

Outcome 7

HEALTH INFRASTRUCTURE, REGULATION, SAFETY AND QUALITY

Improved capacity, quality and safety of Australia's health care system to meet current and future health needs including through investment in health infrastructure, regulation, international health policy engagement, research into health care, and support for blood and organ donation services

Outcome Strategy

The Australian Government, through Outcome 7, aims to support a sustainable world class health system in Australia through support for deregulation, effective regulation, quality and safety, and strategic investments in health infrastructure and research.

The establishment of the \$20 billion capital-protected Medical Research Future Fund from 1 January 2015 is a landmark investment to enable targeted resourcing of national research priorities into the future. The creation of this Fund reflects the Government's recognition of the central role of medical research in driving innovation and improvements in the delivery of health care for Australians.

Consistent with the Government's broader Deregulation Agenda, the Department will ensure the delivery of appropriate and effective regulation across the portfolio, which maintains desired outcomes while safeguarding the health and wellbeing of the community. The Government is aiming for tangible reductions in red tape for businesses, not-for-profit organisations and individuals.

In 2014-15, the Government will fund the Personally Controlled Electronic Health Record (PCEHR). The Government will continue to work with stakeholders with regard to the recommendations from the recent review of the PCEHR to determine how best to proceed with national shared electronic health records, to support improved productivity across the health sector and greater convenience for providers and patients.

Under Outcome 7, the Government also aims to provide Australians with access to an adequate, safe, secure and affordable blood supply and access to life saving and life-transforming organ and tissue transplants.

Outcome 7 is the responsibility of Acute Care Division, Best Practice Regulation and Deregulation Division, eHealth Policy Change and Adoption Division, Office of Health Protection, Pharmaceutical Benefits Division, Population Health Division, Portfolio Strategies Division, Primary and Mental Health Care Division, the Therapeutic Goods Administration, the National Industrial Chemicals Notification and Assessment Scheme, and the Office of the Gene Technology Regulator.

Programmes Contributing to Outcome 7

Programme 7.1: eHealth Implementation

Programme 7.2: Health Information

Programme 7.3: International Policy Engagement

Programme 7.4: Research Capacity and Quality

Programme 7.5: Health Infrastructure

Programme 7.6: Blood and Organ Donation

Programme 7.7: Regulatory Policy

Outcome 7 Budgeted Expenses and Resources

Table 7.1 provides an overview of the total expenses for Outcome 7 by Programme.

Table 7.1: Budgeted Expenses and Resources for Outcome 7

	2013-14 Estimated actual \$'000	2014-15 Estimated expenses \$'000
Programme 7.1: e-Health implementation¹		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	112,115	135,221
	18,309	18,309
Departmental expenses		
Departmental appropriation ³	18,776	22,420
Expenses not requiring appropriation in the budget year ⁴	1,433	1,405
Total for Programme 7.1	150,633	177,355
Programme 7.2: Health information		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	29,042	28,314
Departmental expenses		
Departmental appropriation ³	1,742	1,353
Expenses not requiring appropriation in the budget year ⁴	131	129
Total for Programme 7.2	30,915	29,796
Programme 7.3: International policy engagement		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	12,575	14,912
Departmental expenses		
Departmental appropriation ³	12	11
Expenses not requiring appropriation in the budget year ⁴	1	1
Total for Programme 7.3	12,588	14,924
Programme 7.4: Research capacity and quality¹		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	83,027	82,159
Medical Research Future Fund	-	-
Departmental expenses		
Departmental appropriation ³	7,320	6,213
Expenses not requiring appropriation in the budget year ⁴	543	532
Total for Programme 7.4	90,890	88,904

Table 7.1: Budgeted Expenses and Resources for Outcome 7 (Cont.)

	2013-14 Estimated actual \$'000	2014-15 Estimated expenses \$'000
Programme 7.5: Health infrastructure¹		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	100,797	69,710
Special Accounts		
Health and Hospitals Fund Health Portfolio Special Account ^{5, 6}	599,801	795,233
Departmental expenses		
Departmental appropriation ³	10,237	9,895
Expenses not requiring appropriation in the budget year ⁴	770	756
Total for Programme 7.5	711,605	875,594
Programme 7.6: Blood and organ donation¹		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	16,374	18,058
Special appropriations		
National Health Act 1953 - blood fractionation, products and blood related products - to National Blood Authority	716,039	718,906
Departmental expenses		
Departmental appropriation ³	5,063	4,035
Expenses not requiring appropriation in the budget year ⁴	361	354
Total for Programme 7.6	737,837	741,353
Programme 7.7: Regulatory policy		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	1,304	105
Departmental expenses		
Departmental appropriation ³	30,026	29,548
to special accounts	(13,310)	(15,848)
Expenses not requiring appropriation in the budget year ⁴	922	905
Special accounts		
Special accounts		
OGTR Special Account ⁷	8,142	8,001
NICNAS Special Account ⁸	15,068	13,267
TGA Special Account ⁹	137,334	147,736
Expense adjustment ¹⁰	(3,637)	(8,521)
Total for Programme 7.7	175,849	175,193

Table 7.1: Budgeted Expenses and Resources for Outcome 7 (Cont.)

	2013-14 Estimated actual \$'000	2014-15 Estimated expenses \$'000
Outcome 7 totals by appropriation type		
Administered expenses		
Ordinary annual services (Appropriation Bill No. 1)	355,234	348,479
Non cash expenses ²	18,309	18,309
Special accounts	599,801	795,233
Special appropriations	716,039	718,906
Departmental expenses		
Departmental appropriation ³	73,176	73,475
to Special accounts	(13,310)	(15,848)
Expenses not requiring appropriation in the budget year ⁴	4,161	4,082
Special accounts	156,907	160,483
Total expenses for Outcome 7	1,910,317	2,103,119
	2013-14	2014-15
Average staffing level (number)	1,156	1,149

- 1 This programme includes National Partnerships paid to state and territory governments by the Treasury as part of the Federal Financial Relations (FFR) Framework. National partnerships are listed in this chapter under each program. For budget estimates relating to the National Partnership component of the programme, please refer to Budget Paper 3 or Programme 1.10 of the Treasury Portfolio Budget Statements.
- 2 "Non cash expenses" relates to the depreciation of computer software.
- 3 Departmental appropriation combines "Ordinary annual services (Appropriation Bill No 1)" and "Revenue from independent sources (s31)".
- 4 "Expenses not requiring appropriation in the Budget year" is made up of depreciation expense, amortisation expense, make good expense and audit fees.
- 5 The Health and Hospitals Fund is recorded as an expense by this department and by the Treasury. For more detailed estimates relating to this program refer Budget Paper 3.
- 6 The Health and Hospitals Fund (HHF) is established and funded under the *Nation-building Funds Act 2008*. Following the transfer of the uncommitted balance of the HHF to the Medical Research Future Fund, the *Nation-building Funds Act 2008* is due to be repealed and funding for existing activity is expected to be met by Special Appropriation provisions from 1 January 2015.
- 7 Office of the Gene Technology Regulator Special Account.
- 8 National Industrial Chemicals Notification and Assessment Scheme Special Account.
- 9 Therapeutic Goods Administration Special Account.
- 10 Special accounts are reported on a cash basis. This adjustment reflects the differences between expense and cash, and eliminates inter-entity transactions between the Core department and TGA.

Programme 7.1: eHealth Implementation

Programme Objectives

Operate a national eHealth system

The Australian Government is committed to strengthening the ability to share health care information. In November 2013, the Government commissioned an external review of the PCEHR to examine issues with the existing PCEHR system. In 2014-15, the Government will continue to work with stakeholders with regard to the review recommendations to see how they can best be implemented to maximise the benefits of eHealth for the Australian community.

Provide national eHealth leadership

The Australian Government will lead the national roll out of eHealth technology and services and work with States and Territories to support eHealth foundations. This will include maintaining the eHealth national infrastructure and standards necessary for clinically safe, secure and inter-operable eHealth for adoption by public and private health care providers.

In 2014-15, the Practice Incentive Payment (PIP) eHealth incentive will be used to encourage general practices to safely and securely participate in the use of eHealth systems.

In 2014-15, an evaluation of the Telehealth Pilots Programme will be conducted, with the pilots concluding at the end of September 2014.

Programme 7.1 is linked as follows:

- This Programme includes National Partnership payments for:
 - *Tasmanian electronic patient information sharing.*Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.10 of the Treasury's Portfolio Budget Statements.
- The Department of Human Services (Services to the Community - Programme 1.2) to support operation of the Personally Controlled Electronic Health Record system.
- The Department of Industry (Innovative Industry - Programme 1.2) to administer clinical trial reform in Australia.

Programme 7.1: Expenses

Table 7.2: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	112,115	135,221	12,859	-	-
Non cash expenses ¹	18,309	18,309	18,309	18,308	-
Programme support	20,209	23,825	12,785	11,708	11,351
Total Programme 7.1 expenses	150,633	177,355	43,953	30,016	11,351

1 "Non cash expenses" relates to the depreciation of computer software.

Programme 7.1: Deliverables

Qualitative Deliverables for Programme 7.1

Operate a national eHealth system

Qualitative Deliverable	2014-15 Reference Point or Target
The Department, as the PCEHR system operator, applies good practice principles and methods for the operation and support of the PCEHR system	The PCEHR system operations and practices are regularly reviewed

Provide national eHealth leadership

Qualitative Deliverable	2014-15 Reference Point or Target
Telehealth services are trialled in the home for aged care, palliative care and cancer care	The Department will evaluate the pilot programme on the use of telehealth services in the home

Programme 7.1: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.1

Operate a national eHealth system

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
System availability ¹	N/A	99% of the time (excluding planned outages)	- ²	-	-

Programme 7.2: Health Information

Programme Objectives

Provide support to the Council of Australian Governments (COAG) Health Council and the Australian Health Ministers' Advisory Council (AHMAC)

To ensure a nationally consistent focus on achieving better health outcomes, the Australian Government facilitates collaborative policy development with States and Territories through the COAG Health Council, AHMAC and its six Principal Committees.

In 2014-15, taking account of COAG's endorsed terms of reference for the Health Council, the Department will work to ensure that relevant Australian Government priorities are reflected in the activities of the Health Council.

Programme 7.2: Expenses

Table 7.3: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	29,042	28,314	24,431	23,734	23,768
Programme support	1,873	1,482	1,438	1,417	1,462
Total Programme 7.2 expenses	30,915	29,796	25,869	25,151	25,230

¹ This KPI has changed from 2014 to reflect the operation of the PCEHR system as the Department's core business.

² Funding provided for 2014-15 for operating the system. Targets will be considered following Government decisions on forward year funding.

Programme 7.2: Deliverables

Qualitative Deliverables for Programme 7.2

Provide support to the COAG Health Council and Australian Health Ministers' Advisory Council (AHMAC)

Qualitative Deliverable	2014-15 Reference Point or Target
Australian Government initiated activities undertaken by AHMAC and its Principal Committees support the COAG Health Council in providing leadership on national health issues	Relevant Australian Government priorities are highlighted and progressed in the activities of the Health Council

Programme 7.2: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.2

Provide support to the COAG Health Council and Australian Health Ministers' Advisory Council (AHMAC)

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Number of COAG Health Council meetings that address Australian Government priorities	N/A	2	2	2	2

Programme 7.3: International Policy Engagement

Programme Objectives

Facilitate international engagement on global health issues

The Australian Government, through the Department, will continue to monitor international health policy trends and actively participate in international dialogue on global health policy challenges. Australia's influence and responsibility for international health issues continues through its position on the World Health Organization (WHO) Executive Board over the three year term (2012-2015).

In 2014-15, the Department will continue to manage Australia's bilateral relationships with health ministries and with international multilateral organisations such as the WHO, the Organisation for Economic Cooperation and Development (OECD) and the Asia-Pacific Economic Cooperation (APEC).

During this period, the Department will ensure that Australia continues to have strong participation in international fora focusing on promoting and protecting Australia's priority health interests in the Indo-Pacific region and globally. Priority issues include communicable disease control, including pandemic influenza preparedness and response, malaria, tuberculosis and HIV/AIDS, tobacco control, non-communicable disease prevention and control, and health systems. The

Department will continue to participate in United Nations discussions to finalise the post 2015 global development agenda by promoting substantive country and regional input to health related goals.

The Department will also continue to work with the Department of Foreign Affairs and Trade to promote Australia’s strategic and development goals, including managing bilateral health cooperation relationships with China, India and Indonesia and engaging with Pacific Island nations. The Department will continue to bring a health perspective to the development of whole-of-government positions on free trade agreements. To support international collaboration on best practice approaches to reducing cancer incidence and mortality, the Department engages and supports the WHO’s specialist cancer agency, the International Agency for Research on Cancer (IARC). Australia has been a participating member of the IARC since 1965 and in 2014-15, will be represented at the IARC Governing Council meetings by the Chief Medical Officer.

To support international collaboration, the Department will facilitate the participation of senior health officials and technical experts at international meetings, host international delegations and visitors, and respond to requests from multilateral and regional agencies for data and policy information on Australia’s health system and health status.

Programme 7.3: Expenses

Table 7.4: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year3 \$'000
Annual administered expenses					
Ordinary annual services	12,575	14,912	14,912	14,912	14,912
Programme support	13	12	12	12	12
Total Programme 7.3 expenses	12,588	14,924	14,924	14,924	14,924

Programme 7.3: Deliverables

Qualitative Deliverables for Programme 7.3

Facilitate international engagement on global health issues

Qualitative Deliverable	2014-15 Reference Point or Target
Australia’s interests secured at relevant meetings of key international health bodies and organisations	Departmental representatives will have actively engaged in meetings of the WHO governing bodies, OECD Health Committee, APEC Health Working Group and other international fora

Quantitative Deliverables for Programme 7.3

Facilitate international engagement on global health issues

Quantitative Deliverable	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Number of international health delegation visits facilitated by the Department	20-25	20-25	20-25	20-25	20-25

Programme 7.3: Key Performance Indicators

Qualitative Key Performance Indicators for Programme 7.3

Facilitate international engagement on global health issues

Qualitative Indicator	2014-15 Reference Point or Target
Australia's health interests are advanced through participation in the WHO Executive Board ³	Departmental representatives will have made effective interventions on key agenda items at the WHO Executive Board

Programme 7.4: Research Capacity and Quality

Programme Objectives

Improve research capacity

The establishment of the landmark \$20 billion capital-protected Medical Research Future Fund will provide a vital platform to support Australian researchers to work on the leading edge of basic and applied medical research.

Medical research is vital for the future of the Australian health system, and the Australian economy. It will inform strategies to address the challenges facing our health services and to deliver high quality health care into the future. A world class health system needs to be on the cutting edge of innovation and clinical breakthroughs. The rapid translation of national and international research into improved patient care, and more efficient systems of care is critical to improving outcomes for Australian patients and the sustainability of Australia's health system.

Medical research also makes good economic sense. It is a key driver of productivity and innovation in the health care sector, which employs more than one million Australians. Every \$1 spent on health and medical research generates a health benefit valued at \$2.17 – a return on investment for the nation of well over 100 per cent.

³ This KPI has been updated to better reflect the Department's current international role.

Clinical trials are a critical element of translating research into better care. The Department is working with the Department of Industry and the National Health and Medical Research Council (NHMRC)⁴ to progress recommendations of the Clinical Trials Action Group to reduce the time taken for clinical trial approvals.

The recommendations of the *Strategic Review of Health and Medical Research – Better Health through Research* (McKeon Review released in April 2013) are also informing future policy directions.

Maintain effective health surveillance

The Australian Government funds activities to collect, analyse and publish statistics and information on vaccine preventable diseases and zoonoses, foodborne, and emerging infectious diseases as well as activities to collect, analyse and publish statistics and information on chronic diseases, drug usage, and injury. In 2014-15, the Government will continue to fund the four national research centres for blood borne viruses and sexually transmissible infections, the national drug strategy household survey, the production of small area statistics and estimates of burden of disease and human papillomavirus monitoring. This research will assist in assessing progress with the associated national strategies or plans.

Monitor the use of diagnostics, therapeutics and pathology

The Australian Government supports National Prescribing Service (NPS) MedicineWise to provide information to consumers and health professionals on quality use of medicines and medical testing. This is aimed at improving health outcomes and assisting the ongoing sustainability of the Pharmaceutical Benefits Scheme and the Medicare Benefits Schedule. Support is also provided to the National Return and Disposal of Unwanted Medicines (NatRUM) Programme to collect consumers' expired and unwanted medicines and help avoid accidental childhood poisoning and medication misuse.

In 2014-15, the NPS will continue the development of the MedicineInsight project and deliver reports from this dataset to the Australian Government. The MedicineInsight project will capture, store and analyse General Practitioner (GP) data to better inform GPs on how medicines are being used in clinical practice, and has the potential to improve clinical practice and inform policy development in the quality use of medicines.

Funding available through the Quality Use of Diagnostics, Therapeutics and Pathology programme will be subject to a competitive tender process prior to current funding agreements expiring on 30 June 2015.

Improve safety and quality in health care

In 2014-15, the Department, with States and Territories, will provide policy direction and funding to the Australian Commission on Safety and Quality in Health Care (ACSQHC)⁵ to continue its work on improving safety and quality in

⁴ For further information on the work of the NHMRC, refer to the NHMRC chapter in these Portfolio Budget Statements.

⁵ Further information on the work of the ACSQHC is in the ACSQHC chapter in these Portfolio Budget Statements.

the hospital system. In 2014-15, the Australian Government will implement safety and quality initiatives in priority areas such as clinical management of blood, addressing antimicrobial resistance⁶, reducing unnecessary radiation exposure from diagnostic imaging and identifying clinical variation. This work will strengthen safety and quality arrangements across the health system to reduce patient risks and generate efficiencies.

Programme 7.4 is linked as follows:

- This Programme includes National Partnership payments for:
 - *Vaccine-preventable diseases surveillance.*
 Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.10 of the Treasury's Portfolio Budget Statements.

Programme 7.4: Expenses

Table 7.5: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	83,027	82,159	81,819	83,564	83,576
Medical Research Future Fund	-	-	19,909	76,982	179,327
Programme support	7,863	6,745	6,563	6,477	6,664
Total Programme 7.4 expenses	90,890	88,904	108,291	167,023	269,567

Programme 7.4: Deliverables

Qualitative Deliverables for Programme 7.4

Improve research capacity

Qualitative Deliverable	2014-15 Reference Point or Target
Facilitate research translation into improved health care	Agreement reached by jurisdictions on addressing barriers to streamlined approval of clinical trials

⁶ For more information relating to work on antimicrobial resistance, refer to the Outcome 9 chapter in these Portfolio Budget Statements.

Maintain effective health surveillance

Qualitative Deliverable	2014-15 Reference Point or Target
Produce relevant and timely evidence-based disease surveillance data, information and research	Surveillance information available to inform national strategies

Monitor the use of diagnostics, therapeutics and pathology

Qualitative Deliverable	2014-15 Reference Point or Target
Information regarding quality use of medicines newly listed on the PBS is provided to health professionals where appropriate	The Department will produce information in a variety of formats throughout the year, including the <i>Rational Assessment of Drugs and Research</i> , the <i>Australian Prescriber</i> and an annual evaluation report

Programme 7.4: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.4

Monitor the use of diagnostics, therapeutics and pathology

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Number of general practitioners participating in education initiatives ⁷	14,000	14,500	N/A	N/A	N/A ⁸

Programme 7.5: Health Infrastructure

Programme Objectives

Improve primary health care infrastructure

In 2014-15, the Government will provide new Rural and Regional Teaching Infrastructure Grants totalling \$52.5 million to enable regional and rural GP practices to build facilities to take on more trainees. The grants will support the provision of additional consultation rooms and space for teaching medical students and supervising GP registrars.⁹

⁷ The educational initiatives that GPs participate in are conducted by the NPS, and the Australian Government funding agreement which they are operating under ceases on 30 June 2015.

⁸ Funding in the forward years is subject to negotiation of a new funding agreement.

⁹ This initiative will be supported by the doubling of the Practice Incentives Programme (PIP) teaching payments in 2014-15 to support general practices to provide teaching sessions to medical students.

Invest in other major health infrastructure

In 2014-15, the Government will work with States and Territories, non-government organisations, universities and medical research institutes to progress existing Health and Hospitals Fund (HHF) projects. The Department will pursue negotiations for the remaining projects under the HHF Regional Priority Rounds, with a view to finalising agreements with successful applicants.

The Department will monitor the progress of major cancer infrastructure projects receiving Australian Government funding, including the Chris O’Brien Lifehouse at the Royal Prince Alfred Hospital in Sydney, and the Victorian Comprehensive Cancer Centre in Melbourne. These centres will enhance Australia’s world class cancer care and research.

The Department will also monitor the progress of 13 Regional Cancer Centre projects, five of which are expected to reach practical completion in 2014-15. These Australian Government-funded projects will allow cancer patients living outside metropolitan areas to access treatment and support services close to their community and family.

Programme 7.5 is linked as follows:

- This Programme includes National Partnership payments for:
 - *Health and Hospitals Fund - hospital infrastructure and other projects of national significance; and*
 - *Health and Hospitals Fund - regional priority round.*

Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework.

For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.10 of the Treasury’s Portfolio Budget Statements.

Programme 7.5: Expenses

Table 7.6: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	100,797	69,710	33,959	11,459	7,059
Special account expenses					
Health and Hospital Fund					
Health Portfolio ^{1,2}	599,801	795,233	360,238	70,588	10,318
Programme support	11,007	10,651	10,393	10,279	10,496
Total Programme 7.5 expenses	711,605	875,594	404,590	92,326	27,873

- 1 The Health and Hospitals Fund is recorded as an expense by this department and by the Treasury. For more detailed estimates relating to this programme refer Budget Paper 3.
- 2 The Health and Hospitals Fund (HHF) is established and funded under the *Nation-building Funds Act 2008*. Following the transfer of the uncommitted balance of the HHF to the Medical Research Future Fund, the *Nation-building Funds Act 2008* is due to be repealed and funding for existing activity is expected to be met by Special Appropriation provisions from 1 January 2015.

Programme 7.5: Deliverables

Qualitative Deliverables for Programme 7.5

Invest in other major health infrastructure

Qualitative Deliverable	2014-15 Reference Point or Target
Funding arrangements in place for all successful projects under the 2010 and 2011 Regional Priority Round of HHF grants	Remaining funding agreements signed by 31 December 2014

Programme 7.5: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.5

Improve primary health care infrastructure

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Number of grants to support the provision of additional space for teaching and training to strengthen the rural workforce ¹⁰	N/A	100	75	N/A	N/A

Qualitative Key Performance Indicators for Programme 7.5

Invest in other major health infrastructure

Qualitative Indicator	2014-15 Reference Point or Target
Effective monitoring of HHF projects for compliance with agreed outputs	Reports are received for all projects in the required timeframe and remedial action taken as required

¹⁰ These grants are subject to only one funding round, with expenditure spread over 2014-15 and 2015-16.

Programme 7.6: Blood and Organ Donation

Programme Objectives

Improve Australians' access to organ and tissue transplants

Australians' access to life-saving and life-transforming organ and tissue transplants continues to steadily increase. The Government will support the Australian Organ and Tissue Donation and Transplantation Authority (AOTDTA)¹¹ in implementing, coordinating and monitoring a national approach to organ and tissue donation for transplantation. The functions of AOTDTA and the National Blood Authority will be merged with a view to establishing a new independent authority by 1 July 2015.

To provide patients in need of life-saving stem cell transplants with the best possible chance of finding a suitable stem cell match, the Government will support the Australian Bone Marrow Donor Registry and Bone Marrow Transplant Programme, the National Cord Blood Collection Network, and the expanding Bone Marrow Transplant Programme. In 2014-15, the Department will also consider the findings of an evaluation of the Supporting Leave for Living Organ Donors scheme.

Support access to blood and blood products

The Australian Government will work with States and Territories supported by the National Blood Authority (NBA)¹² to ensure that blood products funded by governments are used as efficiently as possible to achieve evidence-based, best clinical practice. During 2014-15, the Government will work with States and Territories and the NBA to develop and implement waste reduction strategies and options to improve supply chain efficiencies. Work will also be undertaken with the NBA to merge the functions of the NBA and the AOTDTA with a view to establishing a new independent authority by 1 July 2015.

Other priorities in 2014-15, include reducing unnecessary clinical variation in transfusion practice, developing and implementing a National Blood Management Collaborative, and stronger governance arrangements for access to funded intravenous immunoglobulin.

Programme 7.6 is linked as follows:

- This Programme includes National Partnership Payments for:
 - *Hepatitis C settlement fund.*
- Partnership payments are paid to State and Territory Governments by the Treasury as part of the Federal Financial Relations (FFR) Framework. For Budget estimates relating to the National Partnership component of the programme, refer to Budget Paper No. 3 or Programme 1.10 of the Treasury's Portfolio Budget Statements.

¹¹ For further information on the work of the AOTDTA, refer to the AOTDTA chapter in these Portfolio Budget Statements.

¹² For further information on the work of the NBA, refer to the NBA chapter in these Portfolio Budget Statements.

- The Department of Human Services (Services to the Community – Programme 1.2) to administer the Australian Organ Donor Register and the Supporting Leave for Living Organ Donors Scheme.

Programme 7.6: Expenses

Table 7.7: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	16,374	18,058	18,780	20,724	20,880
Special appropriations					
<i>National Health Act 1953 -</i> Blood fractionation, products and blood related products to National Blood Authority	716,039	718,906	764,536	811,816	863,258
Programme support	5,424	4,389	3,900	3,706	3,694
Total Programme 7.6 expenses	737,837	741,353	787,216	836,246	887,832

Programme 7.6: Deliverables

Qualitative Deliverables for Programme 7.6

Improve Australians' access to organ and tissue transplants

Qualitative Deliverable	2014-15 Reference Point or Target
Support the Australian Bone Marrow Donor Registry and the National Cord Blood Collection Network to identify matched donors and stem cells for transplant	Increased diversity of tissue types of donors and cord blood units available for transplant

Support access to blood and blood products

Qualitative Deliverable	2014-15 Reference Point or Target
Effective planning of the annual blood supply through the National Supply Plan and Budget	Implementation of the 2014-15 National Supply Plan and Budget agreed by all Health Ministers in 2013-14

Quantitative Deliverables for Programme 7.6

Improve Australians' access to organ and tissue transplants

Quantitative Deliverable	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2 ¹³	2017-18 Forward Year 3 ¹⁴
Number of banked cord blood units					
• Total	2,379	2,379	2,379	N/A	N/A
• Indigenous	129	129	129	N/A	N/A

Programme 7.6: Key Performance Indicators

Quantitative Key Performance Indicators for Programme 7.6

Improve Australians' access to organ and tissue transplants

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of legitimate Bone Marrow Transplant Programme applications assessed and approved within four days of receipt	100%	100%	100%	100%	100%

Programme 7.7: Regulatory Policy

Programme Objectives

Provide direction and national leadership in gene technology regulatory policy issues, as well as maintain and improve the therapeutic goods and industrial chemicals regulatory frameworks.

¹³ Targets for forward years to be determined by Health Ministers following a review scheduled for late 2014.

¹⁴ Targets for forward years to be determined by Health Ministers following a review scheduled for late 2014.

Programme 7.7: Expenses

Table 7.8: Programme Expenses

	2013-14 Estimated actual \$'000	2014-15 Budget \$'000	2015-16 Forward Year 1 \$'000	2016-17 Forward Year 2 \$'000	2017-18 Forward Year 3 \$'000
Annual administered expenses					
Ordinary annual services	1,304	105	274	279	284
Programme support	17,638	14,605	11,876	11,730	12,047
Departmental special accounts					
OGTR Special Account ¹	8,142	8,001	7,969	9,932	8,019
NICNAS Special Account ²	15,068	13,267	13,583	13,533	13,533
TGA Special Account ³	137,334	147,736	139,265	137,237	135,452
Expense adjustment ⁴	(3,637)	(8,521)	(3,393)	(1,978)	2,833
Total Programme 7.7 expenses	175,869	175,211	169,592	170,751	172,186

1 Office of the Gene Technology Regulator Special Account.

2 National Industrial Chemicals Notification and Assessment Scheme Special Account.

3 Therapeutic Goods Administration Special Account.

4 Special accounts are reported on a cash basis. This adjustment reflects the differences between expense and cash and the elimination of interagency transactions.

Therapeutic Goods

Ensure that therapeutic goods are safe, effective and of high quality

In 2014-15, the Therapeutic Goods Administration (TGA) will continue to identify opportunities for reducing regulatory burden on industry, consistent with the Government’s deregulation and red tape reduction agenda, while continuing to meet the objectives of safeguarding and enhancing the health of the Australian community.

International harmonisation and work sharing

The TGA participates in international harmonisation and work sharing activities with many international agencies and overseas regulators. These activities will help to reduce effort in pre- and post-market evaluation of therapeutic goods, while enabling the TGA to make more informed and consistent regulatory decisions about the safety, quality and efficacy of therapeutic products available in Australia.

Continue therapeutic goods reform process

In 2014-15, the TGA will continue to implement a comprehensive reform agenda which will improve the way the TGA communicates with the public about the benefits and risks of therapeutic goods and will optimise a range of regulatory processes. The reforms will enhance public trust in the TGA’s post-market surveillance capacity. The TGA will continue publishing a half-yearly report on the progress of these reforms.

In a related area, the Department is supporting an industry-led Advisory Group to guide implementation of a range of reforms to strengthen the therapeutic goods industry’s self-regulatory framework for the promotion of therapeutic goods to health care professionals.

Deliverables

Qualitative Deliverables for Therapeutic Goods

Ensure that therapeutic goods are safe, effective and of high quality

Qualitative Deliverable	2014-15 Reference Point or Target
Contribute to the Government's deregulation and red tape reduction agenda by identifying and progressing opportunities to reduce red tape	Complete a review to identify opportunities to reduce regulatory burden and red tape

International harmonisation and work sharing

Qualitative Deliverable	2014-15 Reference Point or Target
Implement international harmonisation, work sharing and joint operations with comparable international regulators	Enhanced cooperation and work sharing including increased reliance on information from international regulators

Continue therapeutic goods reform process

Qualitative Deliverable	2014-15 Reference Point or Target
Implement reforms that enhance TGA's current regulatory processes	Reforms implemented in accordance with the published plan for <i>TGA Reforms: A blueprint for TGA's future</i>

Quantitative Deliverables for Therapeutic Goods

Continue therapeutic goods reform process

Quantitative Deliverable	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Number of reforms implemented to enhance TGA's regulatory processes ¹⁵	10	3	7	N/A	N/A

¹⁵ The TGA Reform Blueprint included 48 recommendations for implementation over the financial years 2011-12 to 2015-16. All of the recommendations are expected to be implemented by 2015-16.

Key Performance Indicators

Quantitative Key Performance Indicators for Therapeutic Goods

Ensure that therapeutic goods are safe, effective and of high quality

Quantitative Indicators	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of evaluations/assessments completed within legislated timeframes ¹⁶ : <ul style="list-style-type: none"> a) Applications lodged under prescription medicines registration (Category 1 applications) processed within 255 working days b) Quality related evaluations of prescription medicines (Category 3 applications) processed within 45 working days c) Conformity assessments for medical devices processed within 255 working days 	100%	100%	100%	100%	100%
Percentage of alleged breaches of the <i>Therapeutic Goods Act 1989</i> received that are assessed within 10 working days and an appropriate response initiated	100%	100%	100%	100%	100%

Outcome 17

¹⁶ Further information available at: [The Australian Register of Therapeutic Goods website](#)
Legislated timeframes refers to various timeframes specified in *Therapeutic Goods Act 1989* and subordinate regulations. The KPIs relating to evaluations that appeared in the 2013-14 Portfolio Budget Statements have been consolidated into one to draw all aspects of TGA evaluations together.

Quantitative Indicators	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of licensing and surveillance inspections completed within target timeframes:					
<ul style="list-style-type: none"> • Domestic • Overseas 	100%	100%	100%	100%	100%
	90%	90%	90%	90%	90%

Industrial Chemicals

Aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) registers introducers of industrial chemicals, assesses industrial chemicals for their risks to human health and the environment and, where relevant, makes recommendations to relevant regulatory authorities regarding risk mitigation. NICNAS assesses the risks to human health and the environment of selected chemicals already in use, prioritised based on volume of use, risk management requirements in comparable countries, and detection in human cord blood. In 2014-15, NICNAS will continue to work with international partners on regulatory harmonisation and efficiency projects.

Consistent with the Government's deregulation agenda, the Department will implement reforms to improve the efficiency and effectiveness of the regulation of industrial chemicals. The reforms will remove unnecessary regulatory burden while maintaining the protection of public health, worker safety and the environment.

Programme 7.7 is linked as follows:

- The Department of Immigration and Border Protection (Border Management - Programme 1.2) for reviewing importation of industrial chemicals.
- The Department of Industry (Programme Support - Programme 1.3) in relation to COAG chemical reforms.
- The Attorney-General's Department (National Security - Programme 1.2) for managing chemicals of security concern.
- The Department of the Environment (Management of Hazardous Wastes, Substances and Pollutants - Programme 1.6), the Department of Employment (Safe Work Australia) and the Treasury (Australian Competition and Consumer Commission) for managing risks arising from industrial chemicals.

Deliverables

Qualitative Deliverables for Industrial Chemicals

Aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use

Qualitative Deliverables	2014-15 Reference Point or Target
Scientifically robust assessments of new and existing industrial chemicals	Peer review and stakeholder feedback support assessment outcomes
High quality assessment outcomes are produced through effective use of the Multi-tiered Assessment and Prioritisation (IMAP) framework	Stakeholder engagement and communication strategies continue to be effectively implemented to contribute to the quality and uptake of assessment outcomes
Contribution to the international harmonisation of regulatory approaches and methodologies for assessing industrial chemicals by reviewing Australian processes	Review international regulatory approaches and methodologies from three key sub-committees of the OECD Chemicals Committee for their application to NICNAS assessments of industrial chemicals
All introducers of industrial chemicals are aware of their legal obligations	Register identified introducers and provide regular information updates
The costs associated with the regulation of industrial chemicals are adequately balanced against the benefits to worker health and safety, public health and the environment	Reforms to NICNAS more efficiently and effectively achieve the objects of the <i>Industrial Chemicals (Notification and Assessment) Act 1989</i>

Key Performance Indicators

Qualitative Key Performance Indicators for Industrial Chemicals

Aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use

Qualitative Indicator	2014-15 Reference Point or Target
Effective use of international information	International hazard assessment information incorporated into assessments Guidance and training on the use of international information provided to assessors

Quantitative Key Performance Indicators for Industrial Chemicals

Aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals and providing information to promote their safe use

Quantitative Indicators	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of new chemical assessments completed within legislated timeframes	96%	96%	96%	96%	96%
Cumulative percentage of Stage One chemicals assessed through effective application of IMAP framework	50%	90%	95%	N/A ¹⁷	N/A ¹⁷
Percentage of NICNAS registrants introducing over \$500,000 of industrial chemicals assessed for compliance with new chemicals obligations	35%	40%	45%	45%	45%

Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

The Australian Government, through the Gene Technology Regulator, will administer the national scheme for the regulation of gene technology to protect the health and safety of people and the environment.

In 2014-15, the Office of the Gene Technology Regulator (OGTR) will implement operational changes agreed in the all of Australian Governments' response to the 2011 *Review of the Gene Technology Act 2000*. OGTR will work with the Department to progress other recommendations to improve flexibility and reduce regulatory burden. OGTR will also review guidelines and processes, in consultation with stakeholders, to enhance efficiency and effectiveness.

During 2014-15, OGTR will ensure that all risk assessments are based on current scientific evidence and represent international best practice by consulting with experts and key stakeholders, and by keeping pace with advances in scientific knowledge and regulatory practice. OGTR will engage in international harmonisation activities and capacity building in the region. Bilateral arrangements with other Australian Government regulators will enhance the reciprocal provision of advice on applications to support timely, efficient and comprehensive assessment of GMOs and genetically modified products.

¹⁷ Subject to the outcome of the programme review in 2015-16.

Deliverables

Qualitative Deliverables for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Qualitative Deliverables	2014-15 Reference Point or Target
Progress improvements to OGTR operations recommended by all Australian Governments' response to the Review of the <i>Gene Technology Act 2000</i>	Implementation completed within agreed timeframes Progress of agreed minor and technical amendments to increase flexibility and reduce regulatory burden
Provide effective regulation of GMOs that is open and transparent	Risk assessments and risk management plans prepared for all applications for licensed dealings Stakeholders, including the public, consulted on all assessments for proposed release of GMOs into the environment Record of GMO dealings and maps of all field trial sites maintained and made publicly available on the OGTR website ¹⁸

Quantitative Deliverables for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms GMOs

Quantitative Deliverable	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of field trial sites and higher level containment facilities inspected	≥20%	≥20%	≥20%	≥20%	≥20%

¹⁸ Further information available at: [Office of the Gene Technology Regulator website](#)

Key Performance Indicators

Qualitative Key Performance Indicators for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Qualitative Indicators	2014-15 Reference Point or Target
Protect people and the environment through identification and management of risks from GMOs	Comprehensive and effective risk assessment and risk management of GMOs ¹⁹ High level of compliance with the gene technology legislation and no adverse effect on human health or environment from authorised GMOs
Facilitate cooperation and provision of advice between relevant regulatory agencies with responsibilities for GMOs and/or genetically modified products ²⁰	High degree of cooperation with relevant regulatory agencies and provision of timely advice

Quantitative Key Performance Indicators for Gene Technology Regulation

Protect the health and safety of people and the environment by regulating work with genetically modified organisms (GMOs)

Quantitative Indicator	2013-14 Revised Budget	2014-15 Budget Target	2015-16 Forward Year 1	2016-17 Forward Year 2	2017-18 Forward Year 3
Percentage of licence decisions made within statutory timeframes	100%	100%	100%	100%	100%

¹⁹ This KPI has been amended to include additional information for the reference point or target against the qualitative indicator.

²⁰ This KPI has been amended to provide a more specific qualitative indicator and reference point or the target.