

PRISON HEALTH CARE SERVICES



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,

A handwritten signature in blue ink, appearing to read 'J. Clark Kelso', is written over the typed name.

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

**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

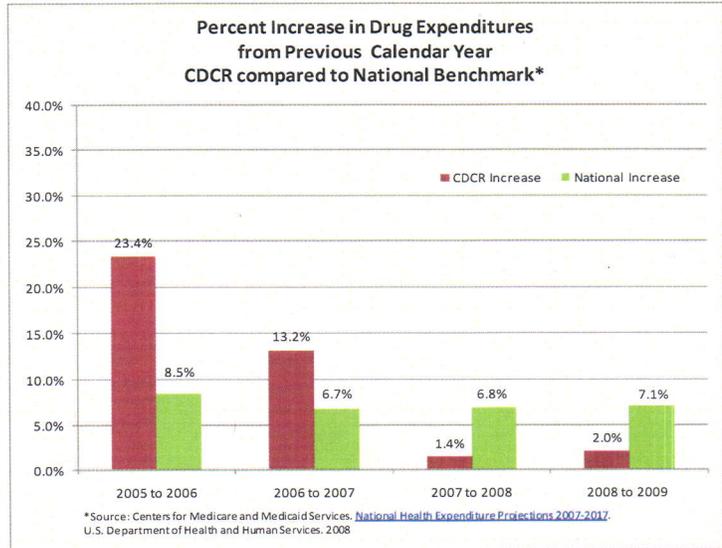
- \$13 million in Return-to-Stock savings are projected for this fiscal year.
- \$4.7 million in credit for returned drugs have been recorded since 2007.

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.

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.

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.

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*

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.*

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.

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.