



**Australian Government**  
**Department of Health**

A large, stylized graphic of a pair of scissors, rendered in a muted olive-green color. The scissors are positioned diagonally across the page, with the blades pointing towards the top left and the handles towards the bottom right. The blades are partially obscured by a red horizontal band.

**Health Portfolio**  
**Annual Deregulation Report**  
**2014**

## Foreword

Under the deregulation agenda, the Government is leading a cultural shift towards a lighter regulatory touch by government, based on the principle that regulation should only be imposed where absolutely necessary.

Through this agenda, the Government is committed to reducing the red tape burden on individuals, businesses and community organisations by \$1 billion every year.



The Health portfolio, including Sport, is committed to the deregulation agenda which provides the opportunity to identify and remove unnecessary or burdensome regulation across all areas of the health sector. This will be progressed without compromising on important health and safety protections for the community.

Over the first year of the deregulation agenda, Health's contribution has been substantial. The benefits from the reforms already implemented are being felt on the ground, such as a change in application approval time for vulnerable people with hearing loss from 4-6 weeks to minutes through the Hearing Services Online portal. In addition, reduced application and reporting requirements for health grants and funding agreements will save considerable time and effort for many organisations. As reforms continue to be implemented the felt benefit will become more noticeable.

Health has identified long-term reform options and areas for future investigation to ensure the portfolio is well placed for 2015-16. This will be built on as further opportunities are identified. In addition, a substantial review is underway into medicines and medical devices regulation with an independent panel due to report its findings in 2015.

I look forward to our continued efforts in reducing regulatory burden and red tape for individuals, businesses and community organisations in the health sector, while maintaining the safety, quality and efficacy of health products and services.

I encourage all interested people and organisations to submit ideas on areas for reform through the Health website.

**The Hon Sussan Ley, MP**

**Minister for Health**

**Minister for Sport**

**18 March 2015**

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## Introduction

Reducing the burden of regulation and red tape is one of the Government's top five priorities, with a reduction target of \$1 billion per year. The deregulation agenda is guided by the principle that regulation should not be the default position for dealing with public policy issues. Regulation is any rule endorsed by government where there is an expectation of compliance. This includes legislation, regulation, quasi-regulation (such as guidelines and forms) and any other aspect of regulator behaviour which can influence or compel specific behaviour by business, community organisations or individuals. It also includes red tape burden imposed by the Commonwealth's procurement, grants and cost recovery frameworks.

Health is a large and multi-faceted portfolio, with regulatory activity covering broad subject matter such as pharmaceuticals, hearing services, nuclear and chemical safety, preventive and public health, therapeutic goods, tobacco, private health insurance, sport and food. In addition, Health uses a number of regulatory models across its regulatory activities: rule-based (or prescriptive), principle-based (or performance-based), self-regulation, and industry self-regulation.

Many of Health's regulatory arrangements are long-standing and protect the safety and wellbeing of Australians, ensure quality goods and services are provided to eligible citizens, and support the payment of significant (in dollar value) Government subsidies.

This Annual Report covers the reporting period of 20 September 2013 to 31 December 2014.

## Portfolio highlights

Health is committed to ensuring the delivery of appropriate and effective regulation which maintains desired health outcomes, upholds public health and safety protections, and implements effective compliance regimes, while reducing unnecessary regulatory and red tape burden on businesses, community organisations and individuals.

The Deregulation Unit was established in December 2013 to promote regulatory performance across the portfolio and provide strategic direction and guidance to support the implementation of the Government's deregulation agenda in Health. The Unit has played an important role in building best practice regulatory capability across the portfolio. Staff engagement in implementing the deregulation agenda is critical to achieve annual reductions in regulatory burden as well as embedding the best practice regulation approach into policy and programme development.

Health is a lead agency in the Commonwealth Deregulation Community of Practice, which is chaired by the Department of Human Services. This forum provides a valuable resource for portfolios to work together on, and share experiences with, implementing the agenda. Indeed, cross-portfolio initiatives will provide important opportunities for future reform and Health is committed to working closely with the Department of Human Services and the Department of Social Services in recognition of the opportunities for reform in the health and social policy environment. In addition, an internal Health Regulatory Reform Community of Practice was introduced for officer level staff to respond to

the policy development needs of the organisation and to encourage and support cross divisional approaches to identifying priorities for reform.

In April 2014 the Health Ministerial Advisory Council (Health MAC) was established to support the Health Ministers in identifying opportunities to reduce regulatory and red tape burden within the Health portfolio, and advise on other key policy matters as required.

## **Summary of key reforms reported in 2014**

Health has reported a range of measures that reduce regulatory burden on businesses, community organisations and individuals by removing ineffective regulation, simplifying existing processes and systems, and reducing duplication. Health has also reported some measures that increase compliance burden, which are predominantly associated with grants and funding agreements.

Online systems have been introduced to replace old paper-based systems which positively benefit stakeholders through reduced costs and time for both businesses and individuals. For example, the Hearing Services Online portal allows many clients to receive services on the same day instead of weeks later. Other online access improvements include the electronic submission of data dossiers for prescription medicine applications for the Australian Register of Therapeutic Goods; online accessible forms for medicines shortages and for listing new brands of Pharmaceutical Benefits Scheme (PBS) medicines; SmartForms for registering information and submitting applications for Health grant rounds.

Health has adopted trusted European assessments for approval of low risk medical devices, which removes duplication for Australian manufacturers and, in many cases, allows faster access to market. In addition, an independent review of medicines and medical devices regulation is exploring how risk assessments, standards and determinations of trusted regulators can be used more extensively in Australia when approving the supply of medicines and medical devices.

Other duplicative processes have also been removed. For example, medication charts in hospitals will replace the requirement for a hard copy PBS prescription; and psychologists under the Better Access initiatives are no longer required to maintain records that duplicate the requirement to undertake and report on relevant continuing professional development activities for their registration with the Psychology Board of Australia.

Cessation of some committees has streamlined approval processes, reduced timeframes, and ultimately freed up the time of clinical experts. For example, ceasing the Pharmaceutical Benefits Pricing Authority; and ceasing the Disease Advisory Committees of the Life Saving Drugs Programme.

Health has implemented standardised funding agreements and grants applications processes, and reduced compliance and reporting requirements commensurate with risk, which reduces grant administration burden for organisations receiving grants. Health has also reduced information requirements for research grant applications and streamlined the review process.

Health has also demonstrated a commitment to better health and safety outcomes for patients through the introduction of new Clinical Quality Registries for high risk implantable breast and

cardiac devices. The Registries initially impose an increased administrative burden in order to allow better information to be developed about the performance of implantable devices.

A detailed list of Health’s regulatory reform measures is in Appendix A.

## Regulation Impact Statements

The following Regulatory Impact Statements were published by the Office of Best Practice Regulation (OBPR). They were assessed by the OBPR as compliant with best practice regulation requirements.

**Table 1: Published Regulatory Impact Statements for the 2014 reporting period**

TITLE	OBPR Assessment System <sup>1</sup>	Date published
Reform of Capital Adequacy and Solvency Standards (Private Health Insurance Administration Council)	Interim September 2013 system	24 September 2013
Protection of images and indicia for major sporting events	March 2014 system	3 April 2014
Changes to Required Advisory Statements for Medicine Labels	June 2010 system	4 July 2014
Pre-market Assessment of Australian-manufactured Medical Devices	June 2010 system	12 November 2014

The Regulatory Impact Statements can be accessed through the Health website ([www.health.gov.au/internet/main/publishing.nsf/Content/regulation-impact-statements](http://www.health.gov.au/internet/main/publishing.nsf/Content/regulation-impact-statements)) or the OBPR website (<http://ris.dpmc.gov.au/category/health/>).

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<sup>1</sup> Office of Best Practice Regulation, Best Practice Regulation Report 2013-2014, released on 4 February 2015 ([www.dpmc.gov.au/office-best-practice-regulation/publication/best-practice-regulation-report-2013-14](http://www.dpmc.gov.au/office-best-practice-regulation/publication/best-practice-regulation-report-2013-14)).

## Portfolio activity supporting the Government's red tape objective

### Deregulation Unit

The Deregulation Unit formally commenced operation in December 2013.

The Deregulation Unit's role is to build best practice regulatory capacity in Health to ensure staff are well equipped to deliver the Government's deregulation agenda now and in the future. Key activities of the Deregulation Unit include:

- Improving regulatory literacy through encouraging staff to think about designing light touch regulation based on best practice policy principles.
  - Over the year, the Deregulation Unit ran more than 25 education seminars and workshops for more than 700 staff to raise awareness of, and provide support, guidance and assistance with the deregulation agenda.
- Training staff on the Regulatory Burden Measurement Framework.
- Providing guidance and support with the regulation impact assessment process, including Regulation Impact Statements.
- Identifying regulatory reform opportunities, including cross-portfolio initiatives, in partnership with programme areas and other agencies.
- The Unit has commenced planning to scope longer-term reforms options, such as reviewing the use of international standards and risk assessments across the portfolio.
- Tracking and reporting progress against the Government's red tape reduction target.
- Supporting the operation of the Health Ministerial Advisory Council.

The Deregulation Unit works with colleagues across Government and other deregulation units on specific cross-portfolio initiatives as well as broader policy issues with a whole-of-government focus. It also engages with regulatory and behavioural economics academics, and (risk and regulatory) practitioners from other jurisdictions.

## Ministerial Advisory Council

In April 2014, the Health Ministerial Advisory Council (Health MAC) was established to provide advice to the Health Ministers about opportunities to reduce regulatory and red tape burden within the Health portfolio. The Health MAC has a role in considering and providing advice on potential health reforms and other key policy matters as required. All members bring with them a wide range of experience in the issues relating to the Health sector. The Health MAC met twice in 2014, on 5 August and 17 November.

The Australian Sports Commission Board has a standing agenda item on deregulation. Information on opportunities to reduce regulation and red tape are conveyed to the Health MAC.

### **Health MAC Membership**

**Chair:** The Minister for Health and Minister for Sport – position held by the Hon Peter Dutton MP during 2014

**Deputy Chair:** The Assistant Minister for Health – position held by Senator the Hon Fiona Nash during 2014.

### **Members:**

Dr David Rosengren	Associate Professor Noel	Mr Rohan Mead
Mr Glenn Keys	Hayman	Ms Rhonda White
Professor John Horvath AO	Dr Sheilagh Cronin	
Dr Michael Harrison	Hon Rob Knowles AO	

### **Health MAC Terms of Reference**

1. The Council will support the Australian Government by providing advice on strategic health policy matters with a particular focus on opportunities for improving the efficiency and effectiveness of its regulatory arrangements.
2. As a first priority, provide advice on deregulation opportunities within the Health portfolio, taking account of the role that appropriate regulation plays in protecting health and safety as well as managing financial risks. The Council is asked to:
  - identify opportunities for regulatory reform across the portfolio's various regulatory systems, as well as opportunities to reduce red tape in the areas of government grants procurement and service delivery;
  - provide advice on potential areas for review and reform based on the outcomes of the audit of regulation administered by the Health portfolio; and
  - provide advice on the progress of regulatory reform within the Health portfolio.
3. As required, provide advice on broader policy matters and Government reform priorities in the context of the health system.



## Letters of Expectation

During 2014 letters of expectation were sent to Health portfolio regulators to outline the deregulation agenda requirements. The letters also provided a reminder to regulators to exercise their functions in accordance with legislation, to utilise their best practice regulatory models and to consider transparency and accountability in discharging their duties. Below is a list of the recipients of the letters of expectation, noting there are a range of policy areas and functions internal to the department which are also subject to the requirements of the deregulation agenda.

**Table 2: Health recipients of letters of expectation**

<b>ORGANISATION</b>
The Office of the Gene Technology Regulator
Australian Radiation Protection and Nuclear Safety Agency
Australian Sports Anti-doping Authority
National Industrial Chemicals Notification and Assessment Scheme
Department of Health
Australian Commission on Safety and Quality in Health Care
Australian Institute of Health and Welfare
Australian National Preventive Health Agency
Australian Organ and Tissue Donation and Transplantation Authority
Australian Sports Commission
Australian Sports Foundation
Cancer Australia
Food Standards Australia New Zealand
General Practice Education and Training Limited
Health Workforce Australia
Independent Hospital Pricing Authority
National Blood Authority
National Health and Medical Research Council
National Health Funding Body
National Health Funding Pool Administrator
National Health Performance Authority
National Mental Health Commission
Private Health Insurance Ombudsman
Professional Services Review

## The Audit of Regulations – major findings

### Summary of findings

As at 3 October 2013, Health had **746** pieces of regulation (see Table 3). In addition there were approximately **2000** pieces of quasi-regulation associated with the 400 programmes that receive grant funding. This includes tender documentation, programme guidelines, funding agreements and reporting templates. These findings are explained below.

**Table 3: Count of Health’s regulation**

TYPE OF REGULATION	COUNT
Primary Acts	57
Legislative Instruments	172
Quasi-regulation	517
<b>Sub total</b>	<b>746</b>
Quasi-regulation associated with 400 programmes receiving grant funding	2000
<b>TOTAL</b>	<b>2746</b>

To identify Acts and legislative instruments within the portfolio, Health reviewed the Administrative Arrangements Orders and ComLaw and excluded: repealed legislation still listed; legislation which was not operative i.e. legacy legislation; amending legislation; legislative instruments with no associated expectation of compliance; and legislation establishing statutory bodies but not including any regulatory function. Multiple determinations made under one provision or part of an Act were counted as one instrument.

Regulations were categorised by broad subject matter into 16 frameworks (see Table 4). These subject-based categories align with stakeholders’ understanding of Health’s regulation and with the way that any reform options would be presented.

A burden rating (see Table 5 for ratings and rationale) was allocated to each framework based on criteria established by PM&C for the purposes of the regulatory audit:

- the type of requirements the regulation imposes;
- the complexity of the regulation;
- the reach of the regulation; and
- the frequency of interactions with the regulation.

In summary, Health identified 4 frameworks with a high burden, 2 medium, 7 low and 3 with nil burden.

Health has estimated approximately **\$383 million** in compliance burden for businesses, community organisations and individuals associated with its regulation.

In calculating the estimated compliance burden, Health adopted a purposive<sup>2</sup> approach to sampling the portfolio's regulatory stock and regulatory compliance costs were attributed at the framework level rather than at the individual regulation level. It should be noted that much of Health's regulation is about 'mutual obligations', or Government requiring something of someone in order for them to gain a benefit or a right to do something. These costs are not included in the compliance burden calculation.

Health's estimated compliance burden may seem lower than anticipated. This is because:

- Burden is attributed to the 'touch points' with government for business, not for profit or community organisations and individuals, which means that all downstream transactions conducted by the Department of Human Services (DHS) as a result of Health policy are counted by DHS. These can be found in the DHS Deregulation Annual Report.
- Associated regulatory burden cannot be strictly applied directly back to Health's list of regulations due to the nature of some legislation being purely declaratory with no expectation of compliance.

**Table 4: Health frameworks and burden category**

FRAMEWORK	BURDEN RATING
Therapeutic goods	High
Grants	High
Medical, pharmaceutical, dental and hearing benefits	High
Health research and data	High
Private health insurance	Medium
Industrial chemicals	Medium
Workforce and health professional regulation	Low
Sports	Low
Health security and international health	Low
Blood and blood products	Low
Food standards	Low
Human cloning and research involving human embryos	Low
Gene technology	Low
Radiation protection and nuclear safety	Nil
Tobacco advertising and plain paper packaging	Nil
Health promotion and support bodies	Nil

<sup>2</sup> A form of non-random sampling. Purposive sampling (or judgemental sampling) is where sampling intentionally selects a portion of the population that is considered more relevant or desirable for analysis based on its characteristics.

**Table 5: Burden rating and rationale**

<b>BURDEN RATING</b>	<b>RATIONALE</b>	<b>No. of Frameworks</b>
HIGH	60 or more pieces of regulation, directly or indirectly impacting a large population, and involving multiple regulated entities	4
MEDIUM	Affecting one or two main groups of stakeholders but with a reasonably high burden for that group	2
LOW	Less than 40 pieces of regulation, with a narrow reach or affecting only a discrete population	7
Nil	Regulations only impose obligations on Commonwealth entities (out of scope), imposes prohibitions or requirements that do not involve any 'touch points' with Government, unless there is non-compliance (if a regulator determines that a regulated entity is non-compliant, any costs incurred by the entity to rectify the non-compliance are out of scope) or establish bodies for the purposes of health promotion and education	3

## Appendix A: Measures reported in 2014

Over the 2014 calendar year, Health reported to Government a number of measures that both decreased and increased compliance burden for businesses, community organisations or individuals. A summary of most reported measures follows. Measures identified as sensitive or including commercial information have not been included.

Measures are reported in association with the decision to progress the particular reform rather than at the time of implementation. The majority of Health's measures were implemented by 31 December 2014. Some measures remain subject to ongoing development, consultation, legislation approval or implementation planning and therefore the benefit is yet to be felt in the community. These measures are marked with a cross-hatch (#).

All regulatory costings ('savings' and 'increases' in compliance burden) have been calculated according to the Regulatory Burden Measurement Framework which was a new approach implemented under the deregulation agenda with flexible parameters over the year.

Some measures have also been published in the 2014 Autumn and Spring Repeal Day Overview documents which are available at [www.cuttingredtape.gov.au](http://www.cuttingredtape.gov.au). Measures marked with an asterisk (\*) differ from earlier reports due to additional information becoming available between publications.

Table 6: Summary of measures reported in 2014

MEASURE	MEASURE DESCRIPTION
<b>National Health Amendment (Simplified Price Disclosure) Bill 2013</b>	<ul style="list-style-type: none"> <li>• The <i>National Health Amendment (Simplified Price Disclosure) Bill 2013</i> was passed by the Senate on 5 March 2014.</li> <li>• The Government's changes will streamline the price disclosure requirements for drugs listed on the Pharmaceutical Benefits Scheme (PBS) so that price reductions occur sooner and more frequently (from 18 months down to 12 months) after medicines become subject to market competition. This will result in a reduction in the administrative burden for industry and benefit consumers via earlier access to cheaper medicines and taxpayers via reduced PBS expenditure.</li> <li>• The Department estimates an annual saving of around \$38,000 in compliance costs.</li> </ul>
<b>* Private Health Insurance Legislation Amendment Act 2013</b>	<ul style="list-style-type: none"> <li>• The <i>Private Health Insurance Legislation Amendment Act 2013</i> simplifies rebate calculation for private health insurers by creating a single adjustment factor that applies across all rebates. It commenced on 9 April upon Royal Assent.</li> <li>• This measure simplifies implementation and reduces implementation costs for private health insurers. It will be easier for private health insurers to communicate to consumers and easier for consumers to understand.</li> <li>• The Department estimates an annual saving of \$10.68 million in compliance costs.</li> </ul>
<b>Business improvement to the Hearing Services Program</b>	<ul style="list-style-type: none"> <li>• In February 2014, the Hearing Services Program's online portal was released to hearing service providers and on 5 May 2014, the Assistant Minister for Health announced its release to the public.</li> <li>• The Hearing Services Online portal improves business processes by enabling real time confirmation of client eligibility and application processing, reducing record keeping requirements, eliminating numerous paper forms and simplifying a variety of administrative tasks. It will benefit approximately 640,000 clients each year and over 250 contracted businesses.</li> <li>• The Department estimates an annual saving of \$19.1 million in compliance costs.</li> </ul>
<b># Pharmaceutical Benefits Scheme Medication Charts in public and private hospitals</b>	<ul style="list-style-type: none"> <li>• In the 2014-15 Budget, the Government announced that it will introduce the supply and claiming of PBS medicines from medication charts in all public and private hospitals, aligning with arrangements being implemented in Residential Aged Care Facilities. This will commence in trial sites from March 2015.</li> <li>• The measure will reduce the regulatory burden on prescribers, pharmacists and nurses. It will improve medication safety for patients and reduce hospital administration costs associated with claiming PBS medicines by removing the hard copy PBS prescription requirement. The quality use of medicines will also improve through reductions in transcription errors.</li> <li>• The OBPR agreed an annual saving of \$40.848 million in compliance costs.</li> </ul>

MEASURE	MEASURE DESCRIPTION
* <b>Improving grants management in Health</b>	<ul style="list-style-type: none"> <li>• The Department of Health has implemented administrative changes to reduce the red tape associated with the administration of grants provided to individuals and organisations.</li> <li>• These changes simplify, standardise, and reduce compliance and reporting obligations for funding recipients.</li> <li>• The Department estimates an annual saving of \$18.158 million in compliance costs.</li> </ul>
* <b>Simplified and Consistent Health and Medical Research</b>	<ul style="list-style-type: none"> <li>• In November 2013, following the Coalition’s election commitment, the Government put in place a streamlined grant administration process for the National Health and Medical Research Council (NHMRC) to reduce information requirements and initiate an early triage of grant applications unlikely to be successful. The NHMRC has also streamlined application and assessment processes, and extended some grants from three to five years to allow for greater certainty for grant recipients. This was announced at the 2014 Autumn Repeal Day.</li> <li>• The Government announced in the 2014-15 Budget funding over five years to develop a nationally consistent approach to the way clinical research trials are overseen and conducted and as well as to streamline and simplify NHMRC grant application and assessment processes. In relation to clinical trials, the Government is looking to assess the feasibility of supporting a small number of human research ethics committees to increase their efficiency and capacity to carry out high quality ethical review of clinical trial applications. This approach aims to ensure there is a nationally consistent approach to clinical trials research and thereby increasing Australia’s international competitiveness as a destination of choice for the conduct of clinical trials.</li> <li>• The OBPR agreed an annual regulatory saving of \$14.537 million.</li> </ul>
<b>Cessation of the Pharmaceutical Benefits Pricing Authority</b>	<ul style="list-style-type: none"> <li>• From 1 April 2014 a new streamlined process to reduce the time taken to list medicines on the Pharmaceutical Benefits Scheme and improve access to medicines was implemented. A key component of this is the cessation of the operations of the Pharmaceutical Benefits Pricing Authority.</li> <li>• The process allows important new medicines to be listed on the PBS at least four weeks earlier. Sponsors will benefit from having additional time in which to finalise pricing submissions following a positive Pharmaceutical Benefits Advisory Committee recommendation.</li> <li>• The Department estimates an annual regulatory saving of \$192,220.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Increased Pharmaceutical Benefits Scheme Claims Threshold (to reduce paperwork for pharmacies)</b>	<ul style="list-style-type: none"> <li>• From 10 February 2014, the Department of Health introduced administrative changes to increase the PBS online claiming threshold for claims less than \$5,000 to claims less than \$10,000. Claims from pharmacies above the threshold require manual handling/immediate provision of paperwork to the Department of Human Services before payments can be made.</li> <li>• This change will help to reduce paperwork for pharmacists and ensure claims are made in a more timely manner as the volume of claims pharmacists have to make will be smaller. It will also improve payment reconciliation times for affected claims for pharmacists as there will be fewer claims for the Department to process.</li> <li>• The Department estimates an annual saving of \$1.315 million in compliance costs.</li> </ul>
<b># Establishment of Primary Health Networks (including cessation of Medicare Locals)</b>	<ul style="list-style-type: none"> <li>• The Government will establish Primary Health Networks (PHNs) as recommended by the Review of Medicare Locals to replace Medicare Locals from 1 July 2015 to increase the efficiency and effectiveness of medical services for patients at risk of poor health outcomes, and improve coordination of care to ensure patients receive the right care in the right place at the right time.</li> <li>• The replacement of 61 Medicare Locals and the Australian Medicare Local Alliance with 30 PHNs will result in reduced regulatory costs.</li> <li>• The Department estimates an annual saving of \$529,150.</li> </ul>
<b>Rural and Regional General Practice Teaching Infrastructure Grants</b>	<ul style="list-style-type: none"> <li>• The Government will provide \$52.5 million over three years for at least 175 infrastructure grants for existing general practices in rural and remote settings to provide additional consultation rooms and space for teaching and training. This investment will strengthen the rural health workforce and improve health service delivery in these communities. The grants will be capped at \$300,000 and successful practices will be required to match the Commonwealth commitment.</li> <li>• Applying for grants generates administrative requirements for the applicants.</li> <li>• The OBPR agreed an annual increase in regulatory burden of \$45,675.</li> </ul>



MEASURE	MEASURE DESCRIPTION
<b>Northern Territory Medical Programme – Consolidation</b>	<ul style="list-style-type: none"> <li>• The measure will reduce red tape for the Northern Territory Medical Programme (NTMP) by ceasing its complex National Partnership Agreement funding arrangements and directly funding Flinders University to deliver the programme in future.</li> <li>• There will be a reduced administrative burden for Flinders University through removal of duplication and introduction of streamlined reporting obligations. This will allow the NTMP to be delivered at a lower cost through consolidation with the Indigenous Transition Pathway and the Northern Territory Remote Clinical School Initiative. Implementation will be staged.</li> <li>• The OBPR agreed an annual regulatory saving of \$98,530.</li> </ul>
<b>Rebuilding General Practice Education and Training to Deliver More GPs</b>	<ul style="list-style-type: none"> <li>• The measure will transform general practice training by increasing commencing GP training places from 1200 a year to 1500 in 2015, with further increases to follow. This will be achieved by ceasing the Prevocational General Practice Placement Program (PGPPP), introducing new GP training positions co-funded by private GP practices and the Commonwealth, reducing funding for training registrars employed by State Governments, and reducing overheads by rationalising administration (abolishing General Practice Education and Training Ltd). The measure will increase GP training places across Australia and reduce the number of organisations involved in administering GP training. The measure will benefit all Australians, as GP registrars provide primary care services to patients while they are in training. This is being implemented over an 18-30 month period as different elements of the measure will be rolled out at different stages.</li> <li>• There will be regulatory burden relating to compliance with tender processes and contract requirements.</li> <li>• The OBPR agreed an annual increase in compliance burden of \$127,735.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Medicine Shortages Information Initiative</b>	<ul style="list-style-type: none"> <li>• The measure will deliver timely, complete and consistent information on medicine shortages that enables timely access to medicines in the event of a supply disruption.</li> <li>• The new business process replaces email, telephone and letter communication between the Sponsor and the TGA with an online, electronic, pre-populated smart form. Use of the form is specified for “all prescription medicine shortages” and the TGA’s preferred method of streamlined, efficient, consistent communication. The form is voluntary as Sponsors are only required, as a condition of registration, to notify the TGA of discontinuations of prescription medicines (cancellations from the ARTG listing), which are a small subset of all the shortages. There is no change to the regulatory requirements for Sponsors. There is a change to the business process to assist Sponsors fulfil their regulatory and non-regulatory supply chain communication obligations.</li> <li>• The Department estimates an annual saving of \$1.061 million.</li> </ul>
<b>Cessation of the Disease Advisory Committees for the Life Saving Drugs Programme and reduction in the administrative burden on treating physicians</b>	<ul style="list-style-type: none"> <li>• On 9 April 2014, the Minister for Health announced the post-market review of the Life Saving Drugs Programme (LSDP) and that the activities of the Disease Advisory Committees (DACs) would be discontinued. From 1 May 2014, the five DACs are no longer used to provide recommendations to the Department about the initial and continued eligibility of individual patients to receive subsidised treatment through the LSDP. Changes were also made to allow treating physicians to submit supporting data for their patients’ ongoing eligibility for the LSDP once per year, rather than twice.</li> <li>• Ceasing the DACs will allow the small group of former Committee members (19 individuals), who are clinical experts in the relevant disease area, to participate fully in the review of the programme and to advocate on behalf of their patients. Additionally, treating physicians are now required to submit data to support ongoing eligibility once yearly, not twice yearly, for their patients receiving treatment through the LSDP. Re-applications for existing patients will only require the provision of supporting evidence that the medicine is effective, once per year, rather than twice. This will directly affect the administrative burden on treating physicians.</li> <li>• The Department estimates an annual regulatory saving of \$65,700 in compliance costs.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>General Practice Rural Incentives Programme</b>	<ul style="list-style-type: none"> <li>• In the 2014-15 Budget, the Government announced it will provide an additional \$35.4 million over two years from 2013-14 to meet higher than anticipated demand for the General Practice Rural Incentives Programme. This programme provides relocation and retention incentive payments to encourage medical practitioners to work in underserved rural, regional and remote areas.</li> <li>• The new assessment process for GP Registrars will create a streamlined payment system that will, for most registrars require zero input from them. This will have the effect of reducing regulatory burden on GP Registrars who are currently required to complete and submit an application.</li> <li>• The Department estimates an annual regulatory saving of \$47,260.</li> </ul>
<b>Supply of HIV self-test kits in Australia</b>	<ul style="list-style-type: none"> <li>• On 7 July 2014, the Minister for Health announced the removal of a restriction preventing the manufacture and sale of HIV home self-tests in Australia.</li> <li>• Companies can now apply to the Therapeutic Goods Administration (TGA) for approval to supply their test kits and, if they meet Australia's rigorous standards and are approved, will be able to be sold direct to consumers. Individuals will have an additional option for testing outside of a clinical setting, in the knowledge that the home self-tests have received TGA approval.</li> <li>• The Department estimates an annual regulatory saving of \$120,000.</li> </ul>
<b>Implementation of electronic submissions of data dossiers (e-CTD)</b>	<ul style="list-style-type: none"> <li>• From March 2014 the TGA has been implementing electronic submissions for applications for the Australian Register of Therapeutic Goods approvals.</li> <li>• This measure allows businesses to have the option of submitting applications electronically instead of hard copy. It potentially impacts 170 businesses and approximately 24,000 transactions annually through a reduction in time in preparing and expense of hard copy dossiers, and transportation costs for boxes of dossiers.</li> <li>• The Department estimates an annual regulatory saving of \$9.011 million.</li> </ul>
<b># Gene Technology Amendment Bill 2014</b>	<ul style="list-style-type: none"> <li>• The proposed reforms to the Gene Technology Act 2000 are minor and technical, and will result in a small reduction in regulatory burden. Legislation has not yet been introduced in Parliament.</li> <li>• The changes include increasing the efficiency of reporting and public notifications, changing licence variation requirements to provide greater flexibility for licence holders and clarifying ambiguous wording.</li> <li>• The Office of the Gene Technology Regulator estimates an annual regulatory saving of \$100,800 for businesses.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Consolidated Indigenous Health Grants Funding</b>	<ul style="list-style-type: none"> <li>• In July 2014, the Indigenous Australians' Health Programme brought together four funding streams, improving the focus on local health needs, reducing overheads and better supporting efforts to achieve health equality between Aboriginal and Torres Strait Islander people and non-Indigenous Australians. A new funding allocation methodology for Indigenous health funding will be developed during 2014-15 and implemented from 2015-16, to ensure funding is directed to need and delivers the most effective outcomes from scarce resources.</li> <li>• The consolidation of Indigenous health grant funding reduces the reporting burden on organisations, particularly those that present low risk to the Government. For example, organisations that are low risk to the Department of Health will not be required to submit an annual budget and will report against agreed performance indicators six monthly through a web based tool. The reduced reporting requirements offset an increase in regulatory burden related to the requirement to report against performance indicators on OCHREStreams (an on-line reporting system designed to streamline reporting Indigenous-specific health services) for a range of activities funded through Indigenous health grants.</li> <li>• The Department estimates an annual regulatory saving of \$293,000.</li> </ul>
<b># Amendments to a new regulatory framework for in-vitro diagnostics (TGA)</b>	<ul style="list-style-type: none"> <li>• The transition period for the implementation of the in-vitro diagnostics framework is extended to allow suppliers and laboratories to comply with the new requirements to ensure the continuity of supply of critical IVDs.</li> <li>• The extension will allow additional time for industry stakeholders to demonstrate compliance with the IVD framework.</li> <li>• The OBPR agreed an annual regulatory saving of \$100,000.</li> </ul>
<b>Moving the Drug Master File administrative details form from paper-based to online</b>	<ul style="list-style-type: none"> <li>• In November 2014, the TGA implemented an online accessible Drug Master File Administration Details form to replace the former paper copy form.</li> <li>• This change will remove administrative processes for medicine sponsors and manufacturers in completing and posting back to TGA a hard copy form. It will benefit both stakeholders and the TGA in time saved and reduced administrative costs.</li> <li>• The Department estimates an annual regulatory saving of \$40,000.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Pre-market assessment requirements for Australian-manufactured medical devices</b>	<ul style="list-style-type: none"> <li>• On 15 October 2014, the Government announced changes to the regulation of therapeutic goods that will allow Australian manufacturers of medical devices to obtain market approval for most of their products using conformity assessment certification from European notified bodies.</li> <li>• The change will allow Australian manufacturers to choose to either have conformity assessment conducted by the TGA or an alternative conformity assessment body, such as a European notified body. This will put Australian manufacturers of all but the highest-risk products on an equal footing with those from overseas, avoiding the need for duplicate conformity assessments for those manufacturers wishing to export their products to Europe. In many cases this could allow locally-made medical devices to get to market more quickly. The new rules will not apply to the very highest risk devices which will still need TGA conformity assessment.</li> <li>• The OBPR agreed an annual regulatory saving of \$6.12 million.</li> </ul>
<b>Amend the PCEHR (Participation Agreements) Rules 2012 to require that the participant agreement must be in the form of a contract rather than a deed</b>	<ul style="list-style-type: none"> <li>• On 7 October 2014, the Minister for Health approved amendments to the Personally Controlled Electronic Health Records (Participation Agreement) Rules that will, among other things, provide that the participation agreement to be entered into by private entities must take the form of a contract instead of a deed, and that the terms of the participation agreement are no longer included as a Schedule to the Rules.</li> <li>• The amendments affect entities wanting to apply to be registered with the PCEHR system (not a consumer). As executing a deed can be complex, the changes to the Rules will simplify arrangements by requiring entities to sign a contract rather than a deed. Using a contract also allows entities to apply through the faster online registration processes.</li> <li>• The Department estimates an annual regulatory saving of \$604,800.</li> </ul>
<b># Development of Clinical Quality Registries for high risk implantable breast and cardiac devices</b>	<ul style="list-style-type: none"> <li>• In May 2014, the Minister of Health approved the development of Clinical Quality Registers for high risk implantable breast and cardiac devices to allow better information to be developed about the performance of implantable devices.</li> <li>• The registries will be used by hospitals and specialist practices to record information about the high risk implantable and cardiac devices used. This can flow through to more proactive monitoring by regulatory and reimbursement agencies, better clinical practice by medical practitioners, and better health and safety outcomes for patients.</li> <li>• The Department estimates an annual regulatory burden of \$337,000.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Diagnostic Imaging Quality Programme – cessation</b>	<ul style="list-style-type: none"> <li>• In the 2014-15 Budget, the Government announced the cessation of the Diagnostic Imaging Quality Assessment Programme. The final funding round occurred in 2012-13. The last project will end in mid-2016.</li> <li>• The regulatory saving arises from the cessation of a grants programme.</li> <li>• The Department estimates an annual regulatory saving of \$451,080 over the next two years to the end of the programme.</li> </ul>
<b>Reduction in the number of Government-funded doping control tests conducted and associated Whereabouts requirements</b>	<ul style="list-style-type: none"> <li>• On 13 May 2014, the Government agreed to an improved intelligence-driven risk-based anti-doping programme, reducing the number of planned Government-funded anti-doping control tests from 3,500-4,200 in 2013-14 to 3,000-3,700 in subsequent years. This testing is run through the Australian Sports Anti-doping Authority (ASADA). A reduction in doping control tests reduces the regulatory burden in that fewer athletes will be required to provide a sample. The Department of Health estimates an annual regulatory saving of \$22,000.</li> <li>• From July 2014, the Australian Sports Anti-doping Authority (ASADA) also reduced the number of athletes in the registered anti-doping testing pool, and therefore the number of athletes required to provide ASADA with advance notice of their whereabouts (Whereabouts Requirements) has decreased.</li> <li>• The Department estimates an annual regulatory saving of \$35,000.</li> </ul>
<b>Increased sports funding for the Gold Coast Suns and 'I Support Women in Sport' award</b>	<ul style="list-style-type: none"> <li>• Funding is provided to two organisations – the Gold Coast Suns and Pacific Magazines ('I Support Women in Sport' awards) - under two separate Funding Agreements.</li> <li>• The Funding Agreements generate reporting requirements for the recipients.</li> <li>• The Department estimates an annual regulatory burden increase of \$2,120.</li> </ul>
<b>Health Insurance Allied Health - Better Access</b>	<ul style="list-style-type: none"> <li>• From 1 November 2014, changes to the <i>Health Insurance (Allied Health Services) Determination 2014</i> removed registered psychologist continuing professional development (CPD) requirements for providing Medicare-rebatable Focussed Psychological Strategies services.</li> <li>• The changes remove the unnecessary duplication of CPD activities undertaken by the Psychology Board of Australia under the <i>Health Practitioners Regulation National Law Act 2009</i>. Psychologists providing services under the Better Access initiative are no longer required to maintain two sets of records of CPD activities or undertake duplicative CPD exemption processes, which will save time.</li> <li>• The Department estimates an annual regulatory saving of \$2.015 million.</li> </ul>

MEASURE	MEASURE DESCRIPTION
# Simplification of the e-Health Program Grants process	<ul style="list-style-type: none"> <li>• In March 2015, the Department of Health will reduce administrative requirements for private radiotherapy facilities in claiming reimbursement under the Radiation Oncology Health Programme Grants.</li> <li>• By linking payments to patient claims, radiotherapy providers will save approximately one day per month in administration duties.</li> <li>• The Department estimates an annual regulatory saving of \$18,500.</li> </ul>
# Cost savings to industry following removal of product from the ARTG through Section 9F	<ul style="list-style-type: none"> <li>• From February 2014, a new Section 9F of the Therapeutic Goods Act 1989 provides a mechanism for the Secretary of the Department of Health to remove products from the Australian Register of Therapeutic Goods that do not meet the statutory definition of a therapeutic good.</li> <li>• The measure will improve the transparency of the regulatory regime and will reduce the administrative burden for businesses associated with registration of the product and continuing compliance.</li> <li>• The Department estimates an annual regulatory saving of \$2.67 million.</li> </ul>
Food Medicine Interface Guidance Tool to assist determining whether a product is food or therapeutic goods (TGA)	<ul style="list-style-type: none"> <li>• In October 2014 the TGA adopted explanatory material and a Food Medicine Interface Guidance Tool to assist users in understanding the current regulatory requirements for determining whether a product is a “therapeutic good” under the Therapeutic Goods Act 1989 or “food” under the Australian and New Zealand Food Standards Code and therefore regulated by the States and Territories.</li> <li>• The FMI tool will decrease the amount of time taken by sponsors or manufacturers in determining if a particular product is a therapeutic good and therefore regulated by the TGA.</li> <li>• The Department estimates an annual regulatory saving of \$644,400.</li> </ul>
Approval of Garcinia gummi-gutta as a New Substance on ARTG (TGA)	<ul style="list-style-type: none"> <li>• From July 2014, products containing Garcinia gummi-gutta can be legally supplied as a listed medicine.</li> <li>• Permitting Garcinia gummi-gutta to be used as a listed ingredient enables sponsors to list (rather than register) medicines using the ingredient and also enables sponsors to legally supply their product in Australia earlier than they otherwise would have been able to.</li> <li>• The Department estimates an annual regulatory saving of \$5,000.</li> </ul>
Reduced paperwork for listing a new brand of PBS medicine	<ul style="list-style-type: none"> <li>• From 1 January 2015, the Department will introduce revised paperwork required to list a new brand of a PBS medicine.</li> <li>• The reform allows the electronic submission of documents and reduces the paperwork required to be supplied by pharmaceutical companies.</li> <li>• The Department estimates an annual regulatory saving of \$501,000.</li> </ul>

MEASURE	MEASURE DESCRIPTION
<b>Implementation of new Capital Adequacy and Solvency Standards for private health insurance industry</b>	<ul style="list-style-type: none"> <li>• Under new Capital Adequacy and Solvency Standards implemented during 2014, private health insurers' (PHI) regulatory capital requirements were lowered and reporting requirements simplified.</li> <li>• This will benefit PHI through lower costs of holding surplus capital and a shorter form for reporting purposes.</li> <li>• The Department estimates an annual regulatory saving of \$16.19 million.</li> </ul>
<b>Australian Sports Commission International Programme Reforms (ceasing and establishing programmes)</b>	<ul style="list-style-type: none"> <li>• The Australian Sports Commission has ceased the Australian Sport Outreach Programme and the Pacific Sports Development Grants, and has revised reporting requirements for partner sports under the Pacific Sports Partnerships.</li> <li>• There are regulatory savings resulting from the two ceasing programmes (removal of reporting requirements and application processes). The Pacific Sports Partnerships has halved the time it takes to complete their annual report and quarterly activity report submissions, and has also reduced the amount of times partner sports are required to provide financial acquittals, from three to two times per year, but has increased the number of partner sports from 10 to 12 which therefore increased the number of partners required to action compliance and reporting requirements.</li> <li>• Overall, the Australian Sports Commission estimates an annual saving of \$153,000.</li> </ul>



MEASURE	MEASURE DESCRIPTION
<b>Australian Sports Commission Programme Grant Reforms (ceasing and establishing grant programmes)</b>	<ul style="list-style-type: none"> <li>• The Australian Sports Commission has ceased the Direct Athlete Support Scheme and commenced a new dAIS programme in September 2014 that provides direct financial assistance to targeted world class athletes to assist with training and preparation. There is a regulatory saving relating to a ceasing programme that offsets the increase in compliance burden from the application and completion of the online training modules for the Australia’s Winning Edge National Sporting Organisations and individual athletes. This balances to an annual regulatory burden of \$18,000.</li> <li>• The Active After Schools Care Programme has ceased and the new Sporting Schools programme commenced in January 2015. There are regulatory savings relating to a ceasing programme which offset the increase in burden for schools required to undertake a grant application process and action a range of compliance and reporting requirements, including submission of an online registration, annual plan, confirmation of programme delivery, acquittal, and undertake an audit. This balances to an annual saving of \$319,000.</li> <li>• In addition, the Australian Sports Commission in partnership with the Australian Government Office for Women has reduced application and reporting requirements for the Women Leaders in Sport grant programme that provides female administrators, coaches and officials with opportunities to undertake intermediate or advanced training within an existing pathway in the sport industry to reach their leadership potential. Applicants and recipients will spend less time completing administrative requirements, with an annual regulatory saving of \$14,000.</li> <li>• Overall, this package represents an annual regulatory saving of \$315,000.</li> </ul>
<b>Australian Sports Commission Changing Compliance Requirements for National Sporting Organisations</b>	<ul style="list-style-type: none"> <li>• The Australian Sporting Commission has increased compliance requirements for reporting for National Sporting Organisations (NSOs) in a number of areas. The exception is the Communication Schedule and Reporting requirements, which have been simplified to include the development of an electronic form for NSOs to report against sports communication requirements under their sports investment agreement.</li> <li>• The increase in compliance requirements for reporting for NSOs will increase regulatory burden, while the simplification of the Communication Schedule Reporting requirements will reduce compliance burden.</li> <li>• Overall, this package represents an annual regulatory burden of \$72,640.</li> </ul>

## Appendix B: Legislation administered

For a complete list of the legislation administered by the Health portfolio, visit the ComLaw website ([www.comlaw.gov.au](http://www.comlaw.gov.au)).

For the list of primary legislation administered by the Minister for Health, see the Administrative Arrangements Order ([www.comlaw.gov.au/Details/C2014Q00003](http://www.comlaw.gov.au/Details/C2014Q00003)).