Act 2001</i> (ANZFA Amendment Act).</p> <p>The Treaty states that a review of the Treaty "shall be conducted and concluded before the conclusion of the review of the Food Regulation Agreement." Consequently, the review of the effectiveness of the Treaty will need to be finalised prior to December 2006 with a view to agreeing to and implementing any necessary improvements.</p>
Consultation Opportunities	Consultation between the relevant Australian Government departments and the New Zealand Government will be undertaken, commencing in 2005.
Expected Timetable	Article 9 of the Treaty requires a review to be conducted and concluded prior to the conclusion of the review of the Food Regulation Agreement, which will be conducted and concluded before December 2006.
Contact Details	<p>Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au</p>

Title	Proposed amendments to the <i>Food Standards Australia New Zealand Act 1991</i>
Description of issue	<p>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.</p> <p>In order to address the areas of concern it will most likely be necessary to amend the <i>Food Standards Australia New Zealand Act 1991</i> (FSANZ Act). However, if simpler mechanisms are identified in the implementation process these will be considered.</p> <p>The proposed amendments to the FSANZ Act will seek to:</p> <ul style="list-style-type: none"> - eliminate unnecessary duplication of regulations; - streamline the food regulatory process; - improve the clarity and consistency of the operations of Food Standards Australia New Zealand (FSANZ); and - in some cases, to implement recommendations of the Senior Officials Working Group report on the new food regulatory system, as endorsed by the Council of Australian Governments (COAG). <p>In summary the proposed amendments seek to:</p> <ul style="list-style-type: none"> - grant the Australian Government Minister for Health the power to implement a national food recall in an emergency situation (as endorsed by COAG); - harmonise the setting of Maximum Residue Levels in foods by FSANZ and the Australian Pesticides and Veterinary Medicines Authority (APVMA); - improve alignment of the standard setting processes of FSANZ with the policy development processes of the Australia New Zealand Food Regulation Ministerial Council; - allow FSANZ to partially approve applications, rather than having to reject an entire application where there is a problem with only one part; and, - allow exemptions from the requirement to undertake consultation in both

	Australia and New Zealand where a draft food standard will only apply in one country.
Consultation opportunities	<p>Public consultation on the proposed amendments is planned for September 2004.</p> <p>Submissions are invited from all interested individuals or organisations. Consultation documents, including a Regulation Impact Statement, will be available to the public on the Food Regulation Secretariat website at: http://www.foodsecretariat.health.gov.au/</p> <p>A range of consumer, industry and public health organisations will be contacted directly about the consultation process.</p> <p>Individuals or organisations that wish to be contacted regarding the consultation process may contact the Food Regulation Secretariat on (02) 6289 4073 to be added to the stakeholder list.</p>
Expected timetable	It is expected that the amendment bill will be introduced to Parliament in the Autumn 2005 sitting.
Contact details	<p>Catherine Gay Food and Healthy Living Branch Department of Health and Ageing Ph: (02) 6289 5133 E-mail: catherine.gay@health.gov.au</p>

Therapeutic Goods Administration

Title	The Industrial Chemicals (Notification and Assessment) Amendment (Rotterdam Convention) Bill 2004
Description of issue	Amendments to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> have been made to enable implementation of the obligations of the Rotterdam Convention. Amendments were required to enhance the information gathering powers of the Director and to facilitate information exchange and provision of information on domestic regulatory actions to the Secretariat and other parties to the Convention.
Date of Effect	18 August 2004 (Day on which the Rotterdam Convention enters into force for Australia).
Consultations	Opportunities for public comment were provided by the NIA and RIS.
Contact details	<p>Sneha Satya Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au</p>
Date Last Modified	22 June 2004

Title	<i>Industrial Chemicals (Notification and Assessment) Amendment Regulations 2004 (No)</i>
Description of Issue	The Industrial Chemicals (Notification and Assessment) Amendment (Low Regulatory Concern Chemicals) Bill 2004, will make a number of changes to the Act. These will have a bearing on the Industrial Chemicals (Notification and Assessment) Regulations 1990 with regard to the definition of synthetic polymer of low concern to be replaced by a new definition of polymer of low concern.
Date of Effect	Regulatory measures came into effect on 9 th August 2004 with the Proclamation of the LRCC Amendment Act.
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date last modified	27 September 2004

Title	NICNAS new chemicals – approved foreign schemes
Description of Issue	The <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> provides for recognition of approved foreign schemes (section 43) and use of an assessment report generated under the approved foreign scheme (section 44). National Industrial Chemicals Notification and Assessment Scheme (NICNAS) New Chemicals input under the OECD New Chemicals program includes work-sharing activities designed to assist in harmonisation of assessments, 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 New Chemicals has finalised such an arrangement with Environment Canada and is working towards recognition of the Canadian scheme as an approved foreign scheme.
Consultation Opportunities	Through the Industry Government Consultative Committee and with key industry stakeholders during 2002-03 and the LRCC consultation process in 2003-04.
Expected Timetable	Bilateral Arrangement with Canada – signed late 2002 renewed August 2004. Recognition of Canadian scheme - June 2005. Other foreign scheme activities ongoing.
Contact Details	Bob Graf New Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8850 E-mail: bob.graf@nicnas.gov.au
Date Last Modified	22 June 2004.

Title	Review of the NICNAS guidelines for confidential listing on the Australian Inventory of Chemical Substances
Description of Issue	New guidelines for confidential listing on the Australian Inventory of Chemical Substances (AICS) were endorsed by the Industry Government Consultative

	Committee (IGCC) in 2000. The guidelines included that a review should take place after two years' of operation, for appropriateness and effectiveness. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Technical Advisory Group commenced the review in mid-2002.
Consultation Opportunities	Consultation meetings were held with industry and the public in Sydney and Melbourne in 2002. A progress report was presented to IGCC in November 2002. The public comment period on the draft guidelines closed in July 2003.
Expected Timetable	Comments from industry were collated and discussed at the TAG meetings. Revised guidelines and forms were sent to NICNAS's Community Engagement Forum (CEF) and IGCC for comments and endorsement. The revised guidelines are expected to be released in the early part of 2004-05
Contact Details	Venky Krishnamurthy Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8834 E-mail venky.krishnamurthy@nicnas.gov.au
Date Last Modified	22 June 2004.

Title	Review of the Existing Chemicals Program
Description of Issue	Objectives of the review of the Existing Chemicals Program are to consider how to set priorities, examine industry and public input into the assessment process and to review process and procedures.
Consultation Opportunities	Stakeholder consultation will include seminars with industry, public and government departments and release of a discussion paper. Proposed changes to the program will be presented to the Industry Government Consultative Committee and Community Engagement Forum.
Contact Details	Jane Weder Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8895 E-mail: jane.weder@nicnas.gov.au
Date Last Modified	22 June 2004.

Title	Proposed amendments to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i>
Description of Issue	Consequential amendments to the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i> are proposed to give effect to the changed administrative arrangements arising from the establishment of the Trans-Tasman Agency on 1 July 2005
Contact Details	Christianna Cobbold Director, Trans Tasman Group Therapeutic Goods Administration Tel:61 2 6232 8189 Email: christianna.cobbold@health.gov.au
Date Last Modified	22 June 2003

Title	The Industrial Chemicals (Notification and Assessment) Regulations 2004 (No)
Description of Issue	To meet Australia's obligations under the Rotterdam Convention in relation to exports, it is proposed that the Regulations be amended to provide that specific chemicals cannot be exported without prior authorisation from NICNAS.
Consultation opportunities	Opportunities for public comment were provided by the NIA and RIS.
Expected timetable	18 August 2004 (Day on which the Rotterdam Convention enters into force for Australia).
Contact Details	Sneha Satya Existing Chemicals Assessment National Industrial Chemicals Notification and Assessment Scheme Ph: (02) 8577 8880 E-mail: sneha.satya@nicnas.gov.au
Date last modified	22 June 2004

Title	Conformity Assessment Standards Order No 1A – Amendment to Conformity Assessment Standards Order No 1.
Description of Issue	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 will be amended to include references to the new ISO 13485-2003 which replaces the previous ISO 13485-1996.
Expected timetable	Expected to commence early in 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	Medical Device Standards Order – Sterilants and Disinfectants for Medical Devices
Description of Issue	Proposed standards for sterilants and disinfectants for medical devices.
Expected timetable	Due to be completed by 31 December 2004.
Contact Details	Shelley Tang Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8793 E-mail: shelley.tang@health.gov.au

Title	Therapeutic Goods Amendment (Regulatory Reform) Bill 2004
Description of Issue	The Amendment Bill proposes a new suite of regulatory sanctions under the Therapeutic Goods Act 1989 which includes higher level penalties with specified aggravating circumstances, strict liability provision with aggravating circumstances, civil penalty, enforceable undertaking, infringement notices and extension of liability to executive officers. The Bill also includes amendments to provisions relating to the release of information, and minor amendments to the advertising provisions.

Expected Timetable	The Bill is currently being drafted and is proposed to be introduced in the Spring Sittings 2004.
Contact Details	Ms Terry Lee Legal Services Group Therapeutic Goods Administration Ph; (02) 6232 8230 Email: terry.lee@health.gov.au
Date Last Modified	25 June 2004

Title	Development and implementation of a trans-Tasman regulatory scheme for therapeutic products
Description of Issue	<p>Until 1 May 2005, 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.</p> <p>To resolve the special exemption, the Australian and New Zealand Governments have agreed to establish a trans-Tasman therapeutic goods agency 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.</p> <p>The agency will assume the role of the Therapeutic Goods Administration in Australia and Medsafe in NZ 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 Australia/New Zealand market.</p> <p>The regulatory activities of the agency will include pre-market assessment or evaluation, product licensing, post-market surveillance, licensing of manufacturers, setting of standards and communicating decisions and information.</p> <p>The agency will provide staff and services in Australia for the Gene Technology Regulator and in the area of chemical safety.</p>
Consultation Opportunities	<p>Australian and New Zealand officials have developed the agency proposals in consultation with a range of stakeholder groups, including industry and consumer representatives and professional associations, over the past two years.</p> <p>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.</p> <p>As part of a communication strategy for the project, a web site, www.jtaproject.com keeps stakeholders informed of progress.</p> <p>An exposure draft of the legislation that establishes the agency will be released for consultation before legislation is introduced.</p>
Expected Timetable	<p>Exposure drafts of legislation – Spring 2004</p> <p>Legislation introduced – late 2004</p> <p>Legislation passed – early 2005</p> <p>Agency commences operations in 2005</p>
Contact Details	Christianna Cobbold Trans Tasman Group

	Therapeutic Goods Administration Ph: (02) 6232 8189 E-mail: jeff.ibbotson@health.gov.au
Date Last Modified	25 June 2004

Title	Amendments to Quarantine Proclamation to require permits for commercial quantities of human blood and blood components
Description of Issue	<p>In March 2001, the previous health Minister, Dr Michael Wooldridge, gave an undertaking to the Chair of the Joint Committee on Public Accounts and Audit (JCPAA) that arrangements to protect human blood supplies from contamination from overseas sourced blood would be pursued. This was in response to JCPAA recommendations relating to an audit of the Therapeutic Goods Administration's (TGA) management of blood fractionation processes in 2001. Overseas sourced blood is processed (for export) in the same facilities as Australian sourced blood.</p> <p>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 s.28 of the Quarantine Proclamation.</p> <p>Before deciding to issue a permit, a Director of Quarantine will be required to be satisfied of certain matters which will indicate that the blood or blood products will not endanger the health of the Australian community by carrying infectious material which could contaminate Australian blood supplies.</p> <p>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.</p>
Consultation Opportunities	Consultation has occurred with relevant stakeholders, including CSL Limited, the Australian Red Cross Blood Service, peak industry associations, the AMA, the Society of Hospital Pharmacists of Australia, the Fertility Society of Australia and the Australian Bone Marrow Registry.
Expected Timetable	Implementation as soon as possible.
Contact Details	Glenn Smith Office of Devices, Blood and Tissues Therapeutic Goods Administration Ph: (02) 6232 8291 E-mail: glenn.smith@health.gov.au

Title	Ministerial Determinations (<i>under subsection 3 C of the Health Insurance Act 1973</i>)
Description of Issue	The Ministerial Determinations will create new Medicare items under the Medicare Benefits Schedule to allow benefits to be payable for certain allied health and dental services on referral by a GP. Allied health professionals and dental practitioners providing services under this measure will be required to register with the Health Insurance Commission.
Consultation Opportunities	Consultation has occurred with relevant stakeholders, including the Australian Medical Association, the Royal Australian College of General Practitioners, the Rural Doctors Association of Australia, the Australian Divisions of General Practice, Allied Health representatives and the Australian Dental Association.

Date of Effect	1 July 2004
Contact Details	Kathy Trembath General Practice Programs Branch Department of health and Ageing Ph: (02) 6289 7829 E-mail: kathy.trembath@health.gov.au

Title	Office of Gene Technology Regulator - review of guidelines for certification of facilities/physical containment requirements
Description of Issue	<p>Certain dealings with genetically modified organisms (GMOs) may be conducted in laboratories and other facilities if those facilities comply with containment conditions that are set out in guidelines issued by the Regulator. The containment conditions manage risks to human health and safety and the environment associated with the performance of dealings with GMOs inside laboratories and other facilities.</p> <p>A review of the relevant guidelines by the Regulator in 2002 identified a range of technical improvements to the guidelines that are necessary or desirable to ensure that they more effectively manage risks to human health and safety and the environment associated with dealings with GMOs that may be conducted in them.</p> <p>As a result, the Regulator has implemented a process to amend the guidelines in those areas where the need for improvements has been identified.</p>
Consultation Opportunities	<p>In the coming period revised guidelines are expected to be released for public comment in respect of certification of:</p> <ul style="list-style-type: none"> • Laboratories to physical containment level PC3 • Arthropod containment facilities to physical containment level PC2 • Aquaria physical containment facilities to containment level PC2 <p>Copies of the draft revised guidelines are expected to be sent to key stakeholders and all accredited organisations.</p>
Expected Timetable	Following consideration of public comments on the draft revised guidelines; the Regulator is expected to issue new guidelines before the end of 2004.
Contact Details	Ian Coleman Licence and Application Management Section Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date Last Modified	June 2004

Title	Office of Gene Technology Regulator – review of guidelines for accreditation of organisations conducting dealings with genetically modified organisms
Description of Issue	Draft Revised Guidelines for Accreditation were prepared in the first half of 2004. These guidelines are intended to improve, streamline and simplify the guidelines dated June 2001 Which set out core criteria for the establishment and

	maintenance of Institutional Biosafety Committees by organisations that propose to conduct dealings with GMOs.
Consultation Opportunities	Draft guidelines are expected to be available for comment in the first quarter of the coming period. A copy of the draft guidelines will be placed on the Office of Gene Technology Regulator's web site: www.ogtr.gov.au Copies will also be available via e-mail: ogtr@health.gov.au or by telephoning 1800 181 030.
Expected Timetable	Final guidelines are expected to be issued by the Gene Technology Regulator before the end of 2004.
Contact Details	Ian Coleman Licence and Application Management Section Office of Gene Technology Regulator Ph: 1800 181 030 Web site: www.ogtr.gov.au E-mail: ogtr@health.gov.au
Date Last Modified	June 2004

Title	Determination under subsection 98B(1)(a) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the annual indexation of the dispensing fee paid to pharmacists for the supply of ready-prepared and extraneously prepared pharmaceutical benefits.
Date of Effect	1 July 2003
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 84C(7) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the allowable additional amounts which pharmacists can charge for pharmaceutical benefits less than the patient contribution, as agreed with the Pharmacy Guild.
Date of Effect	1 August 2003
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 84HA(1) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the fee paid to pharmacists for the issue of a concession/entitlement card.
Date of Effect	1 January 2004
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Planned Regulatory Activity

Department of Health and Ageing

Title	<i>Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004</i>
Description of Issue	The Bill includes the following measure (relevant to PAQ Branch): <ul style="list-style-type: none"> provision for the enable supply of, and payment for, pharmaceutical benefits following the death of an approved pharmacist.
Date of Effect	Late 2004 (presently awaiting 2 nd reading)
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 98B(1)(a) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the annual indexation of the dispensing fee paid to pharmacists for the supply of ready-prepared and extraneously prepared pharmaceutical benefits.
Date of Effect	1 July 2004
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 84C(7) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the allowable additional amounts which pharmacists can charge for pharmaceutical benefits less than the patient contribution, as agreed with the Pharmacy Guild.
Date of Effect	1 August 2004
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 84HA(1) of the <i>National Health Act 1953</i>
Description of Issue	This determination affects the fee paid to pharmacists for the issue of a concession/entitlement card.
Date of Effect	1 January 2005
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Amendment to the <i>National Health (Pharmaceutical Benefits) Regulations 1960</i>
Description of Issue	The definition of an approved pharmacist will need to be amended in accordance with the amendments which will be made under the <i>Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004</i> . Following legal advice, this amendment is not a necessity however it would remove any uncertainty.

Date of Effect	Early to mid 2005
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Amendment to Division 4B of the <i>National Health Act 1953</i>
Description of Issue	Division 4B gives effect to the Australian Community Pharmacy Authority (ACPA) and provides for their functions and administration. This division ceased to have effect on 30 June 2005. Depending on the outcome of a review of the location rules relating to pharmacies approved to supply pharmaceutical benefits (included in Division 4B) and the development of any subsequent pharmacy location arrangements, there is some uncertainty as to whether or not the ACPA will be required beyond 30 June 2005.
Date of Effect	Early to mid 2005 - before 30 June 2005
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Rules for the location of pharmacies approved to supply pharmaceutical benefits
Description of Issue	At present, the pharmacy location rules are determined by the Minister under section 99L of the <i>National Health Act 1953</i> , and will cease to have effect on 30 June 2005 in accordance with Division 4B. Depending on the outcomes referred to in the item above (matters relating to Division 4B), a new determination maybe made under the Act to regulate the location of pharmacies approved to supply pharmaceutical benefits.
Date of Effect	Early to mid 2005 - before 30 June 2005
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	Determination under subsection 91(2) of the <i>National Health Act 1953</i> (relates to provisions proposed under the <i>Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004</i>)
Description of Issue	This determination sets out the documentary evidence required in order for the Secretary to make a decision in respect of an application to permit a person, in the event that an approved pharmacist dies, to continue to supply pharmaceutical benefits and to receive payment for that supply.
Date of Effect	Late 2004 or early 2005 (depending on when the <i>Health Legislation Amendment (Podiatric Surgery and Other Matters) Bill 2004</i> , presently before Parliament, receives Royal Assent)
Contact Details	Catherine Farrell Pharmaceutical Access and Quality Branch Department of Health and Ageing Ph: (02) 6289 8984 E-mail: catherine.farrell@health.gov.au

Title	TGA Cost Recovery Review
Description of	As part of a whole of Government approach to cost recovery agencies, the

Issue	Department of Finance and Administration requires TGA to undertake a cost recovery review.
Expected Timetable	The review commenced in June 2004 and is expected to be completed by September 2004.

Title	National Health Amendment Regulations 2004
Description of Issue	The implementation of regulations to establish performance indicators for the private health insurance industry
Consultation Opportunities	The Department has undertaken consultation with key stakeholders in the industry
Date of Effect	The regulations will take effect from 1 July 2004
Contact Details	Neil Smith Private Health Insurance Branch Department of Health and Ageing Ph: (02) 6289 9434 E-mail: neil.smith@health.gov.au
Date Last Modified	First entry 9 June 2004

Title	National Health Amendment (Prostheses) Bill 2004
Description of issue	The Bill will amend the National Health Act 1953 to make decisions of the Minister subject to process review rather than merit based review. It will also require health funds to provide no gap cover for the cost of appropriate, clinically necessary prostheses and medical devices for each Medicare Benefits Schedule (MBS) admitted hospital procedure.
Consultation opportunities	The Government announced the principles for the proposed new arrangements on 3 April 2003. An extensive review of existing private health insurance regulations for prostheses preceded this announcement which included consultation with all key stakeholders. Future consultation with stakeholders will include communications from the members of the Prostheses and Devices Committee. The Committee will be made up of representatives of all industry stakeholders.
Expected timetable	The first reading of this Bill was 12 August 2004. The Bill was prorogued.
Contact details	Chris Francis Private Health Insurance Branch Department of Health and Ageing PH: (02) 6254 9850 E-mail: christine.francis@health.gov.au
Date last modified	First entry, 6 June 2004.

Title	Medical Indemnity Legislation (Miscellaneous Amendments) Bill 2004
Description of Issue	Addresses a number of anomalies and unintended consequences in current legislation
Consultation Opportunities	The medical indemnity industry and the AMA have been consulted on these issues; and further consultation will occur as the legislation is drafted
Expected timetable	Desirably introduction in spring 2004, with passage in autumn 2005
Contact details	Susan Rogers

	Medical Indemnity Branch 6289 9246
Date last modified	23 June 2004