



Western Australian Auditor General's Report

Pharmaceuticals: Purchase and Management of Pharmaceuticals in Public Hospitals

Report 7 – June 2012





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**Office of the Auditor General
Western Australia**

7th Floor Albert Facey House
469 Wellington Street, Perth

Mail to:

Perth BC, PO Box 8489
PERTH WA 6849

T: 08 6557 7500

F: 08 6557 7600

E: info@audit.wa.gov.au

W: www.audit.wa.gov.au

National Relay Service TTY: 13 36 77
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WESTERN AUSTRALIAN AUDITOR GENERAL'S REPORT

**Pharmaceuticals:
Purchase and Management of Pharmaceuticals
in Public Hospitals**

Report 7
June 2012



**THE PRESIDENT
LEGISLATIVE COUNCIL**

**THE SPEAKER
LEGISLATIVE ASSEMBLY**

PHARMACEUTICALS: PURCHASE AND MANAGEMENT OF PHARMACEUTICALS IN PUBLIC HOSPITALS

This report has been prepared for submission to Parliament under the provisions of section 25 of the *Auditor General Act 2006*.

Performance audits are an integral part of the overall audit program. They seek to provide Parliament with assessments of the effectiveness and efficiency of public sector programs and activities, and identify opportunities for improved performance.

The information provided through this approach will, I am sure, assist Parliament in better evaluating agency performance and enhance parliamentary decision-making to the benefit of all Western Australians.

A handwritten signature in black ink, appearing to read 'C. Murphy'.

COLIN MURPHY
AUDITOR GENERAL
13 June 2012

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Auditor General's Overview

Pharmaceuticals are used in the care, treatment and prevention of illnesses. They range from paracetamol used to ease minor aches and pains, to prescription drugs for ongoing health conditions such as blood pressure and cholesterol, to specialised drugs for treatment of cancers.

Our public hospitals, through their pharmacies, purchase and use pharmaceuticals on a large scale. It is estimated that hospitals spend \$200 million a year on the purchase of thousands of different types of pharmaceutical products. They purchase their pharmaceuticals from companies that spend millions of dollars each year researching and developing drugs, but also on education and promotion of the use of their pharmaceutical products.

Pharmaceutical companies commonly offer to cover travel and other costs of public hospital staff to attend conferences and seminars relating to their products and research. Both public hospital staff and ultimately their patients benefit from this knowledge transfer. However, in allowing staff to accept sponsored travel from private companies, the Department of Health must carefully manage any perceived or real conflicts of interest that may arise when purchasing pharmaceutical products from these companies.

Hospitals must also ensure that the pharmaceutical products these buy are not accessed and used for anything other than authorised patient care. This is particularly important for pharmaceuticals that are associated with addiction and abuse. Unauthorised access and use of pharmaceuticals is illegal for good reason. It not only has a financial impact on hospitals, but more importantly, it can jeopardise the health and safety of users, or in the case of a medical practitioner, anyone under their care.

In this audit we looked at the Department of Health's management of pharmaceutical purchasing, as well as how they minimise the risk of unauthorised access and abuse of pharmaceuticals in their public hospitals. We found that the Department of Health pharmaceutical procurement process and practice had a number of weaknesses. These commonly related to poor documentation of purchasing decisions and poor management of potential conflicts of interest.

We also found that hospitals were not effectively managing all risks associated with access and use of pharmaceuticals. There are effective controls in place to prevent unauthorised access and use in hospital wards, however weaknesses in other areas and instances of non-compliance with mandated controls mean it is still too easy for pharmaceuticals to go missing and for losses to go undetected.

While the Department of Health has made some progress in addressing issues, this audit highlights that more remains to be done.

Executive Summary

Overview

Public hospitals spend millions of dollars each year purchasing pharmaceuticals for patient care. The purchases are governed by government policies that aim to ensure they achieve value for money, give suppliers fair access to government procurement opportunities and demonstrate transparency and accountability. Compliance with the policies also provides assurance to Parliament and taxpayers that public money is spent appropriately. We examined pharmaceutical purchasing to see if it met these standards.

Pharmaceuticals that are purchased by hospitals must be carefully managed to prevent unauthorised access and use. They can be dangerous and some are strongly associated with addiction and abuse. The risks arising from unauthorised access and use of hospital pharmaceuticals are significant and include:

- financial loss to the hospital through theft
- theft leading to illicit sale and distribution of pharmaceuticals
- hospital staff working while under the influence of pharmaceuticals, which is a risk to patient care
- health and social impacts of illicit drug use and addiction
- pharmaceuticals not being available for legitimate patient care.

We assessed how well the Department of Health (WA Health) and six of its hospitals manage pharmaceutical purchasing and how well they control the risks of unauthorised access and use. We tested pharmaceutical purchases for the period between October 2010 and September 2011, and assessed purchasing controls and access to pharmaceuticals through to March 2012.

Conclusion

Controls over WA Health's pharmaceutical purchasing are weak. Because of this there is a risk that purchases may not represent value for money, be transparent and accountable or promote open and effective competition for suppliers.

WA Health has implemented controls to address some of the risks associated with unauthorised access and use of pharmaceuticals. However, some key controls are absent or ineffective. These weaknesses mean there is still an unacceptable risk that pharmaceuticals could be subject to unauthorised access and use.

Key Findings

- Poor controls over pharmaceutical purchasing mean that we cannot give assurance that purchases always represent value for money, are transparent and accountable and demonstrate open and effective competition. Specific weaknesses we found were:
 - Hospital purchasing procedures and practice do not always clearly align with government and Department of Health policies.
 - A significant number of the pharmaceutical purchases examined failed to meet government procurement standards. The most common weakness was failing to adequately document purchasing decisions.
 - Hospitals could make better use of the purchasing system iPharmacy, to help purchasing officers comply with policies.
 - Some aspects of purchasing contract management have been poor.

- Potential conflicts of interest connected with pharmaceutical purchasing are not managed well. This means there is a risk that purchasing decisions could be, or could be perceived to be, inappropriately influenced, however we found no evidence that this had occurred:
 - Hospitals did not have reliable information to identify and manage conflict of interest risks arising from gifts and benefits provided by pharmaceutical companies to hospital employees. In December 2011 the Department of Health implemented a revised policy that clarifies and emphasises staff obligations for reporting acceptance of gifts. The Department is still to finalise its revised policy on acceptance of travel sponsorships. These sponsorships represent the bulk of the benefits received.
 - Two hospitals did not have a formal, documented process to review and approve their officers' choice of pharmaceuticals. No hospital ensured that potential conflicts of interest were identified each time a new pharmaceutical product is selected or recommended for approval.
 - Potential conflicts of interest were not recorded in the October 2011 'refresh' of the common use contract for pharmaceutical products.
- Many key controls have been implemented in hospitals, particularly in patient care areas, and in administering pharmaceuticals to patients. However, some control deficiencies remain, which mean there is still an unacceptable risk of unauthorised access and use of pharmaceuticals:
 - Hospital processes for taking receipt of pharmaceutical deliveries from suppliers were not well controlled.
 - There was no clear guidance for staff on how to measure and account for liquid pharmaceuticals, which may lead to both under and over reporting of losses.
 - Some of the processes used to destroy and dispose of pharmaceuticals were not well controlled.
 - Monitoring of patient care area compliance with regulations and policies was inconsistent and not comprehensive.
- The quantity of addictive and abuse-prone pharmaceuticals that go missing from public hospitals is estimated to be less than 0.04 per cent. Although WA Health investigated each loss, the investigations were not always transparent, making it difficult to determine if all instances of unauthorised access and use were identified:
 - It was not always clear on what basis WA Health made conclusions about the causes of pharmaceutical losses, although documentation of reasons has improved since May 2011.
 - There was limited guidance material available to assist staff to conduct effective investigations.
 - Only 20 per cent of the pharmaceutical losses we examined were reported to the WA Police as required by regulation.
 - WA Health's analysis of whether specific individuals are associated with multiple pharmaceutical losses is limited.

What Should Be Done?

WA Health should:

- ensure relevant stakeholders, such as hospital pharmacies, policy owners, system administrators and contract managers, work together to review and improve policies, procedures, contract management, system controls and staff training to ensure government purchasing standards are met for pharmaceutical procurements.
- Improve its management of conflict of interest risks by:
 - ensuring it has a robust system to enable accurate reporting on the nature and extent of gifts and benefits received by its officers. This includes effective implementation of their new gifts policy and introduction of the revised travel policy
 - implementing independent review of pharmaceutical selection that identifies potential conflicts of interest
 - embedding conflict of interest declarations into all key decision-making processes that impact pharmaceutical purchasing.
- Address control weaknesses in hospitals' management of pharmaceuticals by:
 - improving controls when hospitals take initial receipt of pharmaceuticals associated with addiction and abuse, and ensure these processes are included in its revised compliance monitoring program
 - revising its compliance monitoring activities for patient care areas to ensure there is a coordinated strategy that is comprehensive and avoids unnecessary duplication
 - clearly instructing hospitals on how to measure liquid pharmaceuticals, and decide how to assess liquid pharmaceutical losses
 - formally assessing the costs and benefits of different technology options, such as security card locks, automated dispensing machines and CCTV, to control and record access to pharmaceuticals.
- Improve its reporting of investigations and follow up of pharmaceutical losses by:
 - clearly documenting how it determines the cause of pharmaceutical losses
 - giving more consideration to trends in relation to the individuals who have access to pharmaceuticals when losses occur
 - adhering to its new reporting protocol with the WA Police to ensure every pharmaceutical discrepancy is reported
 - implementing its recently revised policy regarding reporting and investigation of pharmaceutical discrepancies.

Agency Response

The Audit has identified some control weaknesses but the Department is pleased that the OAG has not identified evidence of wrong doing regarding the selection and purchasing of pharmaceuticals.

The Department is concerned that some clinical staff employed in hospitals are alleged to have received gifts that have not been declared. However the Audit did not find evidence of subsequent influence on pharmaceutical purchases, hence there is no evidence of associated wrong doing and it is noted that audit testing of purchases was prior to the introduction of the Department's new policy and controls dealing with the acceptance of gifts.

The Department will be further examining these occurrences where clinical staff have accepted gifts and if proven will undertake all necessary disciplinary action. The Department also notes that our safe storage of pharmaceuticals and our controls over the administration of pharmaceuticals to patients were found to be safe and secure.

Background

WA Health, through its hospitals, spends hundreds of millions of dollars each year on pharmaceutical products. Between October 2010 and September 2011, public hospitals spent more than \$205 million on pharmaceutical products. They made more than a quarter of a million orders from more than 250 different suppliers in that period.

There are 19 public hospitals that currently purchase pharmaceuticals. These hospitals also purchase on behalf of approximately 135 public health care sites across Western Australia (WA). The three largest metropolitan hospitals purchase nearly three quarters of all pharmaceuticals. (Figure 1.)

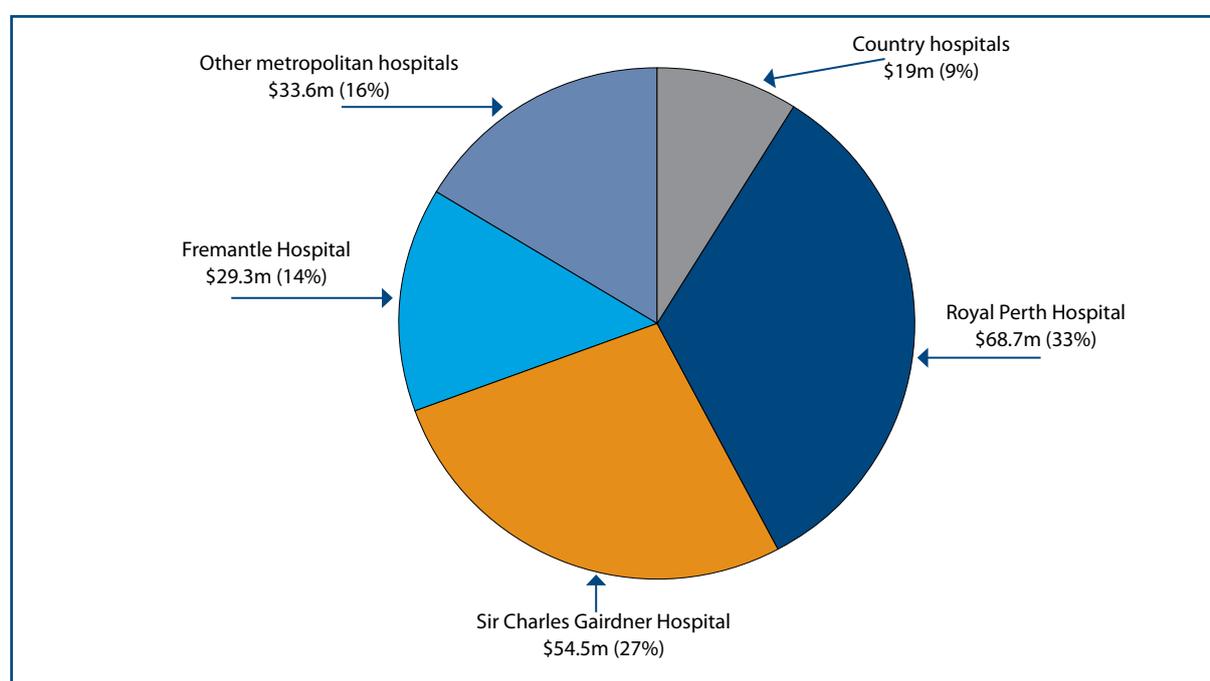


Figure 1: Value of hospital pharmaceutical purchases from October 2010 to September 2011. Total value was more than \$205 million

Agency procurement, including pharmaceutical purchases by public hospitals, must meet the procurement policies set out by the State Supply Commission (SSC). Agencies must be able to demonstrate that their expenditure of public money is consistent with key policy principles, such as:

- achieving value for money
- providing open and effective competition for suppliers
- ensuring probity and accountability, including good management of conflicts of interest.

The *Supply of Pharmaceutical Products to Western Australian Public Health Care Units* (Pharmaceutical Products) contract came into effect in October 2010 following a competitive process to ensure value for money. Public hospitals are required to buy from the suppliers listed in the contract when they purchase any pharmaceutical products listed in the contract.

Most purchasing by WA Health is overseen by the Health Corporate Network (HCN). However, pharmaceuticals are purchased directly by hospital pharmacies using a system called iPharmacy, which HCN do not oversee. HCN's involvement in pharmaceutical procurement is limited to payment of invoices. At the time of our audit there were nearly 10 000 different products listed on iPharmacy. About 750 of these pharmaceutical products are included in WA Health's Pharmaceutical Products contract. The products not included on the contract are generally those under patent or those that are expected to cost less than \$10 000 a year.

Most pharmaceuticals are defined under legislation as poisons in Western Australia. The *Poisons Act 1964* and the *Poisons Regulations 1965* regulate the access, handling, use, storage and security and disposal of pharmaceuticals. The Act and regulations classify pharmaceuticals into different categories, including:

- Schedule 8 (S8) pharmaceuticals, which are considered to be drugs of addiction
- Schedule 4 (S4) pharmaceuticals, which are 'prescription only'.

S8 pharmaceuticals are subject to the strongest legislative controls in WA hospitals. About five years ago WA Health became concerned that some pharmaceuticals listed in Schedule 4 were also at risk of unauthorised access and use in hospitals. In 2008 it introduced new policies requiring hospitals to implement stronger controls over a number of S4 pharmaceuticals. These pharmaceuticals are termed 'Schedule 4 Restricted' (S4R).

What Did We Do?

Our objective was to determine whether six selected hospitals had implemented key controls to ensure compliance with government purchasing policies and to reduce the risk of unauthorised access and use of pharmaceuticals.

Specifically we asked:

- Are hospital pharmaceutical purchases consistent with State Supply Commission and WA Health policies?
- Are pharmaceuticals managed in a way that reduces the risk of unauthorised and improper access and use?

We tested pharmaceutical purchases for the period between October 2010 and September 2011, and assessed purchasing controls and access to pharmaceuticals through to March 2012. The audit also included specific testing of the accuracy of information reported to Parliament relating to acceptance of gifts and benefits by WA Health officers. This testing followed on from a preliminary audit of gifts and benefits that we reported in September 2011 (Report No. 7).

Our testing included a sample of 300 pharmaceutical purchases across six hospitals to see if they adhered to SSC policies. To do this we looked for compliance with the Department of Finance's *Procurement Practice Guide*, which outlines how agencies can best implement SSC policies. We also examined how hospitals managed pharmaceuticals that were at most risk of theft because of their addictive and mood-altering properties. The hospitals included in our audit were:

- Armadale Health Service (Armadale Kelmscott District Memorial Hospital)
- Graylands Selby-Lemnos and Special Care Health Service (Graylands Hospital)
- Royal Perth Hospital
- Southwest Health Campus (specifically, Bunbury and Warren District Hospitals)
- Carnarvon Hospital
- Narrogin Hospital

Our audit included site visits to each hospital. In hospital pharmacies we:

- interviewed staff
- reviewed purchasing procedures
- examined purchase and receipt of pharmaceuticals documentation
- examined records relating to pharmaceutical distribution and destruction
- reviewed the processes used for approving specific pharmaceuticals for use (and therefore purchase) in hospitals.

We visited a selection of 30 patient care areas (wards, operating theatres and emergency departments) across the six hospitals where we:

- interviewed staff
- observed how pharmaceuticals associated with addiction and abuse were stored and secured
- reviewed how access to these pharmaceuticals was controlled
- compared the pharmaceutical quantities in patient care areas' registers to the physical stocks on hand.

We reviewed the development and management of the Pharmaceutical Products contract for compliance with SSC policies. We also assessed how the Department of Health and hospitals monitor compliance with regulations and policies and investigate pharmaceutical losses.

Finally, we tested the reliability of the information WA Health has about the gifts and benefits its officers receive. We asked a sample of 32 pharmaceutical companies listed in the WA Health's purchasing system to inform of us of what gifts and benefits they had provided to Department officers and compared this against the Department of Health's own records.

The audit was conducted in accordance with Australian Auditing and Assurance Standards.

What Did We Find?

Purchasing Controls and Compliance

Weak controls mean that pharmaceutical purchases may not achieve value for money, be transparent and accountable or provide open and effective competition for suppliers

The purchasing environment for pharmaceutical products is busy and complex. In our audit period public hospitals made more than a quarter of a million pharmaceutical product orders.

Despite the complex nature of pharmaceutical purchasing, there is limited central oversight in place. While most purchases are overseen by HCN, the Department's corporate services unit, HCN does not oversee pharmaceutical purchases. In the absence of this oversight, we expected hospitals to have a very strong control framework in place to ensure pharmaceutical purchases are competitive, achieve value for money and are accountable and transparent.

Hospital purchasing procedures do not clearly align with government and Department of Health policies

The Department of Health's *Purchase of Goods and Services* policy forms part of the *Health Accounting Manual*, and outlines purchasing requirements in accordance with the Department of Finance's *Procurement Practice Guide*. Some hospital pharmacies also have procedures to guide purchasing staff on how to make pharmaceutical purchases. However these procedures do not align to the Department of Health's policy that clearly instructs staff on how to meet government procurement standards. Without clear instruction in procedures, there is an increased risk that purchases will fail to comply with policy requirements.

Only three of the six hospitals examined (Bunbury, Carnarvon and Graylands) had some form of written purchasing procedure. All hospital pharmacy purchasing officers reported referring to system User Guides for instructions on how to process orders in the iPharmacy system. These procedures and User Guides did not reflect key requirements of the Department of Health's *Purchase of Goods and Services* policy. For example, no sampled hospital's purchasing procedures specified the need to obtain and document verbal quotes for purchases between \$5 000 and \$20 000.

A significant number of the pharmaceutical purchases failed to meet government procurement standards

Many purchases we examined failed to meet the standards expected for government procurement (see Table 1). This included:

- two hospitals where officers purchased pharmaceuticals without delegated authority
- one hospital that did not obtain and document verbal quotes for purchases above \$5 000 but less than \$20 000
- six hospitals that purchased contracted products from non-contracted suppliers – with at least one hospital paying more than required
- three hospitals that did not consistently review purchases.

Purchases meet government procurement standards:	Royal Perth (RPH)	Graylands	Armadale	Bunbury	Narrogin	Carnarvon
Purchases made by those with delegated authority	✓	✓	✓	✓	✗	✗
Quotes are obtained and documented (when applicable)	✗	✓	✓	✓	✓	✓
Products are purchased from the contract (when applicable)	✗	✗	✗	✗	✗	✗
Purchasing is reviewed	✓	✓	✓	✗	✗	✗
✓ All 50 purchases met the requirement and the relevant control was both formal and consistently applied ✗ Not all purchases met requirement and the relevant control was not always documented or applied						

Table 1: Pharmaceutical purchases by hospitals meet government procurement standards

Ninety-seven of our sample of 300 purchases were orders for products on the Pharmaceutical Products contract. In 17 of 97 cases these products were not purchased from contracted suppliers. Most hospitals advised that they may need to purchase outside of the contract if contracted products are not available, however, the hospitals could not provide evidence that this occurred in the specific instances we found.

Despite the policy requirement to do so, RPH did not obtain and document quotes for purchases over \$5 000. It advised that it does not obtain these quotes because the additional time and resources required to do so may jeopardise patient care. RPH notes that it works to achieve value for money by checking prices online where possible, negotiating with suppliers and building cost considerations into the initial selection of products.

Hospitals that fail to purchase products from contracted suppliers and obtain quotes when required risk contravening key procurement policies, including:

- open and effective competition – contracted suppliers have already been selected through a competitive process
- value for money – without quotes hospitals cannot demonstrate that they chose the cheapest product that met their needs. Further, contract prices are often much cheaper than market prices. In 2010, the WA Health compared some of its pharmaceutical contract prices to other states and found that WA hospitals paid an average of 47 per cent less for those products. Hospitals miss out on these savings if they do not buy off the contract. For example, one hospital paid \$69.74 for a product that was available from a contracted supplier for \$11.20.

At Narrogin and Carnarvon hospitals, purchases were officially authorised by officers who did not have delegated authority from the Director General to make those purchases. Officers must only purchase in accordance with their delegated authority, as they may not have the knowledge, skills and experience required to ensure public money is spent appropriately. We note that although officers at the two hospitals acted outside the delegation framework, these officers had been given specific authority by their managers to approve pharmaceutical purchases.

Three hospitals did not review the purchases that had been made and WA Health had not activated iPharmacy system logs to enable monitoring of changes made to orders. It is good practice for management to review purchases to ensure that purchases are legitimate and meet expected standards. This is particularly important for pharmaceutical purchases because some products are associated with addiction and abuse, and there is very limited external oversight of this purchasing.

WA Health could make better use of iPharmacy to help purchasing officers comply with policies

Although officers at all six hospitals indicated that they referred to iPharmacy User Guides, the iPharmacy system and guidance material do not help purchasing officers comply with government procurement standards. For example, there are approximately 750 contracted products, out of nearly 10 000 products in iPharmacy. However contracted products are not automatically linked to contracted suppliers. This increases the risk of purchases being made from other suppliers at too high a price. We note this is a system control that could be implemented centrally, but has not been.

Other system controls in iPharmacy that have not been implemented include:

- rules to prevent officers without delegated purchasing authority being assigned purchasing abilities
- automated prompts to record verbal or written quotes at relevant value threshold limits.

The pharmaceutical purchasing environment is complex, with high numbers of suppliers, products and transactions. In this context it is important that any purchasing system has inbuilt controls to enable officers to meet their compliance obligations in an efficient manner.

Some aspects of contract management have been poor

Although there is a clear Contract Management Plan for the Pharmaceutical Products contract, two key components of the plan had not been implemented. Specifically, the contract manager had not obtained usage reports from contracted suppliers and had not conducted any pricing audits. This meant WA Health was missing key information to help them understand real and potential savings.

Most products on the contract can be either purchased directly from pharmaceutical companies or through distributors. It is often easier for hospitals to purchase through distributors because hospitals can consolidate a variety of products into one order. Although distributors are expected to supply contracted products at the contracted price, the total value of purchases from each contracted supplier is difficult to identify because WA Health records show these purchases as being made from distributors, not pharmaceutical companies. Contract usage reports would enable WA Health to analyse and report on the total value of the contract, and the value of purchases made from contracted suppliers. This information can help to ensure that government purchasing is transparent (particularly when concerns are raised about some suppliers providing gifts and benefits to hospital employees) and represents value for money. WA Health began obtaining these reports as a consequence of our audit.

Conflict of interest risks are not managed well

There are three key processes that influence which pharmaceuticals hospitals purchase:

- selecting which pharmaceuticals to use in hospitals
- selecting suppliers to include on the Pharmaceutical Products contract
- ordering pharmaceuticals from suppliers.

Potential conflicts of interest must be identified and carefully managed in each of these processes to ensure that gifts and benefits provided by suppliers do not have inappropriate influence (and are not perceived to have inappropriate influence) on purchasing decisions.

WA Health does not have reliable information about the gifts and benefits its officers receive

WA Health is only aware of a small number of the gifts and benefits its officers receive from suppliers. Without accurate information, the Department cannot manage conflicts of interest because it will not know that they exist. Accurate information relies on the recipients of gifts making proper disclosure.

Pharmaceutical companies provide many high value travel sponsorships to hospital officers. Following concerns raised in Parliament, in 2011 we investigated the acceptance of gifts and benefits by WA Health officers. In September 2011 we reported that we could not provide assurance that the Department of Health knew about all the gifts provided to WA Health officers.

During this audit we asked a sample of 32 pharmaceutical companies to inform us of the gifts and benefits they had provided to WA Health officers since 1 July 2010. We received detailed responses from 27 companies. These responses indicated that a total of 200 relevant gifts and travel sponsorships had been provided. We compared the information from the companies to the reports provided to Parliament and found that 169 of the 200 gifts and travel sponsorships were not included in the reports to Parliament for the period July 2010 to April 2011.

Fifteen per cent of the 169 items that did not appear in the reports to Parliament were gifts such as biscuits and chocolates. We note that during the period of our testing, Health policy did not require staff to report gifts. In December 2011 the policy was revised to require declaration and recording of gifts.

The remaining eighty-five per cent of items that did not appear in the reports to Parliament were flights, accommodation and/or registration fees for clinical staff to attend conferences. The Department indicated in September 2011 it would issue a revised travel policy. The Department advised the travel policy has been approved and is soon to be released.

Hospitals do not always identify and manage conflicts of interest that arise from decisions about which pharmaceuticals they will use

Three of the six hospitals did not have formal processes to independently review and approve recommendations about which pharmaceuticals can be used, and therefore purchased, for patient care. Where hospitals do maintain an approved list of pharmaceuticals, known as a 'formulary', applications seeking to add to the formulary do not always declare potential conflicts of interest.

There is a greater risk that conflicts of interest will not be declared or appropriately managed in the absence of independent review of decisions to use specific pharmaceuticals. Problems could arise if pharmaceutical

choices were influenced, or perceived to be influenced, by gifts and benefits from pharmaceutical companies. Independent approval of formulary decisions enables hospitals to explicitly identify and manage potential inappropriate influence from gifts and benefits from pharmaceutical companies.

We expected hospitals to have an approved formulary, as well as independent, documented decision-making processes related to it. Further, we expected formulary decision-making processes to include explicit consideration of conflicts of interest. However, we found this was often not the case (see Table 2).

Conflicts of interest are managed when selecting pharmaceuticals	RPH	Graylands	Armadale	Bunbury	Narrogin	Carnarvon
Hospital have an explicit, approved formulary	✓	✓	✗	✗	✗	✓
Hospitals have a default formulary	-	-	✓	✗	✓	-
There is independent review of applications to add products to the formulary or use non-formulary products	✓	✓	✓	✗	✓	✓
All applications contain conflict of interest declaration prompts	✗	✗	✗	✗	✗	✗
All applications are formally documented and these records are kept	✓	✓	✓	✗	✗	✗
✓	The hospital met the criterion					
✗	The hospital did not meet the criterion					
-	Not applicable					

Table 2: Hospital management of pharmaceutical selection

To check whether conflicts of interest had been declared by officers that applied to change their hospital formulary, we compared WA Health’s information about gifts its staff had received to the available formulary application records. We sought to identify if any of the applications related to pharmaceuticals manufactured by a company that provided the applicant with a gift or benefit.

Only one of the 354 applications we reviewed included a declaration of a potential conflict of interest. Our testing showed that there were an additional four potential conflicts of interest that were not declared. We also note that because the reports to Parliament included only a small portion of gifts and benefits provided by pharmaceutical companies to WA Health officers, the actual number of conflicts of interest may be higher. The form used to request that products be permanently added to formulary includes a field to remind applicants to declare any interests. Application forms used to request non-approved products for a single patient do not.

Failure to identify and declare potential conflicts of interests mean they cannot be appropriately managed. There could remain a perception, at the very least, that applicants have made formulary applications to use particular pharmaceuticals because the company that manufactures those products has influenced their choice. Those who make decisions about whether to approve or reject applications need to be fully informed about potential conflicts of interest that could have influenced applications.

We also tested for conflicts of interest involving officers directly responsible for ordering pharmaceuticals. We did not find any conflicts of interest based on WA Health reports about gifts and benefits its officers have received, but again we note that this information is not complete.

WA Health did not record potential conflicts of interest in its refresh of the contract for pharmaceutical products

In October 2011 the Pharmaceutical Products contract was 'refreshed' so that additional products could be added. Our contract file review found no declarations of interest had been recorded by the selection panel that decided which suppliers to award the 'refresh' to. Although no relevant records were kept, WA Health advised that panel declarations were obtained verbally.

In our September 2011¹ report we noted that the initial supplier selection process for the Pharmaceutical Products contract did include declarations of interest from the selection panel. However those that did declare an interest were not excluded from participating in decision-making. We recommended that they should be excluded, to avoid the perception that the gifts and benefits they had received would influence their decision-making. WA Health has yet to implement our recommendation, and did not record declarations of interest during the contract refresh. We also note that during our 2011 investigation, WA Health committed to issuing a revised gifts and travel policies to better manage conflicts of interest that arise when its officers accept gifts and travel sponsorships from pharmaceutical companies. As previously mentioned the revised gifts policy was released in December 2011, and the new travel policy is about to be released.

Secure Management of Pharmaceuticals in Hospitals

WA Health has implemented many, but not all, key controls to reduce the risk of unauthorised access and use of pharmaceuticals

In Western Australia, the *Poisons Act 1964* and *Poisons Regulations 1965* provide the legislative framework for the management of pharmaceuticals. S8 pharmaceuticals are medicines strongly associated with addiction and abuse, and are subject to strong legislative controls. S4 pharmaceuticals are medicines that can only be supplied to someone with a valid prescription. WA Health has recognised that some S4 pharmaceuticals are also associated with addiction and abuse. These are known as S4R pharmaceuticals and are subject to strong controls which have been required by WA Health policy since 2008.

S8 and S4R pharmaceuticals include strong pain relievers like morphine, anxiety relievers like diazepam, sedatives and anesthetics like ketamine and sleeping pills like temazepam.

Our audit assessed the controls in place at hospitals to prevent unauthorised access and use of S8 and S4R pharmaceuticals.

¹ *Second Public Sector Performance Report 2011*, 'Acceptance of gifts and benefits by public officers in the Department of Health', Office of the Auditor General, 7 September 2011.

Hospital processes for taking receipt of pharmaceutical deliveries were not well controlled

We expected hospitals to have implemented a number of key controls in the way they take receipt of pharmaceuticals from suppliers. Strong controls over this process reduce the risk of unauthorised access and use. We found that most of these controls were not in place (see Table 3). For example:

- no hospital ensured that two people unpacked S8 and S4R deliveries and verified the quantity and type of pharmaceuticals received
- five hospitals had either not ensured that ordering and receipt duties were segregated or did not have documentation to enable us to verify the segregation
- four hospitals did not complete records that verified who took custody of pharmaceuticals after the hospital received them
- when they needed to return S8 and S4R pharmaceuticals to suppliers, five hospitals did not ensure the supplier confirmed the quantity and type of pharmaceuticals when they took custody.

Control	RPH	Graylands	Armadale	Warren	Narrogin	Carnarvon
S8s and S4Rs are unpacked and verified by two people	✗	✗	✗	✗	✗	✗
Ordering and receiving is segregated and segregation is able to be verified.	✗	✓	✗	✗	✗	✗
Custody of products is recorded after initial receipt	✓	✓	✗	✗	✗	✗
Records confirm by signature who took custody of S4R and S8 products if are returned to suppliers	✓	✗	✗	✗	✗	✗
✓ Hospital pharmacies consistently demonstrated this practice ✗ Hospital pharmacies did not consistently demonstrate this practice						

Table 3: Controls in place for receiving pharmaceuticals

Where controls were not in place, hospital pharmacies generally advised they were not aware that such controls were important, or they had not been implemented due to resourcing limitations.

We note that in some cases hospital pharmacies have now implemented stronger controls. For example, following our audit, all the hospital pharmacies we examined now require supplier representatives who pick up returned S8 and S4R pharmaceuticals to sign off that they have taken custody of the products.

Some patient care areas do not comply with security requirements for pharmaceuticals which increases the risk of unauthorised access and use

Hospitals have implemented many key legislative and policy controls in patient care areas to protect pharmaceuticals from unauthorised access and use. However, we found a number of examples of non-compliance (see Table 4). Failure to comply with regulatory and policy requirements in relation to S8 and S4R pharmaceuticals significantly increases the risk that unauthorised access and use could occur, and that losses could go undetected. Losses need to be identified so that they can be investigated. Timely detection and investigation of losses also serves to deter unauthorised access and use.

Legislation and WA Health policy require strong controls over S8 and S4R pharmaceuticals. These include:

- keeping S8 and S4R pharmaceuticals in a locked safe or cupboard, and restricting access to authorised persons
- registering transactions involving S8 and S4R pharmaceuticals, such as distribution, receipt, administration to a patient and destruction. In the case of S8 pharmaceuticals, a second person should sign off each transaction to confirm it has occurred
- frequent and regular stocktakes of these pharmaceuticals in which the physical stock on hand is compared to the balance noted in the register at the time of the last transaction.

Control	RPH	Graylands	Armadale	Warren	Narrogin	Carnarvon
Drugs safes/cupboards are locked	✓	✗	✓	✓	✓	✓
Keys are in possession of authorised personnel	✓	✓	✓	✓	✓	✓
Those with keys have had Criminal Record Checks	✓	✗	✗	✗	✓	✓
People sign when they take responsibility for keys	✗	✗	✗	✗	✗	✗
Stocktakes occur at shift change for S8s	✗	✗	✗	✗	✗	✓
If not at shift change, daily stocktakes for S8s	✗	✓	✓	✓	✓	–
Stocktakes daily for S4Rs	✗	✓	✓	✓	✓	✓
No discrepancy in OAG stocktake test	✗	✓	✓	✓	✓	✓
✓ All patient care areas and personnel met this criterion ✗ Some patient care areas or personnel did not meet this criterion – Not applicable						

Table 4: Security of pharmaceuticals in patient care areas

One S4R cupboard at Graylands Hospital was found to be unlocked at the time of testing. Although the cupboard was not located in an area accessible to the public, the fact it was unlocked means the hospital may not know which persons had access to the cupboard.

We checked to see if pharmacy officers that receive pharmaceutical deliveries and nurses with S8 and S4R keys had been subject to Criminal Record Checks. WA Health had not obtained checks for five of the 37 people in our sample. This means WA Health is missing basic information that would help it assess potential risks associated with the access these people have to S8 and S4R pharmaceuticals.

Some patient care areas did not have registers that clearly identified, and confirmed by signatures, who had control of the keys to S8 and S4R cupboards. Although this is not a legislative or policy requirement, accounting for who has keys makes it easier to determine who had access to the pharmaceuticals at any given point in time, which is essential to enable successful investigation if a loss occurs.

Only one hospital ensured that all patient care areas we tested conducted S8 stocktakes when responsibility for S8 cupboard keys changed hands (at a shift change). This is a regulatory requirement designed to ensure timely identification of any losses. We note that, with the exception of one ward at RPH, all patient care areas tested conducted S8 stocktakes at least once day. The RPH ward concerned also failed to do daily S4R stocktakes.

As part of our audit, we initiated and observed a stocktake of S8 and S4R pharmaceuticals at each patient care area we visited. In one case, this stocktake found that a fentanyl patch listed in the register was missing from the S8 cupboard. This discrepancy dated back to 2010 and was not identified earlier because stocktakes had not been carried out as required.

Patient care areas demonstrated good compliance with controls over administering of pharmaceuticals to patients

Hospitals have good controls over the process of removing S8 and S4R pharmaceuticals from cupboards and administering to patients. These controls ensure there is a record to verify that pharmaceutical use is authorised. We only found a few isolated instances of non-compliance in relation to these controls (see Table 5).

Control	RPH	Graylands	Armadale	Warren	Narrogin	Carnarvon
Patient name recorded	✓	✓	✓	✓	✓	✓
Pharmaceutical name recorded	✓	✓	✓	✓	✓	✓
Pharmaceutical quantity recorded	✓	✓	✓	✓	✓	✓
Date and time recorded	✓	✓	✓	✓	✓	✓
Two signatures for S8 administration to patient	✗	✓	✓	✓	✓	✓
At least one signature for S4R administration to patient	✓	✗	✓	✓	✓	✓
Entries in registers match entries in patient records	✓	✓	✓	✓	✓	✗
✓ All tested patient care areas records met this criterion ✗ Some patient care areas records did not meet this criterion						

Table 5: Administration of pharmaceuticals to patients

Discrepancies between entries in pharmaceutical registers and patient medical records could indicate diversion of a pharmaceutical for unauthorised use. We only found one example of such a discrepancy. Our subsequent follow up found this was most likely the result of a recording error.

There was no clear guidance for staff on how to measure and account for liquid pharmaceuticals, which may lead to under or over reporting of losses

Hospitals and patient care areas use different methods for measuring liquid S8 and S4R pharmaceuticals during regular stocktakes. Some areas physically pour the liquid out of the bottle to measure it, some visually estimate the volume in the bottle, and some simply count the number of full and partially full bottles on hand.

Each of the methods of measurement can affect the outcome of the stocktake. Each time a liquid pharmaceutical is removed from a bottle, either to measure it or to administer it to a patient, some loss occurs because some residue is left behind (in the bottle itself and the receptacles used to measure or administer the product). As physically measuring liquid pharmaceuticals is difficult to do with total accuracy, it is likely that the amount of a liquid measured physically will be less than the sum of the transactions recorded in the register.

On the other hand, visually estimating the volume of liquid pharmaceutical in a bottle is by nature not likely to be accurate. There is risk that loss from unauthorised access and use may not be noticed. Similarly, counting only full and partially full bottles will not enable officers to identify any loss from an open bottle.

WA Health is aware of these problems and RPH has recently completed research to identify the standard amount of loss that can occur when measuring or administering different types of liquid pharmaceuticals. The Department of Health has not yet instructed hospitals about how they should measure liquids.

Destruction and disposal processes for pharmaceuticals were not always adequately controlled

We found there were some gaps in the controls in place to protect S8 and S4R pharmaceuticals from unauthorised access and use during destruction and disposal processes (see Table 6).

Sometimes pharmaceuticals will need to be destroyed rather than administered to patients, for example, if they are contaminated or the use-by date has passed.

Control	RPH	Graylands	Armadale	Warren	Narrogin	Carnarvon
S8R destruction witnessed and recorded in pharmacies	✓	✓	✓	✓	✓	✓
S4R destruction witnessed and recorded in pharmacies	✗	✓	✓	✓	✗	✗
S8 and S4R disposal witnessed and recorded in patient care areas	✗	✓	✗	✗	✓	✗
✓ All tested hospital records met this criterion ✗ Some tested hospital records did not meet this criterion						

Table 6: Destruction and disposal of pharmaceuticals

Regulations require the destruction of S8 pharmaceuticals to be witnessed and documented. All of the pharmacy departments we examined complied with this requirement. Because S4R pharmaceuticals are also associated with addiction and abuse, we checked whether S4R destructions in pharmacy departments were also witnessed and documented. Not all pharmacy departments did this. WA Health advise that it has not made this a policy requirement because the risk is not considered significant enough to warrant the resources required to implement the control.

Disposal of S8 and S4R medications can also occur in patient care areas, for instance, when only part of a tablet or ampoule is administered to a patient. We expected that this process would also be witnessed and recorded in each instance. This was done consistently in only two hospitals.

Monitoring compliance in patient care areas was inconsistent and not comprehensive

Across WA Health a number of different activities are carried out to check compliance with pharmaceutical management regulations and policies. Despite this, there are some hospitals and patient care areas that have not been subject to recent compliance checks. Compliance monitoring both discourages non-compliance and helps to remind people of their obligations.

WA Health compliance monitoring activities include:

- Legislative and policy compliance audits by the Department of Health's Pharmaceutical Services Branch (PSB)
- Hospital reviews of patient care area compliance
- Internal audits by the Department of Health's Corporate Governance Directorate.

The Pharmaceutical Services Branch (PSB) is responsible for monitoring compliance with the *Poisons Act 1964* and the *Poisons Regulations 1965*. Although PSB aim to audit hospitals and retail pharmacies every three years, nine public hospitals have not been audited by PSB for 14 years. PSB advise that it has now prioritised public hospital audits and is currently developing appropriate audit tools.

Five of the six hospitals we examined carried out some form of compliance monitoring in their patient care areas. The extent of this monitoring varied from regular documented checks for both S8 and S4R pharmaceuticals, to informal checks for S8 pharmaceuticals but with no checks for S4R pharmaceuticals. Compliance monitoring was not carried out at all in one hospital.

WA Health investigates instances of missing pharmaceuticals, but investigations are not always transparent

Despite the controls in place to guard against unauthorised access and use of pharmaceuticals associated with addiction and abuse, some losses do occur. In some cases these losses can be attributed to human error such as incorrect counting, poor recordkeeping or accidental destruction or disposal. In other cases, the losses result from unauthorised access and use.

The proportion of S8 and S4R pharmaceuticals that go missing is small. WA Health data shows that less than 0.04 per cent of S8 pharmaceuticals were lost between July 2010 and June 2011. Even though the number of losses and the financial impact of losses is small, it is important that all losses are investigated, so that WA Health can identify the cause of the loss and can take appropriate action in response.

WA Health requires all discrepancies identified in hospital stocktakes of S8 pharmaceuticals to be centrally reported. Current policy allows hospitals some discretion in reporting discrepancies of S4R pharmaceuticals. S4R discrepancies are only required to be reported where hospitals consider there to be reasonable grounds to suspect:

- a theft has occurred
- a loss that cannot be reasonably accounted for
- a staff member with access to pharmaceuticals demonstrates behaviour that indicates they may have a drug related problem or are diverting medicines.

Hospitals advised that in practice all discrepancies found during S4R stocktakes are at a minimum reported to hospital pharmacies for review and advice. However, this is not a formal requirement so there remains a risk that S4R discrepancies will not be subject to central review. WA Health has drafted a revised policy regarding pharmaceutical discrepancy reporting that, when issued, is likely to address this accountability gap.

WA Health investigates when pharmaceuticals go missing, and considers potential misconduct issues

When the Corporate Governance Directorate of WA Health receives reports of pharmaceutical losses from hospitals, it assesses each report to see if it could involve misconduct. This involves some trend analysis such as on-going or multiple losses on particular hospital wards. If trends like this are identified, Corporate Governance considers whether any specific individuals may be implicated. However, there is no system to identify possible relationships between specific people and multiple losses across the whole of WA Health. We consider this a missed opportunity to identify and limit misconduct, particularly in view of the mobility of the health care industry workforce. The Department of Health advises that it does not have the technology required to conduct this analysis within current resources.

When misconduct is suspected, Corporate Governance independently investigates matters. WA Health's Pharmaceutical Services Branch also assesses reports for possible legislative non-compliance and indications of ineffective or inadequate controls.

It was often not clear why WA Health assessed pharmaceutical losses as 'explained' or 'unexplained'

We examined Corporate Governance records relating to 50 discrepancy reports between August 2010 and November 2011. We found that the records did not clearly show why a loss was assessed as 'explained' or 'unexplained'. We expected a loss to be assessed as 'explained' if the cause of the loss could be confirmed, and 'unexplained' if it could not. It is important that these assessments are supported by clear evidence, because unauthorised access and use cannot be ruled out for losses that are assessed as 'unexplained'.

WA Health does not have documented rationale for assessing whether losses are 'explained' or 'unexplained'. In 35 of 50 cases, it was unclear to us, based on the evidence available, how these assessments were decided. Of the 35, there were 32 cases where WA Health had assessed the discrepancy as 'explained' when there did not appear to be clear records to show that the cause of the loss was something other than unauthorised access and use. We note that the assessments WA Health made from May 2011 onwards were clearer than those in the early part of our audit period. The Department advised that this outcome was a result of the implementation of guidelines issued to them by the Corruption and Crime Commission.

There was limited guidance material available to assist staff to conduct effective investigations

After a S8 and S4R pharmaceutical loss has been identified and reported to Corporate Governance, the initial investigations are undertaken by hospital staff, who are not specifically trained for this role. In addition, WA Health policies do not provide guidance on how pharmaceutical losses should be investigated. There is a risk that those that investigate may not take all reasonable steps to identify the cause of a loss, and unauthorised access and use could go undetected.

The records we examined did not always demonstrate that investigations involved key activities such as physical searches, examinations of registers and patient medical records to check for counting or recordkeeping errors, review of CCTV footage or other electronic records where available and interviews with relevant personnel.

As noted above, WA Health has revised its policies for pharmaceutical loss reporting. The new policy materials include clear checklists and flowcharts to assist those charged with investigations. When implemented, the new policy is likely to address our concerns in this area.

Only 20 per cent of the pharmaceutical losses we examined were reported to the WA Police

The *Poisons Regulations 1965* require pharmaceutical losses to be reported to the police. We found that this had occurred in only 10 of the 50 cases we examined. WA Health has addressed this by establishing a new protocol with the WA Police to ensure that the reporting process is efficient for both parties.

Auditor General's Reports

REPORT NUMBER	2012 REPORTS	DATE TABLED
6	Victim Support Service: Providing assistance to victims of crime	16 May 2012
5	Audit Results Report – Annual Assurance Audits completed since 31 October 2011 including universities and state training providers and Across Government Benchmarking Audits: Accuracy of Leave Records; Act of Grace and Like Payments; and Supplier Master Files	16 May 2012
4	Supporting Aboriginal Students in Training	2 May 2012
3	Beyond Compliance: Reporting and managing KPIs in the public sector	19 April 2012
2	Opinion on Ministerial decisions not to provide information to Parliament on the amount of funding Tourism WA provided for some events	22 February 2012
1	Working Together: Management of Partnerships with Volunteers	22 February 2012

REPORT NUMBER	2011 REPORTS	DATE TABLED
11	The Management of Offenders on Parole	23 November 2011
10	Audit Results Report – Annual 2010-11 Assurance Audits	9 November 2011
9	Use of CCTV Equipment and Information	19 October 2011
8	Ensuring Compliance with Conditions on Mining	28 September 2011
7	Second Public Sector Performance Report 2011 – Use of ICT contractors in government – Acceptance of gifts and benefits by public officers in the Department of Health	7 September 2011
6	Right Teacher, Right Place, Right Time: Teacher Placement in Public Schools	31 August 2011
5	Public Sector Performance Report 2011 – Agency Compliance with Procurement Requirements – Managing the Priority Start – Building Policy	29 June 2011
4	Information Systems Audit Report	15 June 2011
3	Audit Results – Annual Assurance Audits completed since 1 November 2010, including universities and state training providers; and Opinion on a Ministerial Notification	25 May 2011
2	Opinion on Ministerial Notification: Ministerial decision to not provide information to Parliament in relation to the theatre production of <i>The Graduate</i>	23 March 2011
1	Raising the Bar: Implementing key provisions of the <i>Liquor Control Act</i> in licensed premises	23 March 2011

The above reports can be accessed on the Office of the Auditor General's website at www.audit.wa.gov.au.

On request these reports may be made available in an alternative format for those with visual impairment.

**Office of the Auditor General
Western Australia**

**7th Floor Albert Facey House
469 Wellington Street, Perth**

**Mail to:
Perth BC, PO Box 8489
PERTH WA 6849**

T: 08 6557 7500

F: 08 6557 7600

E: info@audit.wa.gov.au

W: www.audit.wa.gov.au