The Auditor-General
Audit Report No.39 2009–10
Performance Audit

Medicare Australia's Administration of the Pharmaceutical Benefits Scheme

Medicare Australia

Department of Health and Ageing

Department of Human Services

Australian National Audit Office

ISSN 1036–7632

ISBN 0 642 81131 8

Australian National
Audit Office

Canberra ACT
24 May 2010

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken a performance audit in Medicare Australia, the Department of Health and Ageing and the Department of Human Services in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit and the accompanying brochure. The report is titled *Medicare Australia's Administration of the Pharmaceutical Benefits Scheme.*

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's Homepage—http://www.anao.gov.au.

Yours sincerely

Ian McPhee
Auditor-General

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

For further information contact:
The Publications Manager
Australian National Audit Office
GPO Box 707
Canberra ACT 2601

Telephone: **(02) 6203 7505**
Fax: **(02) 6203 7519**
Email: **webmaster@anao.gov.au**

ANAO audit reports and information about the ANAO are available at our internet address:

http://www.anao.gov.au

Audit Team
David Rowlands
Greg Mazzone
Joe Keshina
Nathan Williamson

Contents

Tables

Figures

Abbreviations

ACPA	Australian Community Pharmacy Authority
APS	Administrative Position Statement
BPA	Business Practice Agreement
CEO	Chief Executive Officer
CEV	Concessional Entitlement Validation
CMC	Corporate Management Committee
CTS	Claims Transmission System
DHS	Department of Human Services
DoHA	Department of Health and Ageing
DVA	Department of Veterans' Affairs
FMA Act	*Financial Management and Accountability Act 1997*
HIC	Health Insurance Commission (now Medicare Australia)
MoU	Memorandum of Understanding
PBB	Pharmaceutical Benefits Branch (within Medicare Australia)
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
QAI	Quality Assurance Intervention process
QCI	Quality Control Intervention process

Glossary

Approved prescriber	Persons who can prescribe PBS medicines. This includes medical practitioners, as well as those dental practitioners and optometrists who have been approved by the Secretary of the Department of Health and Ageing for this purpose.
Approved supplier	A pharmacist, medical practitioner or hospital authority who has been approved by the Secretary of the Department of Health and Ageing to supply PBS medicines.
Authority prescriptions	Restrictions apply to the prescribing of certain medicines under the PBS. These limitations may relate to the use of these medicines to treat predefined medical conditions. The prescribing of these medicines is subject to specific criteria and, in some cases, pre-approval.
Co-payment	The amount that patients generally must pay when obtaining PBS medicines. As at 1 February 2010, the co-payment is $33.30 per medicine for the general public and $5.40 for holders of concession cards issued under the *Social Security Act 1991*.
PBS Safety Net	The PBS Safety Net provides a reduced co-payment for individuals or families who spend a threshold amount on PBS medicines. Patients must register for the program once the threshold is reached, and can then access the reduced co-payment for the remainder of that calendar year.
Online Claiming for PBS	The Internet-accessible system through which Approved Suppliers can validate patient concessional status and claim payments for PBS pharmaceuticals they supply (originally referred to as 'PBS Online').

Summary and Recommendations

Summary

Background

1. Established in 1948, the Pharmaceutical Benefits Scheme (PBS) is an Australian Government funded and administered program designed to give all Australian residents and eligible overseas visitors access to prescription medicines in an affordable, reliable and timely way.[1] This is achieved through the Government subsidising the cost of prescription medicines that have been listed on the PBS Schedule.

2. The Minister for Health and Ageing is responsible for determining which medicines are listed on the PBS Schedule. Before a medicine can be listed there must be an assessment by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body.[2] When recommending to the Minister that a medicine be listed on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.[3]

3. Once a medicine has been listed on the PBS Schedule, an eligible patient who has presented a proper prescription to a pharmacist is entitled to receive a benefit. Generally, the patient will make a limited payment to the pharmacist known as a 'co-payment'. From 1 January 2010, the general rate co-payment was $33.30 or $5.40 for those eligible at the concession rate.[4]

4. In order to make these medicines more affordable, the Government will then pay the pharmacist the balance of the cost of the medicine as listed on the PBS Schedule. Medicines listed on the PBS can cost hundreds or thousands of dollars. It is through effectively capping the cost to the patient at the co-payment level that the supply of medicines by the pharmacist is made more affordable for the patient.

---

1 Medicare Australia, *Annual Report 2008–09*, p. 40.

2 PBAC's membership includes doctors, other health professionals and a consumer representative.

3 <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-pbs-whopays.htm> [accessed 14 December 2009].

4 These rates are adjusted annually according to movements in the Consumer Price Index.

5. In 2008–09, some 182 million services were processed under the PBS, with $7.2 billion in benefits paid. During this period, the PBS Schedule provided patients with access to more than 700 medicines,[5] with approximately 80 per cent of prescriptions dispensed in Australia attracting a PBS payment.[6]

Growth in cost and volume of the PBS

6. In recent years the cost of the PBS and the number of services provided have grown considerably, increasing the demands on Medicare Australia in administering the Scheme. Table S 1 shows that in the 10 year period between 1998–99 and 2008–09, the cost of the PBS grew by 157 per cent, with services growing by 42 per cent.

Table S 1

Pharmaceutical Benefits Scheme: total benefits paid and total number of services provided from 1998–99 to 2008–09

Year	1998–99	2003–04	2008–09
Total benefits paid	$2.8 billion	$5.1 billion	$7.2 billion
Total number of services provided	128 million	165 million	182 million

Source: Health Insurance Commission (HIC), 1998–99 HIC Annual Report; 2003–04 HIC Annual Report; Medicare Australia, 2008–09 Annual Report.

7. The cost of the PBS is a significant component of the Australian Government's health-related budget outlays, comprising approximately 18 per cent of total health costs. While, in the short term, PBS spending is not forecast to grow at the rates of recent years, it is estimated to maintain its relative contribution to total health spending. In that respect, the 2010 Intergenerational Report estimated that total spending on health is expected to remain relatively steady in the medium term[7] but grow from 4 per cent of GDP in 2009–10 to 7.1 per cent of GDP by 2049–50.[8]

---

5 Medicare Australia, *Annual Report 2008–09*, p. 64.

6 <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-aboutus.htm-copy2> [accessed 15 December 2009].

7 4.1 per cent of GDP in 2019-20.

8 *Intergenerational Report 2010*, Appendix A, Table A.3, p. 118.

Legislative framework and governance arrangements

8. The PBS is established by the *National Health Act 1953* with consequential administrative arrangements set out in a range of subsidiary instruments including the *National Health (Pharmaceutical Benefits) Regulations 1960*, ministerial rules and determinations.

9. The Department of Health and Ageing (DoHA) is responsible for PBS program policy development and is accountable for the overall management of the Scheme including the PBS Schedule. Medicare Australia is responsible for the day-to-day delivery of the PBS on behalf of DoHA.

10. Medicare Australia is a prescribed agency under the *Financial Management and Accountability Act 1997;* a statutory agency under the *Public Service Act 1999*, and is part of the Human Services portfolio. Medicare Australia has existed since 2005, after it evolved from the former Health Insurance Commission (HIC), a statutory authority under the *Commonwealth Authorities and Companies Act 1997* that was within the Health and Ageing portfolio.

11. In practice, Medicare Australia is accountable to the Minister for Health and Ageing and the Secretary of DoHA for delivering the PBS, but is also accountable for the service delivery aspect of its operations to its portfolio minister, the Minister for Human Services.

12. In addition to administering the PBS, Medicare Australia delivers a broad range of payments and information in respect of health-related (such as the Medicare program) and other programs (such as the LPG Vehicle Scheme) on behalf of the Australian Government.

Delivery of the PBS

13. In administering the PBS, Medicare Australia's stated objective is 'to deliver a nationally consistent service with convenient access and timely and accurate payments through efficient service channels, particularly electronic'.[9] Apart from processing and paying pharmacists' PBS claims, delivering the PBS requires Medicare Australia to undertake other activities such as approving

[9] Medicare Australia Portfolio Budget Statements 2009–10, p. 95.

pharmacists to supply PBS medicines and approving certain special prescriptions.[10]

14. The PBS has seen a number of challenges and changes in recent years, which have affected both how the Scheme is delivered and its composition. In addition to the challenges presented by the growth of the Scheme in recent years, the introduction of the Online Claiming for PBS system in 2005 was a major change in how Medicare Australia interacted with pharmacists, moving from a manual to a real time web-based process for the initial part of the claiming process. A suite of PBS reforms were also introduced between 2006 and 2008, which were designed to 'give Australians continued access to new and expensive medicines while ensuring the PBS remains affordable into the future'.[11]

Audit objective and scope

15. The objective of this audit was to examine the effectiveness of Medicare Australia's administration of the PBS. In assessing the objective, the audit considered three key areas:

- Medicare Australia's relationship with the PBS policy agency (DoHA) and service delivery policy agency (Department of Human Services (DHS));
- the management arrangements and processes underpinning Medicare Australia's delivery of the PBS (including the means by which Medicare Australia gains assurance over the integrity of the PBS); and
- how Medicare Australia undertakes its three main responsibilities relating to the delivery of the PBS, namely: approving pharmacies; approving authority prescriptions; and processing PBS claims.

16. The Repatriation PBS and the processes supporting the formulation of the PBS Schedule did not form part of the audit scope. Further, the integrity of individual payment transactions between Medicare Australia and pharmacists was not tested as part of this audit.

---

[10] Referred to as 'Authority' prescriptions.

[11] <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs_reform_02feb07.htm> [accessed 14 December 2009]

Overall conclusion

17. The PBS has been in place for over 60 years and is a fundamental part of the Australian health system which facilitates the provision of pharmaceuticals to all Australian residents and eligible overseas visitors in an affordable, timely and reliable way. Having grown rapidly in recent years, in 2009–10, the PBS is expected to cost approximately $8.2 billion, with Medicare Australia processing some 191 million services under the Scheme.

18. Given the size and forecast future growth of the PBS, it is important that Medicare Australia, as the agency responsible for the day-to-day administration of Scheme, implements effective and efficient delivery arrangements to respond to the increasing demand while maintaining the integrity of the claims processing arrangements.

19. Overall, the PBS program operates in an effective and efficient manner for patients and pharmacists, in that patients have affordable and timely access to drugs listed on the PBS Schedule and pharmacists' claims are processed in a timely manner. There remain, however, in relation to Medicare Australia's administration of the Scheme, areas of risk and opportunities for improvement. These include the governance arrangements among agencies involved in the PBS, the operational arrangements and processes supporting Medicare Australia's delivery of the Scheme, and the monitoring and reporting of delivery performance.

Governance arrangements

20. The introduction of Medicare Australia in 2005 and subsequent move to the Human Services portfolio from the Health and Ageing portfolio introduced some complexities in the relationships among the agencies. It was not, however, until after several years of consultations, that a Business Practice Agreement for the PBS between Medicare Australia and DoHA was formally put in place, in May 2009.

21. If implemented effectively and updated as required, this agreement presents an opportunity for the parties to build on the existing relationship that underpins the administration of the PBS and to ensure the respective roles and responsibilities are clarified to meet future demands.

Management and operational arrangements supporting Medicare Australia's delivery of the PBS

22. As with many of its program delivery responsibilities, Medicare Australia relies on a geographically dispersed network of state offices and supporting business functions (such as information technology) to deliver the PBS. Such a system presents challenges to the ability of an organisation to have sufficient oversight of the end-to-end management of a program and increases the risk of gaps or inconsistencies in processes and outcomes.

23. In July 2009, Medicare Australia announced a major operational change with the introduction of a new national program delivery model. This change is intended to provide a greater national focus and better assurance of consistency in the delivery of the PBS. If implemented successfully, the new model should help address identified issues, such as the lack of an accountability point for end-to-end program oversight, and provide improved management arrangements to support Medicare Australia's ongoing administration of the PBS.

24. The changes to the operational management arrangements that Medicare Australia has adopted to deliver the PBS on a day-to-day basis means that attention is also needed in improving guidance to staff and ensuring consistent procedures are used across states. To address inconsistencies both in processes and the understanding of officials about the nature of their role as decision-makers, Medicare Australia should consider including, as part of the current process to update procedural guidance, information clarifying the changed legal arrangements under which decisions are made and the subsequent implications for decision makers in performing their role.

25. Medicare Australia has an organisational risk management policy in place, though this has not been adhered to consistently in producing timely risk management plans for organisational units or projects relating to the PBS. One important risk to the PBS program is the integrity of claim payments. Medicare Australia's routine monitoring of claims processing involves its well-established Quality Assurance Intervention (QAI) and Quality Control Intervention (QCI) processes. Each of these is a management tool that can be used to locate, correct and control errors; however, neither QAI nor QCI—which monitors QAI checking—provides a robust basis for assessing and reporting the accuracy of PBS claims processing. Medicare Australia has introduced a new Payment Accuracy Review process that examines the PBS

process from end-to-end, involving prescribers, pharmacists and patients, and which is designed to help better assess the overall accuracy of payments.

26. To address the identified risk management and quality assurance issues, Medicare Australia has advised that it is updating its 2008 PBS Program Integrity Assurance report to better identify and manage PBS risks, end-to-end.

27. In recent times, Medicare Australia has also made a number of changes to improve the processes and infrastructure supporting the delivery of the PBS, particularly through new technology. For instance, the Online Claiming for PBS system, which was introduced in 2005 and replaced the previous manual system, is now used by approximately 97 per cent of pharmacists, making the payment system more efficient and prompt.

28. While the Online Claiming for PBS system has been successfully implemented, there remain risks, such as the capacity of pharmacists to override process warnings, which require attention and are currently under review by both Medicare Australia and DoHA. The Online Claiming for PBS system also presents opportunities to further improve service delivery such as providing advice to patients regarding qualification for the PBS Safety Net, rather than relying on existing processes, where the patient is responsible for keeping a record of their expenditure and applying for the Safety Net.

Performance monitoring and reporting

29. In administering the PBS, Medicare Australia's existing key performance indicators do not provide adequate assurance of the achievement of its stated objective. This results in stakeholders being unable to ascertain performance in areas such as consistency of service, convenience of access and timeliness and accuracy of payments.

Future delivery of the PBS

30. Notwithstanding the changes that have been made in recent times, there remain areas for improvement. The ANAO has made five recommendations aimed at improving Medicare Australia's existing business practices and its future administration of the PBS. These recommendations focus on guidance to its staff, procedural consistency and assurance, enhanced customer service and improved assessment and reporting of performance.

Key findings by chapter

Arrangements for PBS delivery (Chapter 2)

31. With the successful delivery of the PBS relying on the cooperation and communication of three agencies; Medicare Australia, DoHA, and DHS, a clear and common understanding of the respective roles and responsibilities of each agency is important. After several years of consultations, a Business Practice Agreement between DoHA and Medicare Australia for the delivery of the PBS was signed in May 2009. The Agreement largely contains the elements identified by the ANAO as desirable for such agreements, with the exception of an explicit obligation on Medicare Australia to report its delivery performance to DoHA. Sensitivities about the boundaries between policy and service delivery responsibilities of the agencies contributed to the delay. These sensitivities remain, as exemplified by DHS's continuing desire to be consulted earlier on health policy proposals to bring to bear its service delivery policy perspective.

32. The authority to administer the PBS is now conferred on Medicare Australia staff by (i) a ministerial direction from the Minister for Human Services to the Medicare Australia CEO to perform the function of exercising powers on behalf of the DoHA Secretary and the Minister for Health and Ageing; and (ii) the Medicare Australia CEO then delegating those powers to her staff. This is a different mechanism from that in place when the HIC administered the PBS in the Health and Ageing portfolio in that DHS has provided advice that shows that staff now act, in effect, as agents rather than delegates of the Minister and/or Secretary for Health and Ageing.

33. During audit fieldwork the ANAO observed inconsistencies in Medicare Australia officials' understanding of how the new arrangements affect their role as decision-makers. Given the importance of decisions made by Medicare Australia staff, such as applications from pharmacists to become approved suppliers, PBS administration would benefit from Medicare Australia staff having a clearer understanding of the new arrangements. This could be achieved through the current process of updating procedural guidance to include information on the authority to administer the PBS and how that affects decision making.

Managing PBS delivery (Chapter 3)

34. Since the commencement of the audit, Medicare Australia has introduced a new national program delivery model for managing delivery of the PBS. If successfully implemented, this should provide a better focus on

management of the program as a whole and provide better co-ordination and consistency across the functional and geographic units involved in its delivery.

35. Along with this management change, Medicare Australia has also substantially upgraded its procedural guidance. This should help to address the previous lack of national documentation and dependence on locally-produced (and hence, potentially diverse) guidance observed during the audit. To complement this, Medicare Australia has also taken steps to begin addressing the need for nationally consistent training for PBS processing staff.

36. Medicare Australia has an organisational risk management policy in place, though this has not been adhered to consistently in producing timely risk management plans for organisational units or projects relating to the PBS. Nevertheless, the 2008 PBS Program Integrity Assurance report was a positive step towards identifying and managing PBS risks, end-to-end. Medicare Australia's current plan to update this report and ensure that it provides adequate coverage of the program should assist in identifying any gaps and help provide greater assurance over PBS program integrity.

37. One important risk to the PBS program is the integrity of claim payments. Medicare Australia's routine monitoring of claims processing involves its well-established Quality Assurance Intervention (QAI) and Quality Control Intervention (QCI) processes. Each of these is a management tool that is used to locate, correct and control errors; however, they do not provide a basis for reporting the overall accuracy of PBS claims processing and payments. Medicare Australia has advised that it will review the PBS key performance indicator measures to ensure consistency and appropriateness. In that respect, Medicare Australia's new Payment Accuracy Review process, which examines the PBS process from end-to-end, involving prescribers, pharmacists and patients, is an example of a positive approach to helping gauge the overall accuracy of payments.

38. Medicare Australia's stated objective in delivering the PBS is 'to deliver a nationally consistent service with convenient access and timely and accurate payments through efficient service channels, particularly electronic'.[12] In delivering the PBS, Medicare Australia has three distinct operational responsibilities: approving suppliers of medicines; approving authority prescriptions and processing pharmacists' claims for payment.

[12] Medicare Australia, *Portfolio Budget Statements 2009–10*, p. 95.

39. The key performance indicators identified by Medicare Australia in its Portfolio Budget Statement and reported in its annual report do not provide sufficient information with which to assess performance against the program objective nor do the indicators encompass the organisation's three major operational responsibilities in delivering the PBS.[13] This means stakeholders are not able to ascertain performance in areas such as timeliness and accuracy of payments, consistency of service, and convenience of access. Accordingly, there are opportunities for Medicare Australia to improve its performance information and performance reporting on its delivery of the PBS both at the program and operational levels.

40. At the program level, performance reporting would be more effective if it provided information, to the Parliament and the public, which allowed them to understand how well Medicare Australia is meeting its objective. This involves setting out a small number of indicators, with targets that relate clearly to those objectives, and including all the three operational aspects of Medicare Australia's delivery of the PBS. In this respect, Medicare Australia does have some of these in place for PBS claims processing but they are limited in their effectiveness by the reliance on the QAI and QCI processes.

41. Transparency in performance reporting could also be improved if Medicare Australia were to report consistently in its annual reports against the measures set out in its budget statements and, when it changes a measure, explains what it has done and why. The reader would also benefit from the reporting of any significant assumptions that have been made in calculating the performance indicators.

PBS delivery operations (Chapter 4)

42. The process of approving pharmacies to supply medicines is governed by legislative criteria. However, only limited operational guidance exists to support Medicare Australia staff in their decision making role, which increases the risk of inconsistent processes and decisions. The process of approving and monitoring the ongoing compliance of suppliers of PBS medicines could be improved through enhancing the guidance material for decision-makers. In

[13] The three key performance indicators outlined in the Portfolio Budget Statement are:
- percentage online prescription processing (≥ 98 per cent);
- average revenue per PBS service ($0.72); and
- pharmacist satisfaction (≥ 90 per cent).

that respect, the process should benefit from Medicare Australia's recent adoption of a national program delivery model and the consideration it is giving to nationalising this particular function.

43. In observing Medicare Australia quality assuring dispensed authority prescriptions, the ANAO noted a practice of adjusting Medicare Australia's authority approval records to accord with the medicines actually dispensed in cases where there was a mismatch. This has the risks of failing to react to, or manage, evidence of incorrect dispensing of medicines. Medicare Australia advised that it intends to address this issue through its nationally consistent quality control action plan, which it has recently endorsed.

44. The method for processing claims has changed in recent years with the introduction of the Online Claiming for PBS system. The very high take-up of the system (approximately 97 per cent of pharmacists are using the system) has allowed Medicare Australia to streamline its capture of claims data. This improves efficiency through, for example, providing a facility to verify patient entitlement to claim a concession.

45. In examining the processing that supports the Online Claiming for PBS system, the ANAO also identified risks associated with pharmacists' capacity to override a range of prescription processing warnings. Medicare Australia advised that, jointly with DoHA, it has recently completed a review and implemented changes.

46. There is a widely-established practice among dispensing pharmacists of storing patient data on their pharmacy computer system. The use of these systems is also a necessary practice in accessing the Online Claiming for PBS system.[14] IT security, in general, continues to be an area of growing threats. The recording and retention of patient data on pharmacists' systems is a pharmacist's responsibility, however, if the data were to be compromised this could present a reputation risk to the Commonwealth. In this respect, Medicare Australia advised that its responsibilities extend only to the security of transmission of data from the pharmacy to its own system (transmissions

[14] In relation to Online Claiming for PBS, the Commonwealth has provided both software vendors and pharmacists with various incentives to: amend software packages (Software Vendor Assistance Payments—up to $2000 lump sum payment for software installation at each pharmacy and up to $200 per month for 24 months to provide maintenance support); adopt PBS Online (Online Claiming Incentive—40 cents per script processed by a pharmacist) and maintain business grade broadband Internet connections (Pharmacy Connectivity Incentive).

are encrypted). DoHA advised that it is satisfied that security at the pharmacy is maintained by professional pharmacy practice management and the requirements of privacy legislation. Nonetheless, taking account of the risks to reputation and public confidence in key processes, it would be prudent for the agencies to explicitly address this issue, for example, through clarifying the arrangements and respective responsibilities during pharmacy approval processes.

47. The PBS Safety Net helps patients who require a large number of medicines by reducing the co-payment after they reach a threshold of personal (or family) expenditure on PBS medicines in a calendar year. Medicare Australia has the capacity to identify patients who have become eligible for the Safety Net but who have not sought to register, potentially through a lack of information. In the 2007 calendar year, these patients paid between $6.1 million and $10.8 million more than they would have, if they had been registered for the Safety Net. It would improve customer service and help achieve the outcomes of the program if Medicare Australia were to advise patients in these circumstances, even if, for practical reasons, this advice can only be given later than might ideally be desired due to some expenditure being on medicines that do not attract a PBS subsidy. Recognising that to implement such a change would require policy consideration and involve some cost, Medicare Australia and DoHA would first need to examine options and provide advice to government.

Summary of agency responses

Medicare Australia

Medicare Australia welcomes the assurance provided by the ANAO's report that overall, the PBS program operates in an effective and efficient manner for patients and pharmacists, in that patients have affordable and timely access to drugs listed on the PBS Schedule and pharmacists' claims are processed in a timely manner.

Medicare Australia agrees with Recommendations one through four. Regarding Recommendation 5, Medicare Australia has previously advised the ANAO that changes to the administration of the PBS Safety Net would be a policy matter for the Department of Health and Ageing to consider. Medicare Australia is in a position to provide advice to the Department of Health and Ageing should it be called upon to do so.

Medicare Australia has used the audit process to pursue opportunities for improvement and has already implemented Recommendation one. We are

actively taking steps to implement Recommendations two through four. Medicare Australia is committed to continually seeking to improve our business processes, including the operational arrangements and processes supporting Medicare Australia's delivery of the PBS, and the monitoring and reporting of our performance.

Department of Health and Ageing

The Department notes the audit report's findings and the extensive consultations that have occurred between the Department and the ANAO since 2008 in relation to this audit.

The Department does not agree with Recommendation 5. As previously advised in Departmental responses to the ANAO dated 22 September 2009 and 15 January 2010, the matter of an automated safety net is a policy issue with significant program design and cost implications and is a matter for Government to consider. Medicare Australia is not required to collect the data necessary to enable automated safety net calculations and consequently it is not currently relevant to Medicare Australia's administration of the PBS.[15]

[15] ANAO comment on Recommendation No.5 is provided at paragraphs 4.73 – 4.74.

Recommendations

Recommendation 1
Para. 2.68

Given the change in authority arrangements underpinning the delivery of the Pharmaceutical Benefits Scheme, the ANAO recommends that Medicare Australia provide guidance to its decision-makers that explains the legal and operational business arrangements supporting its delivery.

Medicare Australia response: *Agree*

Recommendation 2
Para. 3.50

Given the previous limited national procedural guidance available to staff, the ANAO recommends that Medicare Australia maintain its current focus under its new national program model to standardise PBS procedural guidance and training materials for operational staff, including appropriate support in the delivery of PBS training.

Medicare Australia response: *Agree*

Recommendation 3
Para. 3.95

The ANAO recommends that Medicare Australia, when it has completed its review of its key program performance indicators, reports its performance in its annual report for all three of its major responsibilities in delivering the PBS.

Medicare Australia response: *Agree*

Recommendation 4
Para. 3.97

As part of its compliance and integrity framework, the ANAO recommends that Medicare Australia review its Quality Assurance Intervention and Quality Control Intervention methodology to clarify the objectives of these processes and ensure that:

- it is obtaining adequate assurance about the accuracy of its claims processing performance; and
- the processes provide sufficient information to form a view as to the soundness of claims for payment.

Medicare Australia response: *Agree*

Recommendation 5
Para. 4.70

The ANAO recommends that Medicare Australia and DoHA examine how the PBS system and data capture arrangements could be enhanced to enable patients to be advised when have reached the PBS Safety Net Threshold, and advise government on options.

DoHA response: *Disagree*

Note:

(1) Medicare Australia has provided a comment on this recommendation, which is set out at paragraph 4.72.

(2) The ANAO has provided a comment at paragraphs 4.73 – 4.74.

Audit Findings and Conclusions

1. Introduction

This chapter explains the purpose of the Pharmaceutical Benefits Scheme and how it is delivered. It also sets out the objective of the audit and how it was undertaken.

The Pharmaceutical Benefits Scheme seeks to make medicines affordable

1.1 The Pharmaceutical Benefits Scheme (PBS) is an important component of Australia's health system and is designed to give all Australian residents and eligible overseas visitors access to prescription medicines in an affordable, reliable and timely way.[16]

1.2 Essentially, the PBS works in two stages:

- first, medicines that are assessed as necessary and cost-effective are listed on the PBS Schedule.[17] The Minister for Health and Ageing is responsible for determining which medicines are listed on the PBS Schedule. Before a medicine can be listed there must be an assessment by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body.[18] When recommending to the Minister that a medicine be listed on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.[19] The process of listing a medicine on the Schedule includes setting a Schedule price to be paid to an approved supplier of medicines (generally, a pharmacist) upon dispensing a Schedule-listed medicine on prescription to eligible patients; and
- second, after a pharmacist dispenses a medicine listed on the PBS Schedule to an eligible patient who has presented a proper prescription for that medicine, Medicare Australia pays the pharmacist in respect of

[16] Medicare Australia, *Annual Report 2007–08*, p. 42.

[17] The PBS Schedule is available online at: <http://www.pbs.gov.au/html/home>, a website maintained by DoHA (accessed 11 June 2009).

[18] PBAC's membership includes doctors, other health professionals and a consumer representative.

[19] <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-list_on_pbac.htm> [accessed 14 December 2009].

that transaction. Medicare Australia expects pharmacists to claim benefits for some 191 million PBS prescriptions in 2009–10 at an expected cost of $8.2 billion in that financial year.[20]

1.3 Generally, the patient also makes a limited payment to the pharmacist at the time the medicine is dispensed. This is called a 'co-payment'.

1.4 In addition to payments to pharmacists for dispensing PBS Schedule-listed medicines, Medicare Australia also provides other payments, such as incentive payments, to use its Online Claiming for PBS system to enter prescription data and, where there are multiple substitutable versions of an item on the PBS, for dispensing premium-free PBS listed products. Medicare Australia also carries out certain other tasks related to the administration of the PBS. The payment process and these other administrative tasks are the subject of this audit.

1.5 The PBS is one of several programs delivered by Medicare Australia on behalf of the Minister for Health and Ageing and the Secretary of the Department of Health and Ageing (DoHA).[21] It also delivers the related Repatriation Pharmaceutical Benefits Scheme (not examined as part of this audit), which supports eligible veterans' and war widows' access to medicines. The two schemes form Medicare Australia's Program 1.2, *Delivery of Pharmaceutical Benefits and Services*.[22]

How individuals benefit from the PBS

1.6 Medicines listed on the PBS can cost hundreds or thousands of dollars. Individual patients benefit from the PBS by paying no more than a certain price—the co-payment—for prescription medicines listed on the PBS Schedule, of which there are some 2500. However, to do this they must first obtain a proper prescription from an approved PBS prescriber.

---

[20] Around 80 per cent of prescriptions dispensed in Australia attract a PBS payment (Medicare Australia, *PBS Program Integrity Assurance*, version 2.0, 22 January 2008, p. 11). The estimated cost of payments under the PBS is set out in the Department of Health and Ageing Portfolio Budget Statement, 2009–10, p. 22:<http://www.health.gov.au/internet/budget/publishing.nsf/Content/2009-2010_Health_PBS> [accessed 11 May 2010].

[21] Medicare Australia is established under the *Medicare Australia Act 1973* to deliver a range of health-related and other programs on behalf of the Australian Government. These include: Australia's universal health insurance program, Medicare; the PBS; the Repatriation Pharmaceutical Benefits Scheme (RPBS); residential aged care subsidies; and a range of other payments and services.

[22] Medicare Australia, *Budget Statement 2009–10*, p. 95.

1.7 Approved PBS prescribers mostly comprise private medical practitioners (GPs and specialists). They also include optometrists,[23] dentists and doctors in state government public hospitals[24] that have been approved by Medicare Australia and issued a prescriber number. Only a prescription made by an approved prescriber for a PBS medicine can attract PBS benefits.

1.8 A patient entering a pharmacy with a prescription can be eligible for PBS benefits at one of two payment levels: a general rate or a concessional rate. Those eligible at the general rate pay the dispensing pharmacist the full price of any medicine up to a maximum of $33.30. Where the cost of the medicine is more than $33.30, the patient pays a co-payment of $33.30. For those eligible at the concessional rate the co-payment is $5.40.[25] To receive prescriptions at the concessional rate the patient must also show the pharmacist a concession card provided by Centrelink or the Department of Veterans' Affairs.

1.9 Therefore, when a patient presents a PBS prescription, before dispensing the medicine, the pharmacist needs to determine whether the patient holds a valid Medicare card[26] and check if they also hold a current concession card. The pharmacist must record the transaction and advise Medicare Australia, usually online. The patient pays any required co-payment and the pharmacist can then provide the prescribed medicine to them.

1.10 If the price of the medicine is less than the relevant rate of co-payment then the patient must pay the pharmacist the full price and the PBS provides no benefit for that transaction. In such a case, Medicare Australia receives no information about the transaction.

1.11 In addition, a PBS Safety Net exists to help those individuals and families who spend substantial amounts of money on prescriptions in a calendar year. Each year, the Commonwealth sets a Safety Net Threshold for

---

[23] Optometrists have been able to issue PBS prescriptions since January 2008. They can only prescribe medicines from separate Optometrical Schedules but not general PBS items.

[24] Doctors in public hospitals can only issue prescriptions for out-patients. This is subject to specific agreements with each hospital, state or territory government, and the Commonwealth government.

[25] See: <http://www.pbs.gov.au/html/home> [accessed 19 January 2010]. These rates are as of 1 February 2010. Rates are adjusted annually according to movements in the consumer price index.

[26] The PBS is available to all Australian residents who hold a current Medicare card. Overseas visitors from countries with which Australia has a Reciprocal Health Care Agreement (RHCA) are also eligible to access the Scheme. Australia currently has RHCAs with: Italy, New Zealand, the Republic of Ireland, Finland, Malta, the Netherlands, Sweden, Norway, the United Kingdom and Belgium.

general and concessional patients.[27] Once individuals' or families' expenditure reaches the threshold amount and they apply for the PBS Safety Net, they are eligible for a reduced co-payment, or free medicines, for the remainder of that calendar year.[28] There were over one million PBS safety net cards issued in each of the calendar years 2004 to 2008.[29]

1.12 Pharmacists record each transaction on their own pharmacy computer systems (using their dispensing software) and, in the great majority of cases, also electronically submit the information into Medicare Australia's Online Claiming for PBS payment system. This allows Medicare Australia to test the details and advise the pharmacist of any errors it detects, for correction. Medicare Australia makes weekly payments to pharmacists for most PBS Schedule items dispensed.[30] These are considered early payments as, after the end of the month or fortnight, pharmacists submit a formal claim with the paper prescriptions against which Medicare Australia can verify the early payment it has already made.

Medicare Australia has three principal responsibilities in delivering the PBS

1.13 Medicare Australia's stated objective for the PBS is 'to deliver a nationally consistent service with convenient access and timely and accurate payments through efficient service channels, particularly electronic.'[31] In delivering the PBS, it undertakes three primary, distinct but related functions:

(1) approving pharmacists (and some others) to supply PBS medicines from particular premises;[32]

---

27 From 1 January 2010, the thresholds were $1281.30 for general patients and $324.00 for concessional payments. Once they reach the threshold, general patients pay $5.40 for each prescription and concessional payments are not charged for their prescriptions.

28 Upon approval for PBS Safety Net, patients with a valid concession card are eligible to receive PBS medicines at no cost while a non-concession card holder can obtain them at the concession rate ($5.40).

29 DoHA, *Expenditure and prescriptions twelve months to 30 June 2009*. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-stats-pbexp-jun09> [accessed May 2010].

30 Medicare Australia advises that it does not make payments for high-cost or high-risk items until after it has received the paper prescriptions.

31 Medicare Australia, *Budget Statement 2009–10*, p. 95.

32 This includes approving certain doctors to supply PBS medicines and approving hospitals to supply PBS medicines to eligible patients.

(2) approving certain special prescriptions called 'authority prescriptions'; and

(3) processing pharmacists' claims and making payments to pharmacists.

1.14 Each of these three functions is summarised below.

(1) Medicare Australia approves pharmacies to supply PBS medicines

1.15 Approved suppliers—mostly pharmacists—perform a central role in the delivery of the PBS. In addition to dispensing PBS prescription medicines and thereby attracting the relevant Schedule payment, they receive a fee for this work plus payments for:

- using Medicare Australia's Online Claiming for PBS payment system;
- maintaining PBS Safety Net records and approving and managing registrations; and
- providing government PBS support information to patients.

1.16 PBS medicines can only be dispensed by approved suppliers, mostly pharmacists.[33] To become an approved supplier from particular premises a pharmacist must make an application on a prescribed form to Medicare Australia for approval.[34] Medicare Australia must then refer the application to the Australian Community Pharmacy Authority (ACPA) for a recommendation. The ACPA assesses new pharmacy proposals (and relocations) using location rules intended to support an effective, efficient and well-distributed pharmacy network in Australia. ACPA then makes recommendations to Medicare Australia and the latter considers those recommendations for approval. Where it approves an application it then provides a letter to the approved supplier.

(2) Medicare Australia approves authority prescriptions

1.17 Certain medicines require specific approval before they can be prescribed under the PBS. Medicare Australia provides this authority to prescribing doctors, most often by telephone. Such prescriptions are called

[33] Doctors can be approved to ensure access in remote areas. Hospitals can also be approved to supply PBS medicines to eligible patients.

[34] Here, Medicare Australia is acting on behalf of the Secretary of the Department of Health and Ageing.

'authority prescriptions' and some 9.7 million are expected to be approved in 2009–10.[35]

1.18 Authority prescriptions are used for selected PBS medicines intended only for people with specific health conditions. They may also be used when the prescribing doctor decides that the patient needs more medicine than normal (an increased number of repeats or a quantity greater than the maximum listed in the Schedule).

1.19 The prescribing doctor is responsible for ensuring that the patient meets the PBS criteria as listed in the Schedule before prescribing the medicine and must endorse the prescription with the authority number. Medicare Australia may then provide specific approval for the prescription before the prescription can be completed.

1.20 After 1 July 2007, for some 200 of the authority-required PBS items—known as 'Authority required (STREAMLINED)' medicines—the prescriber has no longer needed prior approval. Instead, they must place an authority code, listed in the PBS Schedule on the prescription.[36] The purpose of this change was to reduce the administrative burden on prescribers.[37]

1.21 Once a patient has obtained an authority prescription, they can give the form to the pharmacist as they would any ordinary prescription.[38]

(3) Medicare Australia processes pharmacists' claims

1.22 Nearly all pharmacists use computer-based systems to record and process the medicines that they dispense, and to manage their stocks.[39] As a result, the manual recording of dispensing is limited. The great majority of pharmacists (just over 97 per cent) now use Medicare Australia's Online Claiming for PBS payment system to submit prescription details during dispensing.[40] This is carried out over Medicare Australia's 'Business-to-

[35] Medicare Australia, *Budget Statements 2009–10*, p. 96.

[36] This is one of a range of PBS reforms implemented by Medicare Australia from 1 July 2007.

[37] Department of Health and Ageing, *Annual Report 2007–08*, p. 5.

[38] If the patient does not satisfy the authority prescription criteria for a medicine, the prescribing doctor can only prescribe the medicine on a private prescription. In these circumstances the patient must pay the full price charged by the dispensing pharmacist for the medicine.

[39] Pharmacists also use these pharmacy computer systems to monitor patient adherence to their medication regimen as well as identifying potential dose errors/interactions and other related purposes.

[40] Medicare Australia, *Annual Report 2008–09*, p. 87.

Government' Internet-based communications channel and provides for the validation of the data and the lodgement of a request for early payment from Medicare Australia.

1.23 Medicare Australia pays pharmacists the difference between the amount paid by patients (the co-payment) and the PBS Schedule price of the medicines they dispense. It also pays Pharmacists a fee for processing PBS prescriptions, payments for using Online Claiming for PBS, and other payments for providing PBS-related services, such as issuing PBS Safety Net concession cards.

1.24 The Pharmaceutical Benefits Remuneration Tribunal (PBRT), an independent statutory body, determines the amount of remuneration pharmacists receive for their services.[41] The PBRT, however, must give effect to the terms of any agreements between the Minister for Health and Ageing and the Pharmacy Guild of Australia on remuneration.[42] There is currently such an agreement, called the 'Fourth Community Pharmacy Agreement' ('4CPA').[43]

1.25 The Medicare Australia publication *Explanation of PBS Pricing* (February 2009, p. 1) explains that:

> When a pharmacist supplies a medicine that attracts an Australian Government benefit, the pharmacist is entitled to be paid the Australian Government or PBS dispensed price of the medicine, less any patient contribution, if any.
>
> The PBS dispensed price consists of:
>
> - the cost to pharmacists;
> [cost to pharmacists = the manufacturer's price + a margin of seven per cent for the wholesaler]
> - a mark-up by the pharmacist; and
> - dispensing fees and any other fees the pharmacist is entitled to.

[41] The PBRT was established under section 98A of the *National Health Act 1953*.

[42] Section 98BAA of the National Health Act.

[43] The fourth agreement commenced on 1 December 2005 and will lapse on 30 June 2010. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-4cpafact2> [accessed 11 May 2010].

The publication goes on to explain the components of pricing (such as how the amount of pharmacist mark-up varies with the cost of the medicine) and the nature and amounts of applicable fees. However, no current publiccation sets out how much of the total annual cost of the PBS goes to each of the elements making up the PBS dispensed price, as described above. DoHA advised that the proportions of the payments are as set out in Table 1.1 below.

Table 1.1

Constituents of payments to pharmacies (by proportions)

PBS Section 85 drugs, 2008–09

Who pays for medicines		Where the money goes	
Government Benefit (PBS)	83.4%	Ex-manufacturer sales[(a)]	73.0 %
Patient contributions (co-payment)	16.6%	Dispensing fees	13.6 %
		Pharmacy markup	7.9 %
		Wholesaler margin	5.2 %
		Dangerous drug fees	0.14%
		Unallocated	0.07%
		Wastage fees	0.035%
		Container fees	0.002%
	100.0%		**100.00%**

(a) *Price to pharmacy for dispensed quantity less wholesaler margin.*

Source: Data provided by DoHA, 20 November 2009.

Developments in the management of the delivery of the PBS

1.26 Over the last several years, the following three elements have contributed to the challenges of managing the delivery of the PBS:

(1) the continued growth in the volume and cost of the Scheme;

(2) technological and other changes, such as the introduction of the Online Claiming for PBS system and a suite of PBS reforms; and

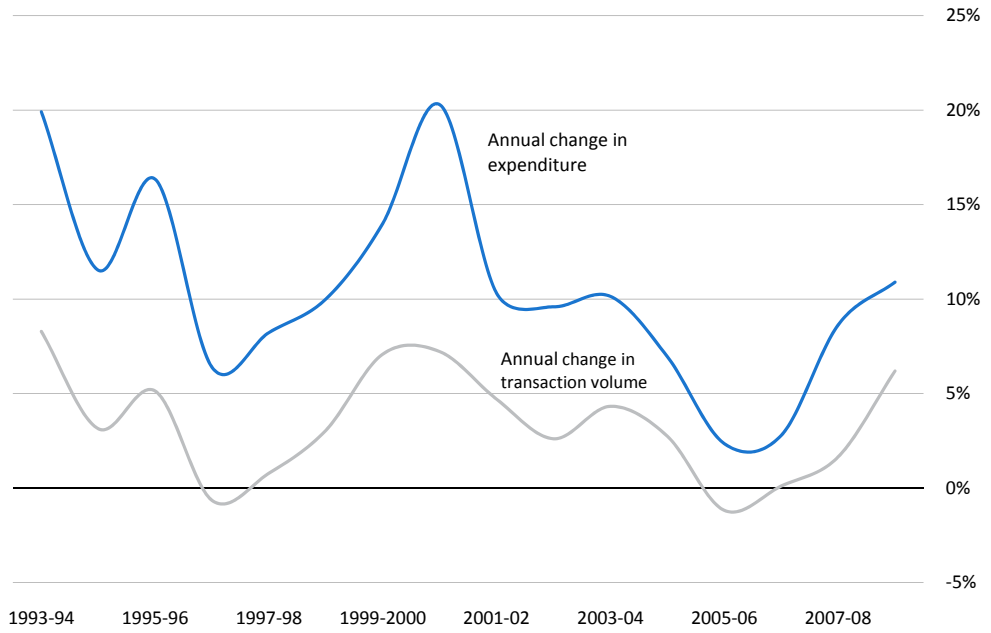
(3) changes in administrative arrangements, with the former Health Insurance Commission being replaced by Medicare Australia, an agency within the Human Services portfolio.

(1) The PBS has continued to grow

1.27 In 2008–09, Medicare Australia processed some 182 million PBS-related services from pharmacists and paid $7.2 billion to them under the Scheme, a 9 per cent rise on the previous year.[44] In general, PBS expenditure and transaction volumes (numbers of services) have grown strongly over the last 10 years as new medicines have been listed (see Figure 1.1).[45]

Figure 1.1

PBS: annual percentage change in expenditure and transaction volume[46]



Source: Chart compiled by ANAO from statistics obtained from the Medicare Australia website, <http://www.medicareaustralia.gov.au/provider/pbs/stats.shtml> [accessed 10 October 2009].

[44] Advice from Medicare Australia, 9 September 2009.

[45] The projected cost of the Scheme in the light of the PBS Reforms has been analysed recently in Victoria University 2009, *The impact of PBS reforms on PBS expenditure and savings, actual and projected from 2008–09 to 2017–18* (author: Dr. Kim Sweeny, Centre for Strategic Economic Studies), p. 21. See: <http://www.vu.edu.au/media/media-releases/pbs-reforms-provide-savings-to-government-and-affordable-access-to-medicine-vu-study> [accessed 11 May 2010].

[46] The figures reported relate to the volume of PBS services that have been processed by Medicare Australia. They refer only to paid services processed from claims presented by approved pharmacies. They do not include any adjustments made against pharmacists' claims, any manually paid claims or any benefits paid as a result of retrospective entitlement or refund of patient contributions.

The cost of delivering the service has also risen

1.28 In addition to the cost of the PBS through government benefit outlays and other payments, Medicare Australia incurs expenses in administering the Scheme. Total funding received by Medicare Australia in recent years for PBS program delivery expenses is shown in Table 1.1. In addition, its Portfolio Budget Statement shows estimated expenses of $156 million in 2009–10.[47]

Table 1.1

Funding received by Medicare Australia to administer the PBS

Year	Total PBS funding ($m)
2004–05	113.8
2005–06	116.0
2006–07	122.1
2007–08	146.5
2008–09	144.7

Source: Medicare Australia, advice of 9 September 2009.

Note: Use of this data to produce a proxy measure of delivery efficiency is discussed at para. 3.66.

(2) Major technological and other changes to PBS delivery

Medicare Australia's Online Claiming for PBS system gets payments to pharmacists earlier

1.29 Online Claiming for PBS is a system implemented by Medicare Australia to deliver payments to pharmacists more efficiently and earlier.[48] Medicare Australia now makes weekly early payments on most dispensed medicines based on the information pharmacists have submitted through the

[47] Note: Medicare Australia advised (9 September 2009) that 'PBS program expenses published in the Portfolio Budget Statements were calculated using a methodology based on a proportional allocation across funding lines to meet the requirements of the revised program structure under Operation Sunlight, which was effective from 2009–10 onwards. Medicare Australia has not been required to report in this format in prior years. For comparative purposes, the same proportions were applied to 2008–09 estimated actuals published in the [Portfolio Budget Statement]. Note that the actual funding for 2008–09 was $144.7 million and the figure in the Portfolio Budget Statements 2009–10 was overstated because the above methodology was used without excluding the effects of new measures introduced in 2009–10.'

[48] Medicare Australia, *Annual Report 2005–06*, p. 105. See: <http://www.medicareaustralia.gov.au/about/governance/reports/05-06/files/ma-0506-annual-report.pdf> [accessed 11 May 2010].

See also Health Insurance Commission, PBS Online—eClaiming, Project Management Plan, Version 0.4, 25 June 2001.

online system.[49] These early payments are subject to review when physical prescriptions are lodged with Medicare Australia after the end of the claiming period.[50]

1.30 More specifically, at the time of dispensing, pharmacists enter prescription details into their dispensing software and transmit this information via Online Claiming for PBS to Medicare Australia. Medicare Australia then applies system-based business rules to do a preliminary check of those details at the time of dispensing. This enables it to verify certain data entered in real-time, for example, patient entitlement to concessions.[51]

1.31 Medicare Australia piloted the system in 2004 and implemented it in 2006. The Australian Government also introduced financial incentive payments to pharmacists and vendors of pharmacists' dispensing software to encourage pharmacists to adopt the new system (see para. 1.33).[52]

1.32 Less than two per cent of prescription details are provided to Medicare Australia by sending disks of data to Medicare Australia using the older Claims Transmission System (CTS). Under the CTS, Medicare Australia approves PBS payments to pharmacists after receiving and processing physical prescriptions and the information from the disks. Medicare Australia does not generally receive a CTS claim for payment until at least a month[53] after the first prescription in a claim was dispensed and pharmacists using CTS claiming are therefore paid more than a month after that event. No early payments are made in these cases.

---

49 Medicare Australia advises that it makes early payments to pharmacies between nine and sixteen days from the date of receipt of the electronic prescription assessed as payable. Payments occur each week on a Friday. Payment is not made for some high value pharmaceuticals or in cases where prescriber errors are detected until pharmacies submit physical prescriptions and Medicare Australia has processed them.

50 The claiming period can be monthly or fortnightly (Medicare Australia advice, 9 September 2009).

51 Business rules in Online Claiming for PBS reject payment in limited circumstances where a critical error has been detected at the time of supply from individual prescription data electronically transmitted to the system.

52 These were introduced as part of the PBS reforms in November 2006.

53 Pharmacists are generally permitted to submit only one claim a month. Claims may relate only to benefits supplied over a period not exceeding 35 days and must be substantiated by a claim form and supporting prescriptions not more than 30 days after the last day of the claim period. Thus, within these rules, some prescriptions may not reach Medicare Australia until 65 days after dispensing.

PBS reforms have been implemented

1.33 A range of PBS reforms were announced by the Australian Government in 2006. These reforms, which have been implemented over the subsequent two years, consisted of:

- changes to the pricing of PBS-listed medicines;
- pharmacy and pharmaceutical wholesaler compensation arrangements;
- streamlined authority approvals for some medicines (discussed at para. 1.20); and
- establishment of an access-to-medicines working group.

1.34 Savings were projected at $1.7 billion over four years (starting in 2007). The government agreed to dedicate $1.1 billion of these savings to reforming the PBS, including a range of incentive payments intended to compensate pharmacies for changes to pricing of PBS medicines and to help them adjust to the new arrangements. These incentives comprised:

- a payment of $1.50 ($1.53 from 1 August 2009) to dispense a substitutable, premium-free medicine. This applies only to PBS-subsidised medicines. Medicines with a price below the co-payment amount and private scripts are not eligible for this payment;
- an incentive of 40 cents for each prescription processed using Online Claiming for PBS; and
- increases in pharmacy mark-ups and dispensing fees.[54]

1.35 It also provided for vendor assistance payments to software vendors who enable their users to use Online Claiming for the PBS.

(3) Administrative arrangements have changed

1.36 Medicare Australia was established in October 2005 as the successor to the Health Insurance Commission (HIC). HIC, formed in 1974, operated as a statutory authority, legally separate from the Commonwealth.[55] Medicare Australia was established with governance arrangements that place it within the legal identity of the Commonwealth and subject to the *Financial*

[54] Medicare Australia, advice of 9 September 2009.

[55] Subject to the *Commonwealth Authorities and Companies Act 1997*.

Management and Accountability Act 1997. The changes also involved abolishing the HIC Board of Directors and creating an executive management structure under a Chief Executive Officer (CEO).

The function has changed portfolio and has new and multiple accountabilities

1.37 Before the October 2005 changes most PBS functions and powers performed by HIC were done by its staff as delegates of the Minister for Health and Ageing and the Secretary of the Department of Health and Ageing (DoHA). In October 2004, a new Human Services portfolio was created and responsibility for HIC was transferred to the Minister for Human Services. PBS functions and powers are now performed by Medicare Australia staff as delegates of the Medicare Australia CEO on behalf of the Secretary to DoHA.

1.38 Under the revised arrangements, responsibility for health policy aspects of the PBS remain with the Health and Ageing portfolio, while service delivery policy falls within the responsibility of the Human Services portfolio. Accordingly, Medicare Australia, as a service delivery agency, is accountable to the Minister and Secretary for Health and Ageing for its delivery of the PBS, but is also accountable for the service delivery aspect of its operations to its portfolio minister, the Minister for Human Services.

The legislative framework for the PBS

1.39 The PBS is established by the *National Health Act 1953*. Consequential administrative arrangements are set out in a range of subsidiary instruments including the *National Health (Pharmaceutical Benefits) Regulations 1960*, ministerial rules and determinations.[56] For example, the *National Health (Community Pharmacy Authority Rules) Determination 2006* sets out the location rules against which the ACPA assess applications by pharmacists to become approved PBS suppliers.

1.40 Medicare Australia is established by the *Medicare Australia Act 1973*, which sets out the structure and functions of the organisation. Medicare Australia is authorised to undertake the delivery of the PBS by the Minister for Human Services by a Ministerial Direction.[57]

---

[56] A number of these rules and determinations have been created by staff of the Department of Health and Ageing as delegates of the Minister for Health and Ageing.

[57] *Medicare Australia (Functions of Chief Executive Officer) Direction 2005*, Clause 20.

Legislative instruments relevant to the PBS

- *National Health Act 1953* and *National Health (Pharmaceutical Benefits) Regulations 1960*
- *National Health (Community Pharmacy Authority Rules) Determination 2006*
- *Medicare Australia Act 1973*
- *Privacy Act 1988*
- Human Service Ministerial Direction to the Medicare Australia CEO
- Other directions given by the Human Services Minister to the Medicare Australia CEO from time-to-time under s.5(d) of Medicare Australia Act.

1.41 Section 135A of the National Health Act imposes secrecy obligations in relation to PBS data. The Privacy Commissioner has also issued Privacy Guidelines for the Medicare Benefits and PBS Programs under section 135AA of the National Health Act. In addition, the *Privacy Act 1988* applies to Medicare Australia.

1.42 Medicare Australia also has responsibilities and obligations flowing from the 4CPA, a five-year agreement between the Commonwealth (represented by the Minister for Health and Ageing) and the Pharmacy Guild of Australia. In relation to the PBS and Medicare Australia's role, the Agreement sets out:

- the amounts payable by Medicare Australia to pharmacists for dispensing PBS products, including financial incentives for using online services and dispensing generic brands;[58]
- Medicare Australia's role in the administration of financial incentives paid to pharmacists; and

[58] The pricing structure established by the 4CPA is given effect in determinations made under subsection 98BAA(1) of the *National Health Act 1953*. Payments to pharmacists cover:

- the cost of the medicine;
- the cost to have the medicine delivered to the pharmacy by a wholesaler;
- a retail mark-up, to cover pharmacists' costs for handling and storage of medicines; and
- a fee for the pharmacist's professional advice and services in dispensing the medicine to the patient.

Note: Medicare Australia, as a service delivery agency, does not determine the amount payable but makes payments as required under the agreement.

- pharmacy location rules used by the ACPA and Medicare Australia when assessing applications/proposals to establish new pharmacies.

Earlier performance audits have examined the PBS

1.43 The ANAO has previously undertaken two performance audits of the PBS, with both focusing on DoHA's role:

- ANAO Audit Report No.44 2005–06, *Selected Measures for Managing Subsidised Drug Use in the Pharmaceutical Benefits Scheme*; and
- ANAO Audit Report No.12 1997–98, *Pharmaceutical Benefits Scheme*.

1.44 In addition, the relationship[59] between DoHA and Medicare Australia for the delivery of health and ageing programs, including the PBS, has previously been examined in ANAO Audit Report No. 5, 2002–03, *The Strategic Partnership Agreement between the Department of Health and Ageing and the Health Insurance Commission*.

1.45 Particular aspects of Medicare Australia's approach to program management (and that of its predecessor, the HIC) have been considered in:

- ANAO Audit Report No.20 2007–08, *Accuracy of Medicare Claims Processing*; and
- ANAO Audit Report No.26 2003–04, *Supporting Managers—Financial Management in the Health Insurance Commission*.

The purpose of the current audit

Audit objective and criteria

1.46 The objective of this audit was to examine the effectiveness of Medicare Australia's administration of the PBS.

1.47 The audit criteria were:

- the arrangements among DoHA, Medicare Australia and DHS provide a sound framework for the delivery of the PBS;

[59] The relationship was considered in the context of a strategic partnership agreement entered into by the two parties when Medicare Australia (then HIC) was part of the Health and Ageing portfolio. The strategic partnership agreement has since ceased to have effect.

- Medicare Australia has adequate management arrangements in place to support the effective delivery of the PBS; and
- Medicare Australia, by carrying out its three primary PBS responsibilities—approving pharmacies; approving authority prescriptions; and processing PBS claims—delivers the PBS effectively.

Scope and method

1.48 This audit examines the design and operation of Medicare Australia's management arrangements for the PBS in each of the identified audit criteria areas. Specifically, it considered: Medicare Australia's relationship with the PBS policy agency (DoHA) and service delivery policy agency (Department of Human Services (DHS)); the processes used and management arrangements Medicare Australia has to deliver the PBS; and the means by which Medicare Australia gains assurance over the integrity of the PBS. The primary focus of the audit, however, was on the processes relied upon by Medicare Australia for PBS delivery.

1.49 The audit did not include:

- the RPBS;
- Medicare Australia's management of financial incentives relating to pharmacy software;
- the processes approved suppliers and PBS prescribers undertake;
- the updating of the PBS Schedule; or
- the work of other statutory bodies such as the Pharmaceutical Benefits Advisory Committee (PBAC), ACPA and PBRT.[60]

1.50 The audit was undertaken by:

- collecting, examining and reviewing Medicare Australia documents and other relevant background material;
- assessing processes used by Medicare Australia staff to perform PBS functions;
- interviews with Medicare Australia, DHS and DoHA staff; and

[60] The PBAC assesses applications for listing of medicines on the PBS to ensure that all products listed as benefits meet the criteria specified in the National Health Act. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/Pharmaceutical+Benefits+Advisory+Committee-1> [accessed 17 November 2009].

- undertaking follow-up research with Medicare Australia, DHS and DoHA on issues that arose during the audit.

1.51 The audit was conducted in accordance with ANAO auditing standards at an estimated cost of $550 000.

1.52 The structure of the report is as follows:

- Chapter 2 considers whether the arrangements among the responsible parties provide a framework for the effective delivery of the PBS;
- Chapter 3 examines whether Medicare Australia has adequate arrangements in place to manage the delivery of the PBS; and
- Chapter 4 examines Medicare Australia's administration of the delivery processes for its three major PBS responsibilities.

2. Arrangements for PBS delivery

This chapter examines whether the arrangements among responsible parties provide a framework for the effective delivery of the PBS.

Administrative responsibility for the PBS

2.1 Responsibility for the administration of the PBS has changed in recent years, with new entities being created and a consequential restructuring of accountability. The delivery of the PBS now relies on three agencies—Medicare Australia, DoHA and DHS—as well as pharmacists.

2.2 Medicare Australia, which is responsible for administering the PBS, has existed in its current form only since October 2005. At that point, its predecessor, the HIC, had relatively recently been placed in a new portfolio, that of Human Services. Medicare Australia continues in the same portfolio: however, it was formed as an FMA agency, closer to core government in terms of accountability, whereas the HIC had a separate legal existence as a statutory authority.

2.3 DHS is required to deal with 'development, delivery and co-ordination of government services, and development of policy on service delivery'.[61] The portfolio includes several major Commonwealth agencies with a service delivery focus, including Medicare Australia and Centrelink.

2.4 The Minister for Human Services is responsible for the Medicare Australia Act. The Medicare Australia CEO is directly accountable to the Minister for the operation of Medicare Australia and the Minister, in turn, is accountable to Parliament for its operation.

2.5 The Minister for Health and Ageing is responsible for the principal legislation governing the PBS (the National Health Act) and DoHA is responsible for pharmaceutical benefits.[62] DoHA is identified by Medicare Australia as responsible for 'program policy development and the overall management of the PBS'.[63] DoHA's Outcome 2 for the 2009–10 Budget year is

[61] The Administrative Arrangements Order of 25 January 2008 gave the Minister for Human Services policy responsibility for service delivery.

[62] Commonwealth of Australia Administrative Arrangements Order, May 2008.

[63] Medicare Australia, *Annual Report 2007–08*, p. 42.

'Access to cost-effective medicines, including through the Pharmaceutical Benefits Scheme and related subsidies, and assistance for medication management through industry partnerships.'[64]

2.6 In practice, as Medicare Australia undertakes the day-to-day functions to deliver the PBS, its staff rely on policy support and guidance from DoHA. Medicare Australia must also interact with DoHA on relevant health policy matters and DHS on service delivery policy.

2.7 Pharmacists also have responsibilities to carry out—many of which are specified in the National Health Act—for the PBS to operate effectively. They are required, as already discussed, first to become an approved supplier from particular premises. As part of their dispensing work, they are required to:

- confirm a patient's eligibility for the supply of PBS medicine;
- where applicable, confirm eligibility at a concessional rate;
- confirm that a PBS prescription is complete and correct;
- record the information that will allow them to assess claims for PBS Safety Net Cards and then issue them where the applicant has reached the relevant threshold;
- obtain the applicable patient co-payment and the patient's signature for receipt of the medicine (or agent details as appropriate); and
- prepare, monthly, a claim for payment to lodge with Medicare Australia (including copies of original prescriptions and a claim for payment form).

2.8 Given these arrangements and the administrative changes in recent years, the ANAO considered whether:

(1) there are arrangements among the parties setting out the current roles, responsibilities and obligations for delivery of the PBS; and

(2) each party has authority to carry out its responsibilities.

[64] Portfolio Budget Statements 2009–10, Budget Related Paper No. 1.10, Health and Ageing portfolio, p. 47.

Organisational arrangements for PBS delivery

2.9 The Commonwealth's legislative framework for the governance of agencies subject to the *Financial Management and Accountability Act 1997*, stresses the ultimate accountability of chief executives. Joint activities need to identify clearly how such accountability requirements are to be met in the context of collaborative arrangements. Cross-agency policy development or operational arrangements should not inadvertently result in an accountability gap where responsibility for outcomes is unclear or ambiguous.[65]

2.10 A written agreement is often used to allocate responsibilities where agents deliver services for other parties.[66] Written agreements also promote transparency about the service delivery expectations of the respective parties to the agreement and allow the inclusion of mechanisms to manage those relationships.[67] This is particularly beneficial where policy and operational activities cross agency boundaries, as occurs with the PBS.

2.11 The audit therefore assessed whether there were service level agreements that clearly identified the governance and accountability measures among DoHA, Medicare Australia and DHS, and which support sound administrative arrangements for PBS service delivery.

An agreement exists between Medicare Australia and DoHA for PBS delivery

2.12 The primary agency relationship in the delivery of the PBS is that between Medicare Australia and DoHA. An earlier, corresponding agreement—known as a 'strategic partnership agreement' (SPA)—between the former HIC and DoHA was considered in an ANAO performance audit in 2002–03.[68] That audit found that the then SPA, together with the administrative arrangements between DoHA and HIC, generally supported PBS

---

[65] ANAO Better Practice Guide—*Public Sector Governance* (Guidance Paper No.7: Cross-agency Governance, July 2003), p. 2.

[66] Australian Public Service Commissioner, *Building Better Governance*, 2007; see <http://www.apsc.gov.au/publications07/bettergovernance.pdf> [accessed 24 July 2009].

[67] The *Medicare Australia Act 1973* includes two formal mechanisms (sections 7 and 7A) through which the Medicare Australia CEO can enter into service delivery agreements with other ministers and secretaries.

[68] ANAO Audit Report No.5 2002–03, *The Strategic Partnership Agreement between the Department of Health and Ageing and the Health Insurance Commission*.

implementation;[69] however, the PBS schedule to the SPA had expired in June 2000.[70] Medicare Australia has advised that the arrangement continued to operate thereafter under the terms of the expired schedule as though it had continued.

2.13 The ANAO considered whether:

(a) there is now a written agreement in place;

(b) the agreement specifies the roles and responsibilities clearly;

(c) the agreement specifies DoHA's expectations of Medicare Australia in delivering the PBS and the latter's reporting obligations to the former (this would include a mechanism to give DoHA assurance that the PBS is being delivered as it reasonably expects);

(d) the agreement provides for Medicare Australia to be consulted by DoHA over policy changes, both to allow the former to prepare for administrative changes and to facilitate policy development by the latter; and

(e) the arrangement includes a mechanism to allow both parties to raise and discuss any problems that arise from time to time.

(a) A written agreement is in place between Medicare Australia and DoHA

2.14 In October 2005, some five years after the expiration of the PBS SPA, Medicare Australia and DoHA began to draft a memorandum of understanding (MoU). It was signed some three-and-a-half years later, during the course of the audit. Shortly after, the same parties signed a Business Practice Agreement (BPA) for the delivery of the PBS.

[69] ibid., p. 13, recommendation 2 and p. 46. A key role in these administrative arrangements was played by a joint management committee which was found to support the relationship governance framework, and to deal effectively with strategic and major operational issues affecting inter-agency relations

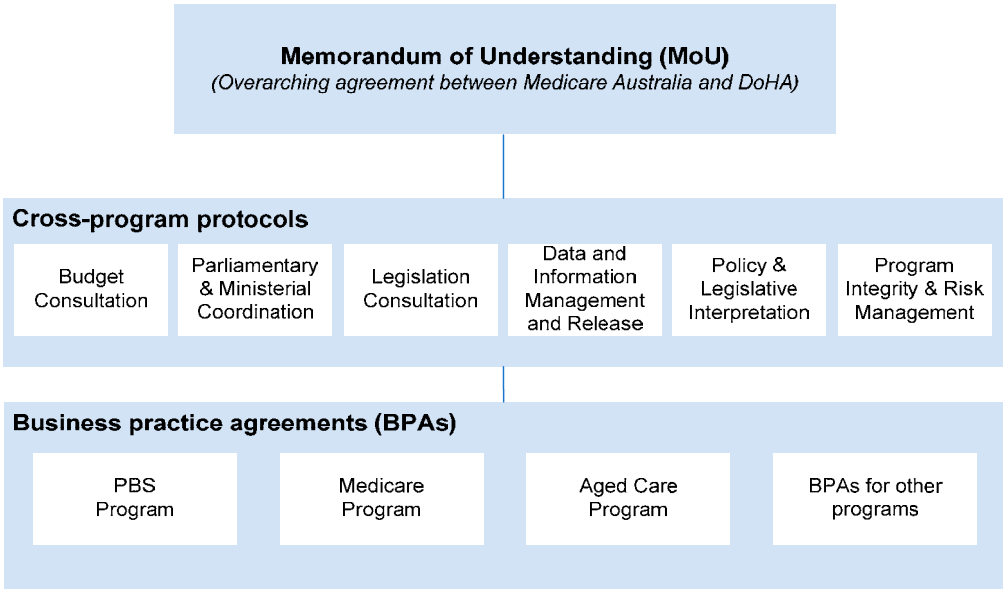
[70] ibid., p. 42, paras 3.15 – 3.18.

2.15 Medicare Australia delivers a range of services for DoHA. To accommodate the specific requirements of each service, the whole agreement is formed by a number of components, signed and agreed separately (see Figure 2.1). These comprise:

- an overarching MoU under s. 7A of the Medicare Australia Act (signed on 8 May 2009);[71]
- cross-program protocols (the Protocols) with application to the PBS (included in the signed MoU of 8 May 2009); and
- a specific business practice agreement (BPA) that relates to the PBS (signed on 14 May 2009).

Figure 2.1

Service delivery governance framework



Source: ANAO analysis of Medicare Australia – DoHA agreements.

2.16 As previously indicated, here had been no formal agreement in place between the expiry of the schedule to the SPA (see para. 2.12, above) and the signing of this MoU in May 2009. DHS had recognised in early 2005 that it was

[71] Section 7A of the *Medicare Australia Act 1973* states that:

The Chief Executive Officer may enter into a written agreement with a Minister or the principal officer of a Commonwealth authority about the exercise or performance of the Chief Executive Officer's powers or functions.

desirable that a new agreement between the HIC and DoHA be negotiated 'as soon as possible', and it was intended that a process and timetable be agreed to achieve this.[72] DHS advised the Minister for Human Services in February 2005 that there was a service agreement covering the PBS between HIC and DoHA 'but it is incomplete and not very effective.'[73]

2.17 DHS provided further impetus when it engaged consultants to review Medicare Australia's compliance programs in 2006. The report concluded:

> Medicare Australia has not had a Memorandum of Understanding (MoU) or similar protocol with the Department of Health and Ageing (DoHA), since the creation of the Department of Human Services (DHS) in October 2004.
>
> The absence of an MoU does not imply a deterioration of the relationship between Medicare Australia and DoHA, however it highlights that important processes for the resolution of compliance issues and matters of operational performance are yet to be agreed.[74]

2.18 The report found that, as an immediate priority, 'Medicare Australia and DoHA need to finalise their MoU to document both agencies' practical commitment to and expectations of compliance.'

2.19 The ANAO raised concerns about the unfinalised status of the MoU and supporting BPAs in the course of the annual financial statement process in 2006–07, 2007–08, and 2008–09. It is apparent from correspondence between ministers and minutes of the MoU Interim Management Committee that sensitivities about the boundary between the policy and service delivery responsibilities of the two agencies were a major reason for the multi-year gap in these arrangements.[75]

2.20 Medicare Australia has advised that it has operated under the terms of a draft of the BPA to the point at which the MoU was signed.

---

[72] Letter from the Secretary, DHS, to the Secretary, DoHA, 28 January 2005.

[73] DHS, minute, 3 February 2005.

[74] Medicare Australia—Compliance Review, September 2006.

[75] A number of letters were exchanged between the Minister for Health and Ageing and the Minister for Human Services between 2006 and 2009 which discussed this matter. Minutes of meetings of the MoU Interim Management Committee also canvass the matter.

(b) Whether the agreement specifies roles and responsibilities clearly

2.21 Adequate specification of roles and responsibilities would include:

(i) a clear statement as to the services Medicare Australia is required to deliver;

(ii) provision for DoHA to provide policy advice about how the PBS should be implemented; and

(iii) clear guidance as to the discretion that Medicare Australia has in designing service delivery arrangements.

2.22 This last point is especially important as there is, otherwise, clear potential for overlap and conflict to arise between, on the one hand, the scope of DoHA's policy requirements in the delivery of the PBS and, on the other, DHS's expectations in discharging its service delivery policy responsibilities.

(i) Services to be delivered

2.23 Section 8 of the BPA lists the services Medicare Australia is required to deliver. More detailed information is set out in appendices, and this generally sets performance standards that Medicare Australia is expected to meet, such as processing claims within a specified number of days of receiving them.

(ii) Providing policy advice

2.24 Medicare Australia staff make PBS decisions under the National Health Act. They do so as delegates of the CEO, acting on behalf of the Minister for Health and Ageing or the Secretary of DoHA. To work effectively, this relationship requires the support of clear guidance from the Minister and Secretary of Health and Ageing to Medicare Australia on how their powers should be exercised. Such guidance would provide a means by which the principals could direct how decision-making is undertaken in any areas for which they retain responsibility.[76]

2.25 Typically, policy guidance for service delivery staff, incorporating interpretation and explanation of legislative provisions, takes the form of a

[76] An example is DoHA's expectations of Medicare in monitoring approved suppliers' ongoing compliance. See paras. 4.15 – 4.17.

written manual or guide for the benefit of service delivery staff or agents.[77] This helps ensure sound and consistent interpretation and application of the relevant legislation. Such guidance should be updated to reflect legislative change or newly identified needs for interpretation and guidance.

2.26 The BPA sets out the responsibilities of both Medicare Australia and DoHA at a high level, including a requirement of DoHA to 'provide policy advice to Medicare Australia in relation to the activities described in the BPA ... with agreed timeframes'. The Medicare Australia Compliance Review in late 2006 noted the importance of prompt, clear policy advice from DoHA:

> Medicare Australia has to meet the Government's primary concern, that is, delivery of payments, while simultaneously adhering to the Government's broader reform agenda, such as containing the increasing cost of health services in line with policy intent. Medicare Australia is reliant on receiving policy guidance from DoHA so that it can meet these broader policy objectives. When that advice does not come, comes slowly, or is ambiguous, Medicare Australia and eventually the Government can suffer significant financial harm.[78]

2.27 From time to time Medicare Australia staff, when faced with an operational issue that requires guidance, contact DoHA. DoHA provides policy guidance to Medicare Australia, but this is on an ad hoc basis and has not been formally recorded in a consolidated policy guide. Medicare Australia also provides procedural guidance to its staff.

2.28 In these circumstances, there is a risk that ad hoc practices and de facto written guides will be developed among Medicare Australia's staff. The ANAO observed that Medicare Australia's operations are dependent on the well-developed knowledge of experienced staff. Their expertise is then drawn on by other staff. However, until relatively recently there has been no single point of reference (such as a consolidated guide or manual provided by either the policy 'owners' in DoHA or Medicare Australia), and there was an

---

[77] Two prominent examples of this type of guidance are: (i) the *Guide to Social Security Law* produced by the Department of Families, Housing, Community Services and Indigenous Affairs (FaHCSIA) and the Department of Education, Employment and Workplace Relations (DEEWR) for Centrelink officers in delivering services <http://www.fahcsia.gov.au/guides_acts/homeint.html>; and (ii) the Department of Immigration and Citizenship's PAM3 policy advice manual, provided both to its own officers and (on subscription) to migration agents through its LEGENDcom system<http://www.immi.gov.au/business-services/legend/about.htm> [accessed 11 May 2010].

[78] Medicare Australia—*Compliance Review*, September 2006, p. 28.

increased risk that practices would develop inconsistencies and vary from state to state or become out-of-date.

2.29 Medicare Australia identified the following items as contributing to the corpus of policy documentation with which it works:

- legislation;
- special arrangements under s. 100 of the National Health Act;[79]
- business rules;[80]
- Business Practice Agreements;
- administrative documents such as the 4CPA; and
- external costing requests.

2.30 Medicare Australia has recently undertaken two initiatives that improve the way in which it provides guidance to staff:

- *eReference*—Medicare Australia has substantially enhanced its online centralised repository of program-related information. It reviewed existing guidance before loading updated information into the eReference system. An owner is identified for each document and a review cycle agreed. It advises that new content is continually being added to the eReference system.
  - Medicare Australia provided evidence that the system is being managed actively, for example, by a 'failed search' reporting mechanism that helps managers identify those items staff unsuccessfully had been seeking information on. The system also keeps track of usage by content item accessed.
  - The system has a feedback mechanism to allow staff to identify gaps in information or seek clarification on content.
  - A weekly online update report draws staff attention to new and amended information.
- *Administrative Position Statements*—In December 2008, the then Minister for Human Services announced a web-based source of information to

[79] This section of the Act is about special arrangements for providing that an adequate supply of pharmaceutical products is available to those who, for example, live in isolated areas.

[80] These relate to the processing specifications in Online Claiming for PBS.

allow health professionals to better understand the benefits they can claim.[81] This includes the PBS. The information is set out in documents that Medicare Australia calls its 'Administrative Position Statements (APS).' The development of these statements resulted from feedback from providers who were concerned with 'national inconsistency of advice and administration of programs by Medicare Australia.'[82] Medicare Australia explains these as follows:

> An [APS] is an authorised and documented position held by Medicare Australia in relation to ... the administration of the ... [PBS] or associated government program, in particular, where there is ambiguity.
>
> The APS process takes issues that are currently ambiguous or questions that cannot be answered using existing knowledge base resources and, through a consultative approach, formulates a definitive response taking into account any legal, clinical or assessing issues.
>
> The process does not involve consideration of health policy matters, but is aimed at the interpretation of administrative issues. The process includes seeking advice from [DoHA] and health professions where required. Exposure drafts will also be released for public review prior to finalisation of each APS.

(iii) Medicare Australia's discretion in designing service delivery arrangements

2.31 DHS has recognised there would be a benefit from clear delineation of how Medicare Australia should balance decisions regarding DoHA's health policy objectives and DHS's service delivery policy objectives, an overlap identified by DHS in February 2005:

> The Government's decision to split Ministerial responsibility for policy and delivery necessarily creates overlap in responsibility and accountability for work done that is neither pure policy nor pure payment (i.e. business rule design, regulatory and compliance work, education).[83]

---

81 See: <http://www.medicareaustralia.gov.au/provider/business/aps/index.jsp> [accessed 17 November 2009].

82 Medicare Australia, '*Administrative Position Statements*', Health Advisory Branch, Program Review Division, (presentation slides, undated), p. 3.

83 Department of Human Services, minute to the Minister, 3 February 2005.

2.32 The MoU is a mechanism which could:

- make clear the respective roles of parties and individuals (those exercising the powers), and
- create a framework for managing competing policy concerns.

2.33 Clause 13 of the MoU provides some definition of the roles and responsibilities of the parties as they relate to policy. In effect, the MoU splits responsibility for both general policy and policy on the interpretation of legislation on the basis of whether it relates to *service delivery* or *health* policy, and assigns them to DHS and DoHA respectively as follows:

> **Legislative and policy interpretation**
>
> The views of the relevant Health and Ageing Portfolio Minister are conclusive in relation to which interpretation of legislation administered by the Minister for Health and Ageing best gives effect to policy intent.
>
> The views of the relevant Health and Ageing Portfolio Minister are conclusive on the interpretation or intent of a policy position in relation to a program (for example, who is eligible for what level of payment under a grant program and in what circumstances).
>
> The views of the Minister for Human Services are conclusive in relation to the delivery of a program (for example, how payments are made; shop front accessibility).
>
> **Policy development**
>
> The Minister for Health and Ageing and his department will consult with the Minister for Human Services, his department and Medicare Australia in regard to service delivery considerations.
>
> The Minister for Human Services, his department and Medicare Australia will consult with the Minister for Health and Ageing and his department on health and ageing policy considerations.

2.34 This approach is consistent with the requirements of the departments and ministers as identified in the Administrative Arrangements Order. Although DHS is not a party to this agreement, it must be presumed that Medicare Australia has kept DHS informed of relevant deliberations between it and DoHA and that this delineates the boundaries of respective policy interests to the satisfaction of both departments.

2.35 However, there is a lack of clarity in the existing documents about what constitutes a service delivery policy issue—a DHS responsibility—and how that might be accommodated within the existing arrangements between Medicare Australia and DoHA. The Administrative Arrangements Order that explicitly conferred DHS's responsibility for service delivery policy took effect on 1 May 2008. The department advised the ANAO that, since that time, it has

not undertaken any new policy initiatives affecting delivery of the PBS that reflect that new responsibility.[84]

(c) Whether the agreement specifies a mechanism to give DoHA assurance that the PBS is being delivered as it reasonably expects

2.36 Section 19 of the BPA requires the MoU Management Committee (which oversees the operation of the agreement—see para. 2.47) to identify any performance-related issues in an annual report. However, the focus of this committee is primarily on the relationship between the organisations.

2.37 Attachments to the BPA specify requirements for certain statistical data, but not performance information. There is no requirement in the BPA (or elsewhere as far as can be determined) for any performance information reports that would provide assurance to DoHA of the satisfactory delivery of the PBS by Medicare Australia.[85] This might include assurance about the accuracy of payments, timeliness of services delivered and compliance with the requirements of the National Health Act and regulations.

2.38 In practice, Medicare Australia has provided DoHA with an annual summary document called its 'Business Practice Agreement Scorecard', which reports performance against targets for selected services, including promptness of processing.[86] Medicare Australia advised the ANAO that:

> accuracy of processing is reported to [*its own Corporate Management Committee*] but not reported in the BPA Scorecard to DoHA. This may be considered an internal measure of efficiency, hence, why it is not reported externally.[87]

---

[84] DHS advice of 14 September 2009.

[85] Medicare Australia has advised that it does report to DoHA 'in accordance with its requirements and as stipulated in the BPA schedule.' However, the BPA requirements are only for *PBS data* to be provided (such as 'line-by-line prescription claim data and reports'), not reports on Medicare Australia's administrative performance in delivering the PBS. Medicare Australia's performance and performance reporting are considered in Chapter 3.

[86] The targets in the scorecard were set internally by Medicare Australia. There is no evidence that DoHA has articulated its expectations or set any targets.

[87] Medicare Australia advice, 9 September 2009.

(d) Whether the agreement provides for Medicare Australia to be consulted by DoHA over policy changes

2.39 Consultation with Medicare Australia over policy changes by DoHA is desirable both to facilitate:

- practical input into the consideration of policy options, including costs and timing of possible changes; and
- forewarning of possible directions to allow adequate service delivery planning and preparation to take place.

2.40 The BPA contains a requirement on DoHA to consult:

> DoHA agrees to consult with Medicare Australia as early as possible on matters requiring policy clarification, and on any variations to policy or administrative requirements that relate to Medicare Australia activity for the PBS. The consultations should, as far as possible, be early enough to enable business requirements and funding issues to be considered before Medicare Australia commits to implementation timeframes (section 9.2, p. 9).

2.41 The *Policy and Legislation Interpretation Cross-program Protocol* document, which forms part of the Agreement, seeks to ensure the various government stakeholders have input into policy decisions that affect their responsibilities. It leaves the determination of the existence and extent of other policy interests, in a practical sense, up to each agency.

2.42 The Agreement could benefit from including a means to progress policy in areas where there is joint interest, responsibility or accountability. While the Protocol (clause 4.3) currently outlines a procedure in cases where officials perceive tension between health and ageing policy and service delivery policy, it provides only limited guidance on its resolution:

> officers will make every effort to agree a policy position which balances the Government's health and ageing policy and service delivery objectives.

2.43 Such an approach may help to address minor areas of common interest, but may prove less useful when there is a joint policy or operational interest in the outcome of decisions, particularly where one party controls funding. Where there is an overlapping policy interest in an initiative or decision there is a need to ensure that all efficiency, effectiveness, and policy concerns are considered within the context of health policy and service delivery policy.

2.44 DHS advised the ANAO that consulting the department only at the point at which an exposure draft of a new policy proposal advanced by the Minister for Health and Ageing is 'not sufficient consultation or involvement

to allow adequate consideration of the service delivery aspects of the policy.' It would prefer DHS and Medicare Australia to be involved at a much earlier stage. Moreover, it has stated that there have been occasions when 'Medicare Australia and DHS have not had visibility of the "big picture" and, if [they] had, may have been able to suggest improvements or efficiencies.'[88]

2.45 In response to a request for examples of this, DHS advised:

> In November 2006, a package of reforms to the [*PBS*] was announced by the former Government. The implementation of the reforms proceeded relatively smoothly due to a number of factors, including a strong collaborative approach between Medicare Australia, [*DoHA*] and DHS, regular and open communications and weekly meetings.
>
> However, this type of approach has not always been evident. During the 2009–10 Budget process, Medicare Australia costed over 100 Budget proposals for [*DoHA*]. In many cases the costings were prepared within an extremely limited timeframe and in the absence of detailed policy objectives, specifications or business requirements.
>
> To give a further example, a policy department was surprised at the costing provided by a Human Services portfolio service delivery agency in relation to a proposal to simplify a particular program. Had there been a closer level of involvement by the service delivery agency in the initial development of the strategy, the policy department would have gained a better understanding of the complexity of the change, and the steps necessary to implement it, earlier in the process. This would have avoided the need to make substantial changes to the proposal during the costing phase.[89]

2.46 On this general point, Medicare Australia stated that it 'has systems in place to ensure that joint policy/operational interests are considered.'[90]

(e) Whether the agreement includes a suitable governance arrangement.

2.47 The MoU provides for the establishment of a MoU Management Committee to:

- oversee the operation of the MoU;
- promote an effective working relationship between the parties;

[88] DHS advice of 14 September 2009.

[89] DHS advice, 19 November 2009.

[90] Medicare Australia advice of 9 September 2009.

- seek opportunities to improve the effectiveness and efficiency of the working relationship;
- resolve disagreements referred by the managers of the Protocols and BPAs; and
- advise the Secretary and the CEO on any matters relevant to the operation of the MoU, including variations to the MoU, the Protocols and BPAs.

2.48 The MoU Management Committee was formally appointed in June 2009. Before this, an interim management committee had met quarterly. Senior DoHA and Medicare Australia officers responsible for the PBS have held regular monthly meetings since September 2007 (now called 'Pharmacy Liaison Meetings'). These meetings provide an opportunity for matters that have arisen between these two agencies to be resolved.[91] Minutes show that these meetings have focused on issues that have arisen, but have not monitored or overseen the adequacy of the business-as-usual delivery.

2.49 The MoU makes provision for the BPAs and Protocols to have appropriate consultation arrangements, including a program-specific governance committee reporting to the MoU Management Committee (sub-clause 9.3). No such sub-committee is provided for in the PBS BPA, and as a result the MoU Management Committee is an important governance structure for the management of the relationship between agencies on the PBS.

2.50 The MoU (clause 19) requires the Committee to submit an annual report to the Secretary of DoHA and Medicare Australia CEO that assesses the relationship between the organisations, identifies where the relationship can be improved and makes recommendations. Medicare Australia advised the ANAO that the first such report was being prepared.[92] The MoU is silent on the involvement, if any, of DHS in the development of these reports.

2.51 The MoU makes provision for the BPAs to require similar reports at a program level (sub-clause 19.4). As a PBS annual report is not specified in the PBS BPA, the MoU annual report, once implemented, will be a key means by which PBS relationship issues are raised and improvements identified.

---

91 Officers representing DHS are not routinely present at these meetings.

92 Medicare Australia advice, 9 September 2009.

Conclusion—arrangements between DoHA and Medicare Australia

2.52 With the successful delivery of the PBS relying on the cooperation and communication of three agencies; Medicare Australia, DoHA, and DHS, a clear and common understanding of respective roles and responsibilities of each agency is important. After several years of consultations, a Business Practice Agreement between DoHA and Medicare Australia for the delivery of the PBS was signed in May 2009. The Agreement largely contains the elements identified by the ANAO as desirable for such agreements, with the exception of an explicit obligation on Medicare Australia to report its delivery performance to DoHA. Sensitivities about the boundaries between policy and service delivery responsibilities of the agencies contributed to the delay. These sensitivities remain, as exemplified by DHS's continuing desire to be consulted earlier on health policy proposals to bring to bear its service delivery policy perspective.

Authority for delivering the PBS

2.53 The ANAO considered how authority is provided to Medicare Australia officers to make PBS decisions. This affects accountability for such decisions made under the National Health Act. This matter is complex, partly because of the administrative changes that have taken place in recent years (see para. 2.2 et seq.)

The Medicare Australia Act and the National Health Act

2.54 Medicare Australia is established by section 4 of the Medicare Australia Act, as comprising the Medicare Australia CEO and staff. The role of Medicare Australia staff is to assist the CEO in the performance of the functions the CEO is assigned under section 5 of the Act.[93]

2.55 The PBS is established by Parts VII, VIII and IX of the National Health Act.[94] The Administrative Arrangements Order (AAO) gives responsibility for the Act to the Minister for Health and Ageing. Medicare Australia's

[93] Section 4A of the Medicare Australia Act states the functions of Medicare Australia; s. 5 states the functions of its CEO.

[94] The National Health Act is a complex piece of legislation under which a range of legislative instruments have been created to supplement the administrative arrangements for PBS delivery, such as specific requirements of prescription forms under the *National Health (Pharmaceutical Benefits) Regulations 1960* and rules for accepting and processing PBS claims for payment. Claims processing requirements are given force as rules made under ss. 99AAA(8) of the National Health Act.

administration of the PBS relies on the relevant functions and powers being conferred on its Chief Executive Officer. In general, where there is a need to confer functions and powers, this can be achieved by delegation or authorisation, and each has practical and operational consequences for decision makers and the conferrer (see box below).

Delegation versus Authorisation[95]

- A delegate acts in their own capacity. They must exercise their own discretion and sign documents in their own name.
- As the delegate is under a personal obligation to exercise the power validly, the delegate must ensure that they understand their legal obligation in relation to the exercise of the power.
- Additionally, while the delegator can still exercise the power being delegated, they are generally not able to direct the delegate in how the power is exercised or place conditions on how to exercise the power. An exception is where there is a specific provision in an Act allowing for the giving of directions to delegates.
- Where a person acts through an *authorisation*, they are acting as the agent of the person in whom the power is vested (the principal). The exercise of power by an agent is as if the principal exercised that power; in effect, decisions by an agent, bind the principal. The principal must ensure that their agents are correctly exercising the power, as the principal is responsible for the agents' decisions.

2.56 When the HIC delivered the PBS, the Minister for Health and Ageing and the Secretary, DoHA, separately *delegated* powers to HIC officers to allow them to exercise those PBS powers. Under the new arrangement, the Minister for Human Services exercised his power under the Medicare Australia Act to make a legislative instrument conferring a statutory function on the Medicare Australia CEO. This legislative instrument enables the Medicare Australia CEO to exercise certain statutory powers under the National Health Act on behalf of the Minister for Health and Ageing and the Secretary of the DoHA. DHS provided advice showing that, where the Medicare Australia CEO

[95] ANAO summary, based on general advice, including, in particular, Australian Government Solicitor, 'Delegations, Authorisations and the Carltona Principle', 14 December 2004. <http://www.ags.gov.au/publications/agspubs/legalpubs/legalbriefings/br74.pdf> [accessed 17 November 2009]. See also Administrative Review Council, *Decision Making: Lawfulness*, Better Practice Guide 1, p. 6, August 2007.

exercises a function on behalf of the Minister or Secretary, as would be the case in respect of the PBS, he or she is effectively acting as the agent of the Minister or Secretary.[96]

2.57 The Medicare Australia CEO has delegated the authority conferred by this legislative instrument to be the agent of the Minister and Secretary to certain officers within Medicare Australia, relying on a provision of the Medicare Australia Act that allows the CEO to delegate his or her powers and functions.[97]

2.58 There is no evidence of specific consideration of how PBS powers were to operate in Medicare Australia before this agency arrangement was made. Until the week before the change-over there was an understanding that direct delegation instruments would be made by the Minister for Health and Ageing and the DoHA Secretary of National Health Act PBS giving powers to the Medicare Australia CEO, who would in turn delegate them to Medicare Australia officers.

2.59 The agency arrangement that was adopted was conceived as part of a broader consideration of the conferral mechanisms to be used across a range of health and ageing programs administered by Medicare Australia. For example, one of the key decisions made was to use a direction rather than regulation to confer a number of Health and Ageing functions.

2.60 This was proposed by DHS on the basis that it:

- consolidated all of Medicare Australia's functions into a single direction document and would reduce confusion;
- allowed greater flexibility to amend directions; and
- removed the possibility of parliamentary disallowance.

2.61 The proposal did not include consideration of how the new framework would actually operate, particularly the shift from delegation to authorisation and the CEO acting, in effect, as the agent of the Minister for Health and Ageing and DoHA Secretary. The operation and validity of these arrangements was considered in a compressed timeframe, including through legal advice, up to and including two days before the arrangements took effect.

---

[96] DHS advice of 7 January 2009.

[97] Section 8AC of the Medicare Australia Act.

2.62 DHS, Medicare Australia and DoHA have advised that they support the view that the direction made by the Minister for Human Services operates to confer legal authority on the Medicare Australia CEO to exercise certain statutory powers on behalf of the Minister for Health and Ageing and the Secretary of DoHA and that the Medicare Australia CEO can validly delegate that authority to staff of Medicare Australia.

2.63 DHS records show that questions about whether and how Medicare Australia officers can be directed in their PBS role were raised at the time the new arrangements were adopted.[98] The matter appears to have been set aside and not resolved before the establishment of the current arrangements. However, this issue becomes important, for example, in the context of making decisions under s. 90 of the National Health Act on applications from pharmacists to become approved suppliers where decision-makers are required to consider policy issues.[99]

2.64 During audit fieldwork the ANAO observed inconsistencies in Medicare Australia officials' understanding of how the new arrangements affect their role as decision-makers. Given the importance of decisions that are made by Medicare Australia staff, such as applications from pharmacists to become approved suppliers, PBS administration would benefit from Medicare Australia staff having a clearer understanding of the new arrangements. The need for clarity in the arrangements is further increased by the fact that, whereas DoHA and the HIC were in the same portfolio, Medicare Australia is in a different portfolio, with the added complexity of being responsible to two ministers.

2.65 Improving the clarity and understanding could be achieved through the current process of Medicare Australia updating procedural guidance to include information on the authority to administer the PBS and how that affects decision making.

---

[98] The advice was dated September 2005, the month before the change from HIC to Medicare Australia. DHS had also noted earlier (January 2005) that a number of matters required resolution regarding the level of control over HIC that the Health and Ageing Minister would exercise, its limits and the implications for HIC where a direction by the Health and Ageing Minister was not supported by funding provided to the HIC or inconsistent with a policy direction of the Human Services Minister.

[99] This issue is considered in more detail in Chapter 4.

Conclusion—arrangements for making PBS decisions

2.66 The authority to administer the PBS is now conferred on Medicare Australia staff by (i) a ministerial direction from the Minister for Human Services to the Medicare Australia CEO to perform the function of exercising powers on behalf of the DoHA Secretary and the Minister for Health and Ageing; and (ii) the Medicare Australia CEO then delegating those powers to her staff. This is a different mechanism from that in place when the HIC administered the PBS in the Health and Ageing portfolio in that DHS has provided advice that shows that staff now act, in effect, as agents rather than delegates of the Minister and/or Secretary for Health and Ageing.

2.67 During audit fieldwork the ANAO observed inconsistencies in Medicare Australia officials' understanding of how the new arrangements affect their role as decision makers. Given the importance of decisions made by Medicare Australia staff, such as applications from pharmacists to become approved suppliers, PBS administration would benefit from Medicare Australia staff having a clearer understanding of the new arrangements. This could be achieved through the current process of updating procedural guidance to include information on the authority to administer the PBS and how that affects decision making.

Recommendation No.1

2.68 Given the change in authority arrangements underpinning the delivery of the Pharmaceutical Benefits Scheme, the ANAO recommends that Medicare Australia provide guidance to its decision-makers that explains the legal and operational business arrangements supporting its delivery.

Medicare Australia response

2.69 **Agree.** This action has been completed. Medicare Australia has recently issued a reminder to staff about the availability of best practice guides on Administrative Law to assist decision makers in 'getting it right'. These best practice guides were produced by the Administrative Review Council and in June 2009 were tailored to include a Medicare Australia focus. Staff were originally advised about these guides in July 2008.

3. Managing PBS delivery

This chapter considers whether Medicare Australia has adequate arrangements in place to manage the delivery of the PBS.

Elements of managing PBS delivery

3.1 Effective program delivery has a range of key components including: an accountable organisational structure; a structured and integrated approach to risk management; an operational framework that sets out the procedures for how the business will operate; staff who have the right skills and capacities; a system of performance monitoring; and external reporting on actual performance that provides accountability to the Parliament and the public.

3.2 In examining the delivery of the PBS, the ANAO considered whether Medicare Australia has in place:

- a management structure with clear accountability;
- a systematic approach to risk management;
- procedural guidance supported by an adequate training program; and
- a robust performance information framework.

Management structure

3.3 A management structure with clear accountability shows where responsibility for all aspects of the delivery of a program sits in an organisation's hierarchy. It is achieved by all parties having a clear understanding of those responsibilities, and having clearly defined roles through a robust structure.[100] Having a clear point of accountability ensures that an end-to-end view of the program is taken, which minimises the risk of poor co-ordination. Poor coordination can arise where functional groupings are in distinct 'silos' with some essential tasks requiring cross-functional oversight.

3.4 To deliver the PBS, Medicare Australia employs a dispersed network of staff in the national and state offices around Australia, supported by a common IT system. Their combined efforts enable the routine processing of

[100] ANAO, *Public Sector Governance: Better Practice Guide*, July 2003, vol. 1, p. 8.

prescriptions, the payment of pharmacy claims and the implementation of PBS changes in response to policy decisions (including any guidance from DoHA).

3.5 Medicare Australia's organisational structure has a combination of functional and geographical units. Some, such as the Pharmaceutical Benefits Branch (PBB) are dedicated to the PBS, while others, such as the Information Technology Services Division (ITSD), provide shared services across the 21 programs administered by Medicare Australia.

3.6 At the commencement of the audit, it was apparent that PBB played a central role in the delivery of the PBS but with only a limited focus on its end-to-end program management. While Medicare Australia relied on its various organisational units to deliver the PBS, there was no single area with the whole of the program within its purview. That is, there was no specific manager coordinating PBS roles and responsibilities and ensuring accountability and communication across the functional teams. Rather, responsibility for PBS program management relied on a collaborative approach.

A new national program delivery model has been adopted

3.7 From 1 July 2009, Medicare Australia implemented a national program delivery model. This means that there is now one individual (Chief Operating Officer) directly responsible for delivering programs nationally. A Business Operations Manager with specific responsibility for the operations of the PBS program, working directly with the Manager, Pharmaceutical Benefits Branch, supports the Chief Operating Officer. Medicare Australia has also established a Business Performance Sub-Committee (BPSC) to focus on strategic matters that affect business and operational performance.

3.8 Medicare Australia characterises these two changes as major, and advises that roles and responsibilities are, in its view, much clearer, and coordination is greatly enhanced. As the national program delivery model commenced after audit fieldwork had been completed, the ANAO did not test the new arrangements in operation.

Managing risk as a part of program assurance

3.9 Comprehensive risk management practices are a key element of an effective management approach because they can facilitate the development of an integrated and wide ranging understanding of business processes and practices. Further, building on this understanding, risk management provides assurance that risks are being identified (risk assessment) across a program

and steps are being taken to minimise the likelihood of those risks occurring to an acceptable level (risk treatment).

3.10 Risk management for the PBS is not approached and managed at a program level. There is no program-level risk management plan for the PBS that can provide assurance that program risks are being systematically identified and then managed from an end-to-end program perspective.

3.11 In the absence of such a plan, the ANAO considered how PBS program assurance might be gained from other risk management/assurance activities:

- risk management policies and practices;
- the organisational compliance strategy; and
- a PBS program integrity report developed by a management committee.

Implementation of organisational risk management policies

3.12 The Medicare Australia CEO has made it a requirement under the Chief Executive's Instructions (CEIs) that risks are managed in line with policies set by the Audit and Risk Assurance Services (ARAS) manager.[101]

3.13 Each of the functional teams contributing to the delivery of the PBS has risk management responsibilities aligned with the functions they provide. This responsibility includes both risk assessment and risk treatment activities, such as ensuring that internal business controls within their area of operation are adequate to mitigate risks to an acceptable level.

ARAS risk management policies and support

3.14 Consistent with the CEIs, the ARAS manager has issued a risk management policy. ARAS provides supporting guidelines and templates and a dedicated resource to give risk management support to all Medicare Australia divisions and business units nationally. The ARAS policy requires risk management plans both for projects and business units, in line with accepted business practice.[102] It requires an annual planning cycle, supported by three-monthly reviews to ensure plans remain current.

---

[101] Specifically, this instruction is set out in CEI 7.1.

[102] Projects can involve cross-branch or cross-divisional teams, whereas business units are generally branches or teams within branches.

PBS risks: implementation of the ARAS risk management policies

3.15 ARAS has sought to co-ordinate a comprehensive set of risk management plans across business units involved in PBS delivery. This, however, relies on business units' co-operation, which has been inconsistent. An example is that PBB did not complete a Risk Management Plan for 2006–07 and had only a draft 2007–08 plan under development as of February 2009. However, later during the audit, Medicare Australia was able to provide a completed PBB Risk Management Plan 2009–10.[103]

Internal audit report on online claiming for PBS processing

3.16 In April 2008, a Medicare Australia internal audit noted that, in relation to Online Claiming for PBS, some risk assessment work had been undertaken early in the project (2004), but none had been done recently. It recommended that PBB undertake 'a comprehensive risk assessment of the online claiming system.' The report suggested that any such risk assessment would assess the 'settings for the random QAI and QCI processes to determine whether the levels of intervention would satisfy business objectives.'[104]

3.17 Medicare Australia provided a copy of its *Online Claiming for PBS Risk Management Plan* for 2009–10.[105] However, that plan did not assess settings for the QAI or QCI processes.

Use of the cross-program compliance strategy to manage risks

3.18 Within Medicare Australia, PBS program compliance is the responsibility of the Program Review Division (PRD). PRD's approach to compliance is outlined in Medicare Australia's annual National Compliance Program (NCP). Medicare Australia described this document as setting out its:

> compliance approach, which includes an appropriate mix of education, support, deterrence and enforcement in order to encourage the maximum levels of voluntary compliance. The NCP outlines what risks Medicare Australia will focus on, how it will manage and treat these risks and what

[103] The plan was completed on 7 September 2009.

[104] Medicare Australia, Audit & Risk Assurance Services, '*Online claiming for PBS processing*', Report No. 08/2008. QAI (Quality Assurance Intervention) is a process designed to locate and correct errors. QCI (Quality Checking Intervention) monitors QAI checking. These processes are discussed further at para. 3.79 et seq.

[105] The plan was completed on 7 September 2009.

compliance activities it has planned for the next 12 months. Risks to the PBS are included in the NCP.[106]

3.19 The NCP details a number of broader risks affecting compliance risks.[107] PRD's approach identifies compliance risks that are likely to have the greatest effect on the programs Medicare Australia delivers, including the PBS. It has developed its compliance program to treat those risks. The NCP 2008–09 outlines the approach taken by PRD to compliance:

> Our payment services are designed to require minimal up front verification without claiming complexity. Our focus is to take a post-payment approach using risk management techniques to monitor and confirm payment accuracy and integrity.[108]

3.20 In line with PRD's focus on program compliance, its risk register only identifies program risks in line with PRD's approach of ensuring 'The right person receives the right payment at the right time—no more, no less.'[109] Accordingly, risks that may have a security or privacy implication are not considered and hence are not documented in the risk register.

3.21 PRD's compliance approach is not designed to monitor and manage the end-to-end program risks associated with PBS delivery. Accordingly, any assurance that can be gained from its compliance activities is limited to ensuring the right person is paid the right amount at the right time.[110]

Use of committee reports for PBS risk management

3.22 Medicare Australia's management committees include a Program Integrity Committee (PIC), whose role is to develop, implement and review the organisation's program integrity framework, and advise the CEO. The PIC has not been convened since November 2007, although strategic oversight of compliance and program integrity has moved to a portfolio level.[111] One of the

---

106 Medicare Australia advice, 18 September 2009.

107 These risks range from increasing program complexity; to growth in health care items provider groups; changing business practices affecting the provision of health services; e-business changes; and increasing community demand for health services.

108 Medicare Australia, National Compliance Program 2008–09, p. 1.

109 Medicare Australia, National Compliance Program 2008–09.

110 Such assurance is gained through IT processing controls enforcing program eligibility requirements and the adequacy and effectiveness of controls surrounding manual processes such PBS safety net processing.

111 Medicare Australia advice, 18 September 2009.

PIC's last activities was a PBS integrity assurance review with an objective of mapping 'the end-to-end process for the [PBS] and [to] identify issues that threaten program integrity, and specify existing measures that reduce or mitigate these threats.[112]

3.23 The project drew on existing documentation about PBS processes from prescribing to dispensing, pharmacy payment and review. The outcome, the *PBS Program Integrity Assurance* report (January 2008), identified activities undertaken by Medicare Australia that were contributing to program integrity and affirmed the need for overall co-ordination.[113]

3.24 The report indicated that various program integrity framework steps/processes were yet to be formalised or completed. It noted that program integrity had not been defined, and the incomplete status of business process mapping. These are prerequisites to finalising a framework.

3.25 The report also suggested that there is 'end-to-end' coverage of PBS delivery. However, it did not identify integrity risks systematically at the various stages of the PBS process, nor match these to mitigation strategies by the various assurance/control activities. This is difficult, given the incomplete status of the business process mapping.

3.26 The intent behind developing a report to assess end-to-end PBS program integrity is a positive initiative towards managing PBS risks. It is a first step, seeking to understand current integrity activities. The execution of the review, however, focused on providing details of the existing activities and did not consider their adequacy by design, their coverage (end-to-end), or completeness (legislative requirements, privacy, or ethical obligations). The report therefore provides only a limited assurance over PBS program integrity.

[112] Medicare Australia, PBS Program Integrity Assurance, p. 5.

[113] Chapter 4 considers specific risks in the delivery of the PBS and draws further on this report.

3.27 While the report highlighted that the process of getting a complete understanding of program processes was still under way, it concluded that Medicare Australia has the program controls required to assure program integrity. The report cites statistics to support its conclusion, specifically:

1. Medicare Australia meets the requirements of the ANAO in its ability to guarantee that less than 1% of PBS payments are paid inappropriately.[114]

2. Furthermore, Medicare Australia conducts quality control on a sample of its payments to ensure that payments are made in accordance with business rules. The latest QC statistics demonstrate that 98.31% of payments are made in accordance with government policy intent, and that 98.34% of authority approvals are made accurately.[115]

3.28 The underlying analysis does not clearly support these conclusions. For example, QCI statistics do not provide a measure of payment accuracy nor of consistency with policy intent. This is discussed below in the analysis of Medicare Australia's performance information on PBS delivery.

3.29 Medicare Australia advised that, in 2007–08, there was a joint review of compliance management across agencies in the Human Services portfolio by the Department of Human Services and the Department of Finance and Deregulation. This led to a cross-portfolio, strategic approach to fraud and non-compliance and the elevation of strategic oversight of compliance and program integrity to a portfolio level, rather than the agency-specific focus that the Program Integrity Committee previously provided.

3.30 It further advised that PRD:

> implemented a restructure on 1 July 2009. This restructure created a branch specifically responsible for oversighting compliance strategy in relation to PBS. This area has commenced a review of the program integrity report commissioned by the PIC with a view to updating it and ensuring that an end-to-end review of the integrity of the PBS program is undertaken.

[114] Medicare Australia has advised (22 April 2010) that the statement in the PBS Program Integrity Assurance report of an 'ANAO requirement of 1% error rate' is incorrect and that it has corrected this in the latest draft of the document.

[115] Medicare Australia, PBS Program Integrity Assurance, January 2008.

Conclusion—risk management

3.31 Medicare Australia has a risk management policy in place, though this has not been adhered to consistently in producing timely risk management plans for organisational units or projects relating to the PBS. Nevertheless, its PBS Program Integrity Assurance report was a positive step towards identifying and managing PBS risks, end-to-end. Medicare Australia's current plan to update this report and ensure that it is comprehensive should result in the identification of any gaps and provide greater assurance over PBS program integrity.

Procedures and training for the PBS

3.32 The development, implementation and maintenance of comprehensive and consistent procedural guidance for staff throughout the organisation is needed to support any major continuing service delivery program. This is especially the case with a program like the PBS which has a large number of staff in state and territory offices across the country. Use of these procedures needs to be supported by training courses for the staff required to implement them.

National procedures have been put in place

3.33 In Medicare Australia, PBS decisions of the same nature are made by staff in state offices around Australia. A nationally consistent, up-to-date set of procedures available to all PBS processing staff is desirable to support correct and consistent decision-making for pharmacists and patients.

3.34 Early in the audit, the ANAO identified only a limited range of national procedures available within Medicare Australia for the PBS. As an apparent consequence, each state office had developed its own operational level procedures. There was no national management of operational procedures across state offices.

3.35 The ANAO found that documentation setting out and supporting these state-based procedures was generally held by the officers who principally relied on the procedures. Some documentation was more widely available, for example, one state office had provided some guidance to its team members through a local shared network drive.

Medicare Australia recognised a need for national procedures

3.36 Medicare Australia recognised the need to provide guidance to processing staff. To help achieve consistency in PBS claims processing, it began

to provide PBS reference information to its officers in its eReference database on its Intranet site. The ANAO found during the audit, however, that the eReference database provided information to support officers in some decision areas, but did not provide the procedural level guidance available in the state-level documentation mentioned above. Further, staff stated that they mainly referred to state-level documentation in the course of their work.

3.37 An ongoing lack of nationally consistent and coordinated procedural guidance would present a risk that similar administrative decisions could be inconsistently determined among the states. Areas identified in the audit where this risk was apparent included:

- there were no routine processes to quarantine, further identify, refer for investigation or correct a prescription claim that includes an invalid prescriber name and number, if the physical prescription details match those entered into Online Claiming for PBS by the pharmacist; and
- there was no national guidance on the actions that state offices should take to follow up suppliers who fail to submit physical prescriptions on time to support their PBS claims.

3.38 In addition to the various forms of documented PBS procedural guidance, there have been regular forums involving national office and State offices to discuss processing matters. These forums have identified problems and provided an opportunity to disseminate consistent messages across the Medicare Australia office network.

A PBS New Claims Processing System Reference Manual is now available

3.39 During the audit, Medicare Australia advised the ANAO that procedural level documentation developed by each state had been sought by the PBB as a step towards developing nationally consistent processes for inclusion in the eReference database. This work resulted in the development of a comprehensive set of PBS procedures, with the PBS *New Claims Processing System Reference Manual* being endorsed by the PBB manager in April 2009.

3.40 Medicare Australia advised that it now has a process in place under the national program delivery model from 1 July 2009 for national management of operational procedures across state offices.[116] Under these arrangements, it stated, use of ad hoc systems is being addressed and staff are being

[116] Medicare Australia advice, 18 September 2009.

encouraged to use the eReference suite as the most up-to-date source of information.

3.41 Medicare Australia also stated that it had completed transferring the information in its old Reference Suite system to eReference. Material in eReference for Online Claiming for the PBS had been reviewed and updated, with new content being added regularly. It provided the ANAO with a copy of its *Online Claiming for PBS—New Claims Processing System Reference Manual* (Version 2.1, April 2009).

3.42 Medicare Australia also provided evidence that, during the course of the audit, it had put in place a new national process to follow up suppliers who fail to submit physical prescriptions on time to support their PBS claims.[117]

Nationally consistent training and guidance is being developed

3.43 As similar roles with respect to the PBS are undertaken across state offices, access to nationally consistent training and guidance material would support Medicare Australia staff in undertaking their work to a uniform standard.

3.44 Training has largely been provided 'on-the-job' and delivered by staff from the same state office with prior experience in the work. While some reference material was available online through the eReference database, the operational guidance mainly used is in the form of the locally-developed state office procedures. Some of this guidance had not been kept up-to-date. In general, it was apparent there was no nationally consistent training for staff engaged in PBS operations across state offices.

3.45 Medicare Australia identified a lack of consistency in training materials provided to staff. However, progress to address this has been slow. For example, while an internal audit in 2006 recommended that Medicare Australia implement improved arrangements for training PBS telephony staff to ensure that consistent material is used as the basis for training courses, the content was not due to be finalised until June 2009. Further, a second internal audit looking at Online Claiming for PBS claims processing has identified

[117] Medicare Australia advice, 18 September 2009. The new procedure is dated 9 July 2009. Medicare Australia estimated that, at that time (August 2009), about 30 pharmacies out of a total of 5104 were not submitting their formal claims on time.

inconsistent processing practices and training for service officers as areas for improvement.

3.46 The ANAO had raised the issue of lack of central controls for managing state training for the PBS system in October 2007.[118] Medicare Australia then agreed that State Learning and Development teams would be reporting to a centralised national team and it would put in place consistent state structures to deliver operational training.

3.47 In September 2009, Medicare Australia advised that, although development of a nationally consistent PBS training curriculum is 'an ongoing process', several training modules had been completed.[119] It also advised that on-screen guidance is provided within the new claims processing system and that this ensures all staff processing PBS claims have nationally consistent guidance. This is a significant proportion of PBS work carried out in processing centres around the country.[120]

Conclusion—management structure, procedures and training

3.48 Since the commencement of the audit, Medicare Australia has introduced a new national program delivery model for managing delivery of the PBS. If successfully implemented, this should provide a better focus on management of the program as a whole and provide better co-ordination and consistency across the functional and geographic units involved in its delivery.

3.49 Along with this management change, Medicare Australia has also substantially upgraded its procedural guidance. This should help to address the previous lack of national documentation and dependence on locally-produced (and hence, potentially diverse) guidance observed during the audit. To complement this, Medicare Australia has also taken steps to begin addressing the need for nationally consistent training for PBS processing staff.

---

[118] ANAO, Financial Statements Audit 2006–07, Final Management Letter, p. 15.

[119] Medicare Australia advice, 18 September 2009. It provided a list of completed and updated modules. However, it did not provide a timetable for completion of the process of developing the nationally consistent PBS curriculum.

[120] As well as online claims, CTS and manual claims are also processed in this system.

Recommendation No.2

3.50 Given the previous limited national procedural guidance available to staff, the ANAO recommends that Medicare Australia maintain its current focus under its new national program model to standardise PBS procedural guidance and training materials for operational staff, including appropriate support in the delivery of PBS training.

Medicare Australia response

3.51 **Agree.** PBS procedural guidance for operational staff has been available for several years through Medicare Australia's claim processing system and the eReference intranet system available to all staff. Medicare Australia is progressively developing a complete set of operational training modules designed to ensure national consistency in the delivery of PBS training to staff in all sites. These national training materials replace state-based training materials that have existed for a number of years. A total of thirty operational training modules were identified as being required and twenty-five of these training modules have already been completed and are available for staff to use. The remaining five PBS operational training modules are expected to be completed before the end of 2010.

PBS performance information

3.52 Management generally needs a means of accurately measuring and reporting performance in the delivery of its programs. A sound performance information framework provides, first, a basis for agency accountability, particularly through important documents such as the relevant portfolio budget statement and the agency annual report. Second, performance information is also used as a management tool both to monitor progress and to steer the agency more effectively. Good performance indicators will be clear, precise and relevant, and will address all important aspects of agency performance in delivering the program.

3.53 The ANAO considered Medicare Australia's use of performance information first, at the level of agency accountability and, second, as a management tool.

Medicare Australia's public reporting of performance information

3.54 At the highest level, performance information should reveal whether, and to what extent, a program is delivering what is expected. Medicare Australia states in its Portfolio Budget Statement that its objective in delivering

the PBS is 'to deliver a nationally consistent service with convenient access and timely and accurate payments through efficient service channels, particularly electronic.'[121] In the same document, Medicare Australia specifies three Program Key Performance Indicators (KPIs) but also identifies, separately, other variables by which performance can be assessed as 'deliverables'.

Selection of performance indicators

3.55 The three KPIs identified are:

- percentage online prescription processing (≥ 98 per cent);
- average revenue per PBS service ($0.72);[122] and
- pharmacist satisfaction (≥ 90 per cent).

3.56 Sound performance indicators measure how well the agency is performing against its objectives. However, none of these three indicators can directly provide a measure of timeliness or accuracy of payments, as described in Medicare Australia's program delivery objective, above. Instead, those measures are encompassed in its consideration of 'deliverables' (see below). Further, reporting the percentage of online prescription processing may be of limited ongoing value as take-up has already reached a very high proportion.

3.57 Medicare Australia specifically states in its Portfolio Budget Statement that it performs three distinct major functions in delivering the PBS. An adequate selection of performance indicators would provide some measure of its performance for each of them. Typically, such measures would provide some assessment of quantity, quality (accuracy, customer satisfaction), timeliness and cost.

3.58 Also in the Portfolio Budget Statement, under the heading 'Key Performance Indicators', Medicare Australia states:

> In line with the objective of this program, Medicare Australia will improve the convenience and ease of access to rebates. In addition Medicare Australia will

[121] Medicare Australia Portfolio Budget Statements 2009–10, p. 95.

[122] Medicare Australia has advised (13 November 2009) that this figure of $0.72 was calculated as at 24 April 2009. However, program expenses had been derived by regression from aggregate figures. Timelines prohibited Medicare Australia from taking further late adjustments into account in finalising this figure.

continue to implement process improvement within its operations to increase the efficiency of program delivery.[123]

3.59 It provides projected figures across five years for each of the above KPIs, including that representing processing efficiency, 'average revenue per PBS service.' Despite Medicare Australia's expressed intention to implement process improvement to increase program efficiency, the projected figures are constant—72 cents per service—across all five years. That is, they show no projected improvement or change, indicating that another choice of indicators may better reflect the organisation's expectations.

Other performance indicators identified as 'deliverables'

3.60 In the Portfolio Budget Statement under the heading 'Program 1.2 Deliverables', Medicare Australia also provides forecasts over five years of certain essential activities: the volume of processing (numbers of prescriptions processed) and the numbers of prescription authorities provided. These also include two further items that could be seen as performance indicators: 'accuracy of processing' and 'prompt payment processing'. The performance standards for each of these are, respectively, '98 per cent or above' and '100 per cent' across each of the five years. It is not clear from the context why these are not considered key performance indicators or what the difference is between this set of variables and those listed as KPIs in the Portfolio Budget Statement.

3.61 Medicare Australia has advised that it had set the performance target for promptness of payment (100 per cent) some five years ago when the focus was processing PBS claims paperwork within 17 days of a pharmacy lodging its PBS claim. Now that the majority of community pharmacies use Online Claiming for PBS, it has reviewed its performance indicators.

3.62 In November 2008, revised indicators were set:

- Accuracy of PBS processing—98 per cent of claims processed correctly.
- Timeliness of PBS processing—98 per cent of claims processed within 14 calendar days and the remainder within 17 calendar days.

3.63 In April 2009 DoHA wrote to Medicare Australia seeking a change to the processing requirement for PBS claims set out in the BPA. This request to

[123] Medicare Australia Budget Statements 2009–10, p. 96. The ANAO presumes that the term 'rebate' here refers to payments made by Medicare Australia to pharmacists under the PBS in accordance with the PBS Schedule. Elsewhere it is referred to as a 'subsidy'.

amend the BPA originated with the Pharmacy Guild of Australia. The performance requirement is now to:

- process CTS claims within 17 days of receipt of claim;
- process online claims within 17 days of receipt of claim;
- make advance payments for payable prescriptions transmitted and assessed online within 9 to 16 days from receipt of electronic assessment.[124]

Reporting performance against the Portfolio Budget Statement KPIs

3.64 Agency reporting against stated performance indicators acts as an important accountability measure that informs stakeholders as to an organisation's performance; while also providing an assurance that the agency is aware of its own progress.

3.65 For performance reporting arrangements to work effectively, the items reported should generally be consistent with the performance indicators identified in the earlier Portfolio Budget Statement (see para. 3.55). The *Medicare Australia Annual Report 2008–09* reports KPIs in a 'balanced scorecard'.[125] Of the three indicators nominated in the Portfolio Budget Statement, only pharmacist satisfaction is included as a directly comparable item. The Portfolio Budget Statement also includes information on online processing but it is not clear whether the same measure is being used. It does not include 'average revenue per PBS service' even though, prima facie, it is possible to derive this indicator from other information.

3.66 The balanced scorecard reports 'PBS online take-up—number and percentage of participating pharmacies', with an achieved value for the latter of 97.03 per cent.[126] Prima facie, this relates to the KPI 'percentage online prescription processing' set out in the Portfolio Budget Statement. However, the balanced scorecard table reports 'n/a' against the relevant target whereas the Portfolio Budget Statement provides a target of '≥98 per cent'. It is not clear whether the two measures are of the same variable, as Medicare Australia

[124] Medicare Australia advice, 18 September 2009.

[125] Medicare Australia, *Annual Report 2008–09*, p. 87. See: <http://www.medicare.gov.au/about/governance/reports/08-09/files/annual-report0809-fullversion.pdf> [accessed 11 May 2010].

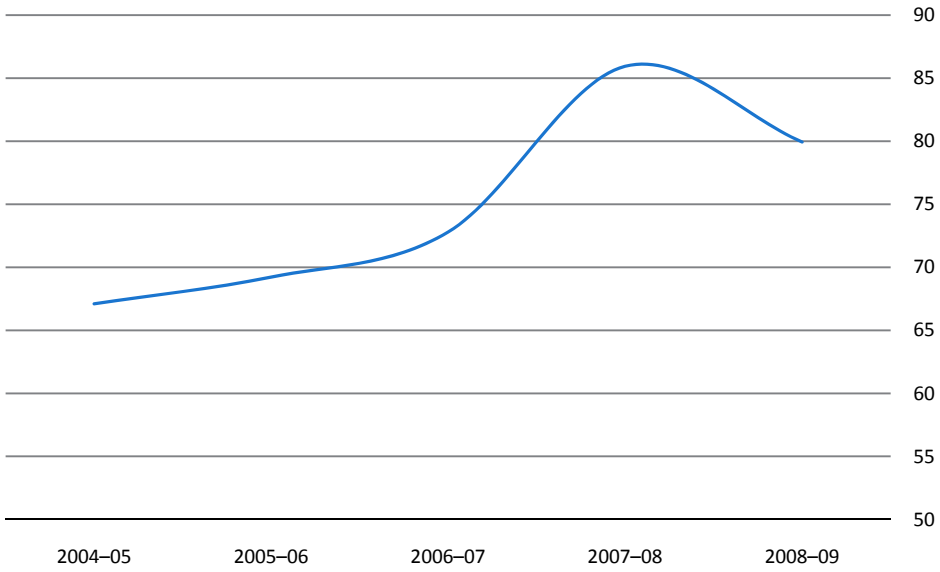
[126] Note: In this case the Annual Report uses the older term 'PBS Online' for *Online Claiming for PBS*.

provides no explanation.[127] Further, the figure it reported in the previous year's balanced scorecard was 99 per cent, but it does not explain in the latest report the decline in performance to 97.03 per cent.

3.67 Although it is not explicitly reported, it is possible to derive a proxy measure of delivery efficiency from the annual cost of Medicare Australia's PBS services (Table 1.1) and the reported number of PBS services delivered. This can be expressed in terms of cents/service (see Figure 3.1, below).

Figure 3.1

Cost of PBS services, by year (cents/service)



Source: ANAO analysis, based on program expenses—Medicare advice (see Table 3.1, above) plus projected expenses for 2008–09; numbers of services a year— statistics obtained from the Medicare Australia website, 10 October 2009 <http://www.medicareaustralia.gov.au/provider/pbs/stats.shtml> [accessed 11 May 2010].

Reporting on deliverables

3.68 The *Medicare Australia Annual Report 2008–09* includes a report on actual accuracy of PBS claim processing (98.3 per cent). This information was

[127] For instance, it is not clear if, in some instances, the focus is on the *proportion of pharmacies* using the system and, in others, the focus is on the *proportion of transactions*.

obscured in the previous report by being included in a more general 'claim processing accuracy' figure that aggregates Medicare and PBS claims.[128]

3.69 Promptness of processing is not included in Medicare Australia's balanced scorecard, despite being listed as a 'deliverable' in its Portfolio Budget Statement, with a target figure. Indeed, the balanced scorecard reports only three variables that relate directly to Medicare Australia's delivery of the PBS. The ANAO has also reviewed evidence of internal reporting, such as in the Operational Performance Report prepared for Medicare Australia's Corporate Management Committee. However, this report also provides information on only a limited number of indicators.[129]

3.70 Medicare Australia advised that it reports on timeliness of processing to DoHA in its BPA scorecard. However, it does not report accuracy of processing as 'this may be considered an internal measure of efficiency.'[130] It is not clear how Medicare Australia reached this view, given that a target for accuracy of processing is set in its Portfolio Budget Statement.

3.71 In response to the questions raised by the ANAO, Medicare Australia has advised that it will:

> review the PBS KPI measures of performance to ensure consistency and appropriateness of each measure in relation to:
>
> - timeliness of authorities processing;
> - accuracy and timeliness in claims processing and payments; and
> - pharmacy approvals (pharmacists, certain doctors, public and private hospitals).

3.72 It has also stated that actual performance reporting for its KPIs will be included in Medicare Australia's annual reports from 2009–10 onwards, consistent with those set out in its Portfolio Budget Statements.

---

[128] <http://www.medicare.gov.au/about/governance/reports/07-08/files/8275-2007-08-ar-complete.pdf>, p. 92. [accessed 11 May 2010].

[129] For example, the Operational Performance Report dated 1 April 2009 details PBS telephony performance by 10 variables, but 'PBS Services' performance is related in two indicators, both relating to the speed of claims processing. The Medicare Australia Corporate Management Committee balanced scorecard reports timeliness and accuracy of processing of PBS claims.

[130] Medicare Australia advice, 9 September 2009.

Medicare Australia's use of performance information as a management tool

3.73 In considering Medicare Australia's use of performance information for management purposes, the ANAO examined:

- *PBS Random Compliance Audits.* As discussed below, Medicare Australia has now discontinued that program and introduced a new approach, Payment Accuracy Reviews (PARs); and
- *Quality Assurance Intervention (QAI) and Quality Assurance Checking (QCI).* These are Medicare Australia's main internal processes for maintaining PBS payment integrity.

PBS Random Compliance Audits

3.74 Medicare Australia formerly conducted random compliance audits of PBS claims to provide assurance of payment integrity and identify threats to that integrity.[131] In providing an assessment of PBS program integrity, Part D of Medicare Australia's *PBS Program Integrity Assurance* report states that:

> Program integrity is currently measured through the use of PBS Random Compliance Audits (RCAs). Payments should only be made in accordance with government policy intent. The Random Compliance Audits *provide an assurance of the proportion of payment[s] which are appropriate and in accordance with policy* [emphasis added].[132]

3.75 A year before Medicare Australia developed this report, DHS had contracted consultants to review Medicare Australia's compliance activities. One objective had been: 'to provide an understanding of the efficiency and effectiveness of Medicare Australia's current approach to compliance and maintaining program integrity'. In contrast with the view reported above, the Review concluded:

> Random Compliance Audits, as currently defined and undertaken by Medicare Australia, are not a valid compliance tool as *they do not ensure that policy intention is being met* nor do they identify sources of, or measure financial leakage (emphasis added).[133]

---

[131] Medicare Australia advised that it ceased using random compliance audits (RCAs) in June 2008. (Medicare Australia advice, 18 September 2009).

[132] Medicare Australia, *PBS Program Integrity Assurance* report, p. 68.

[133] Medicare Australia – *Compliance Review*, September 2006, p. 13.

3.76 The Review found that RCAs did not detect over-servicing, systematic fraud or inappropriate servicing and saw this as a 'significant source of risk to Medicare Australia.' It recommended, with immediate priority: 'Medicare Australia should cease to use RCAs as a compliance tool in their current format.'

> Random Compliance Audits are post payment audits conducted annually to ascertain that MBS and PBS payments were made in accordance with legislation. In 2005–06, 5,294 PBS prescriptions from 127 pharmacies were examined with the audit finding that 99% were supplied, claimed and paid properly. ... While the this type of audit may satisfy accounting standards and be of value in the preparation of financial statements, the Review Team sees little merit in using this type of audit for compliance purposes as it is highly unlikely to detect fraudulent or inappropriate behaviour. This is demonstrated in the results of these audits which consume valuable PRD resources.[134]

RCAs have ceased and Payment Accuracy Reviews (PARs) commenced

3.77 Medicare Australia advised that, after the commencement of the audit, it ceased using RCAs, having recognised their limitations as a compliance tool. In 2008–09 it introduced Payment Accuracy Reviews (PARs).[135] Their purpose is to 'provide an estimate of the overall level of payment accuracy in the administration of the PBS and Medicare programs.'

3.78 To conduct a PAR, Medicare Australia takes a random sample of electronic PBS claims and interviews providers and patients to confirm eligibility and that services took place. It reports that its initial analysis of the PARs over 2008–09 shows that an estimated 0.21 per cent of PBS payments are incorrectly made. This is based on its review of 5377 PBS services.[136]

Quality Assurance Intervention detects errors on a risk basis

3.79 To help ensure program integrity, Medicare Australia staff examine a sample of prescriptions in claims at the time of processing to enable them to verify their validity and detect errors.[137]

---

[134] Medicare Australia – Compliance Review, September 2006, p. 34–5.

[135] Medicare Australia, *Annual Report 2008–09*, p. 106; <http://www.medicare.gov.au/about/governance/reports/08-09/files/annual-report0809-fullversion.pdf>. [accessed 11 May 2010].

[136] Medicare Australia advice, 18 September 2009; Medicare Australia, *Annual Report 2008–09*, p. 106.

[137] Medicare Australia, *PBS Program Integrity Assurance*, January 2008, p. 26.

3.80 A Quality Assurance Intervention (QAI) review starts when Medicare Australia receives a claim. A claim contains the individual prescription forms processed by a pharmacist in a given claim period. The prescriptions selected for review are automatically identified by the New Claims Processing System (NCPS), mostly on the basis of risk characteristics. These include high pharmaceutical values, authority prescriptions, and warning flags.[138] The checking process then carried out is called a 'Quality Assurance Intervention'.

3.81 The officer performing the checking process, the QAI reviewer, compares each of the sampled physical prescriptions with the electronic system data (previously entered by the pharmacy into Online Claiming for PBS) to check that the information has been correctly entered and that the prescription has been completed correctly (for example, that it has been signed, endorsed, has a patient name and Medicare number).

3.82 The objective of the QAI process is to detect errors and correct them. Therefore, where errors that cannot be corrected are detected, the prescription is returned to the supplier and payment for that prescription is rejected.[139]

Quality Control Intervention checks the accuracy of QAI

3.83 Medicare Australia has implemented a follow-on step to monitor the accuracy of the QAI process. This is known as 'Quality Control Intervention' (QCI). QCI works in a similar fashion to QAI, except that it selects a random sub-sample from the prescriptions that have already been reviewed during QAI. A team leader undertakes QCI. As it involves checking the quality of the original QAI decision it can result in the provision of feedback and coaching to the QAI reviewer.

3.84 Medicare Australia conducts QCIs daily on a sample of the previous day's claims. The sample is selected by its NCPS system from among those prescriptions that have been subjected to QAI.

---

[138] The risk-based prescriptions sampled are supplemented by a small number which are randomly selected. For example, the ANAO observed one claim comprising 2773 prescriptions, of which 49 prescriptions were selected for QAI on the basis of risk characteristics and one selected randomly.

[139] In most cases, an early payment in respect of the erroneous case will already have been made. Upon receiving the physical prescription document the pharmacist can attempt to correct any issues and re-submit. Where an early payment for a prescription is found not to be payable, the early payment can be recovered from a subsequent payment.

QAI and QCI methodology

3.85 Medicare Australia's routine monitoring, provided in a monthly *Heart Report*, presents, as a key performance indicator, the QCI error rates and types. However, neither QAI nor QCI provides a basis for reporting accuracy of PBS claims processing:

- QAI, as a risk-based technique, helps Medicare Australia detect and correct prescriptions and claims with errors. Therefore, although it could be a useful tool for controlling errors, it does not provide a basis for assessing accuracy.
- QCI monitors the accuracy of QAI reviewers' work and not the accuracy and validity of prescriptions or claims.

3.86 As a result, Medicare Australia cannot validly gain assurance from the *Heart Report* statistics about the overall accuracy of its prescription processing. For example, if the quality of work done by QAI reviewers were to deteriorate substantially, this should show up in changes to the QCI statistics even if the underlying prescription accuracy were to remain constant.

3.87 To help address the level of assurance that can be gained, a process similar to QAI, but based on random sampling, could be the focus of any assurance reports to management on the effectiveness of overall prescription processing.

3.88 Medicare Australia has acknowledged that it is 'timely to consider undertaking a review, noting the take-up rate of online claiming for PBS and the changes in our operations.'[140]

Assurance of the veracity of pharmacists' claims

3.89 QAI reviews are also undertaken to meet ss 99AAA(8) of the National Health Act, which obliges the Medicare Australia CEO to institute reasonable checks to be satisfied that:

- the information provided by the approved supplier in respect of a claim accurately reflects the information recorded on the prescriptions submitted in support of the claim (Rule 9(a)); and
- the approved supplier is entitled to be paid under the Act or Regulations an amount in respect of the claim (Rule 9(b)).

[140] Medicare Australia advice, 18 September 2009.

3.90 To form a view as to the accuracy of information provided by the approved supplier in comparison with that recorded in the prescriptions requires a comparison with the data collected in Online Claiming for PBS. This is reflected in Medicare Australia's current compliance strategy of taking a 'post-payment approach using risk management techniques to monitor and confirm payment accuracy and integrity.'

3.91 Medicare Australia confirmed that it considers a reasonable check of accuracy of the data supplied by an approved provider is performed by Medicare Australia's QAI process, supported by its other checking processes.[141] QAI identifies prescriptions for checking on a risk basis. That is, not every prescription in a claim is checked against the data supplied by the provider because it is not necessary to achieve reasonable confidence in the accuracy of that data. When such checks as are flagged by the QAI process have been undertaken, a claim that satisfies those checks is considered payable.

Conclusion—performance information

3.92 Medicare Australia's stated objective in delivering the PBS is 'to deliver a nationally consistent service with convenient access and timely and accurate payments through efficient service channels, particularly electronic'.[142] In delivering the PBS, Medicare Australia has three distinct operational responsibilities: approving suppliers of medicines; approving authority prescriptions and processing pharmacists' claims for payment.

3.93 The key performance indicators identified by Medicare Australia in its Portfolio Budget Statement and reported in its annual report do not provide sufficient information with which to assess performance against the program objective nor do they encompass the organisation's three major operational responsibilities in delivering the PBS.[143] This means stakeholders are not able to

[141] Medicare Australia advised that it considers that the system-based checking by its IT system-based assessment engine, QAI, QCI and (selected) payment accuracy reviews in combination provide reasonable assurance that the information provided by approved suppliers in respect of claims accurately reflects the information recorded on prescriptions. The ANAO notes, however, that the checks performed by the assessment engine, although important in detecting invalid claims or other errors, do not verify the data provided by approved suppliers against that written on prescriptions. Prima facie, the processes that substantially perform the ss 99AAA(8) function are QAI and payment accuracy reviews.

[142] Medicare Australia Portfolio Budget Statements 2009–10, p. 95.

[143] The three key performance indicators outlined in the Portfolio Budget Statement are:

- percentage online prescription processing (≥ 98 per cent);
- average revenue per PBS service ($0.72); and
- pharmacist satisfaction (≥ 90 per cent).

ascertain performance in areas such as timeliness and accuracy of payments, consistency of service, and convenience of access. Accordingly, there are opportunities for Medicare Australia to improve its performance information and performance reporting on its delivery of the PBS both at the program and operational levels.

3.94 In relation to Medicare Australia's use of information as a management tool, one important risk to the PBS program is the integrity of claim payments. Medicare Australia's routine monitoring of claims processing involves its well-established Quality Assurance Intervention (QAI) and Quality Control Intervention (QCI) processes. Each of these is a management tool that is used to locate, correct and control errors; however, they do not provide a basis for reporting overall accuracy of PBS claims processing and payments. Medicare Australia has advised that it will review the PBS key performance indicator measures to ensure consistency and appropriateness. In that respect, Medicare Australia's new Payment Accuracy Review process, which examines the PBS process from end-to-end, involving prescribers, pharmacists and patients, is an example of a positive approach to helping gauge the overall accuracy of payments.

Recommendation No.3

3.95 The ANAO recommends that Medicare Australia, when it has completed its review of its key program performance indicators, reports its performance in its annual report for all three of its major responsibilities in delivering the PBS.

Medicare Australia response

3.96 **Agree.** The first opportunity to report on Medicare Australia's new key performance indicators is in its 2009–10 annual report. Medicare Australia will report its performance for all three of its major responsibilities at that time.

Recommendation No.4

3.97 As part of its compliance and integrity framework, the ANAO recommends that Medicare Australia review its Quality Assurance Intervention and Quality Control Intervention methodology to clarify the objectives of these processes and ensure that:

- it is obtaining adequate assurance about the accuracy of its claims processing performance; and
- the processes provide sufficient information to form a view as to the soundness of claims for payment.

Medicare Australia response

3.98 **Agree.** A review of the PBS Quality Assurance and Quality Control processes has been undertaken.

3.99 Medicare Australia considers Quality Assurance Intervention and Quality Control Intervention to be only part of the overall package of measures undertaken to ensure the integrity of PBS claims and payments. Payment Accuracy Reviews are another part of this package designed to form a view as to the soundness of claims for payment by an approved supplier.

4. PBS delivery operations

This chapter examines Medicare Australia's administration of the delivery processes for its three major PBS responsibilities.

Identifying risks in delivering the PBS

4.1 In designing its operations to deliver the PBS, it is reasonable to expect that Medicare Australia will have identified risks to its successful operation, considered whether each of these needs any mitigating treatment, and implemented any necessary controls to limit those risks.

4.2 Although there is no formal risk management plan for delivery of the PBS, the *Pharmaceutical Benefits Scheme: Program Integrity Assurance* report was intended to assess the processes in the administration of the PBS and give an assessment of program integrity for the Medicare Australia CEO.[144] As part of the organisation's governance framework, this report is intended to address the legal and ethical obligations required by government. The document acknowledges that 'Medicare Australia has a responsibility to ensure the integrity of the PBS in order to provide assurance and accuracy in its administration.' However, it notes that the administration of the PBS relies substantially upon voluntary compliance: 'on the ability of prescribers and approved suppliers [generally, pharmacists] to practise within the boundaries of legislation and within the additional rules set out by Medicare Australia.' It concludes that 'Medicare Australia has a suitable level of program controls to assure program integrity'.[145]

4.3 The *PBS Program Integrity Assurance* report states, in respect of the relevant legislation, 'Some of the sanctions to prevent inappropriate practice/ use could be more effective if they provided a greater deterrent'. Medicare Australia advised that it has no legal authority to obtain evidence of the validity of a claim: that is, participation by prescribers is voluntary. The National Health Act does not require a prescriber to provide verifying

[144] Medicare Australia, *Pharmaceutical Benefits Scheme: Program Integrity Assurance*, version 2.0, 22 January 2008. Note that risk management in relation to the delivery of the PBS is considered in Chapter 3.

[145] ibid., p. 6.

documentation as part of a compliance audit and some may refuse to co-operate with a request. It added:

> A number of options to review legislative provisions, increase sanctions and provide for increased compliance activity in relation to the PBS program have been put forward in the context of budget proposals.[146]

4.4 The framework for assuring program integrity is described in the report as providing 'working definitions only' and yet to be formally agreed. The ANAO notes that, although this report identifies and discusses many aspects of program integrity, its main focus is on payments and minimising the risk of fraud and inappropriate payments. The document specifically refers to obligations such as those imposed by the Privacy Act as falling within Medicare Australia's program integrity framework. However, it does not examine other issues such as the security of program data.[147] Medicare Australia advised that its Program Review Division proposes to review the document over 2009–10.[148]

4.5 Taking note of this report, where relevant, the ANAO considered the service delivery process for each of the three functions that Medicare Australia undertakes in delivering the PBS:[149]

- approving pharmacies;
- approving authority prescriptions; and
- claims processing.

Approving pharmacies

4.6 Pharmacists seeking to obtain approval to become approved suppliers of PBS medicines at particular locations can apply to the Secretary of DoHA under section 90 of the National Health Act. Medicare Australia officers make these decisions. Medicare Australia received 426 applications for new or re-located pharmacies in 2007–08 and 388 in 2008–09.[150]

---

146 Medicare Australia advice, 18 September 2009.

147 Medicare Australia, *Pharmaceutical Benefits Scheme: Program Integrity Assurance*, version 2.0, 22 January 2008, p. 9.

148 Medicare Australia advice, 18 September 2009.

149 The report deals only with the latter two items and does not address the process of approving pharmacies.

150 Medicare Australia advice, 18 September 2009.

4.7 The ANAO sought to identify:

- whether Medicare Australia officers have guidance on interpretation of the legal requirements relating to these decisions, since this has a bearing on achieving both correct and consistent decisions; and
- whether Medicare Australia had implemented a suitable compliance regime for this aspect of the PBS.

Limited guidance exists

4.8 The legislative criteria against which pharmacy approval decisions must be made contain a number of explicit limitations on the right of the Secretary to approve applications, an obligation to refer applications to the Australian Community Pharmacy Authority (ACPA), and a restriction that the Secretary can only approve applications recommended by ACPA.[151]

4.9 Medicare Australia state office staff make decisions on applications from pharmacists within their state or territory to become PBS approved suppliers. Approval decisions are aimed at ensuring that applicants have met the objectively specified criteria of the National Health Act, which is framed in terms of eligibility at the time of an approval decision.

4.10 The Act also requires approval decisions to take into account judgments on behalf of the Secretary of DoHA. Examples are whether the proposed pharmacy will be publicly accessible at reasonable times and that the pharmacist can supply pharmaceutical benefits at the proposed premises. Consistent with Medicare Australia's eReference guidance material, state office staff generally check whether pharmacies are ready to commence dispensing and have obtained state pharmacy board approval before approving applications.[152]

[151] The ACPA applies a rules-based merits test of the application and provides a recommendation to the Secretary.

[152] Guidance on some matters is available on Medicare Australia's Intranet site (Medicare Australia Portal) in a database called 'e-Reference'.

4.11 Medicare Australia raised concerns over pharmacy approval arrangements with DoHA in 2008. Medicare Australia was concerned that the respective roles of its decision-makers and ACPA had become blurred.[153]

4.12 Medicare Australia advised that it has obtained legal advice about the factors that its decision-makers should take into account when making an approval decision. The advice notes that it would be reasonable for them to have regard to matters such as:

- the need to ensure that Australians can gain access to pharmaceutical benefits under the PBS without having to travel long distances and in a setting that is convenient and accessible for them;
- the desirability of maintaining a viable and competitive community pharmacy sector in the interests of consumers; and
- the desirability of minimising inappropriate disruption to the commercial interests of other pharmacists when a relocation is planned.

4.13 Medicare Australia has advised that it sees 'significant benefits' in taking a national operations approach to pharmacy approvals:

> This function is an area of national focus with the Operations Division undertaking work to consider the nationalisation of the approvals function. This will assist in ensuring greater consistency across this function. Training in decision-making for delegates is also planned for the 09–10 year.[154]

4.14 Achieving consistency in decision-making is likely to be challenging in circumstances where officers in multiple locations across states are trying to make nationally consistent approval decisions in accordance with the National Health Act. They each need to consider and be personally satisfied about pharmacy accessibility, readiness to operate and policy considerations relating to the viability and competitiveness of pharmacists. The national operations approach now proposed by Medicare Australia is, in part, intended to help ensure consistency.

---

[153] The Australian Community Pharmacy Authority (ACPA) is an independent statutory authority established under section 99J of the *National Health Act 1953* (the Act). The role of the ACPA is to consider applications for approval to supply pharmaceutical benefits under section 90 of the Act and make recommendations to the Secretary as to whether or not an application should be approved. The final decision, however, remains with the Secretary.

[154] Medicare Australia advice, 18 September 2009.

Monitoring of approved suppliers' on-going compliance

4.15 The National Health Act also provides discretionary powers to cancel an approval if a pharmacy is not operating from the approved location or is not accessible to the public at reasonable times.[155]

4.16 Medicare Australia advises that it acts on communication from the public or other pharmacies in relation to pharmacy access concerns. However, this has occurred rarely and only in 'very unusual circumstances.' Therefore, compliance is not perceived as a risk and there is no formal compliance mechanism for state offices to monitor and assess whether approved suppliers are meeting operating and accessibility requirements on an ongoing basis. Medicare Australia operates on the assumption that pharmacies are driven by commercial viability and that it is in a pharmacy's interests to be open at times when it will attract business.

4.17 At the national level, PBB conducts monthly monitoring through a 'low volume' report. This ensures that approved suppliers are active in supplying pharmaceutical benefits. The report identifies approved suppliers who have lodged less than ten claims (scripts) for each of the past two months.[156] Medicare Australia states that it analyses the data to identify any who may have ceased trading and takes appropriate action.

Approving authority prescriptions

4.18 Some medicines in the PBS Schedule are listed as 'authority-required'. This means that prescribers must seek approval from Medicare Australia before prescribing them.[157] Some medicines always require this pre-prescribing approval, while others do so only where the dosage or quantity is in excess of that specified in the PBS Schedule. Medicare Australia refers to this as 'the opportunity ... to ensure that the prescriber is aware of the requisite criteria ... for their patient to be legally eligible for PBS subsidy of their medication.'[158] Approvals are available over the telephone or via a written request to

[155] Subsection 98(3) of the *National Health Act 1953*.

[156] Medicare Australia did not state the basis on which it selected this number of scripts as a threshold for follow-up.

[157] They can prescribe these medicines without authority but the prescription will not then attract a PBS payment.

[158] Medicare Australia, *PBS Program Integrity Assurance*, January 2008, p. 16.

Medicare Australia and the details of any approvals given by Medicare Australia are recorded in its authority-required approvals database.

4.19 Since 1 July 2007, certain authority-required PBS items, have been labelled 'Authority required (STREAMLINED)' medicines and, for these medicines, the prescriber needs only to place an authority code, listed in the PBS Schedule on the prescription.

4.20 Where a prescriber prescribes a dose or strength of medicine that does not match the dose or strength approved by Medicare Australia, as recorded in the authority-required database, the Online Claiming for PBS processing system may select that prescription for QAI review by Medicare Australia officers.

Authority-required prescriptions not properly checked

4.21 During fieldwork the ANAO observed Medicare Australia's claims checking processes and noted that where the quantity of a medicine supplied did not match the quantity approved by Medicare Australia, as recorded in its authority-required database, it was normal practice to change the authority-required database to reflect the amount supplied, in order to progress payment.

4.22 In one example, the ANAO observed the processing of an authority-required prescription that involved the supply of a narcotic. The PBS prescription had been flagged for QAI review as the number of tablets that had been supplied (200 tablets) exceeded the amount recorded in the Medicare Australia authority-required database as authorised (150 tablets).

4.23 During the QAI review process, the reviewing officer checked Medicare Australia's authority approval database, which recorded that 150 tablets had been approved with no repeats. The information submitted via Online Claiming for PBS by the pharmacist listed 50 tablets and three repeats (200 tablets in total). The QAI reviewer considered the electronic information and the physical prescription and inferred that the approval was probably intended to cover 50 tablets and two repeats. The QAI reviewer then amended the Medicare Australia authority-required database to reflect the actual amount dispensed, being 200 tablets.

4.24 There are a number of potential problems that the processing of this prescription raises. The first is that the authority-required database was amended to reflect the actual amount supplied. There would be no further routine review of this by Medicare Australia.[159]

4.25 Secondly, the pharmacist dispensed the original and all repeats at the same time, an amount sufficient for greater than the maximum permitted one month's supply. This was also done even though Online Claiming for PBS warned the pharmacist of the mismatch, and the doctor had explicitly indicated on the physical prescription to 'dispense fifty tablets per ten days'.[160]

4.26 The ANAO was advised by PBS claims processing staff that amendments to authority system records are made when they are unable to determine whether a prescriber had made an error or the Medicare Australia telephony officer providing the approval had incorrectly recorded the approval in the authority recording system. Accordingly, Medicare Australia officers did not necessarily enforce the requirement for a prescription of an authority medicine to be in line with the record of approval.

4.27 If Medicare Australia is to ensure that the government's requirements for authority-required medicines are appropriately managed it must be able to ensure that its officers make valid and consistent decisions and record them correctly. Where QAI staff change the information in the authority-required database to enable payment for a supply to be made, this has a potential to diminish the integrity of the authority-required element of the program. Specifically, program integrity is affected if approvals are not being enforced because there is doubt about the reliability of the information being recorded by Medicare Australia or if officers are simply not enforcing the approval given. There are also obvious risks from failing to react to or manage observed dispensing of potentially hazardous quantities of medicines.

---

[159] The ANAO raised this with the Program Review Division, who indicated they do not specifically examine the extent or appropriateness of such events.

[160] The PBS Regulations do allow for either the prescriber or the approved supplier to dispense more than once from a prescription at a single time, subject to conditions outlined in Regulation 24 and 25. However, this is only where immediate supply is required and noted on the prescription by the pharmacists. In this case the pharmacist did not write on the prescription. Supply of 200 tablets of a narcotic is, at best, a suspicious occurrence.

4.28 Medicare Australia stated that:

> [It] acknowledges that there is a risk (albeit minimal) where a phone authority is incorrectly transcribed by the Medicare Australia operator.

4.29 It did not provide any estimate of the size of this risk. It went on:

> In these instances, the pharmacy would dispense the item as written on the script. The pharmacy (if using Online Claiming for PBS) would receive a warning message to alert them that the authority details do not match those stored by Medicare Australia. In these instances the pharmacy would re-check the information on the prescription and, if correct, over-ride the warning message. When the prescription is received by Medicare Australia it would come up for QAI where the operator would check the prescription details versus that on our systems. Where there is a mismatch our details would be changed. This process is to ensure that both pharmacist and patient are not disadvantaged.[161]

4.30 This does not, however, necessarily address the possibility of a prescriber making an error. The ANAO suggests that an appropriate level of risk-based monitoring in this area would enable Medicare Australia to identify any patterns of behaviour yielding persistent 'errors' from prescribers so that it could target education on these matters.

A nationally consistent quality control program is planned

4.31 Medicare Australia's *PBS Program Integrity Assurance* report states that:

> Plans are underway to implement a nationally consistent QC program to guarantee high quality of PBS authority approvals. The program will be based on a model that has been implemented in Queensland.[162]

4.32 Medicare Australia advises that this initiative has been 'included within the PBS Continuous Data Quality Improvement Action Plan 2009–10 as a new initiative.' Further, the action plan has been endorsed and timelines for deliverables will be established shortly.

[161] Medicare Australia advice, 18 September 2009.

[162] Medicare Australia, *PBS Program Integrity Assurance*, January 2008, p. 46.

Processing pharmacists' claims for payment

4.33 The major element among Medicare Australia's PBS delivery responsibilities is paying pharmacists' claims after they have dispensed PBS medicines. Claims processing relies on a combination of automated and manual processes.

4.34 In June 2009, 5099 pharmacies (comprising about 97 per cent of community pharmacies) were claiming online, facilitating early payment.[163] Some 98.2 per cent of prescriptions are lodged online out of a total of about 190 million a year. State office staff use manual processes to make decisions on a range of routine operational activities including:

- reviewing PBS claims submitted by pharmacists—in 2008–09, some 3.56 million QAI reviews were undertaken;[164] and
- processing PBS Safety Net claims—in 2008–09, 1 017 817 Medicare card holders (encompassing 1 517 511 patients) received PBS Safety Net benefits.[165]

4.35 The ANAO considered the primary stages of the process leading to payment and subsequent action, including:

(a) original entry of the prescription details into Online Claiming for PBS;

(b) payment by Medicare Australia; and

(c) submission of the formal claim by the pharmacist.

(a) Prescription details are almost all entered into Online Claiming for PBS

4.36 Online Claiming for PBS allows pharmacists to lodge a request for early payment with Medicare Australia through the Internet at the time of supplying a PBS medicine. When supplying the PBS medicine, pharmacists enter details of the physical prescriptions presented by patients into their pharmacy

[163] Minister for Human Services, Address to the Australian Pharmacy Professional Conference, Gold Coast, 3 April 2009.

[164] An IT system supports the review of PBS claims by Medicare Australia staff. This IT system automatically selects the specific prescriptions from within a pharmacy claim for review by a Medicare Australia officer. During the review process officers can access context-specific on-screen help and guides.

[165] Data for these and the preceding item supplied by Medicare Australia, 1 December 2009. PBS Safety Net cards are issued by pharmacists, who then are required to provide supporting documentation to Medicare Australia. Medicare Australia then manually enters the details into its system.

dispensing system[166] together with any patient concessional entitlement information. This sends a transaction to Medicare Australia, whose systems then perform a preliminary online integrity check (for example, under its New Claims Processing System it verifies a patient's concessional status by checking against Centrelink records). Medicare Australia returns a message to the pharmacist advising whether the claim will be payable under the PBS. There may also be a need to correct an error or omission. The pharmacist then supplies the medicine to the patient.[167]

4.37 Later, pharmacists must submit the physical prescriptions to Medicare Australia to allow for the substantiation of the prescription early payments. This is accompanied by a signed formal claim for payment.[168]

4.38 Online Claiming for PBS was created to replace manual claims submission and processing with the objective of addressing pharmacies' requests for better and faster ways to claim and be paid. It also streamlines administration within Medicare Australia and the health sector. Before Online Claiming for PBS, most pharmacists sent in monthly claims for payment to Medicare Australia on floppy disks. Since Online Claiming for PBS became available to most pharmacies in March 2007, it has been widely and quickly adopted.[169]

Concessional Entitlement Validation

4.39 Concessional Entitlement Validation (CEV) was implemented in July 2004 to allow pharmacists to undertake an online real-time check of a patient's concessional status while processing a prescription. At the time the initiative was announced in the 2003–04 Budget,[170] the measure was expected to produce net savings of $30.7 million over four years.

4.40 With the introduction of Online Claiming for PBS, CEV became integral to data entry. Figure 4.1 shows:

---

[166] Pharmacists enter the information into a computer system, which is owned and operated by themselves, that has been certified by Medicare Australia as suitable for connection to the Medicare Australia PBS systems. This is done over the Internet.

[167] Medicare Australia, *PBS Program Integrity Assurance*, January 2008, p. 21.

[168] Ibid., p. 25–9.

[169] Approximately 97 per cent of pharmacists were registered as *Online Claiming for PBS* users as at June 2009; most of the balance continue to submit claims using floppy disks, with a small number of suppliers submitting paper based claims.

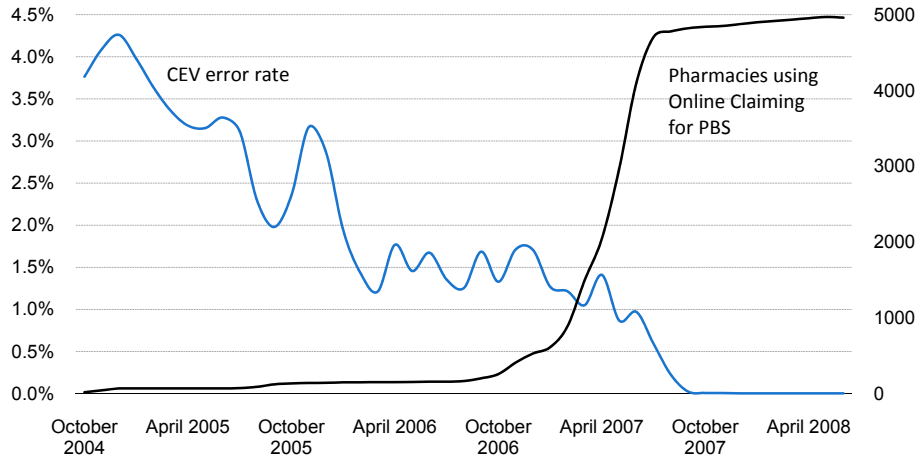
[170] Budget Paper 2, 2003–04, Expense Measures, pp. 192–3.

- the CEV error rate (percentage of cases paid by Medicare Australia for the supply of medicines on concessional scripts when—as revealed by later checking—no concessional entitlement existed at the time; against
- the take-up of Online Claiming for PBS by approved suppliers.

4.41 Access to concessional information online is associated with a decline in CEV error rates, with the rates dropping by half even before the widespread adoption of Online Claiming for PBS from March 2007. The error rate declined further when online entitlement checking was incorporated into Online Claiming for PBS.

Figure 4.1

CEV error rates and the take-up of Online Claiming for PBS



Source: ANAO analysis of Medicare Australia-supplied data.

4.42 Understanding and measuring the effect of policy changes is important to ensuring accountability, program evaluation, and supporting continuous improvement of program delivery. However, Medicare Australia does not monitor the savings outcomes. Therefore, while a correlation is apparent between the increase in Online Claiming for PBS and the decrease in the CEV error rate, the ANAO could not establish whether Medicare Australia had achieved the savings anticipated by the 2003–04 Budget initiative.

4.43 DoHA stated that it reports to the Department of Finance and Deregulation annually on the achievement of savings according to an agreed

reporting methodology.[171] However, DoHA provided no evidence to support this, nor any evidence as to the savings calculated or realised.

4.44 The ANAO notes that while introducing the CEV feature has been successful in reducing inappropriate access to concessions, it has not been expanded to assist in ensuring that eligible recipients are informed of their concession entitlement. This is an opportunity for an agency in the Human Services portfolio to improve customer service.

4.45 Medicare Australia advised that it received concession data from Centrelink (an agency in the same portfolio) to verify a person's eligibility via their entitlement number:

> PBS Online [*Online Claiming for PBS*] was not built with the functionality of informing a person of their concessional entitlement, nor is this Medicare Australia's responsibility. In the context of the PBS, it is a person's responsibility to prove their entitlement to the pharmacy so that claim can be made to Medicare Australia.[172]

Medicare Australia pays pharmacists to enter prescription data

4.46 Under the 4CPA the Minister for Health and Ageing agreed to pay pharmacists 40 cents per prescription processed through Online Claiming for PBS. This commenced on 1 July 2007 and ceases when that agreement terminates, on 30 June 2010.[173] As noted earlier, a major reason for developing Online Claiming for PBS was in response to pharmacies' requests for better and faster ways to claim PBS benefits. It is not clear, however, what the basis is for paying an incentive payment for pharmacists to use a facility that they had sought in the first place. DoHA advised that the incentive payment was 'a negotiated outcome of the PBS Reform process and is a policy matter for further consideration by government.'[174]

4.47 Medicare Australia advised that it had made incentive payments of $55 million in 2007–08 and $87.8 million in 2008–09 to pharmacies under the 40 cent incentive payment scheme, a total of $142.8 million. It also advised that

---

[171] DoHA advice, 22 September 2009.

[172] Medicare Australia advice, 18 September 2009.

[173] Fourth Community Pharmacy Agreement, section 20.1. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-4cpa> [accessed 11 May 2010]. See also: http://www.budget.gov.au/2010-11/content/bp2/html/bp2_expense-13.htm [accessed 12 May 2010].

[174] DoHA advice, 22 September 2009.

it has saved a cumulative $2.3 million in reduced salaries and associated on-costs through the use of Online Claiming for PBS from 2006–07 to 2008–09.

Payments to pharmacists include amounts for other tasks during dispensing

4.48 Following the Third Community Pharmacy Agreement (December 2002) pharmacists began to be paid for supplying Community Medicine Information (CMI) to patients.[175] The rate was 10 cents per PBS prescription. There was also a 'readiness' payment of $3000 per pharmacy paid in 2001 to help pharmacists to meet the set up costs associated with providing CMI.[176]

4.49 Since the 4CPA, the CMI fee has been included in the dispensing fee paid by Medicare Australia to pharmacists. However, there has been widespread concern among pharmacists' organisations that this provision of CMI is not being done consistently by pharmacists.[177]

4.50 Medicare Australia advised that it does not monitor this process nor is it funded to do so. Moreover, it also stated that 'it would not be possible to have an ongoing monitoring process in place and, in any event, would be extremely costly.'[178]

4.51 Medicare Australia also pointed out that CMI payments, as with all payments under the 4CPA, 'would be under review during negotiations for the Fifth Community Pharmacy Agreement.'

4.52 There are risks in making a payment for services to be provided at public expense and not having a means to ensure that the services being paid for are consistently and properly carried out. It would be prudent for DoHA to

---

[175] The Pharmaceutical Society of Australia has specified professional standards for the provision of CMI. These hold that CMI should generally be provided: when a medicine is first provided to a consumer; on provision of a medicine where a significant change to the CMI has been notified by the sponsor or where the dosage form has been changed; with each supply of medicine for which there are valid reasons for regular reinforcement of information. For example where the patient has special needs or where there are major contraindications for use of the medicine; when the patient requests the information; and at regular intervals for medicines used for long term therapy.

[176] Department of Health and Ageing, Therapeutic Goods Administration, *Second Discussion Paper: Improving access to Consumer Medicines Information (CMI) and Product Information (PI)*, January 2007; available at: <http://www.tga.gov.au/meds/accesspmi2.htm> [accessed 21 July 2009].

[177] For example, Australian Pharmacy Council, 'CMI's—The Patient has a right to know', press release, September 2008; <http://www.pharmacycouncil.org.au/PDF/Media%20Release%20Consumer%20Medicine%20Information.pdf>; Pharmaceutical Society of Australia, *Ask for a CMI with your next prescription*, Media Release: 7 March 2006 <http://www.psa.org.au/site.php?id=227> [accessed 11 May 2010].

[178] Medicare Australia advice, 18 September 2009.

take account of this in providing advice to government in finalising the Fifth Community Pharmacy Agreement.

Risks to the security of patient information recorded by pharmacists

4.53 Entry by pharmacists of patient data into their computers when dispensing medicines poses a risk to the privacy and security of that data. Privacy of this information is governed by the National Privacy Principals in the *Privacy Act 1988*. However, much of pharmacists' processing of patient data could be viewed as being carried out to meet PBS program requirements. Therefore, the ANAO considered whether there may be a consequential risk to the Commonwealth of exposure.

4.54 Pharmacists enter prescription data into a local computer in their pharmacy using one of several commercial pharmacy dispensing software packages. These packages are designed to help them manage their business and perform functions such as stock control to maintain necessary medicines on the pharmacy premises. These software packages have also been amended to facilitate the operation of Online Claiming for PBS, in particular, the transmission of information to Medicare Australia, and to enable verification processes to take place at data entry.[179]

4.55 Data communications between each pharmacy and Medicare Australia is encrypted. However, the data entered by the pharmacist can also—and is likely to be—recorded on their pharmacy computer system. This enables pharmacists to maintain records of their dealings with individual patients and facilitates work they perform for the Commonwealth, such as identifying patients who may qualify for Safety Net provisions.

4.56 Most pharmacists recorded personal information on their computer systems before Online Claiming for PBS was introduced.[180] The National Health Act allows them to record Medicare numbers and expiry dates either to meet a request to fill a prescription or to 'facilitate the supply of pharmaceutical benefits at a later time or times'.[181] Recording of this data is

[179] In relation to Online Claiming for PBS, the Commonwealth has provided both software vendors and pharmacists with various incentives to: amend software packages (Software Vendor Assistance Payments – up to $2000 lump sum payment for software installation at each pharmacy and up to $200 per month for 24 months to provide maintenance support); adopt PBS Online (Online Claiming Incentive – 40 cents per script processed) and maintain business grade broadband internet connections (Pharmacy Connectivity Incentive).

[180] Medicare Australia advice, 18 September 2009.

[181] National Health Act, s. 86D.

permitted, however, only with the authorisation of the person providing the Medicare number (being the person seeking to have the prescription filled).[182]

4.57 The Pharmacy Guild of Australia has produced Computer Security Self-Assessment Guidelines for Community Pharmacies. Additionally, under 4CPA, DoHA has funded the Quality Care Pharmacy Program. The Commonwealth provides a financial incentive for pharmacies to implement this voluntary program, which includes an information technology quality standard that covers aspects of information security.[183] However, this standard is not sufficient to provide meaningful assurance that patient information is adequately protected. This is because an assertion by the pharmacy is all that is required to meet aspects of certification to this IT Standard. The standard requires no testing by an independent assessor.[184]

4.58 Agencies have not sought any assurance from pharmacists on these matters, either in connection with the quality care pharmacy program or otherwise. Medicare Australia advised the ANAO:

> It is the responsibility of pharmacists to implement basic computer and network security controls (e.g. Firewalls, anti-virus, internet protection) in using PBS Online. Medicare Australia recommends the use of internet protection tools such as virus and firewall protection in its documentation about PBS Online. Medicare Australia is not in a position to mandate the use of these type of controls to pharmacists.[185]

4.59 When asked their respective positions on the security of patient records on pharmacy computer systems, both Medicare Australia and DHS advised that they were 'not responsible for the privacy and security of data entered by the pharmacist onto their computer system.'[186] Medicare Australia 'does not

---

[182] Medicare Australia's *PBS Program Integrity Assurance* report does not mention this process of recording patient data.

[183] 'Standard 18—Information Technology', see <http://www.guild.org.au/qcpp/content.asp?id=777>. [accessed 11 May 2010].

[184] A clause in Standard 18 is 'Maintain and follow systems to minimise the potential for external attack on computers (e.g. viruses, worms, spyware). The Pharmacy Guild Implementation and Rulings guide states: Question—'Does a pharmacy have to show the assessor the installed computer programs used to protect against potential external attack?' [Answer:] 'The 'evidence required at assessment' requires an explanation only for the systems the pharmacy uses. The assessor is not required to sight evidence of installed programs.' See: <http://www.guild.org.au/uploadedfiles/Quality_Care_Pharmacy_Program/Standards/Implementation.pdf> [accessed 11 May 2010].

[185] Email advice from Medicare Australia to the ANAO, 16 September 2008.

[186] Medicare Australia, advice of 18 September 2009; DHS, advice of 14 September 2009.

accept that any risk to patient information recorded by pharmacists is a risk owned by Medicare Australia.'[187] Further, it ensures that pharmacists and patients are aware of the relevant information privacy rules through a privacy note printed on the reverse side of prescription forms and its regular mechanism for providing information to pharmacists.

4.60 DoHA, as policy owner of the PBS program, when asked how it gains assurance that this aspect of the National Health Act is administered soundly, advised that:

> DoHA considers that this issue is addressed through:
>
> - professional pharmacy practice management;
> - privacy legislation constraints on the use of and confidentiality of data; and
> - Medicare Australia's PBS Online registration requirements relating to technical encryption and data protection requirements.

4.61 Nonetheless, given that, in general, IT security continues to be an area with growing threats, it would be prudent for agencies to explicitly address this issue. This could be achieved by clarifying the arrangements and the respective responsibilities during the pharmacy approval process.

Improving customer service: advising customers when they reach the PBS Safety Net Threshold

4.62 The PBS Safety Net helps patients who need a large number of medicines by reducing the co-payment after they reach a threshold of personal (or family) expenditure on PBS medicines in a calendar year.[188]

4.63 Patients are required to keep a record of their expenditure on PBS medicines and seek to register for the PBS Safety Net, through a pharmacist, when they believe they have qualified. Keeping track of relevant information to support this process is likely to be a particular challenge for those patients who use more than one pharmacist during a calendar year, including those that do so because they have moved residence.

---

[187] Medicare Australia advice, 18 September 2009.

[188] In 2010, once a general patient has spent $1281.30 on PBS medicines the co-payment is reduced from $33.30 to $5.40. For a concession card holder, the threshold is $324 and once a patient has reached that level the co-payment is reduced from $5.40 to $0.

4.64 Between 83 288 and 144 075 patients who were eligible for the Safety Net did not apply in the 2007.[189] These people paid between $6.1 million and $10.8 million more than they would have, had they been Safety Net-registered.

4.65 Medicare Australia does not capture every medicine purchase that might count toward the Safety Net Threshold, such as those which do not attract a PBS payment.[190] Therefore, without capturing further data, it cannot necessarily identify in all cases the time when a patients' expenditure makes then eligible for the Safety Net. Medicare Australia is also not required to advise patients that they have reached or are approaching the threshold.

4.66 Medicare Australia advised that it has developed the capacity to enable the displaying of a person's/families' PBS data online. This was to provide the public with secure information allowing them to view their PBS claims history. However, it has not activated this function. One reason is that around 20 per cent of PBS expenditure is not captured because that proportion of prescriptions is for medicines that attract no subsidy. Therefore it could not display information that is necessarily complete and timely for Safety Net purposes.

4.67 An automated safety net function could be introduced if Medicare Australia were provided with data on the supply of under co-payment prescriptions. This is a matter that DoHA has had under notice for some years.[191] The Minister for Health and Ageing and the Pharmacy Guild agreed in 2005 to make 'all reasonable efforts' to facilitate the online collection and recording of relevant data on PBS prescriptions supplied by community pharmacies that are priced below the patient co-payment, and also agreed that

[189] Medicare Australia data. Care should be taken when interpreting the data. To develop a Safety Net entitlement estimate it was necessary for Medicare Australia to make some assumptions about persons that might have been entitled to participate in the Safety Net based on the spending of their family unit. Accordingly, three methods were used to identify potential family units including: persons linked to the same Medicare card, persons linked to a Centrelink concession card, and a third method that blended information from both. The figures are provided as a range that reflects the highest and lowest estimates.

[190] This may occur in relation to scripts for medicines that have a price that is equal to or less than the applicable patient co-payment.

[191] See, for example, 'Consultancy in Electronic Prescribing and Dispensing of Medicines (ePrescribing)', Final Report, June 2008, pp. 67–8. http://www.health.gov.au/internet/main/publishing.nsf/Content/80B878329CD34C6ACA25715700229B28/$File/DOHA08-ePrescribing%20report-Final290708.pdf [accessed 11 May 2010].

the appropriate mechanism is Medicare Australia's Online Claiming for PBS system.[192]

4.68 Even without the supply of under co-payment data to Medicare Australia and the development of an automated safety net mechanism, Medicare Australia currently has the capacity to identify many patients who have become eligible for the Safety Net but who have not sought to register, potentially through a lack of information. That is, Medicare Australia could use the data that has been submitted via the Online Claiming for PBS system to calculate eligibility. From this data, it could identify eligibility with certainty for those patients whose PBS expenditure—above the co-payment level—has exceeded the threshold, and advise them of their eligibility. This would not require any change in data collection arrangements.

4.69 Recognising that it would likely require policy consideration and some cost, customer service could be improved, consistent with the outcomes of this aspect of the program, if patients who are known to have satisfied Safety Net eligibility are advised, even if, for practical reasons, this advice can only be given later than might ideally be desired.

Recommendation No.5

4.70 The ANAO recommends that Medicare Australia and DoHA examine how the PBS system and data capture arrangements could be enhanced to enable patients to be advised when they have reached the PBS Safety Net Threshold, and advise government on options.

DoHA response

4.71 **Disagree.** The Department does not agree with Recommendation 5. As previously advised in Departmental responses to the ANAO dated 22 September 2009 and 15 January 2010, the matter of an automated safety net is a policy issue with significant program design and cost implications and is a matter for Government to consider. Medicare Australia is not required to collect the data necessary to enable automated safety net calculations and

[192] Fourth Community Pharmacy Agreement, November 2005, section 39.1, p. 25. See: <http://www.health.gov.au/internet/main/publishing.nsf/Content/pharmacy-4cpa> [accessed 11 May 2010]. The Online Claiming for PBS system was then referred to by its former name, 'PBS Online'. The Fifth Community Pharmacy Agreement (signed on 3 May 2010) requires pharmacists to provide to the Commonwealth certain data on PBS prescriptions priced below the general patient co-payment. This agreement commences on 1 July 2010 and terminates on 30 June 2015. See: http://www.guild.org.au/uploadedfiles/National/Public/Community_Pharmacy_Agreement/Fifth%20Agreement%20Document%20signed.pdf [accessed 12 May 2010].

consequently it is not currently relevant to Medicare Australia's administration of the PBS.

Medicare Australia comment

4.72 As Medicare Australia has previously advised the ANAO, this is a policy matter for the Department of Health and Ageing to consider. Currently, Medicare Australia is not required to collect all the relevant data. Medicare Australia is in a position to provide advice to the Department of Health and Ageing should it be called upon to do so.

ANAO comment

4.73 Introducing a fully automated safety net facility would require policy consideration and involve a cost. However, using the information currently collected by Medicare Australia to help patients to identify their eligibility for the PBS Safety Net would be consistent with the reason for having a safety net, the service delivery reform agenda within the Human Services portfolio and the reforms proposed in '*Ahead of the Game–Blueprint for the Reform of Australian Government Administration*', concerning delivering better services for citizens.

4.74 The ANAO notes that, in the 2010–11 Budget, the Australian Government announced an initiative to collect certain data on pharmaceuticals which are priced below the PBS general co-payment.[193]

(b) Medicare Australia pays pharmacists mostly by early payment

The claim process

4.75 Pharmacists now submit almost all claim data online by a secure link each time a pharmacy dispenses a PBS medicine. Medicare Australia assesses each transaction electronically against PBS rules and for patient entitlement validation. It returns a message to the pharmacist advising whether the claim is payable and alerting them to any apparent error or omission, with a reason code. This gives the pharmacist an opportunity to correct errors or omissions and resubmit the data. Medicare Australia then pays the pharmacist for the great majority of the claims whose data has been submitted electronically.

4.76 Periodically, pharmacists must submit to Medicare Australia the paper prescriptions for each medicine dispensed. Although Medicare Australia's own advice states that this is for 'audit and verification' it is, in fact, the formal

[193] See: http://www.budget.gov.au/2010-11/content/bp2/html/bp2_expense-13.htm [accessed 12 May 2010].

claim process.[194] By the time it receives the formal claim Medicare Australia will already have paid most claims. These are strictly 'early payments' on the basis of the checking process performed by Online Claiming for PBS.

4.77 The way in which pharmacists claim PBS payments from Medicare Australia and how the latter then pays them is specified by the National Health Act (s. 99AAA) and in rules set out in writing by the Minister for Health and Ageing under that section of the Act. The specified claim process sets out what information must be provided, its format and whether a particular item is mandatory or optional.[195]

4.78 The entry of information into Online Claiming for PBS is not, formally, a claim process. It provides the data and facilitates early payment of pharmacists, but it must be followed by the formal claim or the payment can be recovered.[196] Medicare Australia advised that it had:

> used words interchangeably between the online activity and the formal process involving the receipt of the supporting paperwork. To our knowledge this hasn't caused confusion although we appreciate that to an outsider greater clarity may be desirable.
>
> The word 'claiming' is currently being used to describe both the provision of electronic information which results in the making of advance payments and the subsequent submission of claims information and original prescriptions etc. ...
>
> Pharmacists consider that they are making an online claim when they send prescription data to us and receive a response advising them whether the claimed prescription is payable. This process results in an advance payment being sent for payable prescriptions transmitted and assessed online within 9 to 16 days lag time from receipt of electronic assessment.

---

[194] See, for example, the information page on Online Claiming for PBS on Medicare Australia's website: <http://www.medicareaustralia.gov.au/provider/pbs/online/index.jsp> [accessed 17 November 2009].

[195] Commonwealth of Australia, *National Health Act 1953*, Pharmaceutical Benefits Rules under Subsection 99AAA(8); No. PB 49 of 2008. The National Health Act also provides for the Secretary to make rules ('terms and conditions ... in writing') under which early payments can be made to pharmacists for the supply of PBS medicines (Instrument No. CEO-SEC-NHA-DEL1/09). It has been delegated to two Deputy Chief Executive Officers, the General Manager, PBS and Aged Care Programs, the Manager, Pharmaceutical Benefits Programs, and the Manager, Program Delivery, Pharmaceutical Benefits Programs. Medicare Australia advises that the power has not been exercised by any of the Medicare Australia officers to whom the power has been delegated (18 September 2009).

[196] See para.4.94 et seq. for further discussion of this.

4.79 There are risks in the developing difference between how Medicare Australia presents operational claiming practice and its legal underpinning. For example, if pharmacists consider that they are making actual claims online they are less likely to attribute importance and priority to the later submission of prescriptions to Medicare Australia even though this is, in fact, the formal claim and legally necessary.

4.80 One option to address this risk may be for Online Claiming for PBS to become the formal claim process for PBS payments. The ANAO suggests that Medicare Australia and DoHA conduct an analysis of the risks, costs and benefits of this course. Subject to this analysis, agencies could then advise government on options to formalise the process, including any necessary legislative amendment.

System-based business rules are applied in the claim process

4.81 A feature of Online Claiming for PBS is that it applies business rules during the dispensing of medicines by the pharmacist, and gives immediate feedback, such as:

- confirming concessional entitlement eligibility; and
- identifying inconsistencies in the prescription details as provided by the patient to the pharmacist at the time of dispensing.

4.82 In this way, Online Claiming for PBS allows for some pre-processing validation to occur at the time medicines are dispensed, which enables early detection and correction of errors and omissions. Medicare Australia addresses other integrity and validity problems when the physical prescriptions are submitted.

Some system-generated errors can be overridden

4.83 During the Online Claiming for PBS dispensing process, pharmacists can be presented with errors and/or warnings if the data submitted has triggered a business rule that has not been satisfied. Errors stop the processing of a prescription for PBS purposes and require the pharmacist to enter a change or correction into the system for prescription pre-approval. In contrast, warnings require a pharmacist to review a piece of information and, subject to the pharmacist's review, can be overridden by the pharmacist at their discretion.

4.84 The Online Claiming for PBS system is currently configured to show warnings where, prima facie, errors might be more appropriate (see box

below). For example, under the prescribed rules set by the Minister for Health and Ageing, the prescriber number is a mandatory item to be submitted. However, under the current system, failure to provide it or provision of an invalid or non-existent prescriber number does not necessarily prevent the claim transaction.

Prescription processing warnings which can be disregarded by a pharmacist

W 043 – The prescriber number was not provided

W 044 – The prescriber number provided was invalid

W 095 – The prescriber number provided does not exist

W 108 – The Medicare number provided has expired

W 130 – The safety net number is no longer valid

W 131 – The safety net number has been cancelled

W 154 – Prescriber number does not match to authority approval

W 155 – Patient details provided do not match authority approval

W 158 – Quantity provided is greater than the quantity for this authority approval

W 162 – Item provided does not match to the authority approval

W 184 – The public hospital provider number provided is invalid or does not exist

W 232 – The Medicare number provided has been reported lost and cancelled

W 318 – Authority request has been pended and not approved by Medicare Australia.

W 319 – Authority request has not been approved by Medicare Australia.

4.85 A prescription can be entered into Online Claiming for PBS and have an invalid prescriber name and number, and trigger system warnings only. The pharmacist can then subsequently supply the PBS medicine to the customer and register the prescription in Online Claiming for PBS.

4.86 The ANAO identified an example of this during fieldwork, which, when reviewed by a state office staff member, was approved. This was consistent with the on-screen guidance provided to the Medicare Australia reviewing officer, which instructed officers to approve the claim if the information provided on the physical prescription matched the information submitted by the pharmacist on the Online Claiming for PBS (or old CTS)

system. In this case the reviewer was not required to consider whether the prescriber's details were valid, just that the physical prescription matched the electronically submitted details. When examined by the ANAO the prescriber details were not valid.

4.87 Medicare Australia advised that:

> It needs to be acknowledged that there are some situations where it is appropriate for pharmacies to have the capacity to ignore a warning message and submit a prescription for review and/or take action to address the warning message. One example is where the pharmacy has what is a seemingly valid prescription for an authority required item, but they have received a warning that prior authority approval has not been granted for the item prescribed.[197]

4.88 Medicare Australia informed the ANAO that a review of warning messages, conducted jointly with DoHA, has now been completed and 'relevant changes implemented'. The detail of those changes, however, was not provided as part of that advice.[198]

4.89 Medicare Australia does not automatically flag some overridden warnings for further review.[199] For example, based on a 2001 agreement between DoHA and the Pharmacy Guild, prescriptions will not be rejected where there is a mismatch between the patient's first name on their Medicare card and that on their prescription. Currently, if a prescription has a mismatch for either or both of the patients' first and surname, the system will issue a warning. As pharmacists are able to override warnings and supply PBS medicines when both the patient's first name and surname does not match with their Medicare card number; this creates a risk to prescription validity.

4.90 There were no routine processes that would identify, investigate or correct this situation. Such occurrences do not trigger a referral of a prescription-specific incident for Medicare Australia compliance staff investigation, and it is unlikely that the particular prescription would be identified through routine analysis.

---

[197] Medicare Australia advice, 13 January 2010.

[198] Medicare Australia advice, 13 January 2010.

[199] Targeted reviews are part of an intervention/quality assurance processes used by Medicare Australia. The ANAO found that some warnings are not automatically selected for targeted review. There is, however, a possibility that some of these prescriptions may be selected for intervention amongst the very small proportion of prescriptions in each claim that are targeted on a random basis.

4.91 More generally, Medicare Australia did not have in place any processes for the systematic monitoring of the occurrence of warning and error codes at a state or national level, nor is there any trend analysis undertaken.

4.92 Medicare Australia had earlier advised that:

> it has looked at behaviours of pharmacists that could lead to non-compliance and may use warning or rejection codes as a way of identifying pharmacies who appear to have poor claiming practices. Our data mining tool for the PBS also examines some of the rejection codes which may indicate practices which appear to be different and potentially non-compliant. We are currently conducting a review of the PBS online assessing rules and warning/rejection codes to identify areas that may assist with the routine identification of specific non-compliant behaviours.[200]

4.93 DoHA has advised the ANAO that a further review of warning/ rejection codes will be listed for consideration by the successor to the Online Claiming for PBS Implementation Working Group, the PBS Forum. This forum comprises representatives of DoHA, Medicare Australia and the Pharmacy Guild.

(c) Pharmacists submit their formal claims for payment after receiving early payment

4.94 The Minister's rules for submitting and processing formal claims for payment to Medicare Australia include the following requirements:

- Claims may relate only to benefits supplied over a claim period not exceeding 35 days. This is a mechanism that promotes more manageable claim sizes for processing and regular reconciliation and lodgement of prescriptions by approved suppliers.
- Claims must be substantiated through the provision of a claim form and supporting prescriptions not more than 30 days after the last day of the claim period. This requirement is important because:
  - Medicare Australia can only verify the correctness of early payments and undertake its quality assurance processes once pharmacists have submitted physical prescriptions; and

[200] Medicare Australia advice, 18 September 2009.

– the early payment made to pharmacists is approved during the later physical claim processing, making it a payment.

4.95 There is only limited scope for these rules to be set aside, and these circumstances require active consideration of other factors by the Medicare Australia CEO or delegate.[201] In particular, Medicare Australia can process claims received after the 30 day period only where the CEO is satisfied that a pharmacist was unable, through circumstances outside their control, to comply with this requirement.

4.96 When the physical claim documentation is processed by Medicare Australia staff the claim becomes approved, and accordingly the advance payments, generally made from 9 to 16 days after submission of the electronic prescription by pharmacists, become approved.

4.97 However, the PBS claims processing system examined by the ANAO did not show the number of days that had passed since the claim period ended. During audit fieldwork Medicare Australia staff advised that a claim received more than 30 days after the last day of the claim period receives the same treatment as a claim submitted on time. There are no mechanisms to consider whether a late submission is due to 'circumstances beyond the control of the approved supplier' nor an opportunity to record details of how the 'CEO of Medicare is satisfied' of such.

4.98 There are currently no system enforced business rules to quarantine or reject claims that fail to meet these legislative criteria. Further, there are no warnings in the Online Claiming for PBS system to alert staff to claims that do not conform with either requirement. Consideration of the validity of claims against these requirements is not routinely a part of Medicare Australia's claims processing.[202]

4.99 The risk associated with this absence of processing controls is highlighted by the following example: in one instance discovered by a state office, a pharmacist had been using the same claim period for eight months (rather than the required maximum of 35 days) during which 12 000 prescriptions had been supplied.

---

[201] See subsections 3(d), (e) and (f) of *National Health Act 1953—Rules under subsection 99AAA(8)*.

[202] Reports available to Medicare Australia staff do not provide sufficient information to enable this analysis. While one report suggests that it may provide some information for this analysis, closer examination indicated that this was not the case as the information was mislabelled; in particular, information in this report labelled, 'claim received date', is instead the date the claim period started.

Medicare Australia has not followed through on its legal advice about late claims

4.100 In November 2007, Medicare Australia state office staff advised PBB that some pharmacists were failing to submit physical prescriptions supporting their claims. State offices had contacted some of these pharmacists and requested the submission of the required documentation. However, in the absence of national guidelines, state office approaches to this problem have been inconsistent.

4.101 PBB subsequently obtained internal legal advice and commenced forming a framework for addressing the late submission of claims and failure to lodge claims documentation. The legal advice was that, by not lodging documentation to substantiate claims in line with the legislated timeframe, any early payments made relating to these claims would be invalid and the early payments should be recovered as debts to the Commonwealth.

4.102 In August 2008 the PBB asked each state to provide a list of overdue claims, which the branch then collated. The resulting report identifies 47 approved suppliers with over $6 million in outstanding claims (an average of almost $70 000 per supplier listed). However, state offices used different criteria to generate their lists and the information PBB collected was incomplete.

4.103 During the audit, it became apparent that the Online Claiming for PBS reporting system could not produce a report of outstanding claims. This meant that Medicare Australia could not quantify the number and value of unsubstantiated claims. Also, as the new Online Claiming for PBS system could not identify late claims during processing, there was no opportunity for the CEO (or delegate) to give the required consideration to factors that would allow processing past the prescribed period.[203]

4.104 Medicare Australia has advised that the new claims processing system can now generate a 'Claim Paper Receipt Overdue' report. Further, it advises that state processing centres regularly monitor pharmacy claiming to follow up where paperwork has not been received.

4.105 Medicare Australia has also advised that, after consultation, it has now implemented a revised process to address the problem of pharmacies failing to

[203] This is because the IT system does not record claim period end dates or any approvals Medicare Australia has given to vary the number of days in claim periods.

lodge their PBS claims as required by the law.[204] The process involves three steps:

- a telephone call to the pharmacy in the first instance to advise them that their paperwork is outstanding and advise them of the legislative requirement to lodge their claims paperwork;
- following the telephone call, a Notice of failure to lodge supporting documentation for PBS claims letter is sent. The pharmacy will have 21 days to lodge the outstanding claims paperwork;
- if the claims paperwork is not received at the end of this period (21 days from date of letter) a second letter, Final Notice prior to recovery action: failure to lodge supporting documentation for PBS claims paid will be sent to the pharmacy. The pharmacy will then have 14 days to lodge the supporting documentation for their PBS claims prior to recovery action being taken.[205]

4.106 Medicare Australia advised that at August 2009, there were 'approximately 30 pharmacies that had outstanding paperwork for their Online Claiming for PBS claims.' A consequence of the outstanding paperwork is that the legislative basis of the formal claim for payment itself is also missing.

Conclusion

4.107 The process of approving pharmacies to supply medicines is governed by legislative criteria. However, only limited operational guidance exists to support Medicare Australia staff in their decision making role, which increases the risk of inconsistent processes and decisions. The process of approving and monitoring the ongoing compliance of suppliers of PBS medicines could be improved through enhancing the guidance material for decision-makers. In that respect, the process should benefit from Medicare Australia's recent adoption of a national program delivery model and the consideration it is giving to nationalising this particular function.

4.108 In observing Medicare Australia quality assuring dispensed authority prescriptions, the ANAO noted a practice of adjusting Medicare Australia's authority approval records to accord with the medicines actually dispensed in cases where there was a mismatch. This has risks of failing to react to, or

[204] The procedure is dated 9 July 2009.

[205] Medicare Australia advice, 18 September 2009.

manage, evidence of incorrect dispensing of medicines. Medicare Australia advised that it intends to address this issue through its nationally consistent quality control action plan, which it has recently endorsed.

4.109 The method for processing claims has changed in recent years with the introduction of the Online Claiming for PBS system. The very high take-up of the system (approximately 97 per cent of pharmacists are using the system) has allowed Medicare Australia to streamline its capture of claims data. This improves efficiency through, for example, providing a facility to verify patient entitlement to claim a concession.

4.110 In examining the processes supporting the Online Claiming for PBS system, the ANAO also identified risks associated with pharmacists' capacity to override a range of prescription processing warnings. Medicare Australia advised that jointly with DoHA, it has recently completed a review and implemented changes.

4.111 There is a widely-established practice among dispensing pharmacists of storing patient data on their pharmacy computer system. The use of these systems is also a necessary practice in accessing the Online Claiming for PBS system.[206] IT security, in general, continues to be an area of growing threats. The recording and retention of patient data on pharmacists' systems is a pharmacist's responsibility, however, if the data were to be compromised this could present a reputation risk to the Commonwealth. In this respect, Medicare Australia advised that its responsibilities extend only to the security of the transmission of data from the pharmacy to its own system (transmissions are encrypted). DoHA advised that it is satisfied that security at the pharmacy is maintained by professional pharmacy practice management and the requirements of privacy legislation. Nonetheless, taking account of risks to reputation and public confidence in key processes, it would be prudent for the agencies to explicitly address this issue, for example, through clarifying the arrangements and respective responsibilities during pharmacy approval processes.

[206] In relation to Online Claiming for PBS, the Commonwealth has provided both software vendors and pharmacists with various incentives to: amend software packages (Software Vendor Assistance Payments—up to $2000 lump sum payment for software installation at each pharmacy and up to $200 per month for 24 months to provide maintenance support); adopt PBS Online (Online Claiming Incentive—40 cents per script processed by a pharmacist) and maintain business grade broadband Internet connections (Pharmacy Connectivity Incentive).

4.112 The PBS Safety Net helps patients who require a large number of medicines by reducing the co-payment after they reach a threshold of personal (or family) expenditure on PBS medicines in a calendar year. Medicare Australia has the capacity to identify patients who have become eligible for the Safety Net but who have not sought to register, potentially through a lack of information. In the 2007 calendar year, these patients paid between $6.1 million and $10.8 million more than they would have, if they had been registered for the Safety Net. It would improve customer service and help achieve the outcomes of the program if Medicare Australia were to advise patients in these circumstances, even if, for practical reasons, this advice can only be given later than might ideally be desired due to some expenditure being on medicines that do not attract a PBS subsidy. Recognising that to implement such a change would require policy consideration and involve some cost, Medicare Australia and DoHA would first need to examine options and provide advice to government.

Ian McPhee
Auditor-General

Canberra ACT
24 May 2010

Series Titles

ANAO Audit Report No.1 2009–10
Representations to the Department of the Treasury in Relation to Motor Dealer Financing Assistance
Department of the Treasury
Department of the Prime Minister and Cabinet

ANAO Report No.2 2009–10
Campaign Advertising Review 2008–09

ANAO Audit Report No.3 2009–10
Administration of Parliamentarians' Entitlements by the Department of Finance and Deregulation

ANAO Audit Report No.4 2009–10
The Management and Processing of Annual Leave

ANAO Audit Report No.5 2009–10
Protection of Residential Aged Care Bonds
Department of Health and Ageing

ANAO Audit Report No.6 2009–10
Confidentiality in Government Contracts – Senate order for Departmental and Agency Contracts (Calendar Year 2008 Compliance

ANAO Audit Report No.7 2009–10
Administration of Grants by the National Health and Medical Research Council

ANAO Audit Report No.8 2009–10
The Australian Taxation Office's Implementation of the Change Program: a strategic overview

ANAO Audit Report No.9 2009–10
Airservices Australia's Upper Airspace Management Contracts with the Solomon Islands Government
Airservices Australia
Department of Infrastructure, Transport, Regional Development and Local Government

ANAO Audit Report No.10 2009–10
Processing of Incoming International Air Passengers
Australian Customs and Border Protection Service

ANAO Audit Report No.11 2009–10
Garrison Support Services
Department of Defence

ANAO Audit Report No.12 2009–10
Administration of Youth Allowance
Department of Education, Employment and Workplace Relations
Centrelink

ANAO Audit Report No.13 2009–10
Major Projects Report 2008–09
Defence Materiel Organisation

ANAO Audit Report No.14 2009–10
Agencies' Contract Management
Australian Federal Police
Austrade
Department of Foreign Affairs and Trade

ANAO Audit Report No.15 2009–10
AusAID's Management of the Expanding Australian Aid Program
AusAID

ANAO Audit Report No.16 2009–10
Do Not Call Register
Australian Communications and Media Authority

ANAO Audit Report No.17 2009–10
Audits of the Financial Statements of Australian Government Entities for the Period Ended 30 June 2009

ANAO Audit Report No.18 2009–10
LPG Vehicle Scheme

ANAO Audit Report No.19 2009–10
Child Support Reforms: Stage One of the Child Support Scheme Reforms and Improving Compliance

ANAO Audit Report No.20 2009–10
The National Broadband Network Request for Proposal Process
Department of Broadband, Communications and the Digital Economy

ANAO Audit Report No.21 2009–10
Administration of the Water Smart Australia Program
Department of the Environment, Water, Heritage and the Arts
National Water Commission

ANAO Audit Report No.22 2009–10
Geoscience Australia

ANAO Audit Report No.23 2009–10
Illegal Foreign Fishing in Australia's Northern Waters
Australian Customs and Border Protection Service

ANAO Audit Report No.24 2009–10
Procurement of Explosive Ordnance for the Australian Defence Force
Department of Defence

ANAO Audit Report No.25 2009–10
Security Awareness and Training

ANAO Audit Report No.26 2009–10
Administration of Climate Change Programs
Department of the Environment, Water, Heritage and the Arts
Department of Climate Change and Energy Efficiency
Department of Resources, Energy and Tourism

ANAO Audit Report No.27 2009–10
Coordination and Reporting Australia's Climate Change Measures
Department of Climate Change and Energy Efficiency
Department of Innovation, Industry, Science and Research

ANAO Audit Report No.28 2009–10
The Australian Electoral Commission's Preparation for and Conduct of the 2007 Federal General Election

ANAO Audit Report No.29 2009–10
Attorney–General's Department Arrangements for the National Identity Security Strategy

ANAO Audit Report No.30 2009–10
Management of the Strategic Regional Program/Off-Network Program
Department of Infrastructure, Transport, Regional Development and Local Government

ANAO Audit Report No.31 2009–10
Management of the AusLink Roads to Recovery Program
Department of Infrastructure, Transport, Regional Development and Local Government

ANAO Audit Report No.32 2009–10
Management of the Overseas Owned Estate
Department of Foreign Affairs and Trade

ANAO Audit Report No.33 2009–10
Building the Education Revolution—Primary Schools for the 21st Century
Department of Education, Employment and Workplace Relations

ANAO Audit Report No.34 2009–10
The Management and Use of Double Taxation Agreement Information Collected Through Automatic Exchange
Australian Taxation Office

ANAO Audit Report No.35 2009–10
Administration of the Superannuation Co-contribution Scheme
Australian Taxation Office

ANAO Audit Report No.36 2009–10
Emergency Management and Community Recovery Assistance in Centrelink
Centrelink
The Department of Families, Housing, Community Services and Indigenous Affairs

ANAO Audit Report No.37 2009–10
Lightweight Torpedo Replacement Project
Department of Defence

ANAO Report No.38 2009–10
Campaign Advertising Review July 2009 - March 2010

Current Better Practice Guides

The following Better Practice Guides are available on the Australian National Audit Office website.

Innovation in the Public Sector	
Enabling Better Performance, Driving New Directions	Dec 2009
SAP ECC 6.0	
Security and Control	June 2009
Preparation of Financial Statements by Public Sector Entities	June 2009
Business Continuity Management	
Building resilience in public sector entities	June 2009
Developing and Managing Internal Budgets	June 2008
Agency Management of Parliamentary Workflow	May 2008
Public Sector Internal Audit	
An Investment in Assurance and Business Improvement	Sep 2007
Fairness and Transparency in Purchasing Decisions	
Probity in Australian Government Procurement	Aug 2007
Administering Regulation	Mar 2007
Developing and Managing Contracts	
Getting the Right Outcome, Paying the Right Price	Feb 2007
Implementation of Programme and Policy Initiatives:	
Making implementation matter	Oct 2006
Legal Services Arrangements in Australian Government Agencies	Aug 2006
Administration of Fringe Benefits Tax	Feb 2006
User–Friendly Forms Key Principles and Practices to Effectively Design and Communicate Australian Government Forms	Jan 2006
Public Sector Audit Committees	Feb 2005
Fraud Control in Australian Government Agencies	Aug 2004
Better Practice in Annual Performance Reporting	Apr 2004
Management of Scientific Research and Development Projects in Commonwealth Agencies	Dec 2003

Public Sector Governance	July 2003
Goods and Services Tax (GST) Administration	May 2003
Building Capability—A framework for managing learning and development in the APS	Apr 2003
Administration of Grants	May 2002
Performance Information in Portfolio Budget Statements	May 2002
Some Better Practice Principles for Developing Policy Advice	Nov 2001
Rehabilitation: Managing Return to Work	June 2001
Building a Better Financial Management Framework	Nov 1999
Building Better Financial Management Support	Nov 1999
Commonwealth Agency Energy Management	June 1999
Controlling Performance and Outcomes	Dec 1997
Protective Security Principles (in Audit Report No.21 1997–98)	Dec 1997