SPECIAL REPORT

LOST OPPORTUNITIES FOR SAVINGS WITHIN CALIFORNIA PRISON PHARMACIES

OFFICE OF THE INSPECTOR GENERAL

DAVID R. SHAW
INSPECTOR GENERAL

STATE OF CALIFORNIA
APRIL 2010

April 15, 2010

J. Clark Kelso, Receiver
California Prison Health Care Receivership Corporation
501 J Street, Suite 100
Sacramento, California 95814

Dear Mr. Kelso:

Enclosed is the Office of the Inspector General's special report on California Prison Pharmacies. We conducted this review under the authority of California Penal Code section 6126, which assigns the Office of the Inspector General responsibility for oversight of the California Department of Corrections and Rehabilitation

This special report found missed opportunities for significant savings due to the failure to restock unused medications, lack of adherence to approved formulary medications, an unreliable pharmacy inventory system, and inconsistent practices among prisons when transferring inmates with medications. This report contains the results of our review of California Prison Pharmacies and presents four findings and twelve recommendations.

Thank you for the courtesy and cooperation extended to my staff during the special review. Please call Samuel Dudkiewicz, Chief Assistant Inspector General, at (916) 830-3600 if you have any questions.

Sincerely,

David R. Shaw
Inspector General

Enclosure: Special Report: Lost Opportunities for Savings within California Prison Pharmacies

Contents

Executive Summary

In 2001, the Prison Law Office filed a class action lawsuit on behalf of California inmates alleging that the state provided inadequate medical care at its prisons, in violation of inmates' constitutional rights.

As a result of this lawsuit, in October 2005, the U.S. Northern District Court of California imposed a Receivership on the California Department of Corrections and Rehabilitation (CDCR) to raise the delivery of medical care to constitutional standards. The court suspended CDCR's jurisdiction over prison medical health care, giving jurisdiction to the Receiver. The court found CDCR prison pharmacy operations, in particular, to be "unbelievably poor."

Findings in Brief

The Office of the Inspector General finds that:

- Usable medications not being restocked in prison pharmacies cost California taxpayers at least $7.7 million annually.
- Not ensuring the use of approved medications costs California taxpayers an additional $5.5 million annually.
- Unreliable computer inventories in prison pharmacies result in additional staff labor and increased costs.
- Inconsistent practices in handling medications for inmates who transfer between prisons result in waste and increased costs.

In January 2007, the Receiver entered into an agreement with Maxor National Pharmacy Services (Maxor) to assist in implementing an action plan it had created to improve CDCR's pharmacy operations. The Receiver retains overall responsibility for pharmacy operations and Maxor is responsible for providing guidance to facility level pharmacy staff in order to implement the objectives contained in the agreement. However, a vacuum in leadership was created when prison pharmacy managers started reporting to Maxor rather than through the Receiver's management team who were more familiar with the challenges and complexities of state government.

In the summer of 2009, during our regular, semi-annual inspections of CDCR facilities, inspectors for the Office of the Inspector General (OIG) were approached by pharmacy staff concerned about the sheer amount of wasted medication in prison pharmacies. This prompted us to look into policies and operational controls for pharmacy management; we discovered that controls were weak. Concerned about potential drug diversion and waste, we surveyed additional prisons, where we found such serious operational inconsistencies that we launched an in-depth review, selecting nine prison pharmacies as the sites of our close review.

This report highlights the results of our review and focuses on waste in prison pharmacy operations in four areas: the failure to restock millions of dollars in unused medications each year; the lack of adherence to the formulary, which is an approved list of medications, resulting in millions of dollars overspent on medications each year; the functionally unreliable computerized pharmacy inventory system that bears no relation to the actual stock of medications at any prison pharmacy; and the inconsistent practices among prisons when transferring inmates with medications, resulting in excess medications that are most often destroyed.

Contrary to expectation, there are almost no procedures for identifying and restocking medications. This managerial void costs taxpayers at least $7.7 million, and very likely close to $20 million, every year. In addition, due to the absence of oversight, CDCR clinicians routinely prescribe non-formulary medications, costing taxpayers at least another $5.5 million in 2009 alone.

Additional costs are incurred for staff time as pharmacists find ways around the state-wide computerized inventory system, a system so unreliable that pharmacists prefer to rely on handwritten tallies. And in the absence of consistent medication transfer procedures when inmates are transferred among prisons, prison pharmacies routinely generate unnecessary prescription refills, which are often destroyed. Since over 100,000 inmates on medications are transferred among CDCR prisons each year, with each of those inmates receiving an average of 5.5 prescription medications, the costs of filling and destroying unnecessary and unused prescriptions are tremendous.

Recommendations

In this special report, the Office of the Inspector General shines a public light on specific areas lacking oversight and accountability in CDCR's pharmacy operations resulting in millions of dollars in unnecessary costs to the taxpayers.

To address the deficiencies identified in this report, the California Prison Health Care Receivership Corporation should take the following actions:

Medication Restocking

- Establish and enforce procedures to maximize the restocking of usable drugs.
- Develop guidelines to determine when to purchase unit dose versus loose tab medications to maximize the return of drugs to pharmacy inventory, and monitor purchases to ensure compliance.
- Review existing staffing levels within pharmacies to ensure that adequate resources are available to restock drugs to inventory.

Formulary Adherence

- Monitor the prescribing of over-the-counter items that have a limited medical necessity and develop processes to limit prescribers' ability to provide such items.
- Identify institutions and individual prescribers that consistently do not adhere to the formulary and provide instructions to rectify the prescribing behavior.
- Ensure that there is a strong clinical pharmacy presence at prisons to provide training and direction to reduce the use of non-formulary prescriptions, maintain accurate inventories, and promote efficiencies.

Inventory control

- Develop and implement procedures to ensure an accurate computer inventory system in order to monitor inventory shrinkage, reduce staff labor, provide accurate management reports, and provide accountability.
- Provide guidance to pharmacy staff on how to use the computer inventory system to account for medications dispensed to prison hospitals.
- Ensure that the auto-refill and auto-reorder systems work effectively without manipulating the electronic inventory.

Inmate transfers

- Monitor transferring inmates and identify any prisons that are not forwarding medications to the receiving prison; identify the cause of the failure to follow procedure and take appropriate action.
- Ensure that prisons transferring inmates to other institutions take into account the quantity of previously dispensed medications before requesting a three-day supply from the pharmacy, and monitor for compliance.
- Develop a procedure to ensure that the receiving institution's pharmacy does not refill medication before it is necessary, and monitor for compliance.

Introduction

This report presents the results of a review of pharmacy operations in California Department of Corrections and Rehabilitation (CDCR) prisons. The Office of the Inspector General (OIG) originally became aware of concerns regarding pharmacy operations during our regular, semi-annual inspections of CDCR facilities.

During the summer 2009 institutional inspections, pharmacy staff showed OIG inspectors substantial quantities of returned medications awaiting disposal which pharmacy staff believed could be reused. This prompted OIG inspectors to inquire about operational controls along with policies and procedures for handling medications returned to the pharmacy. The lack of controls raised concerns about potential drug diversion and waste. Consequently, we surveyed additional prison facilities and found operational inconsistencies among the various prison pharmacies in the packaging and restocking of medications, in inventory control, in the medication transfer process, and in maximizing the use of the CDCR formulary.

The OIG conducted this review under the authority of California Penal Code section 6126, which assigns the OIG responsibility for oversight of the CDCR.

Photo 1: Unused medication returned to a pharmacy from facility clinics.

Source: Office of the Inspector General.

Background

History of CDCR's Pharmaceutical Program

CDCR provides for the custody and care of approximately 167,000 inmates, which includes pharmacy services at each of the 33 adult prisons. Between 2000 and 2005, CDCR's management of its pharmacies has been the focus of several audits and reviews, all of which have identified major issues that impede pharmacy operations. Even though the auditing agencies made recommendations for improvement, CDCR routinely failed to implement meaningful changes. This failure contributed to a class action lawsuit filed in 2001 by the Prison Law Office on behalf of California inmates alleging that the state provided inadequate medical care at its prisons, in violation of inmates' constitutional rights.

In October 2005, the U.S. Northern District Court of California imposed a Receivership on CDCR to raise the delivery of medical care to constitutional standards. The court determined that the management of prison pharmacy operations was "unbelievably poor." The court found that there was no statewide coordination among pharmacies and no statewide pharmacist to provide centralized oversight, control, and monitoring of the pharmacy program. The court also found that the failure to transfer medications among prisons or to accept prescriptions from other institutions disrupts the continuity of medical care and results in waste.

The court order appointing the Receiver outlined the Receiver's duties in restructuring CDCR's medical delivery system. The Receiver was required to develop a plan of action that included goals, tasks, and metrics, and was required to make progress reports to the court. The court gave the Receiver the powers necessary to fulfill those duties.

At the same time, and for the duration of the Receivership, the court suspended the Secretary of the CDCR's jurisdiction over prison medical health care. The Secretary, however, was ordered to assist with the accomplishment of the Receiver's duties.

The Receiver's action plan includes the objective to "establish a comprehensive, safe and efficient pharmacy program." In March of 2006, then-Receiver Robert Sillen requested that Maxor National Pharmacy Services (Maxor) conduct a review to identify the actions necessary to improve the California prison pharmacy operation.

In June 2006, Maxor concluded its review and issued a report titled, "An Analysis of the Crisis in the California Prison Pharmacy System Including a Road Map from Despair to Excellence." In this report, Maxor asserted that the "CDCR pharmacy program does not meet minimal standards of patient care, provide inventory controls or ensure standardization." Maxor found:

- Lack of centralized oversight and coordination among pharmacies, resulting in poor management controls.
- Lack of an effective clinical management process to ensure medically-appropriate and cost-effective treatment through use of the drug formulary.

- Lack of consistency in ordering and managing inventory.
- Lack of an electronic information system capable of medication monitoring and cost containment.

In addition to outlining numerous deficiencies in the program, the Maxor report included a plan for improving the CDCR pharmacy operation. The plan, which incorporated many of the recommendations from previous audits, consists of seven goals along with measurable objectives to achieve those goals. An abbreviated description of the goals follows:

- Develop meaningful, effective centralized oversight, control and monitoring of the pharmacy program.
- Implement and enforce effective clinical management processes (including formulary controls, a pharmacy and therapeutics committee, disease management guidelines and regular audits).
- Review, audit, and monitor pharmacy contracting and procurement for cost efficiency.
- Develop a pharmacy human resource program.
- Redesign and standardize institution pharmacy drug distribution, including development of a centralized pharmacy.
- Design and implement a uniform pharmacy information management system.
- Develop processes to ensure that pharmacy accreditation standards are met.

In January 2007, the Receiver entered into a contractual agreement with Maxor to provide management consulting services to the prisons' pharmacies. This agreement included an operating budget for Maxor of just over $15,000,000 for the three-year period of the contract from January 1, 2007 to December 31, 2009. Two subsequent revisions to the original agreement resulted in changes to the scope, a one-year extension, and a total revised budget of almost $40,000,000. Although Maxor is responsible for providing guidance to facility level pharmacy staff in order to implement the objectives contained in the agreement, Maxor is under the direction of the Receiver, who maintains overall responsibility for the delivery of medical services, including pharmacy operations. However, when prison pharmacy staff contacted the Receiver's office to resolve issues, they were re-directed to Maxor; this created confusion regarding the management structure of pharmacy operations.

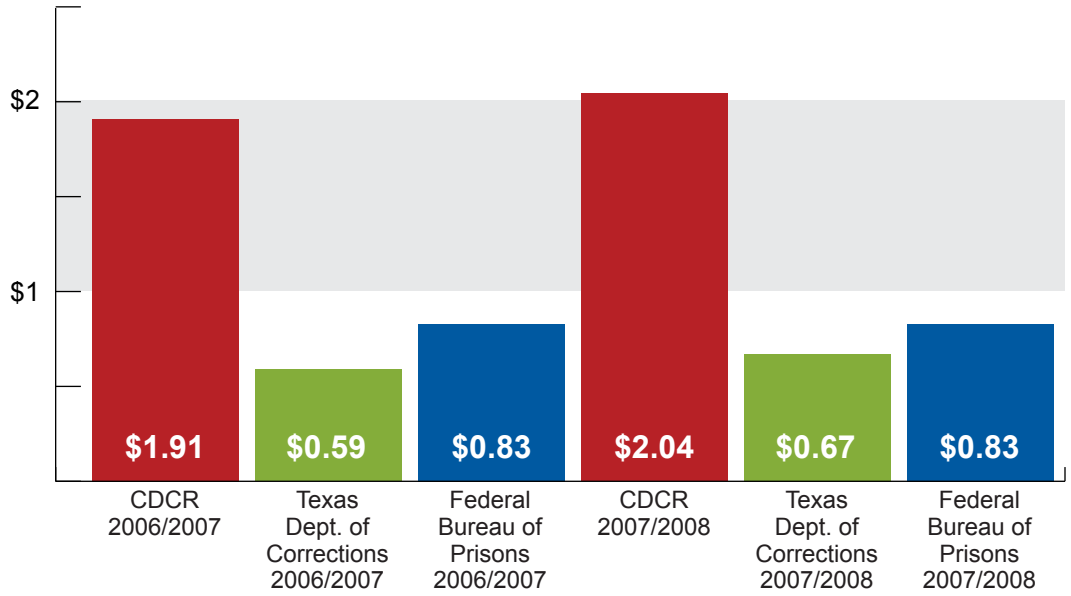
In its original agreement, Maxor developed seven goals and numerous objectives for improving pharmacy operations. The majority of the objectives related to our findings were scheduled for completion during the first 12-24 months, or by December 31, 2008.

Pharmacy Costs

In the past decade, the amount of money spent annually on medications for California's inmates between 2000 and 2008 (the latest year for which we had complete data) has more than doubled.

Figure 1: Cost for pharmaceuticals per inmate per day.

Compared with two other large correctional operations and adjusting CDCR for pricing differentials, CDCR spends two and three times as much per inmate per day on medications.



This is far greater than the seven percent increase in the inmate population at its peak and the 33 percent increase in the cost of prescription drugs over the same time period (See Figure 2 on page 8). However, during the last two years (2007-2008), the rate of increase is significantly less than the previous three years. Facility pharmacy staff attributed this improvement to better drug purchasing contracts negotiated by Maxor and the Receiver.

For the fiscal year 2009-2010 Governor's budget, CDCR proposed to spend close to $2 billion to provide medical, dental and mental health care services to California's inmates. Almost 10 percent of that amount, $190 million, is allocated for pharmaceuticals. In comparing California with other large correctional operations for fiscal years 2006/2007 and 2007/2008, we find that the daily pharmaceutical cost per inmate is significantly higher at CDCR (see Figure 1). Even after adjusting CDCR's cost per inmate downward to account for preferential pricing advantages that Texas and the Federal Bureau receive, CDCR spends more than two times the amount that the Federal Bureau of Prisons spends per inmate per day on medications, and more than three times the amount spent by the Texas Department of Corrections.

In reviewing data for approximately 111,000 inmates in July, August and September of 2009, we found that 65 percent or 73,000 inmates received 403,000 prescribed medications. These 73,000 inmates averaged 5.5 prescriptions per inmate. Given the amount of money and the number of prescriptions involved, the potential for waste is significant.

Pharmacy Operations and Medication Delivery

Each prison pharmacy is under the direction of a Pharmacist-In-Charge, employed by CDCR, who is referred to as a lead pharmacist for the purposes of this report. The lead pharmacist has

oversight and supervision of the storage, distribution and control of all prescription medications. Each pharmacy uses an electronic database to assist in tracking orders placed, medications received, medications dispensed, and medications returned. In addition to electronically recording medications purchased and drugs dispensed, physical inventories are conducted.

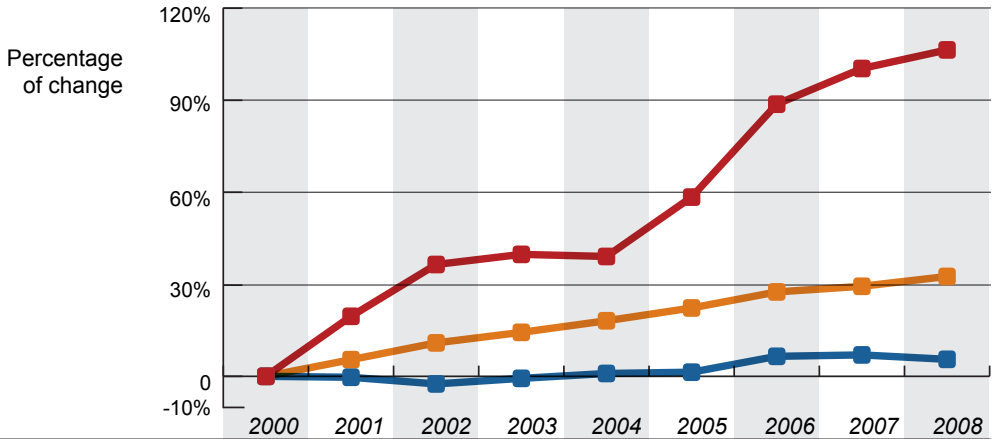
The lead pharmacist purchases medications to stock the prison pharmacy and fill prescriptions. Depending on the type of medication, the lead pharmacist facilitates the purchase of the medication in either prepackaged unit doses or in loose tablets. Policy requires that pharmacists substitute generic medication—drugs no longer protected by a patent—for patented name-brand medication, unless otherwise specified. However, it is health care providers that determine which medication is prescribed to the patient. They can specify any medication in their prescriptions, including name-brand medication, by submitting a non-formulary drug request to prescribe a drug not listed on the CDCR drug formulary.

The drug formulary is a list of approved medications, many of which are the generic versions of name-brand medications. Provided to all CDCR licensed medical professionals, the drug formulary is developed by CDCR's Pharmacy and Therapeutics Committee to help clinicians provide medically appropriate and cost effective treatment. The Pharmacy and Therapeutics Committee consists of medical, dental, nursing, psychiatry and pharmacy staff as well as court-appointed experts from the Coleman (mental health) and Perez (dental) lawsuits. Only this committee can add or delete items from the formulary. Since formulary medications cost, on average, 65 percent less than non-formulary medications, adherence to the formulary to the extent possible can result in considerable cost-savings to CDCR.

The lead pharmacist supervises the pharmacists and pharmacy technicians who prepare and dispense medications upon orders from appropriately licensed medical professionals. After

Figure 2: Comparing rates of change, 2000 - 2008.

From 2000 to 2008, CDCR more than doubled its spending on inmates' medications, yet the total inmate population increased only seven percent at its peak. During that same period, the cost of prescription drugs rose only by a third.



	2000	2001	2002	2003	2004	2005	2006	2007	2008
CDCR pharmeceutical expenditures	0	19.56	36.45	39.75	39.07	58.42	88.71	100.34	106.40
CDCR prison population changes	0	-0.31	-2.48	-0.66	0.93	1.35	6.52	6.98	5.54
Consumer price index of prescription drugs	0	5.43	10.9	14.33	18.11	22.28	27.51	29.35	32.55

a medication is dispensed, it is then sent to the designated housing unit clinic for delivery to the inmate. For certain medications, the entire prescription is given to the inmate to take as directed. Other medications are kept in the facility medical clinic, where a nurse provides the medication to the inmate and observes the inmate take the medication. This medication delivery method is called Direct Observation Therapy (DOT).

If, for some reason, medication is unused by an inmate, it is to be returned to the pharmacy for disposition. When medication is returned to the pharmacy, pharmacy staff determine whether it should be returned to inventory (restocked), returned to the manufacturer for partial credit, or incinerated. Restocking of medications involves consideration of:

- Delivery method – only medication that remained in the control of health care staff can be considered for restocking.
- Type of packaging and storage – whether the medication is in unit dose packaging or loose tablets and stored in a manner as to ensure it has not been adulterated or that the efficacy of the medication has not been compromised.
- Expiration date.

When inmates transfer in and out of an institution, a coordinated effort among custody staff, health care staff and pharmacy staff is required to ensure that required medication accompanies each transferring inmate. When inmates transfer between CDCR prisons, they are required to have at least a three-day supply of their prescribed medications. If there is less than a three-day supply of already dispensed medication available prior to transfer, the pharmacy is to be notified to provide a minimum of a three-day supply. Upon an inmate's arrival at the receiving institution, health care staff verify the receipt of medication; the pharmacy receives the transferred prescriptions and makes medication available.

Parameters of Review

This review was conducted to determine whether California 's state prison pharmacies effectively manage the expenditure of state funds for the distribution of medications to inmates.

Although there are seven goals and numerous accompanying objectives contained in Maxor's action plan and CDCR has reportedly met objectives in some areas, our review does not address all seven goals. Our report focuses specifically on the issue of waste, which has considerable cost implications for CDCR and, more importantly, California taxpayers. This report focuses on four areas: inventory control, inmate transfer medications, the return to stock of unused medications, and the practice of formulary adherence. These are the areas of primary concern brought to our attention by pharmacy staff during facility inspections.

We surveyed 16 prison pharmacies, which included reviewing management reports and interviewing pharmacy, medical and custody staff to identify potential problems and their impact on pharmacy operations. As a result of our survey, we selected nine prisons to perform a more in-depth review of pharmacy operations. The nine prisons were:

- California State Prison, Corcoran
- California State Prison, Sacramento
- California Substance Abuse Treatment Facility and State Prison, Corcoran
- Central California Women's Facility
- Deuel Vocational Institution
- Mule Creek State Prison
- Pleasant Valley State Prison
- Salinas Valley State Prison
- Valley State Prison for Women

In the process of performing this review during the second half of 2009, we:

- Interviewed pharmacists, pharmacy staff, custody and other related medical staff.
- Reviewed the medication restocking process in which prescribed medications not picked up by inmates can be placed back into inventory.
- Reviewed inventory reports and manually counted selected pharmaceutical medications.
- Reviewed the auto-reorder procedures where medications are automatically reordered when the inventory runs low.
- Reviewed the auto refill procedures where an inmate's prescription is automatically refilled.

- Reviewed the non-formulary request process whereby prescribers order medications that are not on the formulary list.
- Reviewed the transfer process where medications are sent with inmates when they are transferred from one prison to another.

Based on our analysis of the data collected, we developed four findings and twelve recommendations regarding the management of pharmacy operations.

Finding 1

Usable medications not being restocked cost California taxpayers at least $7.7 million annually.

Due to lack of direction and oversight, CDCR pharmacies have lost taxpayer money by failing to restock returned medications. We estimate that not maximizing the restocking of medications costs taxpayers at least $7.7 million annually.

Unused medications may be returned to the pharmacy for a number of reasons. For example, unused medications are returned when they are refused by the inmate, or when left behind after an inmate is paroled or transferred to another institution. Pharmacy staff evaluate the unused medication to determine whether it should be incinerated, returned to inventory (restocked), or returned to the manufacturer for partial credit. While many of the returned medications are routinely destroyed, they could be restocked and re-dispensed if they meet certain conditions involving their packaging and distribution thereby saving millions of dollars.

Photo 2: Returned unused medication waiting to be sorted.

Because many pharmacies lack the staffing to sort returned medication for possible restocking, returned medications are often incinerated. Source: Office of the Inspector General.

Depending on the medication, the pharmacy normally dispenses medications in one of two delivery methods. Some medications are picked up by the inmate for use as prescribed. Other medications require direct observation therapy (DOT), in which nursing staff gives the medication to the inmate and observes the inmate take the medication. Prison pharmacies typically provide the DOT medications either in unit dose packaging (pills individually wrapped by the manufacturer) or in loose tablets placed in baggies by pharmacy staff. DOT medications that have been dispensed to nursing staff but are unused can possibly be restocked; however, medications picked up by inmates, irrespective of their packaging, cannot be restocked.

Photo 3a, 3b: Unit dose medication and loose medication.

Under certain circumstances, unused unit dose medication may be restocked for later use. Unused loose tablets of medication are usually not restocked. Source: Office of the Inspector General.

Appropriate direction is not provided to prison pharmacies to minimize waste

Although a computerized inventory system has been implemented by the Receiver to "track returned medications and re-circulate returns when possible to maximize inventory value," the Receiver's policy regarding the disposition of medications returned to the pharmacy did not describe when a medication could be restocked. Instead, it provided guidance on when a medication could not be restocked. According to the policy, a medication cannot be restocked if it is past the expiration date, contaminated, mislabeled, or recalled. As a result, there is no uniform protocol to channel returned medication back into prison pharmacy stock.

However, some of the pharmacists we spoke to have developed criteria for identifying medications that can be restocked. The consensus among these pharmacists was that returned medications could be restocked if they:

- had been continually maintained by a health care professional only and;
- are packaged as unit dose, unadulterated and;
- have not expired as indicated by the manufacturer's expiration date.

Although purchasing medications in unit dose packaging facilitates medication restocking and therefore facilitates savings, other variables in purchasing also affect savings. To determine the difference between the costs of purchasing in unit dose packaging versus loose tablet form, we selected eight medications that were commonly restocked; four were name brand and four were generic medications. We found that there is no difference in the cost of name brand medications when purchased in either unit dose packaging or in loose tablet form. Generic medications, however, on average doubled in cost when purchased in unit dose packaging. Therefore, when ordering medications, pharmacists must consider the availability and cost of unit dose packaging, compared with loose tablet form, in both name brand medications and generic medications.

In discussing with pharmacists how they determine whether to purchase medications in unit doses or in loose tablet form, we found significant inconsistencies among purchasing practices. Pharmacists did not take into account both the medication's initial cost and the ability to restock the medication. Although our sample indicates that name brand drug manufacturers charge the same price for either unit dose packaging or loose tablets, several pharmacists preferred to buy loose tablets because they believed that they were choosing the less expensive option. They explained that loose tablets have historically been less expensive than unit dose packaging. Other pharmacists noted that they buy medications in loose tablets because loose tablets take up less space on their shelves, and that space is a critical factor in their particular pharmacies (photo 4). These pharmacists also told us that although they were encouraged to purchase drugs in unit dose packaging, they had not been given any verbal or written directives.

When a pharmacist was asked why he only purchased loose tablet drugs, he responded:

"Because that is just the way we have always purchased our drugs."

— Lead Pharmacist

Pharmacies do not evaluate returned medications in a timely manner

Some pharmacies incinerate returned unit dose medications because the pharmacy staff does not evaluate the returned medications in a timely manner. The evaluation process includes sorting the returned medications according to whether they are to be destroyed, returned to the manufacturer for partial credit, or restocked. We observed large quantities of returned medications stored in tote bins and plastic bags, waiting to be sorted.

Several of the pharmacists said they did not have adequate staffing to sort the returned medications. These pharmacists estimated that it would take 20 to 60 hours of staff labor per month to sort returned medications, but explained that they have no control over their staffing. The pharmacists claimed that the focus was primarily on filling and completing the inmate prescriptions, rather than on sorting returned medications. We did not verify these pharmacists' assertions; however, the large quantities of unsorted returned medications indicate ineffective oversight of the pharmacies' restocking processes.

Photo 4: Loose tablet medications stored in bulk.

Adequate space to store medications is a concern at many prison pharmacies. Source: Office of the Inspector General.

Even without additional resources or assistance though, some pharmacists changed their staff's responsibilities and successfully demonstrated how medications could be restocked.

One pharmacist told us that he addressed the staffing shortage in his pharmacy by authorizing overtime for pharmacy staff to sort returned medications. This pharmacist estimated that sorting returned medications at his pharmacy takes 20 hours and costs approximately $500 per month in overtime, but he believes that paying the overtime is justified by the savings derived from returning the drugs to stock. To illustrate his point, he noted that during a three-month period in 2009, his pharmacy reported $191,000 in drugs returned to stock at a cost of approximately $1,500 for overtime.

Another pharmacist made sorting returned medications part of the daily duties for his pharmacy staff. He reported $235,000 in medications returned to stock during the three month period from April through June 2009. In comparison, another pharmacy of comparable size in pharmaceutical purchases that didn't make sorting a priority reported only $14,000 in medications returned to stock during the same period.

Photo 5: Typical shelving of bulk and unit dose pharmaceutical stock.

Bottles contain up to 1,000 pills while unit doses are typically ten to a card. Source: Office of the Inspector General.

Such differences in results suggest that the intended objective of ensuring that all pharmacies maximize their restocking of medications was not met.

Certain pharmacies achieve higher restocking rates by purchasing in unit dose forms and focusing on restocking

Based on our review of pharmacy reports, we noted that some pharmacies had higher rates of restocking medications than other pharmacies. We found that the pharmacists at the high-restocking rate pharmacies purchased medications in unit dose form, which facilitated the restocking of the drugs back into the pharmacy's inventory, and that they incorporated restocking responsibilities as part of their staff's duties.

We reviewed the return-to-stock data for twenty prisons for the period of April through June 2009. For those twenty prisons, the average return-to-stock rate was 3.9 percent of the pharmaceutical expenditures for that three-month period. The range of the return-to-stock percentage varied greatly from a low of .05 percent to a high of 14.87 percent. If we project the 3.9 percent to the total pharmaceutical expenditures of $188 million for 2008-2009, the amount of the return to stock would be $7.3 million.

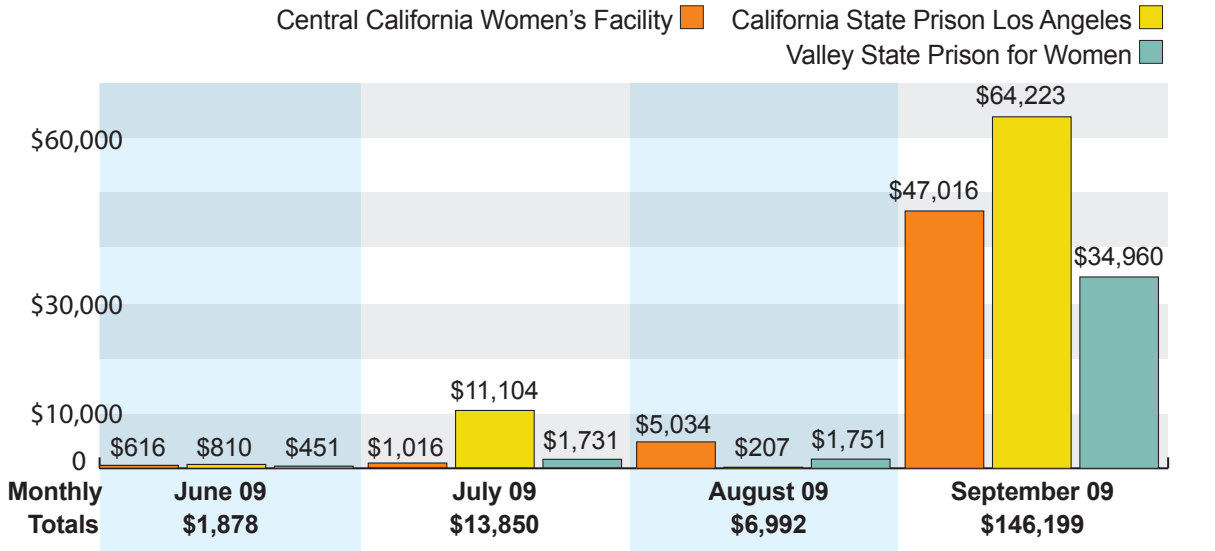
On September 2 and 3, 2009, we visited three prisons and had in-depth discussions with

pharmacy staff regarding their restocking procedures. Following our visits, these three prisons immediately increased their return-to-stock percentage. The data from return-to-stock reports included in Figure 3 below show return-to-stock rates for these institutions before and after our visits. The return-to-stock rate for August at these institutions was less than ½ of one percent; however, after our visit, the return-to-stock rate increased to more than 8 percent for the month of September. Given that the restocking applied to medications purchased before our visits, it is unlikely that there were any significant changes in the packaging of the medications. These increases resulted directly from our review.

The financial implications are significant. If the average return-to-stock percentage at all CDCR prison pharmacies statewide were to increase from 3.9 percent to 8 percent, which we believe is a conservative number, the increased restocking would generate an additional savings of $7.7 million. Moreover, additional data we gathered indicate that the savings from restocking could be even higher. We evaluated three other prisons specifically because their pharmacists had already made restocking a priority. We analyzed their return-to-stock data for different periods in 2009 and found that those pharmacies had an even higher average return-to-stock rate of 14.3 percent. If the statewide return-to-stock rate were to increase from 3.9 percent to 14.3 percent, the increased restocking would generate a savings of $19.6 million.

In addition to seeing an increase in restocking values after our site visits, we learned that the policy on returned medications was clarified during an October, 2009 meeting with the lead pharmacists. However, there was no reference to the need for uniform purchasing practices that take into account initial costs and the ability to restock medications, or to the need for the timely processing of returns.

Figure 3: Savings from procedural changes in restocking



Finding 2

Not ensuring the use of approved medications costs California taxpayers an additional $5.5 million annually.

CDCR spent $5.5 million more than necessary as a result of health care providers prescribing non-approved medications. The expenditures for non-approved medications have increased significantly because medical staff ignore approved medical alternatives or prescribe items that have a questionable medical necessity. In addition, there is inconsistent oversight of non-approved medication expenditures.

The list of approved medications is referred to as a formulary. This list represents the collective clinical judgment of CDCR's Pharmacy and Therapeutics Committee for the treatment of disease and the prevention of illness. It is a tool to assist health care providers to prescribe treatment that is both medically appropriate and cost effective. Because the Food and Drug Administration authorizes a number of new medications, alternative preparations for existing medications, and over-the-counter combinations of medications each year, medical and mental health professionals can use a formulary to ensure they are providing cost-effective medications that are therapeutically appropriate.

"There is a lot of waste in non-formulary items."

— Lead Pharmacist

There are occasions when physicians need to prescribe medications that are not on the formulary. In some cases, formulary agents are ineffective or not tolerated by the patient. In addition, the only available drug to treat a specific condition may be a non-formulary selection. In these cases, the medical or mental health care professional is expected to make a written request to their supervisor justifying the non-formulary medication as a clinically prudent choice. The medical or mental health supervisor then either approves the request or suggests an alternative.

Photo 6: An example of a prescription item.

Items available over the counter outside of prisons are prescribed to inmates. Some of these items are not on the formulary because they may not be considered medically necessary. Source: Office of the Inspector General.

During the course of our review, the OIG analyzed prescription information for 24 prisons for the months of July, August and September, 2009. Our analysis revealed that the average amount spent on non-formulary prescriptions was approximately $2,200,000 per month for the 111,000 inmates in our sample, or $19.85 per inmate per month (PIPM). In 2007, the amount spent on non-formulary prescriptions was $19.76 PIPM and CDCR successfully reduced that rate to $14.98 PIPM in 2008. However, in 2009, the rate increased by almost a third over the previous year to $19.85 PIPM.

The need to minimize the amount of non-formulary use is because non-formulary prescriptions are typically significantly more expensive than formulary prescriptions. During the months of July, August and September, 2009, the average cost of a formulary prescription for the 24 prisons was 35% of a non-formulary prescription ($30.54 compared to $86.74). As a result, if the average PIPM rate for non-formulary prescriptions for 2009 stayed at the same rate as 2008, adjusted for inflation, and the medications were prescribed off the formulary, we estimate CDCR would have saved in excess of $5.5 million.

In addition, health care providers write prescriptions for many items that are not included on the formulary because they have limited medical necessity. Items such as sunscreen, fish oil, vitamin E, and cough drops, which are sold over-the-counter outside of the prison environment, are often prescribed for inmates who would have difficulty accessing these items in prison. However, some of the items we found, such as the sunscreen (photo 6), could be available in the canteen.

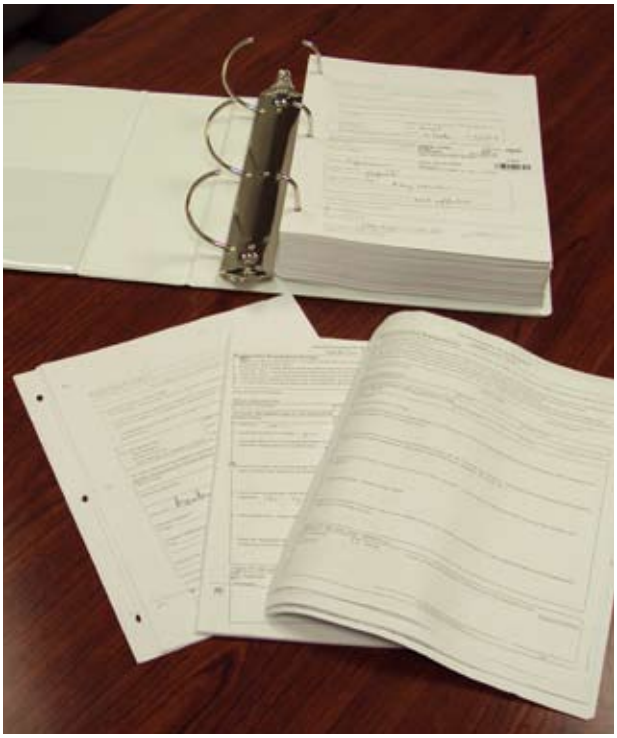


Photo 7: This binder shows 760 non-formulary requests at one prison over a two month period.

Source: Office of the Inspector General.

In its 2006 analysis of CDCR's pharmacy system, Maxor found that there was a lack of adherence to the existing formulary, observing that

(s)ystem-wide policies and procedures for a formulary are established, but left open to institution level interpretations and compliance … . In short, while the CDCR health services central office states that updated policies and procedures and formulary have been implemented, institution level observations revealed that in many cases, guidelines are not followed and prescribing practices follow individual institution developed formularies and treatment approaches. With the absence of central office oversight, compliance and monitoring are difficult at best.

In an effort to correct this issue, Maxor included two goals in its action plan: A) to

develop meaningful and effective centralized oversight, control and monitoring over the pharmacy services program, and B) to implement and enforce clinical pharmacy processes including formulary controls.

"Over here we do a lot of non-formulary, and it seems like every request for non-formulary gets approved. We very rarely see one denied, so I think the process needs to be looked at. 99.9% are approved, only three denials in two years."

— Lead Pharmacist

The plan for ensuring formulary compliance included 1) reconstituting the Pharmacy and Therapeutics Committee, 2) issuing an up-to-date formulary along with the related policies and procedures, 3) developing a monitoring tool, and 4) creating a group of clinical pharmacy specialists who would conduct reviews of formulary adherence at each institution and provide feedback at both the regional and institutional level. While the Receiver successfully implemented the first three objectives, the monitoring function was never fully implemented due to budget reductions eliminating the positions in 2009, midway in the implementation of the new pharmacy program. Elimination of these positions has contributed to the inconsistent oversight of non-approved medication expenditures.

Finding 3

Unreliable computer inventories in prison pharmacies result in additional staff labor and increased costs.

Concern over pharmacy inventories is not new to CDCR. In its 2006 review of CDCR pharmacies, Maxor noted significant inventory problems, noting that "based on a sampling of selected medications, it appears that millions of dollars of purchased medications are not accounted for in the prescription dispensing data." In the same report, Maxor observed, "Such disturbing variances (in excess of 30%) indicate a serious lack of pharmacy management and inventory control, as well as a high level of waste and potential for drug diversion."

Maxor's solution to the inventory problem is laid out as a goal in its pharmacy implementation plan, whereby Maxor proposed that "[a] computerized perpetual inventory system with integrated reclamation software will be utilized to achieve inventory control, monitor diversion, increase inventory turns, track returned medications, and re-circulate returns when possible to maximize inventory value."

The purpose of this goal was to "implement a perpetual inventory system in which dispenses are subtracted from inventory in real-time and daily inventory orders are automatically posted to the individual pharmacies' inventory."

The GuardianRx computerized inventory system had been in use for at least six months in all nine prisons that we reviewed and it includes many useful tools such as drug interaction detection, readily accessible medication profiles, and medication utilization data. However, most pharmacy staff told inspectors that the new computer inventory system was not accurate and could not be trusted. While visiting one pharmacy, an inspector took a bottle of medication from a shelf and asked the pharmacist if anyone would notice if he removed the bottle. The pharmacist replied, "Probably not." Pharmacy staff at three additional institutions gave similar answers.

"The computer inventory is not a useful tool for us."

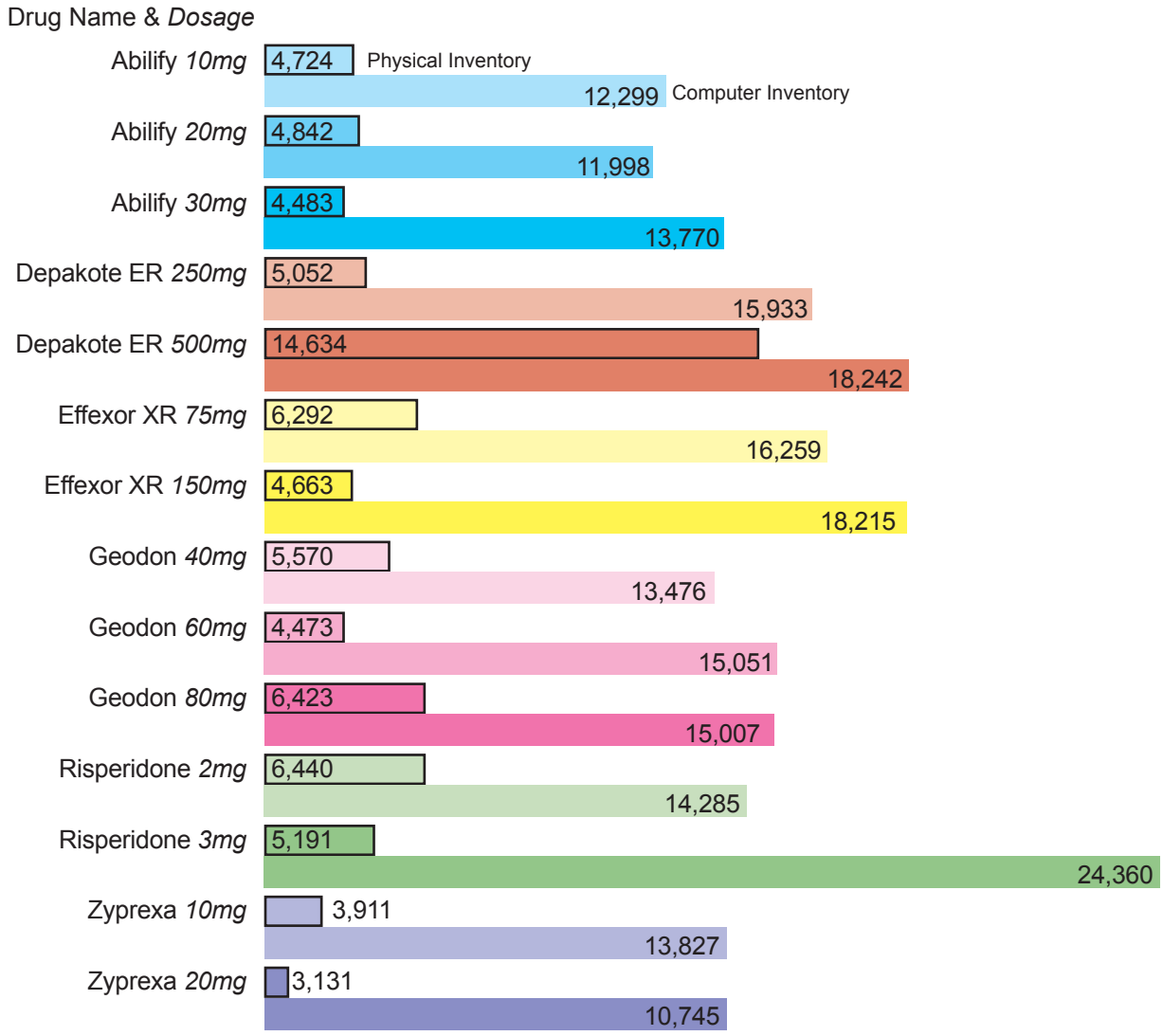
— Lead Pharmacist

In order to test the accuracy of the computer inventory system, we selected 14 medications from the most expensive stocked in prison pharmacies, and compared the physical inventory to the computer inventory at the nine prisons reviewed.[1] The following chart illustrates the differences between the computer inventory and the actual stock on hand of these 14 medications at all nine prisons. The most significant disparity was in Risperidone 3mg., of which inspectors counted 5,191 actual tablets while the computer inventory indicated a stock of 24,360 tablets. This is a difference of 470 percent. The discrepancy between the computer inventory and the physical inventory of these medications demonstrates the unreliability of this system.

1 Narcotics are maintained in a separate, controlled environment and are not included in this data.

Figure 4a: Comparison of computer inventory of 14 selected medications with the actual stock on hand at the nine prisons reviewed.

Source: Office of the Inspector General



At $0.58 per unit, the difference between the cost of the actual stock of Risperidone 3mg. and the cost of the computer inventory for that medication is more than $11,000. As Figure 4b demonstrates, the cost difference between the computer inventory of the selected medications and the actual stock on hand at these nine prisons alone comes to more than a million dollars.

When we inquired about the inventory disparity, pharmacy staff provided several explanations, including:

- Medications are added to the computer inventory when ordered instead of when they are received.
- If, for some reason, stocked medications are returned to the supplier, they are not consistently removed from the computer inventory.

Figure 4b: Cost comparison of computer inventory with physical inventory for 14 drugs.

Source: Office of the Inspector General

Drug Name & Dosage	Actual Total	Total Computer	Total Difference	Cost Per Unit	Total Cost Differential
Abilify 10mg	4,724	12,299	7,575	$12.60	$95,445.00
Abilify 20mg	4,842	11,998	7,156	$17.81	$127,448.36
Abilify 30mg	4,483	13,770	9,287	$17.81	$165,401.47
Depakote ER 250mg	5,052	15,933	10,881	$1.76	$19,150.56
Depakote ER 500mg	14,634	18,242	3,608	$3.23	$11,653.84
Effexor XR 75mg	6,292	16,259	9,967	$1.75	$17,442.25
Effexor XR 150mg	4,663	18,215	13,552	$4.49	$60,848.48
Geodon 40mg	5,570	13,476	7,906	$5.93	$46,882.58
Geodon 60mg	4,473	15,051	10,578	$7.19	$76,055.82
Geodon 80mg	6,423	15,007	8,584	$7.19	$61,718.96
Risperidone 2mg	6,440	14,285	7,845	$0.52	$4,079.40
Risperidone 3mg	5,191	24,360	19,169	$0.58	$11,118.02
Zyprexa 10mg	3,911	13,827	9,916	$12.40	$122,958.40
Zyprexa 20mg	3,131	10,745	7,614	$24.80	$188,827.20

Total for 9 institutions: **$1,009,030.34**

- Medications dispensed through a prison hospital are not automatically removed from the computer inventory.

In addition to the explanations provided by pharmacy staff, we observed instances in which staff practices contributed to the inventory discrepancies:

- In one pharmacy, we found medications that had been returned from prison yards were scanned back into the computer inventory and then discarded, thereby creating inaccuracies.

- In another pharmacy, we found that staff were returning medications to stock without scanning them back into the inventory.

Inventory counts are of no value

We were informed that a physical count of each pharmacy's inventory is taken once a year by an outside vendor; however, pharmacy staff explained that this yearly inventory is not a meaningful tool because the computer inventory system is not reconciled to the stock on hand.

In an effort to perform a timelier inventory check in addition to the yearly inventory, Maxor implemented routine cycle counts, an inventory control procedure in which selected medications are periodically inventoried. Cycle counts can only be done when no orders are pending, which means they must be performed before or after the day's work. Some pharmacy staff said that it is not feasible to conduct cycle counts because the high volume of prescriptions they process daily does not leave them enough time to complete this task. One pharmacist

commented that Maxor had requested cycle counts but had never followed up, so staff did not conduct them. Another pharmacist explained that his staff had originally performed the cycle counts, hoping to correct their inaccurate computer inventory; the inventory problem persisted, however, so they stopped doing the cycle counts.

Ultimately, we question the value of the yearly physical counts and the cycle counts, since pharmacy staff are merely adjusting the electronic inventory to match the physical inventory without determining the causal factors for the disparity.

Automated features "auto-refill" and "auto-reorder" require manual correction

The failure to maintain an accurate computerized pharmacy inventory has also resulted in additional staff workload. Pharmacy staff explained that the computer inventory is tied to the daily "auto-refill" component of the dispensing system, an automated function which fills an individual's ongoing prescriptions, such as blood pressure medication. These ongoing or maintenance medications are filled for 30 days at a time. Each pharmacy refills hundreds of these orders daily.

Because the computer inventory is not accurate, the auto-refill's functioning impedes the pharmacy staff, who manually override the computer system in order to accomplish their tasks. For example, the computer system will only allow prescriptions to be filled if the computer inventory shows that there is stock available to fill the prescriptions. If the computer inventory shows less than is needed, the computer program will not allow the prescription to be filled, even if there is actually a sufficient stock on hand. Pharmacy staff must then manually override the system to fill each of the prescriptions, or manually change the computer inventory to show a sufficient quantity to fill the prescriptions. Inspectors noted that this manual adjustment of the computer inventory also contributes to the disparity between the electronic inventory and the physical inventory.

"The issue is the inventory control problem. Auto-refill cannot work with inventory as it is."

— Lead Pharmacist

The computer system also includes an "auto-reorder" component, which, in theory, should track dispensed medications and create orders to replace those medications in the pharmacy inventory. In reality, however, an inaccurate computer inventory system also results in the need for pharmacy staff to manually track the dispensed medications so that they can order new stock.

"We used the auto-reorder at first because Maxor insisted, but we got so much stuff we didn't need that it would be dysfunctional to trust the system."

— Lead Pharmacist

Pharmacy staff described instances in which they had allowed the system to automatically place their medication reorder, only to receive unneeded items and/or excessive quantities. One staff member estimated that 70 percent of the items suggested by the auto-reorder function were not needed. For example, when staff allowed the auto-reorder system to place an order at one men's prison, they received birth control pills; pharmacy staff who used the auto-reorder function at another men's prison noted that they received a shipment of vaginal estrogen tablets.

Rather than relying on the automated system, pharmacy staff members keep a daily list, which they use to place reorders. In one pharmacy, inspectors observed a cardboard box with empty medication containers in it. Pharmacy staff told inspectors that the empty containers are placed in the box and later used to place an order at the end of the day. Because staff is unable to rely on the computer inventory system, they estimated that it took between thirty minutes to three hours of additional work daily to prepare the reorder to replenish their medications inventory.

Finding 4

Inconsistent practices in handling medications for inmates who transfer between prisons result in waste and increased costs.

CDCR transfers approximately 156,000 inmates a year among its various prisons throughout the state. Over 100,000 of those inmates are taking prescribed medications. Since each of the 100,000 inmates receives an average of five and a half prescriptions, the amount of medication involved in the transfer process is enormous. While the Receiver has the ultimate jurisdiction to ensure that inmates have access to their medications in an efficient and economic manner, a coordinated effort among medical, pharmaceutical, and custody staff at both the sending and receiving institutions is necessary to minimize waste and ensure that there is no interruption to an inmate's drug therapy. As a result of the numerous staff involved in the process, our review into this area focused on six prisons.

We found that four of the six prisons over-dispense medications when they transfer inmates to another institution. We also found that a high percentage of inmates arrive at the receiving prison without their prescribed medications. And we discovered that once inmates arrive at the receiving prison, all of their medications are refilled, regardless of the amount of medication sent from the previous prison. All extra medications are returned to the receiving prison pharmacy, where it is highly unlikely they are restocked.

Photo 8: Incoming inmate transfer medication.

Source: Office of the Inspector General.

Our findings are similar to those referred to in the 2005 court decision to appoint a Receiver, in which the court found that prescriptions were not consistently transferred with the inmates, resulting in large quantities of medication being discarded, and that the receiving prisons routinely disregarded prescriptions from the sending prisons.

Some pharmacies dispense more medication than is required for transfer

To ensure the continuity of medical treatment when an inmate is transferred to another institution, the prison's staff is required to ensure that a minimum three-day supply of all currently prescribed and essential medications is sent along with the inmate. When an inmate's remaining supply is less than the prescribed dosage for three days, the nursing staff notifies the pharmacy, which dispenses the additional dosages.

If an inmate's prescription was recently filled, there may be several days or weeks' worth of dosages already dispensed and available to be sent with the inmate. However, we found that pharmacies at four of the six prisons we visited dispense at least a three-day supply of each inmate's prescribed medications, regardless of the number of dosages already available. A nurse at one institution said she routinely orders a three-day supply of medication to be sent with each inmate transferring as a safety precaution. One lead pharmacist's reason for preparing a three-day supply of an inmate's current medications is that he cannot be sure the remaining medications will be transferred.

The fifth prison's pharmacy staff explained that they only fill a three-day supply if the inmate's medication record shows that less than five days' doses remain, based on the date the medication was last dispensed. The sixth prison's pharmacy staff said that about one year ago, they stopped their practice of routinely filling a three-day supply for all inmates who were scheduled to transfer. Instead of relying on an inmate's medication record, pharmacy staff at that prison rely on the nurses assigned to the transfer unit to advise them if an inmate has less than three days' worth of medication on hand. This pharmacy has not filled a transfer order of medications in over a year because the nurses have not indicated a need for transfer medications. However, data from one receiving prison shows that in one month, over half of the inmates sent from this prison did not arrive with their required medications.

Inconsistent practices result in some inmates arriving without their prescribed medications

Some inmates do not arrive with their prescribed medications, even though medical staff at the transferring prison are supposed to pick up all medication from the inmate's housing unit clinic, prior to the inmate's departure, and transfer the medication. Inmates in possession of self-administered medications are supposed to give their medications to staff. The medications are then packaged with the inmates' medical records and taken by transportation officers to the receiving prison. We spoke with some of the nurses screening new arrivals and learned the following:

- One prison reported that of the total of 49 inmates arriving from other institutions in a week, only half came with their required medications.

- At another prison, a review of inmates who arrived in a one week period showed that about a third arrived without their medication.
- A nurse at a third prison reported that out of 20 inmates who arrived on one day, 15 had at least one prescription for medication, yet almost half of the 15 arrived without their medication.

Upon arrival, inmates are prescribed additional medications whether they need them or not

When inmates arrive with a supply of medications, those medications are not used up before a new prescription for the same medication is reordered by the medical staff at the receiving prison. At five of the prisons we visited, we were told that when inmates arrive with a supply of medication, that medication is sent to the housing units' clinics, where it will be administered only until a new refill is dispensed from the pharmacy, which is usually the same day or the next day. The unused medication is returned to the pharmacy, but it can only be re-stocked under very specific conditions. The sixth prison's lead pharmacist explained that their general practice is that only medications filled from their own pharmacy are sent to the housing units and that any medication coming from other prisons is destroyed.

For inmates with self-administered medications, such as inhalers, new refills are also dispensed shortly after arrival. Pharmacy staff showed inspectors a bag full of inhalers found in the possession of one inmate. The inmate had been transferred between prisons and had several unused inhalers he received from at least two prisons. The pharmacist stated that one inhaler was dispensed upon arrival at the receiving prison, which was two days after the inmate had last received one from the sending prison.

Photo 9: Overdispensed inmate medication.

The inhalers shown have an approximate value of $1200
Source: Office of the Inspector General.

Recommendations

To address the deficiencies identified in this report, the California Prison Health Care Receivership Corporation should take the following actions:

Medication Restocking

- Establish and enforce procedures to maximize the restocking of usable drugs.
- Develop guidelines to determine when to purchase unit dose versus loose tab medications to maximize the return of drugs to pharmacy inventory, and monitor purchases to ensure compliance.
- Review existing staffing levels within pharmacies to ensure that adequate resources are available to restock drugs to inventory.

Formulary Adherence

- Monitor the prescribing of over-the-counter items that have a limited medical necessity and develop processes to limit prescribers' ability to provide such items.
- Identify institutions and individual prescribers that consistently do not adhere to the formulary and provide instructions to rectify the prescribing behavior.
- Ensure that there is a strong clinical pharmacy presence at prisons to provide training and direction to reduce the use of non-formulary prescriptions, maintain accurate inventories, and promote efficiencies.

Inventory control

- Develop and implement procedures to ensure an accurate computer inventory system in order to monitor inventory shrinkage, reduce staff labor, provide accurate management reports, and provide accountability.
- Provide guidance to pharmacy staff on how to use the computer inventory system to account for medications dispensed to prison hospitals.
- Ensure that the auto-refill and auto-reorder systems work effectively without manipulating the electronic inventory.

Inmate transfers

- Monitor transferring inmates and identify any prisons that are not forwarding medications to the receiving prison; identify the cause of the failure to follow procedure and take appropriate action.
- Ensure that prisons transferring inmates to other institutions take into account the quantity of previously dispensed medications before requesting a three-day supply from the pharmacy, and monitor for compliance.
- Develop a procedure to ensure that the receiving institution's pharmacy does not refill medication before it is necessary, and monitor for compliance.

California Prison Healthcare Receiver's response to the special report (page 1 of 8)

STATE OF CALIFORNIA
PRISON HEALTH CARE SERVICES

J. Clark Kelso, Receiver

April 7, 2010

Mr. David R. Shaw
Inspector General
Office of Inspector General
P.O. Box 348780
Sacramento, CA 95834-8780

Re: Response to OIG Special Report – Lost Opportunities for Savings within California Prison Pharmacies

Dear Mr. Shaw:

We have reviewed the Office of the Inspector General draft report on California Prison Pharmacies. While we welcome and concur that there are opportunities for further improvements in our pharmacy operation, tremendous investment and efforts have been undertaken as described in our enclosed response.

Again, we would like to thank you and your staff for the valuable review and recommendations.

Sincerely,

J. Clark Kelso
Receiver

Enclosure

cc: Honorable Thelton E. Henderson
Elaine Bush, Chief Deputy Receiver, CPHCS
Bonnie Noble, Director, Allied Health Services, CPHCS
Wayne Gohl and Eugene Roth, Chief (A), Pharmacy Services, CPHCS
Brenda Epperly-Ellis, Director, Policy, Planning and Evaluation, CPHCS
Johnny Hui, Chief, Internal Audit, CPHCS

P.O. Box 4038 • Sacramento, CA 95812-4038

California Prison Healthcare Receiver's response to the special report (page 2 of 8)

Response to
OIG Audit
SPECIAL REPORT
LOST OPPORTUNITIES FOR SAVINGS WITHIN
CALIFORNIA PRISON PHARMACIES

Response Overview

As demonstrated in the history presented in the report, reform of the CDCR pharmacy program has represented a significant challenge. Transforming the system from one consisting of 33 separate and poorly performing pharmacy operations, each of which operated independently from one another, to an effective centrally coordinated pharmacy program has required significant time, resources and effort and remains a work in progress. As a part of the Turnaround Plan put in place by the Receivership, a progression of carefully planned steps are being taken to put in place a centrally administered, standardized approach to the delivery of pharmacy services that is already resulting in a more responsive and cost-effective program. While there remains much work to achieve these goals, significant progress has been made.

This document represents the California Prison Health Care Services (CPHCS) Receiver's response to the final draft of the "Special Report: Lost Opportunities for Savings within California Prison Pharmacies" received on March 30, 2010 from the Office of the Inspector General (OIG). The following pages provide a summary response to the key findings and recommendations noted in the report prepared by the OIG regarding the CDCR prison pharmacy program.

The following provides highlights of our response and recent achievements accomplished for the pharmacy operation:

Pharmaceutical Costs

- CDCR drug expenditures were increasing at double-digit rates. Since implementing our program improvement, pharmacy expenditures have increased 2% or less each year, which is a fraction of the national trend of 6-7%.
- This change is even more significant when one considers that many of the related medical care improvement initiatives being implemented concurrently have increased the numbers of inmate-patients being treated and the level of access to care.

Medication Management

- $20.3 million in cost avoidance achieved in 2009 due to formulary management and targeted drug contracting efforts.
- 80% of the prescription drugs are filled using generic medications.
- $2.6 million per year in decreased use of non-formulary drugs ($19.76 per inmate in 2007 to $18.38 in 2009).

Return to Stock and Waste

- $13 million in Return-to-Stock savings are projected for this fiscal year.
- $4.7 million in credit for returned drugs have been recorded since 2007.

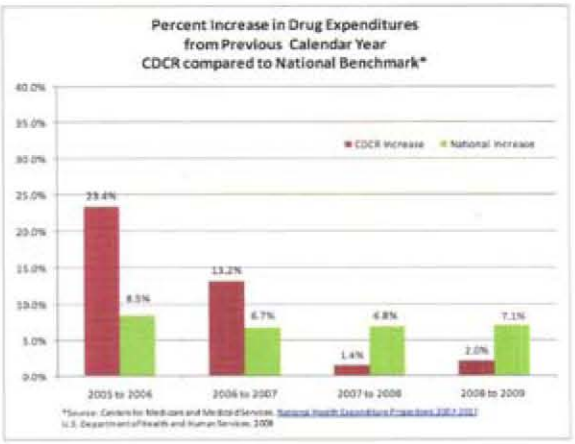
Additional benefits with Central Fill Pharmacy

- Standardized bar code labeling and automation will allow for efficient and accountable reclamation.
- Significant inventory benefits by shifting most of the prescription processing to a central facility with economies of scale and centralized, automated controls.

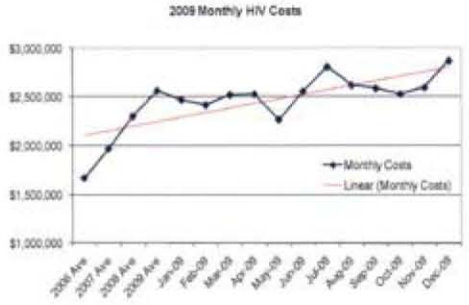
1

Pharmacy Costs

While pharmacy costs have risen slightly over the last three years, the rate of rise is dramatically lower than that experienced prior to the Receivership's efforts to reform the pharmacy program. Efforts to control the costs of pharmacy care have resulted in a significant lowering of the annual increases seen in prior years. These efforts, led by an actively engaged Pharmacy and Therapeutics Committee, have included such actions as requiring the use of generic medications whenever possible, actively managing the formulary, employing targeted drug contracting strategies, utilizing therapeutic interchanges, developing disease guidelines and optimizing dosing in medication therapies. As illustrated in the adjacent chart, the percentage increase in drug expenditures in 2009 (2.0%) is well below the 23.4% and 13.2% increases seen in 2006 and 2007 respectively. In addition, in comparing benchmark projections, the increase was about a third of that expected nationally.



This change is even more significant when one considers that many of the related medical care improvement initiatives being implemented concurrently have increased the numbers of inmate-patients being treated and the level of access to care. For example, the charts that follow illustrate the increased costs experienced in HIV and Hepatitis C medications respectively resulting primarily from increased access to treatment for these conditions. By the end of 2009, CDCR was spending almost double the amount of money each month for HIV medications than in 2006 before the reform efforts began. Over that same time comparison, Hepatitis C medication spending has increased almost eightfold. In dollar terms, CDCR spent $11.1 million more in 2009 than in 2008 for HCV medications and $3.1 million more for HIV medications.



Ongoing program savings have also been demonstrated due to direct activities related to formulary management and targeted drug contracting. Through the P&T committee, certain drugs are targeted for specific purchase agreements that provide additional discounts in price through preferred formulary status. These efforts resulted in $20.3 million in cost avoidance in 2009 alone. This same initiative yielded a cost avoidance of $16.4 million in 2008.

Facility Pharmacy Oversight

To address issues relating to the oversight of facility level pharmacy operations, the Receiver's Office took steps in December 2009 to establish a clear line of authority for pharmacy operations with the appointment of the Chief of Pharmacy (A). This state employee has direct line and disciplinary authority over the pharmacies and is charged with enforcement of statewide pharmacy policies and practices. Regular communications, including monthly

meetings of all Pharmacists-In-Charge at each facility are being conducted to review and reinforce policies and expectations.

Reducing Medication Waste/ Return to Stock

The reduction of medication waste has been a matter of ongoing attention throughout the pharmacy improvement initiative, providing for the first time a means of accounting for the amounts returned and wasted. This fiscal year, more than $13 million in return to stock is projected.

†① A need identified early on was the lack of a functional returns contract. Subsequently, a contract was negotiated and approved by the Receiver with Guaranteed Returns to provide a means for which medications that could not be reclaimed could be legally returned and credit obtained when possible. Since the contract was initiated in 2007, returns credit of approximately $4.7 million has been recorded.

② Subsequent to that effort, as a part of the GuardianRx pharmacy operating system implementation, a Return-to-Stock (RTS) function was developed to provide for the first time a mechanism to account for and track the reclamation of medication within the system. Evidence of such efforts can be found by examining the chart to the right which documents the increasing engagement in the RTS process by CDCR facilities. *Tracking of this issue was first initiated in September 2008, with the first month reporting about $300,000 in RTS. By February 2010, the RTS amounts have more than quadrupled to almost $1.3 million per month.*

In just the first eight months of this FY, actual RTS amounts are over $7.8 million. We project that the value of RTS captured in the current fiscal year will be over $13 million.

The report suggests that the presence and discussions by the OIG inspectors with three prisons resulted in an immediate increase in their RTS results. While not denying that the OIG discussions may have had an impact on the facilities, to say their presence was the direct reason for the increase ignores the fact that other facilities, not visited by the OIG also reflected increases in RTS throughout the last 18 months since tracking of these activities began. In fact, during September 2009, (the month referenced in the report) the overall amount of RTS recorded increased by $344,000, only about a third of which is accounted for by the three facilities named. The report also acknowledges that higher restocking rate facilities have been more successful by employing the very strategies that have been part of our ongoing training efforts: incorporating the restocking duties into the regular workday routines and using unit dose medications when available. The process of transferring such "best practices" from one facility to the others is an ongoing part of the overall work involved in the Receivership's effort to improve pharmacy operation.

While the Return-to-Stock process continues to show improvement and will be a point of continued emphasis, it is also important to acknowledge other Receiver initiatives aimed at reducing the need for facilities to use the return to stock processes. There are two primary initiatives of the Receiver's pharmacy improvement efforts that will have substantial near term and long-term impacts on reducing waste. These two projects are the establishment of a Central Fill Pharmacy (near-term) and the development of an eMAR or electronic medication administration record (longer-term).

The Central Fill Pharmacy (CFP) project entails the construction and equipping of a centralized prescription packaging and automated distribution system. The automated centralized pharmacy is designed to gain advantages of scale related to efficient purchasing, inventory control, volume production, drug distribution, workforce utilization, and increased patient safety. To achieve these advantages, the new centralized pharmacy building will assume the majority of the drug distribution functions for all CDCR facilities, with the exception of immediate needs fill, and such items as medications requiring refrigeration and intravenous solutions. *The CFP will order bulk pharmaceuticals to be delivered*

† Circled numbers correspond to OIG's response (beginning on page 37) to CDCR's response text.

to the CFP thereby consolidating drug purchasing, decreasing system-wide inventory and the current need to maintain duplicative inventories at each facility. CFP automation will be used to package bulk pharmaceuticals into 30-day dose blister packs; fulfill prescription and stock orders for all CDCR correctional facilities; label medications as required to meet state and federal prescription requirements; provide bar-code validation matching the drug to the specific prescription; and to sort the completed orders for shipping and next-day delivery to the facilities. *By using the CFP prepared blister packs for medication, the advantages cited in the report for unit dose packaging will be achieved for all the drugs (brand and generic) that are issued.* Stock at the facilities for immediate needs fill will also be packaged in this manner and provided by the CFP. The Central Fill Pharmacy will also be equipped with automation to sort and reclaim returned medications eligible for reuse. *Instead of having each facility reclaim medications, the medications will be returned to the CFP where the standardized bar code labeling and automation will allow for efficient and accountable reclamation.* The CFP is scheduled to begin operation in May 2010 and will be deployed to all facilities over the subsequent 18 month period. Equipment installation and training of staff begins in April 2010, followed by final system testing and initial stock preparation activities in May. Beginning in June and July, respectively, two facilities will be implemented as test sites to validate the implementation processes. Beginning in August 2010, two additional facilities will be added to the CFP each month until all facilities have been converted.

A longer term solution is the implementation of an Electronic Medication Administration Record to transform the medication administration process and provide important benefits that improve patient care, increase accountability and result in a more cost effective medication administration process. These benefits represent significant improvements in access to care and a decrease in the amount of health care and corrections staff time required to ensure that the right medication is administered to the right patient, in the right dosage, at the right time. Further, an eMAR assures continuity of care by making patient profiles available at any medication administration area statewide. *The system would reduce waste and address inmate-patient movement by using standard bar coded blister cards for stock medications, rather than patient-specific cards.* The medication profiles would be available for any patient at any authorized eMAR terminal. The patient presents and his/her scheduled medications are displayed and can be immediately administered via a stock card. The inventory of the medication is decremented and the medication administration is recorded. The eMAR initiative will require an extensive effort and must be coordinated with other long-term infrastructure and information technology projects underway within the Receivership. At this time, development of the eMAR system is anticipated to begin in about 24 months.

Non-Formulary Medication Approval Process

Management of both formulary and non-formulary costs is an ongoing effort led by the CDCR Pharmacy and Therapeutics (P&T) Committee and clinical leadership. The formulary management processes put in place through the Receiver's efforts are designed to push prescribing towards the most cost-effective medications. Under current policies, drugs are purchased in their generic form when available and automatically substituted for the corresponding brand name product. *In CDCR, 80% of the prescription drugs are filled using generic medications.* Prescribers may not use propriety product when a generic equivalent is available unless a non-formulary request is approved by their superior. Some medications are also placed on non-formulary status to force a second-level review of their use because of such factors as their high cost or their risk profile. It is important to understand that placement of a drug on non-formulary status does not mean the medication is not medically necessary, but rather that a more careful review of its use is indicated.

When examining non-formulary costs, it is important to recognize that such costs constantly change as the P&T Committee adds and deletes items from the formulary each month. These decisions, which normally take about 90 days to be implemented, regularly shift costs between the formulary and non-formulary categories. For example, during the months cited in the report, the P&T Committee converted from Effexor XR to the newly available generic ER form of the drug. The spending (shift to NF) for Effexor XR was $366,483 for the six months from July-December of 2009. This one example accounts for about $0.38 per inmate per month of the non-formulary costs over this time period. As the shift to the generic ER is fully realized, the costs for the Effexor XR version that were shifted from the formulary to non-formulary will go down.

Additionally, an examination of non-formulary costs should also account for any outlier situations that can impact the costs. For example, during the period from July-December 2009, one state prison had a patient requiring a highly expensive antihemophilic factor medication resulting in an unanticipated $1,310,794 in costs, all non-formulary. These costs contributed significantly to the higher non-formulary costs for this period.

The report cites a calculation of $19.85 per inmate per month in non-formulary costs for a three-month period in 2009 for 24 prisons and compares those costs to the system wide data (for all 33 prisons) for 2007 and 2008. The system wide data is tracked based on actual purchases and reported monthly to the P&T Committee. That data shows that the system wide cost per inmate per month for non-formulary medications in 2009 was actually $18.38. *A three year comparison for all 33 facilities shows non-formulary costs been reduced from an average of $19.76 in 2007 to $18.38 in 2009, without adjusting for inflation, representing more than $2.6 million in savings per year.* ③

CPHCS leadership has, over the last year been actively engaged in several efforts to improve medication utilization. In recent months, the clinical leadership team has identified and distributed a Medication Efficiency and Quality Improvement (MEQI) initiative that has targeted several goals related to medication utilization including a reduction in non-formulary medications to three percent or less of total prescriptions. *Initial results of these efforts are promising. In January and February of 2010, non-formulary costs per inmate per month averaged $16.01, significantly lower than the $18.38 average for 2009.*

CPHCS clinical leadership has also been actively examining the use of over-the-counter (OTC) medications and has implemented a strategy to reduce the use of non-medically necessary items. An initiative was launched in February 2010 that will *remove certain OTC products from the formulary* that have been determined to be non-medically necessary. Examples of items that have been discontinued include fish oil, glucosamine, muscle rub, certain vitamins and vapor rub. *Other OTC items have been moved to a non-formulary status* requiring the prescribing provider to document the medical need for the items, including lotions, digestive aid (Lactaid) and diphenhydramine (Benadryl).

Pharmacy Inventory Management

The effective management of pharmacy inventory requires an integrated set of strategies and is a work in progress. The three primary strategies adopted by the Receivership involve the deployment of the GuardianRx pharmacy system; the implementation of a centralized pharmacy; and the development of an eMAR system. These three components provide a foundation for a comprehensive inventory management process. As these strategies are implemented, associated improvements in inventory management will be gained.

④ The GuardianRx pharmacy operating system provides for the first time, a number of tools for the pharmacies to use to manage their work. The system includes a comprehensive set of tools for managing inventories and the ordering process. Additionally, unlike the prior ineffective data systems, the GuardianRx system ensures compliance with established legal and regulatory requirements and maintains data needed to manage the work effectively. The changeover to this system has entailed extensive training and changes to pre-existing workflows. The inventory system contained within the GuardianRx operating system provides an effective tool for managing inventory that is used successfully to manage pharmacy inventories across the nation. Pharmacy management has recognized that effective use of the inventory system requires additional training, especially in light of the prescription workloads that must also be addressed each day as a first priority. Management has responded with an ongoing effort to revisit institutions to provide them with the technical assistance and training tools necessary to fully utilize the system, including a series of "go-back" visits by pharmacy operations teams. These "go-back" efforts are targeting additional education on inventory and related functions, such as the RTS, auto refill and auto order functions.

Implementation of the Central Fill Pharmacy will provide significant inventory benefits by shifting most of the prescription processing to a central facility where economies of scale and centralized, automated controls can be put in place. Without this component, current pharmacy operations would remain decentralized, with duplicative inventory. By redirecting much of the workload from the facilities, the CFP initiative will significantly reduce the inventories needed at the facility level and will allow the facility pharmacy staff to better utilize their limited resources to manage the inventories.

The final component in improving the management of medication inventory is the long-term deployment of an eMAR to provide accountability for medications from the point of purchase to the point of administration. The benefits of an eMAR are discussed earlier in this response.

Transfer of Medications

Management of the transfer of medications is a complex issue that involves many more disciplines than simply pharmacy. Custody, transportation, nursing, medical and pharmacy staff are all involved in the process. Extensive effort is underway to address these issues, but much work remains. Policies and procedures have been

developed that require the sending facility to transfer remaining patient medication to the receiving facility. If the remaining quantity is less than 3 days, the sending pharmacy is required to fill a three-day supply. The receiving facility is expected to accept and use the transferred medications. Policies have also been developed to address the issues related to inmates with multiple keep on person medications, such as inhalers. To prevent hoarding and for safety reasons, medical policies state that patients are expected to complete a "one for one" exchange of such items when they are issued (e.g., in order to obtain a new inhaler, the inmate is expected to turn in the old one). Education efforts related to these processes are ongoing.

As a result of the implementation of the Central Fill model, the standardization of labeling and packaging should help to mitigate this issue. One point of resistance to allowing prescriptions from other prisons has been concern over their legitimacy, given the wide variance in packaging and labeling. As noted earlier, the long term resolution of this complex issue rests with the deployment of an eMAR system that would virtually eliminate the need to transfer nurse-administered medications. The inmate's electronic medication profile would be available at any facility throughout the system and could be filled using stock cards with no wasted doses.

Recommendations

CPHCS generally concurs with the recommendations of the OIG as summarized below. In many cases, activities related to the recommendations are already underway.

- *Establish and enforce procedures to maximize the restocking of usable drugs.*
  Steps to establish and enforce procedures to maximize the restocking of drugs are already underway. As documented in our response, these steps are already resulting in reclamation savings each month. With the recent appointment by the Receiver of the Chief of Pharmacy (A), who has direct line and disciplinary authority over the pharmacies, enforcement of these efforts will be enhanced. As the CFP comes online increased opportunities for reclamation will be realized through the use of standardized blister packaging and much of the restocking activity will shift to the CFP and be automated. Over the long term, the eMAR solution proposed for the CDCR system will eliminate much of the need for restocking.

- *Develop guidelines to determine when to purchase unit dose versus loose tab medications to maximize the return of drugs to pharmacy inventory, and monitor purchases to ensure compliance.*
  Through the P&T committee, pharmacy administration will review and update relevant policy and procedures to provide more guidance relating to the purchase of unit dose versus loose tablet medications. As the new CFP assumes responsibility for processing the majority of the prescriptions, the use of blister packaging will resolve this issue and maximize the opportunities to reclaim medications eligible for reissue.

- *Review existing staffing levels within pharmacies to ensure that adequate resources are available to restock drugs to inventory.*
  Staffing levels are and will continue to be assessed on a quarterly basis and recommendations for adjustments made as necessary. A staffing pattern for the CFP implementation includes the responsibility for inventory oversight as a primary duty of prison level pharmacy staff. Pharmacy administration will continue to work with Pharmacist-In-Charge's on prioritizing inventory and restocking tasks within daily pharmacy workflows.

- *Monitor the prescribing of over-the-counter items that have a limited medical necessity and develop processes to limit prescribers' ability to provide such items.*
  The Receiver's clinical leadership team has already developed and has sent out for implementation a program targeting OTC utilization. Developed by a multidisciplinary clinical team, the initiative is designed to reduce the use of non-medically necessary OTC products. Pharmacy Services is supporting the initiative with the production of monthly OTC data as a part of the managed care report sets. This data will assist regional and local clinical leadership to manage OTC usage.

- *Identify institutions and individual prescribers that consistently do not adhere to the formulary and provide instructions to rectify the prescribing behavior including disciplinary action if warranted.*
  This recommendation is already being addressed. Monthly medical utilization reports provide tools that the regional medical director and service chiefs can use to review and evaluate prescribing patterns. These reports drill down to the prescriber level. In addition, the monthly Medication Efficiency and Quality Improvement and

medical program management reports provide data for the supervising physicians to use to influence prescribing behavior.

- *Ensure that there is a strong Clinical Pharmacy Specialist presence at prisons to provide training and direction to reduce the use of non-formulary prescriptions, maintain accurate inventories, and promote efficiencies.*
  In lieu of placing clinical pharmacists at prison sites, the clinical pharmacy focus has shifted to providing and educating clinical leadership on the managed care tools available to them. Pharmacotherapy medication consults have been initiated at a number of facilities, providing specific recommendations to address issues such as non-formulary utilization. In the longer term, the tentative CPHCS pharmacy administration structure calls for three regional pharmacists who will exercise operational and clinical oversight. In addition, the implementation of CFP is intended to allow facility level pharmacists to spend more time interacting with prescribers to optimize pharmacotherapy and reduce costs.

- *Develop and implement procedures to ensure an accurate computer inventory system in order to monitor inventory shrinkage, reduce staff labor, provide accurate management reports, and provide accountability.*
  Pharmacy administration will review and develop as necessary additional procedures outlining the use of the computerized inventory system. The policies and procedures will provide more specific guidance with clear responsibilities and expectations outlined. Pharmacy administration will require that the PICs run inventory adjustment reports regularly to ensure the inventory is being maintained. With the recent appointment by the Receiver of the Chief of Pharmacy (A), who has direct line and disciplinary authority over the pharmacies, oversight of this area will be strengthened.

- *Provide guidance to pharmacy staff on how to use the computer inventory system to account for medications dispensed to prison hospitals.*
  To account for medications dispensed to prison hospital settings, pharmacy administration will continue to encourage the conversion to a 7 day fill process that eliminates the need to make manual adjustments. This process has been successfully employed in several facilities within CDCR already. In addition, supplemental training will be provided to allow single day fill sites to account for inventory.

- *Ensure that the auto-refill and auto-reorder systems work effectively without manipulating the electronic inventory.*
  The Receiver's pharmacy consultant will conduct an application logic review of the auto refill and auto reorder systems to ensure that they work as intended and to document how they do so. Written procedures and additional training material detailing the correct methods of maintaining and adjusting inventory in the computer system will be developed and disseminated by pharmacy administration.

- *Monitor transferring inmates and identify any prisons that are not forwarding medications to the receiving prison; identify the cause of the failure to follow procedure and take appropriate action*
- *Ensure that prisons transferring inmates out take into account the quantity of previously dispensed medications before requesting a three day supply from the pharmacy, and monitor for compliance.*
- *Develop a procedure to ensure that the receiving institution's pharmacy does not refill medication before it is necessary, and monitor for compliance.*
  To monitor inmate transfers and identify prisons that are not forwarding medications, the Receiver and CDCR Executive teams will appoint an interdisciplinary work group to review the medication transfer issue. The work group will include medical, mental health, dental, nursing, pharmacy, custody and transportation representatives and be charged with the goal of standardizing the processes involved in transfer of medications. Additionally, this work group would be charged with establishing responsibilities for reporting, following up and correcting facilities who fail to follow the standardized processes.

The Office of the Inspector General's Comments on the Receiver's Response

Although we are not responding to all of the Receiver's statements as outlined in their response, we are commenting on the following specific issues to provide clarity and perspective:

‡ ① The Receiver points out that since 2007, there has been a $4.7 million offset to the reported $7.7 million annual loss resulting from what the Office of the Inspector General reported as the lack of an effective usable medications restocking policy. The offset was a credit received from a contract with Guaranteed Returns for medications returned to the pharmacy and subsequently destroyed through the program.

However, we found that pharmacists used the Guaranteed Returns program inappropriately by destroying drugs that could have been restocked. Although the Guaranteed Returns program provided partial credit for drugs that met specific criteria, pharmacists used this program as a quick and easy way to process the returned drugs out of the pharmacies instead of taking the time to identify the drugs that were eligible for restocking. Consequently, pharmacies likely received pennies on the dollar and had to purchase drugs to replenish drug inventories.

② The Receiver noted that return-to-stock (RTS) reports initiated in September 2008 reported a total savings for that month of $300,000. Returns since that date have reportedly quadrupled, so that by February 2010 the amount of savings was nearly $1.3 million per month.

However, it is important to note that when the report was initially generated in September 2008, only 15 prisons were on the GuardianRx inventory system. By February 2010, there were at least 29 prisons on GuardianRx, almost twice the number of prisons that were reporting in September 2008. Therefore, it is unclear whether the dramatic increase in RTS figures is the result of a more effective restocking program or is merely the result of more prisons using the GuardianRx inventory system.

③ In response to our finding that not ensuring the use of approved medications costs California taxpayers an additional $5.5 million annually, the Receiver asserts that non-formulary costs decreased from $19.76 per inmate per month in 2007 to $18.38 per inmate per month in 2009.

However, we note that the non-formulary costs were reduced in 2008 to $14.98 per inmate per month. The basis for our report's finding was the difference between the failure to maintain this lower 2008 rate of $14.98 and the resulting significant increase (almost a third) in 2009. As we reported in our finding, the consequence of this lack of oversight was an additional cost to California taxpayers.

---

‡ Circled numbers correspond to CDCR's response text beginning on page 30.

④ Even though we found that the GuardianRx inventory system was unreliable, resulting in increased staff labor costs, the Receiver believes that the "GuardianRx operating system provides an effective tool for managing inventory that is used successfully to manage pharmacy inventories across the nation." The Receiver does acknowledge the need for additional training on the system.

However, the Receiver's response did not address our findings that inventory counts were of no value, and that the auto-refill and auto-reorder processes lacked functionality. Clearly, in the manner currently being used by the Receiver in California, the GuardianRX system is an ineffective management tool. This unreliable system results in increased costs.

The Receiver also believes that the Central Fill Pharmacy project will provide significant inventory benefits.

However, it is yet to be determined what effect this will have in maintaining an accurate automated inventory system. We further note that the Central Fill Pharmacy project, developed by the Receiver and originally scheduled for operation in February 2009, has been delayed until May 2010.

SPECIAL REPORT

LOST OPPORTUNITIES FOR SAVINGS WITHIN CALIFORNIA PRISON PHARMACIES

OFFICE OF THE INSPECTOR GENERAL

David R. Shaw
INSPECTOR GENERAL

Samuel Dudkiewicz
CHIEF DEPUTY INSPECTOR GENERAL (A)

Kerry McClelland
DEPUTY INSPECTOR GENERAL, IN-CHARGE (A)

Rusty Davis
DEPUTY INSPECTOR GENERAL

Chris Eagle
DEPUTY INSPECTOR GENERAL

Anna Galvan
DEPUTY INSPECTOR GENERAL

Sueann Gawel
DEPUTY INSPECTOR GENERAL

Debra Maus
DEPUTY INSPECTOR GENERAL

STATE OF CALIFORNIA
APRIL 2010

WWW.OIG.CA.GOV