

1 **IN THE UNITED STATES DISTRICT COURT**
2 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

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4
5 MARCIANO PLATA, et al.)
6 Plaintiffs,)
7 vs.)
8 ARNOLD SCHWARZENEGGER,)
9 et al.)
10 Defendants.)
11

No.: C01-1351 T.E.H.

**EXHIBITS TO THE RECEIVER'S SIXTH
QUARTERLY REPORT**

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1 **APPENDIX OF EXHIBITS**

2 **EXHIBIT #**

- 3 1. An Analysis of the Crisis in the California Prison Pharmacy System Including a Road
4 Map from Despair to Excellence.
- 5 2. Pharmacy Management Consulting Services Monthly Progress Report to the California
6 Prison Health Care Receivership Corporation June 2007
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EXHIBIT 1



*An Analysis of the Crisis in the California Prison
Pharmacy System Including a Road Map from
Despair to Excellence*

**Prepared and Submitted by
Maxor National Pharmacy Services Corporation**

**To
Robert Sillen, Court-Appointed Receiver
Plata v. Schwarzenegger
June 2006**

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Maxor would like to acknowledge and thank the following individuals for their guidance and direction during the course of preparing this report:

**U.S. District Judge Thelton E. Henderson
Receiver Bob Sillen
John Hagar, Court Appointed Correctional Expert
Matthew L. Cate, CA Inspector General**

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**California State Auditor
FOX Systems, Inc.
Office of the Inspector General
Senate Advisory Commission on Cost Control in State Government**

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EXECUTIVE SUMMARY

In a letter from Court Appointed Correctional Expert, John Hagar, dated March 30, 2006, Maxor National Pharmacy Services Corporation (Maxor) was requested on behalf of Receiver Robert Sillen to initiate an immediate and comprehensive identification of actions necessary to improve the California prison pharmacy operation. Since correctional pharmacy services are a major expense to the California Department of Corrections and Rehabilitation (CDCR) and a critical component to improving the quality of offender healthcare, the Receiver requested a high priority be given to this vital area.

The CDCR pharmacy service review commenced with an initial assessment that focused on fact finding and updating the current status of the CDCR pharmacy operation. Primary emphasis was given to a review and analysis of available documentation to include previous audits, findings and recommendations. Additionally, during the period 11-13 April 2006, a Maxor team of experienced professionals with extensive backgrounds in pharmacy operations and management of large correctional pharmacy programs performed on-site visits with CDCR staff and selected institutions. On April 13, 2006, the Maxor team gave a close-out briefing of their review and on-site inspection observations to U.S. District Judge Thelton E. Henderson, Receiver Robert Sillen, John Hagar and invited guests.

"In recent years, providing adequate health care to inmates has been increasingly problematic for the Department of Corrections and Rehabilitation. In February 2006, the U.S. District Court for the Northern District of California appointed a receiver over the department's health care operations in connection with a class action suit, Plata v. Schwarzenegger. Under the terms of the court's action, the receiver has broad powers to achieve the goal of 'restructuring day-to-day operations and developing, implementing, and validating a new, sustainable system that provides constitutionally adequate medical care to all class members as soon as practicable.' The receiver's powers include the duty to control and direct 'all administrative, personnel, financial, accounting, contractual, legal, and other operational functions of the medical delivery component' of the department."

(2006 OIG Accountability Audit 8).

It is universally accepted that the effective and efficient operation of pharmacy services is an integral component of a quality health care service delivery system. However, despite the recommendations of numerous audits, external reviews and other such evaluations, the CDCR pharmacy services operation remains in a state of disrepair.

Among the deficiencies detailed in prior audits and confirmed by this review are: (1) **lack of effective central oversight and leadership;** (2) **lack of an operational infrastructure of policies, processes, technology and human resources needed to support an effective program;** (3) **excessive costs and inefficiencies in the purchasing processes employed;** and (4) **ineffective systems for contracting, procurement, distribution and inventory control.**

In summary, initial findings by Maxor confirm that notwithstanding numerous state audits, studies and evaluations followed by specific, detailed recommendations for improvement, the CDCR pharmacy operation remains costly, inefficient, and unsafe. The California taxpayers continue to be denied the most out of their pharmaceutical dollar and more importantly, offender patients are not receiving clinical drug therapy in accordance with quality standards found in the community at large.

Based on the information provided at the time of this report, between January 2005 and April 2006, the State of California incurred avoidable CDCR pharmacy expenditures in excess of \$7 million dollars. A portion of those expenditures amounting to approximately \$1.3 million can be recaptured by immediate, aggressive and prudent pharmacy management actions. However, the opportunity for saving the remaining \$5.8 million has passed and, with it, so has the ability to better utilize scarce resources for improving substandard offender health care.

More alarming, 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. An analysis comparing CDCR institutional CY 2005 drug purchases with CDCR CY 2005 prescription dispensing data identified major discrepancies in the amounts purchased versus the amounts recorded as dispensed. 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

"Procedures to prevent diversion vary greatly between facilities. This variance is not only in the existence of a method, but also the methods themselves and the rigor of enforcement. Over the past 3 years there have been 4 Feasibility Study Reports that have included automated tracking of medications from receipt in the Pharmacy to delivery to a patient or return to the Pharmacy. Each of these proposals have been delayed due to lack of funding"
(CDCR response 05/22/06).

and potential for drug diversion. The discrepancy in purchases versus dispenses also creates a precarious clinical environment in which the potential for adverse outcomes is high due to the failure to properly manage, track and evaluate patient medications and

outcomes. When questioned about the procedures for detecting diversion, CDCR responded to Maxor that a "lack of funding" had thwarted efforts to track and account for medications. CDCR management's repeated failure to respond to this critical issue, as well as the failure of State overhead and control agencies, is fiscally irresponsible to the California taxpayers.

The variance in drugs purchased and prescriptions dispensed, combined with CDCR's and the State's failure to take corrective action may explain, in part, why the taxpayers of California pay two-and-a-half to four times more for offender medications than other comparable entities such as the Federal Bureau of Prisons and the State of Texas. The findings tend to show that the absence of corrective action is attributable to a lack of pharmacy management and oversight as opposed to a "lack of funding". As illustrated in the financial analysis section of this report, if the CY 2005 CDCR drug costs per inmate day were commensurate with that of other major correctional programs (systems with nearly as many prisoners as in California), as much as \$78-99 million dollars would have been saved and been available for allocation toward improving medication accountability and patient care. Even after taking into account the cost differences due to the other programs' access to preferential pricing, CDCR's CY 2005 drug costs were still \$46-80 million higher.

While confirming that many of the deficiencies noted in prior reports remain, Maxor also identified an additional key recommendation that must be addressed to implement an effective pharmacy services program. In the past, the CDCR Pharmacy audits and studies have not given primary attention to the establishment of a patient-centered, outcome-based system. Previous emphasis centered on drug distribution and central administration, but included minimal recommendations for an outcome-based, performance-driven system redesign. Future priority and effort must be given to outcome-based decision making as a means of guiding processes, educational focus and infrastructure redesign. By focusing on improvements to how patients are treated clinically and measuring and assessing disease outcomes obtained, the pharmacy systems, policies, prescribing patterns, and necessary competencies can be tailored to meet CDCR system goals. To accomplish this requires a system with measurable performance metrics, the technology to capture and analyze such data and a management team with the knowledge and authority to act upon the data findings in a timely manner. As well, State controlled overhead agencies, State mandated business practices and State laws, rules, regulations, and union contracts

The system focus is decentralized and product-driven rather than patient-centered and outcome-driven.

must be revised in order to enable CDCR's Health Care Services Division (HCSD) to accomplish its tasks and reach its goals.

At this time, the CDCR pharmacy program does not meet minimal standards of patient care, provide inventory controls or ensure standardization. The system focus is bureaucratic rule-driven and product-driven rather than patient-centered and outcome-driven. Therefore, opportunities for improvement based upon the creation of standardized policies, procedures, and a performance-based organizational structure have not been realized.

The action plan included herein provides a detailed road map designed to effectuate the restructuring and development of a constitutionally adequate pharmacy services delivery system. The plan builds from the recommendations of prior audits and reviews, as well as the findings and recommendations of the Maxor team. The action plan identifies key goals and objectives necessary to achieve those goals. Proposed timelines for actions are provided, along with a set of performance metrics to evaluate and monitor progress and success. Priority is given to immediate and/or short-term measures designed to improve safety, efficacy, cost and clinical care of offender patients.

In April 2006, the California Office of Inspector General documented that the CDCR pharmacy services operation has a long history of audits and reviews with repeated identified shortfalls that have yet to be remedied. The lack of meaningful action and the failure to address deficiencies has resulted in a standard of pharmacy care below acceptable industry and community levels. The program requires immediate and comprehensive corrective action. The expeditious implementation of the plan of action outlined in this document will result in a pharmacy services program that is sustainable, effective, outcome-driven, responsive to change and efficient. **Most importantly, patient care will be improved and, as past experiences of other correctional health care models have demonstrated, with enhanced care, fiscal accountability and cost containment follow.**

BACKGROUND

Over at least the past six years, the CDCR pharmacy services program has been reviewed and audited repeatedly. And repeatedly, the CDCR, its parent overhead and control agencies, and the State government itself has failed to effectively implement meaningful improvement in this vital health care delivery system component. This report does not attempt to revisit each and every prior audit report and recommendation. However, it is beneficial to gain a sense of the number, scope and similarity of prior audit findings and recommendations thereby laying the foundation for corrective action. Listed below are excerpts from a number of these prior reviews assembled under several general themes found throughout the documentation. Despite some efforts by CDCR to address these recommendations, the major issues identified by prior audits continue to restrict the ability of the pharmacy system to operate in an effective manner.

The CDCR pharmacy services program has been reviewed and audited repeatedly. And repeatedly, the CDCR, its parent overhead and control agencies, and the State government itself has failed to effectively implement meaningful improvement in this vital health care delivery system component.

Need for Meaningful, Effective Oversight and Management

"The absence of centralization and standardization has led to a lack of coordination and effective communication amongst pharmacies, inability to take advantage of 'best practices' at prison pharmacies, non-compliance with policies and procedures, increased medication cost, staff turnover and general inefficiency" (FOX 9).

"Although there are individual organizations within CDC who are attempting to improve the pharmacy operations within their facility, there seems to be no overall coordinated effort by management to bring together all of the correctional institutions in a unified approach to the pharmacy operations" (Senate Advisory Commission on Cost Control in State Government 25).

"Consistent with the findings of these recent audits and studies, the Office of the Inspector General has found significant evidence of poor management controls over pharmacy operations in management review audits of state correctional institutions" (2003 OIG 7).

Need to Implement and Enforce Effective Clinical Management Processes

"The present system of clinical management is ineffective, resulting in discontinuity of care and inability to control cost or manage patient care through formulary and drug therapy management" (FOX 8).

"Because it has not updated its formulary in several years and because it does not monitor compliance with its formulary, Health Care Services is unable to identify and enforce preferred treatments for specific conditions and to identify which medical practitioners have prescribing practices that are inappropriate or not cost-effective." (California State Auditor 26)

Need to Improve and Monitor Pharmacy Contracting and Procurement

"Business process analyses of ordering and inventory management practices at CDC prisons revealed a number of areas for potential improvement...controlling inventory levels in drug stock areas, management of unused or outdated drugs, and reporting on inventory usage by medical area" (FOX 7).

"There have been issues such as duplicate shipments, delivery of medications for discharged patients, inadequate detailed accounting of items returned for credit and how credit was applied. The contractor may not have followed the criteria for delivering services" (Senate Advisory Commission on Cost Control in State Government 30).

Need to Improve Pharmacy Workforce

"Many pharmacy or nursing medication administration process findings that were problematic seemed to stem from staff's lack of knowledge or proper procedures and inadequate training of pharmacy and/or nursing staff" (FOX 10).

"CDC has not been able to compete with the private sector to recruit adequate highly trained personnel. Although there is a national shortage of pharmacists, CDC functions with barriers to satisfactory staffing due to low salaries, inadequate working conditions and rural or less desirable locations. This has resulted in inadequate pharmacy staffing at many facilities" (Senate Advisory Commission on Cost Control in State Government, Executive Summary vii).

Need to Redesign Pharmacy Distribution System

"The lack of efficient workflow as a result of physical facility limitations and no space planning is negatively impacting productivity and resulting in increased staffing costs. In addition, inadequate space for pouring medication prior to Direct Observed Therapy (DOT) medication administration has resulted in practices that produce a higher probability of medication errors. These errors include missed doses, duplicate doses, administration of the wrong medication and medication documentation inaccuracies" (FOX 13).

"The physical limitations of pharmacies in California's 33 prisons are a significant hindrance to efficiency and an obstacle to meaningful modernization" (Senate Advisory Commission on Cost Control in State Government 30).

Need for a New Pharmacy Information Management System

"The outdated information system has contributed significantly to process inefficiencies for drug dispensing and this system complicates otherwise beneficial process improvements such as central dispensing from remote dispensing facilities" (FOX 8).

"The pharmacy prescription tracking system that the Department of Corrections uses cannot support today's complex medication monitoring and cost-containment requirements or the day-to-day management of its pharmaceutical services. The system contains data on drug interactions that is out-of-date; it cannot transfer data electronically between prisons; and it is unable to track data critical to managing pharmacy operations" (California State Auditor 39).

"The pharmacy information technology system cannot support needed functions. The limitations of the 20-year-old Pharmacy Prescription Tracking System, which is used by all of the institutional pharmacies, prevent the Health Care Services Division from effectively managing the department's use of pharmaceutical supplies to control costs or even to insure that prescription practices are appropriate [...] The system also cannot perform automated checks to prevent the following:

- *Negative reactions from patient allergies to a drug or from incompatible medications.*
- *Filling prescriptions too soon or too late.*
- *Inmates stockpiling medications.*

- *Duplicate therapy from a patient taking more than one drug with similar therapeutic benefits.*
 - *Dosages outside acceptable therapeutic ranges.*
 - *Prescribing non-formulary medications without required authorizations.*
- (2003 OIG 7)

MAXOR ON-SITE INSPECTION OBSERVATIONS

In advance of the on-site visits, Maxor requested and reviewed previous audits, reports and information provided by the CDCR. During the period 11-13 April 2006, a Maxor team of experienced pharmacy managers with correctional backgrounds visited CDCR health services administrative staff and inspected six institutions (California Medical Facility, Corcoran State Prison, Substance Abuse Treatment Facility, San Quentin, Sacramento and Folsom institutions.)

Upon completing the on-site visits, follow-up discussions and correspondence were continued with CDCR staff, State Attorneys and designated California State Agency personnel.

Based on visits and follow-up information, a summary of key observations is provided:

-- Dr Peter Farber-Szekrenyi, Director, CDCR Correctional Health Care Services and his staff facilitated the Maxor visit and arranged opportunities to interview central office and selected institution staff. For the most part, CDCR personnel were courteous, professional and responsive to the visit.

-- It was readily apparent that a number of CDCR health service personnel had made considerable effort to improve the overall pharmacy operation to the extent they could, given the lack of appropriate tools available to fix previously identified deficiencies. However, these efforts are in isolation, resulting in a disjointed system. The resultant lack of standardization places patients at risk for continuity of care failure and medical errors.

-- There was a clear absence of central office management and oversight of institution level pharmacy operations. Headquarters-based Pharmacy Services Managers were not empowered with direct line authority and operated in more of an advisory role as "subject matter experts" rather than managers. While these individuals do possess extensive knowledge of the CDCR system, they lack the necessary clinical, managerial, and technological support structure and experience to perform their jobs.

There was a clear absence of central office management and oversight of institution level pharmacy operations.

-- A key issue identified in previous audits is the need for an effective centralized Pharmacy and Therapeutics Committee (P&T). CDCR has responded that a P&T Committee has been established and is functioning well. Based on interviews with CDCR staff, review of P&T minutes, and more importantly results of committee actions, the current CDCR P&T committee is a shell entity

The current CDCR P&T committee is a shell entity with little or no meaningful impact on the overall pharmacy process.

with little or no meaningful impact on the overall pharmacy process. There is little or no support from central medical authorities in regards to P&T Committee participation. Formulary and procedures are not always followed at the institution level and there is no systematic way to monitor formulary compliance. Some one-way, top-down communication regarding formulary, drug use controls and procedures occurs. Data is collected for some parameters (although not clinical outcome-driven) and sent back to administration. No follow-up is provided. There is limited or no cross-pollination between institution pharmacies or collaboration between central administration and institution level teams. A quality, evidence-based guideline for the treatment of HCV was developed, but workforce level education and training appeared lacking and no outcome-based follow-up was conducted to determine if the guideline is used or if desired results are achieved.

-- System-wide policies and procedures for a formulary are established, but left open to institution level interpretations and compliance. Most institutions are aware of the central office directives but elect to develop their own as they deem necessary. 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.

-- Due to continued high pharmacy vacancy rates and resultant prevalence of registry staff, there is a discernible division between State and registry personnel, leading to staff morale issues, management challenges, and continuity in terms of constructing a well-trained pharmacy services team with common fiscal, clinical, and operational goals. The heavy reliance on the use of registry pharmacy staff has not only resulted in extremely high costs, but because many of the registry staff are designated Pharmacists-In-Charge, there is little incentive to recruit State employees as replacements. This would be especially true if some of the registry employees are also owners of the contract organizations furnishing the temporary staff. Vacancy rates

currently average 28 % overall and 43 % for pharmacists (*Pharmacy Series Vacancy as of March 31, 2006*).

-- Based on CDCR pharmacy staff vacancy reports and what appear to be excessive hours billed to certain institutions, a total system wide registry staffing audit should be accomplished at the earliest possible opportunity. As of December 2005, 63.5 vacancies existed, although the State was billed for registry hours equaling 95.32 positions (*CDCR Vacancy Information for Pharmacy Classifications Statewide Information December 2005*) at a cost of \$5,942,539 during the first 6 months of fiscal year 2005-2006. From 07/01/05 thru 12/31/05, 1,509 hours were billed at a rate of \$108.41 per hour for a Pharmacist-In-Charge (1.45 FTE's) at one institution, whereas at another institution 4,569 hours were billed at \$51.23 for a Pharmacist-In-Charge, equaling roughly 4.39 FTE's (*HCCUP Report, 07/01/05 thru 12/31/05*).

-- **Fundamental drug dispensing patient safety controls are bypassed**, including a pharmacy prepared, patient specific prescription dispensing process. There is still large-scale use of bulk bottles to dispense medication doses to patients by medication aides with no pharmacist oversight. The standard of care is to dispense medication through a pharmacy after pharmacist review. The medication should be dispensed in a quantity consistent with the prescription needs and specifically labeled with critical information such as the patient name, date, drug, strength and directions for use as well as other labeling requirements. In the acute care setting, medications may be dispensed for single day needs in unit-dose packaging. Non-patient specific medications used for initial doses during hours when the pharmacies are not open or in emergencies should be provided in the most ready to use form such as in unit-dose or other non-bulk systems. The use of bulk bottles of medication is not a safe or responsible method of dispensing or distributing medication. Inconsistency in the drug use process and delayed information regarding patient location results in duplication and/or delays in prescription processing and delivery. Basic safety precautions including regular audits of all drug stock to assure dating and proper storage are not always completed. Error avoidance strategies such as separating high-risk medications from other drugs and quarantine of look-alike, sound-alike drugs are not employed. Pharmacist interventions (provider contacts to improve patient therapy or prevent harm) and medication errors are not systematically documented or trended to identify patient risk and opportunities for improvement. There is no evidence of a system to complete failure mode and effects analysis or root cause analyses on serious medical errors identified in an effort to prevent further comparable problems.

-- In the April 2006 OIG Report referenced earlier, CDCR reports significant progress in monitoring drug utilization and patient care, however, without a sophisticated data warehouse, **there is no capability of tracking utilization and prescribing trends, nor monitoring formulary compliance.** Currently, prescription logs must be transmitted to headquarters on a quarterly basis, at which point the pharmacy services manager must painstakingly extract the data to compile rudimentary reports for managerial oversight. Maxor discovered significant issues with the integrity of this prescription data; in some cases, entire quarters of data were missing from a facility. Prescription data cannot be accessed outside of the pharmacy in which the prescription was dispensed, so real-time patient profiles with relevant medication history and allergies information are not available to medical staff at neighboring prisons or community-based private providers to facilitate the inmate transfer process.

The pharmacy information system is unsatisfactory from a patient safety standpoint.

-- The pharmacy information system is unsatisfactory from a patient safety standpoint. All modern pharmacy systems provide real-time notifications to alert the pharmacist of potentially dangerous drug-to-drug interactions, drug-to-allergy interactions, under-dosing, and over-dosage. The clinical information within the current systems is outdated, so pharmacists must perform manual drug utilization review (DUR), thus relying on their memory and clinical knowledge, which is, unfortunately, not always current or extensive. Even a well-trained pharmacist would not be able to safely perform DUR on the volume of prescriptions processed, especially considering the complexity of many inmates' medication regimen to treat, HCV, HIV, and mental illness.

-- **Key Maxor Finding:** While the previous audits identified centralized clinical management and control issues, **the CDCR Pharmacy recommendations lacked a patient-centered, outcome-based focus.** The focus has been on drug distribution and central clinical administration such as formulary management, drug use evaluation and treatment guidelines, but lacks a patient-centered, outcome-based, performance-driven focus. The healthcare system should use outcome-based criteria to drive treatment decisions, processes, educational focus and infrastructure redesign. By reviewing how patients are treated, and assessing disease outcomes obtained, systems / prescribing / competency can be tailored to meet determined goals.

The healthcare system should use outcome-based criteria to drive treatment decisions, processes, educational focus and infrastructure redesign.

-- An example of the system described would include an ongoing monitoring of primary morbidity and mortality over time. If CDCR asthma death rate and/or emergency room visit rate were found to be in excess of the benchmark, an analysis would ensue. The investigation would include an evaluation of the actual treatment approach to asthma, including the drugs used, monitoring methods, frequency of follow-up and patient care teaching. Other parameters assessed would be patient compliance to medications and the approach to treatment once the asthma exacerbation occurred. The actual data would be compiled and an interdisciplinary team would develop evidence-based treatment guidelines addressing all factors for implementation with an educational focus on those parameters identified in which previous treatment approach was inconsistent with best practices. The formulary and procedures would be adjusted to meet the newly identified needs. Thereafter, data would be gathered at a defined frequency to follow the implementation and adherence to the treatment approach as well as the clinical patient outcomes. The cycle would continue until the outcomes met defined goals. This approach marries the centrally administered clinical programs to patient-centered care to develop an outcome-driven system based on sound scientific principles and health care improvement methodologies.

FINANCIAL ANALYSIS

A financial analysis of CDCR's pharmacy services was conducted using CDCR and Department of General Services (DGS) purchasing data obtained directly from the drug wholesalers. In addition, CDCR provided Maxor with dispensing data to facilitate an in-depth analysis of product purchased versus drug dispensed. During the course of this analysis, numerous contacts were initiated and maintained with the California Attorney General's Office, CDCR, and DGS regarding Maxor findings and observations. On several occasions, either DGS or CDCR provided new or previously requested information which Maxor integrated into the analysis. The financial data presented herein is based upon the most recent information available at the time of finalizing this report.

-- The financial analysis, coupled with Maxor's on-site observations and CDCR's responses to the findings, indicate an overall lack of central oversight, infrastructure and technology to properly manage drug costs, including contracting, procurement, distribution, reclamation and inventory control. The fragmentation of responsibilities and oversight of the CDCR/DGS pharmacy procurement and distribution program has resulted in the absence of clear lines of authority and

The fragmentation of responsibilities and oversight of the CDCR pharmacy procurement and distribution program has resulted in the absence of clear lines of authority and accountability, a breakdown in communications, inefficiencies, waste and the potential for illegal diversion, the sum result of which has seriously endangered the quality and appropriateness of offender health care.

accountability, a breakdown in communications, inefficiencies, waste and the potential for illegal diversion, the sum result of which has seriously endangered the quality and appropriateness of offender health care. The current system has minimal controls to preclude or detect diversion and does not meet basic patient care and safety needs, fundamental standards of practice, or medical/pharmacy practice regulations. Furthermore, the system's lack of such controls places patients at serious risk and opens the door to large scale fraud and/or theft of State property in the form of prescription drugs.

-- Based on the information provided at the time of this report, between January 2005 and April 2006, the State of California incurred avoidable CDCR pharmacy expenditures in excess of \$7 million dollars. A portion of those expenditures amounting to approximately \$1.3 million can be recaptured by immediate, aggressive and prudent

pharmacy management actions. However, the opportunity for saving the remaining \$5.8 million has passed and, with it, so has the ability to better utilize scarce resources for improving substandard offender health care.

-- The CDCR data provided to Maxor in April 2006 overstated CY 2005 drug purchases by approximately \$6.3 million (See table below). CDCR reviewed Maxor's findings and concurred that information received later from DGS more accurately reflects actual CY 2005 purchases.

CDCR Prime			
	Vendor Data	DGS Data	Difference
Jan-05	\$ 10,016,235.00	\$ 9,907,014.94	\$ 109,220.06
Feb-05	\$ 13,821,425.00	\$ 9,575,967.66	\$ 4,245,457.34
Mar-05	\$ 10,971,804.00	\$ 10,732,744.70	\$ 239,059.30
Apr-05	\$ 10,812,253.00	\$ 10,585,400.61	\$ 226,852.39
May-05	\$ 10,699,424.00	\$ 10,425,006.63	\$ 274,417.37
Jun-05	\$ 12,081,102.00	\$ 12,031,147.81	\$ 49,954.19
Jul-05	\$ 10,898,567.00	\$ 10,306,956.53	\$ 591,610.47
Aug-05	\$ 12,229,335.00	\$ 12,146,795.05	\$ 82,539.95
Sep-05	\$ 11,191,672.00	\$ 10,996,363.06	\$ 195,308.94
Oct-05	\$ 11,032,125.00	\$ 10,837,864.93	\$ 194,260.07
Nov-05	\$ 11,806,804.00	\$ 11,788,596.08	\$ 18,207.92
Dec-05	\$ 12,146,176.00	\$ 12,056,879.94	\$ 89,296.06
	\$ 137,706,922.00	\$ 131,390,737.94	\$ 6,316,184

-- No demonstrable controls over purchasing or inventory were seen, nor was there evidence of process standardization. There is no mechanism for maximizing inventory turns or tracking / quantifying the financial loss due to returned medications that must be destroyed. Rudimentary systems to determine serviceability of returned medications do exist, but are minimal to non-existent due to the labor intensiveness involved in the process.

-- In spite of repeated assertions by DGS that they are not an enforcement agency and do not have the authority to enforce the pharmacies' contract adherence, it seems as though California has succeeded on at least one occasion to control costs by implementing market share type contracts. This initiative alone resulted in savings of approximately \$945,000 to the State and a 98% contract penetration rate. CDCR developed and implemented a treatment protocol for HCV in concert with a market share purchasing agreement to coincide with that treatment protocol. This is an excellent example of how savings can be achieved when pharmacy operations, contracting, and clinical authorities are successfully integrated.

-- DGS has also negotiated favorable drug manufacturer rebate contracts, although it is clear that there is no central reconciliation of rebates, as evidenced by the estimated \$650,000 in outstanding rebates CDCR, through DGS, has yet to receive. Similarly, there is no systematic method for ensuring that DGS-contract pricing is honored by the wholesaler and that individual pharmacies purchase contract items in lieu of more expensive non-contract items. As a result, during CY 2005, the State of California was overcharged by more than \$700,000 and failed to take advantage of another \$5.8 million in preferable contract pricing by not purchasing the most cost effective DGS contracted items. Maxor compiled all Generic Code Numbers (GCN's) in CDCR's purchase data and within each GCN, determined the most cost-effective National Drug Code (NDC) and compared it to the NDC purchased, adjusting for package size. The difference between what should have been purchased and what was actually purchased for each GCN is the missed savings opportunity of \$5.8 million. The table below illustrates CDCR's top 20 missed savings opportunities in 2005-2006.

CDCR TOP 20 MISSED SAVINGS OPPORTUNITIES

GCN	Generic Name	Missed Savings Opportunity
33530	OMEPRAZOLE 20 MG CAPSULE	\$761,732.77
46223	PAROXETINE HCL 20 MG TABLET	\$212,780.58
13724	FLUCONAZOLE 200 MG TABLET	\$154,033.18
6460	LOVASTATIN 20 MG TABLET	\$130,658.14
41805	GABAPENTIN 600 MG TABLET	\$129,405.13
4240	METHADONE HCL 10 MG TABLET	\$124,231.54
11673	RANITIDINE 150 MG TABLET	\$111,872.74
47198	QUETIAPINE 300MG	\$105,624.92
8350	IBUPROFEN 800 MG TABLET	\$94,223.96
8349	IBUPROFEN 600 MG TABLET	\$87,189.24
46451	MIRTAZAPINE 30 MG TABLET	\$86,329.77
4521	PHENYTOIN SOD EXT 100 MG CAP	\$83,389.92
8362	NAPROXEN 500 MG TABLET	\$81,354.49
46203	CITALOPRAM HBR 20 MG TABLET	\$76,909.91
1775	GLYBURIDE 5 MG TABLET	\$70,924.41
4655	METHOCARBAMOL 750 MG TABLET	\$69,536.19
21414	GABAPENTIN 300 MG CAPSULE	\$67,801.03
9339	CLINDAMYCIN HCL 150MG CAPS	\$57,922.28
8182	HYDROCHLOROTHIAZIDE 25 MG TB	\$55,652.66
384	ENALAPRIL MALEATE 10 MG TAB	\$55,226.04

-- Maxor compared the quantity of doses dispensed by CDCR pharmacies to the quantity of doses purchased during CY 2005. The dispensing data was provided by CDCR and the purchasing data was obtained from McKesson, the CDCR drug wholesaler used in 2005. The drugs compared included some commonly used antipsychotic medications and narcotic controlled substances used for pain control.

The expectation is that the drugs purchased should equal the drugs dispensed by the pharmacy plus the amount of medication used for stock and some very small amount of product that expires unused. Stock would be expected to include the inventory within the pharmacy (can be estimated based on the inventory turns and would be expected to be <5% of annual purchases) and a small amount of floor stock medication placed in treatment areas for doses needed during emergencies and the hours the pharmacies are closed.

However, significant discrepancies in the prescription dispensing data were identified that indicate a high potential for drug diversion and negative clinical outcomes. Upon initial review, the difference between quantity purchased and quantity dispensed was up to 99% varying by drug and facility, indicating that purchases exceeded documented use by vast margins. It was later explained to Maxor by CDCR staff that the quantity dispensed may be documented in the computer system in nontraditional ways. A quantity entered as "one" in the PPTS system at one institution might actually translate to a quantity of 60 units dispensed (one per med pass). This practice seems in direct conflict with California pharmacy regulations. Moreover, this practice is variable even within the same facility. At the same institution, one might observe the same medication being dispensed as a quantity of 60, to meet the same med pass needs. Following the practice described, every effort was made to determine the most likely quantity dispensed. Even after adjusting for the explanation provided, however, the quantity purchased frequently exceeded the quantity dispensed by over 30%.

There are a number of reasons that might contribute to the purchasing versus dispensing disparity, such as reprinting a label, but not documenting a new prescription or refill dispensed. Maxor staff was told that this is a common practice to save time; despite the fact that medications are being dispensed without documentation legally required by California regulations. Beyond the fact that this practice is inconsistent with California pharmacy regulations, patient safety concerns are particularly alarming. A pharmacist reviewing the patient profile in the future would not know that the medication had been dispensed and was being taken by the patient. There is a clear risk that the patient could still be taking the medication when an unknowing pharmacist dispenses a new medication with a serious adverse drug

interaction consequence. In the event that the dates are changed in the computer during reprint of the label, there would be awareness that the patient is on the drug. However, it would not be possible to determine the actual dates or quantities dispensed for a compliance assessment, nor would legal requirements be met.

Other reasons for the gap might be medication administered without pharmacist involvement. This could include medication administered from floor stock by nurses or aides with a doctor's order. This is an acceptable process in the event that there is an emergency and the provider is present or after hours when there is no pharmacist available to review the patient profile and dispense the medication. However, as soon as the pharmacy opens, a clinical review of the new order should be conducted and a prescription processed after completing all the appropriate safety and clinical reviews. CDCR staff has acknowledged that this is not necessarily the practice and that dispensing of floor stock medication without pharmacist involvement and without record in the pharmacy system is commonplace. Nonetheless, this should only account for a very small amount of the disparity between purchases and dispenses.

*Excerpt from California Code of Regulations
Division 17. Article 2. Pharmacies
1707.1. Duty to Maintain Medication Profiles*

(B) For each prescription dispensed by the pharmacy:

1. The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
2. The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
3. The date on which a drug was dispensed or refilled;
4. The prescription number for each prescription; and
5. The information required by section 1717.

Another explanation is the disturbing possibility that medication is being administered without a prescription. For example, during the April 2006 site visit to San Quentin, a Maxor team member came across a recently documented medication error which described a pharmacist giving methadone pills, a narcotic controlled substance, to a nurse without proper documentation. Without further review, it is not possible to determine how widespread such occurrences are, but this incident raises serious practice standard, patient safety, and legal concerns. Startlingly, this practice may occur quite frequently in an unresponsive system in which medication delays occur, despite the fact that such practice is prohibited by State and Federal regulations. Nursing staff can become desensitized by delays and assume that since the patient has been on a medication for some time, they are still supposed to be, and continue to administer the

medication based on historical treatment. The patient safety concern is that the drug may have been intentionally not renewed. The provider is now under the assumption that the patient is not taking the drug. This can lead to dangerous combinations of medications, toxicity or misdirected treatments when the physician is no longer aware of the patient's overall regimen and makes changes based on misinformation. The pharmacist will not have a current medication profile and will not be able to support the patient safety and clinical review process accurately. Due to the size of the health care system and large volume of medications used, poor inventory control and lack of central oversight, it is highly reasonable to assume that serious drug-to-drug interactions, drug-to-disease interactions and medication errors with potential for serious harm and death have and are occurring. In the case of HIV therapy, continuing the wrong medication when a change was intended, or improper dosing and/or combinations is very likely to result in significantly increased toxicity or a rapid loss of antiviral activity, causing the virus to become resistant to the limited drug combination options available. The result is a patient at risk for advancing illness with early progression to AIDS and the associated life-threatening infections, as well as avoidable financial consequences.

-- Of crucial note, two line items with the highest percentage of discrepancies are narcotic controlled substances with a very high abuse potential. Roxicodone® and Oxycontin® had greater than 95% gaps between purchases and dispensing as shown in the table below. See Appendix A for greater detail of the purchases versus dispenses analysis.

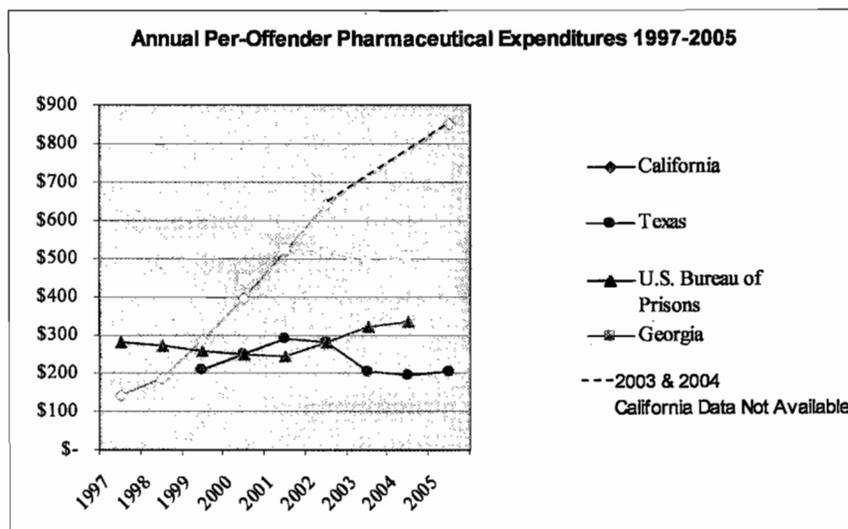
CDCR Purchases vs. Dispenses of Selected Antipsychotic and Narcotic Medications – CY 2005

Institution	Drug	Qty Purchased	Qty Dispensed	Qty Difference	% Not Dispensed
SOL	RISPERIDONE 2MG	41,040	2,738	38,302	93.33
SOL	SEROQUEL 300 MG	63,120	5,679	57,441	91.00
PBSP	GEODON 80 MG	32,320	15,279	17,041	52.73
CIW	GEODON 20 MG	3,440	1,767	1,673	48.63
CMF	ROXICODONE 5 MG	186,000	5,488	180,512	97.05
SOL	OXYCONTIN 20 MG	9,175	280	8,895	96.95

In summary, none of the examples provided are justifiable explanations for such a shocking disparity between quantities dispensed and purchased. Moreover, the dispense data is so grossly inconsistent and unreliable that it is virtually impossible to provide a meaningful audit of pharmaceutical dispenses. The entry of dispense data is so inconsistent that attempting to track, identify or prevent diversion under the current systems is not possible. It is noteworthy that even after Maxor adjusted the quantities

dispensed upward, the differences in purchases versus dispenses remain questionable. The potentially catastrophic effect on clinical patient care and safety cannot be overstated. Some of the medications in question are serious pain medications that should be used with extreme caution and oversight, especially in a population of patients in which substance abuse prior to incarceration is widespread. The street value, high abuse potential, and propensity towards diversion of these medications are well established. It is for these very reasons that State and Federal regulations dictate the prescribing and dispensing of such medications to be tightly controlled – regulations that CDCR does not always follow. The enormous discrepancies between purchases and dispenses warrant an immediate, system-wide controlled substance audit. On June 19-21, 2006, agents from the CDCR Office of Internal Affairs conducted an emergency audit/inventory of specific narcotics at the California Medical Facility (CMF) and California State Prison-Solano (SOL). A memorandum of the Internal Affairs findings and Maxor’s response are included as Appendix F.

-- The dramatic difference between CDCR drug cost per offender and other comparable adult correctional health care programs, as identified in the 2003 OIG report, continues to worsen. In the chart below, 1997-2002 data has been reproduced from the 2003 OIG Report. Because of the previously identified CDCR overstatement of drug expenditures, Maxor was unable to verify reported drug purchases for 2003 and 2004. However, Maxor was able to verify that CY 2005, actual annual drug expenditures per inmate were 400 % higher in California than in Texas (\$836 compared to \$204). Even with factoring out the favorable 340b (public health) drug purchasing arrangement achieved by Texas, CDCR is still 250 % above benchmarks achieved by another large governmental entity. Similar differentials were evident in comparison with the Federal Bureau of Prisons.



-- The table below quantifies the aggregate differential in 2005 drug costs between California and other adult correctional health care programs. Maxor projected 2005 medication expenditures utilizing actual data for California and Texas and trending the Federal Bureau of Prisons and Georgia's actual 2000-2004 expenditures forward (Federal Bureau of Prison Pharmacy Services OIG Audit Report 2005, Georgia DOC Health Care Services Overview 2004, Texas CMHCC Quarterly Reports, 2003-2005). Additionally, Texas and the Federal Bureau of Prison numbers were adjusted upward to reflect their ability to achieve preferential pricing (e.g. 340 B, Federal Supply Schedule). Each system's 2005 adjusted drug cost per inmate day was then multiplied by California's 2005 average daily census to estimate total drug expenditures for each system based on California's inmate population. The "difference" illustrates the aggregate variation in drug expenditures when comparing California to other analogous systems and adjusting for preferential pricing and population. In summary, California's 2005 drug costs are approximately \$46 to 80 million dollars higher than comparable correctional programs, even after adjusting for pricing and population.

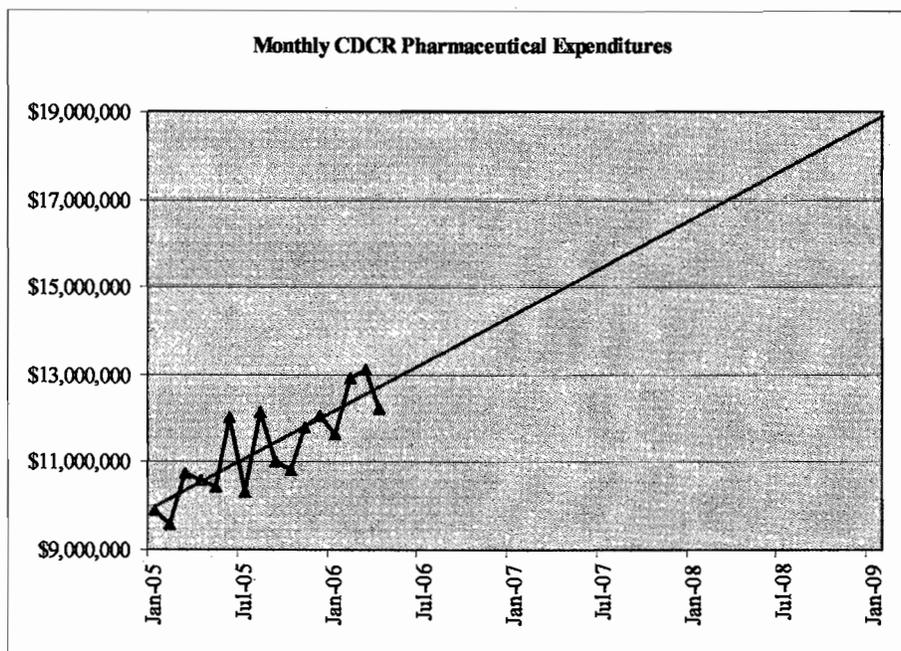
DRUG COST EXPENDITURES COMPARISON 2005

	California	Texas	Federal Bureau of Prisons	Georgia
Drug Cost Per Inmate Day	\$2.29	\$0.56	\$0.93	\$1.42
Adjusted Drug Cost Per Inmate Day	\$2.29	\$0.90	\$1.49	\$1.42
Adjusted Drug Cost Per Inmate Year	\$835.85	\$327.04	\$543.12	\$518.30
Average California Inmates	157,149	157,149	157,149	157,149
Total Drug Expenditures	\$131,352,992	\$51,394,009	\$85,350,765	\$81,450,327
Difference		\$79,958,983	\$46,002,227	\$49,902,665

Maxor recognizes that some may point out that adjusting these benchmarks for the preferential pricing available in some jurisdictions does not account for differences in utilization of items such as psychotropic medications between the jurisdictions. However, it is our belief, given the size of the differentials illustrated, and our observations and analysis, that the lack of adequate, effective pharmacy management is manifesting itself in the high costs experienced by the CDCR.

-- In spite of numerous audits identifying the need to improve pharmacy management, accountability, and internal controls, CDCR, DGS, and the State have repeatedly failed to implement meaningful change, as evidenced by the fact that

pharmaceutical expenditures continue to rise at an alarming rate. If immediate and substantial corrective action is not initiated, CDCR offender drug purchases are projected to rise more than 50 % over the next three years.



-- Pharmaceutical procurement and management of purchasing is an important aspect of cost control. However, the greatest cost controls are obtained by designing rational therapeutic regimens that encompass sound scientific evidence, patient specific morbidity and co-morbidity, and purchasing contracts. The CDCR has not developed clinical guidelines utilizing this methodology. The optimal system designs treatment approaches that step through therapy becoming more complex and expensive as patient factors dictate. Properly applied, the same clinical outcomes can be obtained for a fraction of the cost. Because this equation is complex, it is unrealistic to expect each prescriber to independently derive the best combination of effectiveness, safety and cost consciousness for all diseases. As a result, development of the disease treatment guidelines require input from persons experienced in the disease, pharmacy benefits management and pharmacotherapy. As an example, hypertension basic guidelines recommend starting with a single agent, often a diuretic, then adding additional agents as needed and in deference to the patient's concomitant diseases and physiologic condition. In general terms, one could choose not to use a diuretic and then instead choose an expensive proprietary agent of preference. As therapy steps up, the dosage can be increased, or a new agent can be added. Once again, preference may be an expensive brand agent. As an alternative, a clear treatment guideline can identify

optimal choices for each step incorporating most concomitant diseases and use equally effective, yet different drugs that are available in generic forms. The dosage ranges can target optimal response and avoid side effects from too high or too low a dosage. The result is a regimen that may cost 75-90% less. This methodology also allows regimens to be designed that are less likely to be a patient safety risk due to toxicities and interactions.

-- The findings of this financial analysis correspond with the observations and findings noted by the Maxor team in their on-site reviews detailed earlier in this report. They echo many of the findings from previous audits and reviews. The lack of meaningful and effective corrective action has directly contributed to the ongoing difficulties and challenges faced by the pharmacy services program within CDCR. Only by taking immediate, determined, and enforceable action can these challenges be addressed. A patient-centered, outcome-driven, accountable, cost-efficient and effective pharmacy program can be achieved through a commitment to reforming the program as outlined in this report. This includes revising, as necessary, existing State laws, rules, regulations, policies and operating procedures of overhead/control agencies of State government.

THE ROAD MAP CONCEPT

This document outlines a road map for achieving necessary improvements to the CDCR pharmacy services. The road map envisions a three year program that relies on outside expertise and leadership to assist the State of California, CDCR and the Receiver to implement many of the recommendations offered by past audits and reviews, thus achieving a clinically sound, professionally managed and cost-effective pharmacy operation. **The road map maintains a primary focus on producing sustainable, patient-centered, outcome-driven processes. The goal is to create a stand-alone, CDCR managed and operated “best practice” pharmacy system over 3 years.**

As clearly demonstrated by past audits and recent reports, change in the way of doing business does not come easy or quickly. Obstacles such as resistance to change, lack of resources, inadequate staffing, and antiquated technology will not be corrected overnight.

Therefore, the road map’s goals and supporting objectives are packaged in a crawl, walk and run sequence that outline the destinations that must be reached and a general timeframe for reaching them. Should the goals and objectives in this report be formally adopted, detailed scheduling for each goal and objective will follow. The “road to recovery” will begin with critical, incremental steps (“crawl”) toward progress. By building on the strong foundation achieved in the “crawl” phase, greater progress will be achieved in the “walk” phase, with the eventual “run” phase in which all the previous steps culminate into a high performing system. In all phases, however, improved patient care remains the first priority and a primary driver.

Key performance goals in the “crawl” phase will be to provide the Receiver with experienced pharmacy managers who have centralized direct line authority over all pharmacy operations. Soon thereafter, regional clinical pharmacists will be trained and deployed to assist institutional pharmacy operations. Immediate, proactive steps will be taken with the Receiver/CDCR clinical leadership to develop purchasing and inventory controls, treatment guidelines, re-engineer the formulary and establish a meaningful and credible pharmacy and therapeutics committee.

“In light of the flexible options likely to be available under the February 2006 federal court order appointing a receiver over the (CDCR) department’s medical health care delivery system, reconsider the option of contracting with a private pharmacy services management firm to implement the recommendations submitted in the (previous California) reports and studies conducted since 2000” (2006 OIG Accountability Audit 64).

As the plan progresses to the “walk” phase, greater emphasis will be placed on the establishment of key performance metrics and management reporting systems. Performance metrics will be provided to the Receiver with progress toward the achievement of corrective actions. Prescribing practices, adherence to formulary treatment guidelines, drug utilization reviews, and patient outcomes will become paramount in the “walk” phase, as new systems are implemented to allow for better reporting. Creative measures will be implemented to bridge the gap between existing information technology and readily available, off-the-shelf, relatively inexpensive pharmacy management software.

In the second year of the plan, the design, construction and operation of a centralized pharmacy facility must become a reality. The concept of a central fill allows institutional pharmacists to focus less on “pushing the pills” and more on clinical pharmacology and patient care. Comprehensive, clinically integrated, system-wide policies and procedures coupled with treatment guidelines and associated formulary management under the oversight of a proactive P&T committee will establish the road to success.

The road map is outlined in seven key goals. Each of the goals is supported by a number of objectives outlining necessary tasks to be accomplished to achieve the desired outcome. Each objective is further defined by identifying detailed actions to be taken. It should be noted that the actions proposed herein are based on what is presently known. This document should be considered a living plan that will change and adapt to the conditions encountered as actions move forward. Nevertheless, **effective implementation will result in a system that is sustainable over the long haul – that means making changes, internalizing those changes, and having mechanisms in place to continually evaluate, modify and improve the overall pharmacy systems.**

This document should be considered a living plan that will change and adapt to the conditions encountered as actions move forward.

COMPREHENSIVE ACTION PLAN

Purpose: To provide bi-monthly reporting to the Receiver and CDCR HCSD regarding progress, successes, and impediments to progress action items to be addressed. To outline in detail the steps necessary to achieve meaningful improvement in the quality, efficiency and effectiveness of pharmacy operations for the Receiver, California Department of Corrections and Rehabilitation, HCSD, and State government. To establish a state-of-the-art, accredited pharmacy services operation that assures optimal outcomes and safety for patients, as well as cost-effectiveness for the State of California.

KEY ACTION PLAN GOALS

- Goal A:** Develop meaningful and effective centralized oversight, control and monitoring over the pharmacy services program.
- Goal B:** Implement and enforce clinical pharmacy management processes including formulary controls, Pharmacy and Therapeutics committee, disease management guidelines, and the establishment of a program of regular prison institution operational audits.
- Goal C:** Establish a comprehensive program to review, audit and monitor pharmaceutical contracting and procurement processes to ensure cost efficiency in pharmaceutical purchases.
- Goal D:** Develop a meaningful pharmacy human resource program that effectively manages staffing, compensation, job descriptions, competency, performance assessment, discipline, training, and use of the workforce including temporary employees and non-pharmacist staff.
- Goal E:** Redesign and standardize overall institution level pharmacy drug distribution operations for inpatient and outpatient needs. Design, construct and operate a centralized pharmacy facility.

- Goal F:** Based on a thorough understanding of redesigned work processes, design and implement a uniform pharmacy information management system needed to successfully operate and maintain the CDCR pharmacy operation in a safe, effective and cost efficient way.
- Goal G:** Develop a process to assure CDCR pharmacy meets accreditation standards of the designated healthcare review body (NCCHC or ACA) and assist in obtaining accredited status.

KEY ACTION PLAN GOALS, DESCRIPTIONS, AND OBJECTIVES

Goal A: Develop meaningful and effective centralized oversight, control and monitoring over the pharmacy services program.

The central leadership team will provide direction, continuity and standardization in reaching the goals outlined in the roadmap.

A critically necessary component of the plan identified by every audit group is the development of a core pharmacy leadership structure using key staff with demonstrated performance in strategic and operational development skills matched to the project. The central leadership team will provide direction, continuity and standardization in reaching the goals outlined in the roadmap. The team will include a senior leader, an administrative director, a clinical director and two central pharmacy operations supervisors (for the central pharmacy facility). The team will serve in line authority over all pharmacy staff and as liaisons to other disciplines within health care and corrections. The leadership team office will be established in proximity to medical leadership and moved into the central pharmacy facility once constructed.

Clinical pharmacy specialists are integral to institution level implementation and training of centrally developed clinical strategies and disease management guidelines. In concert with the leadership team, six to eight highly trained clinical specialists will provide regional and institution level feedback regarding performance of the institution level health care team, providers and pharmacy staff, as well as training and clinical care consultative support to front-line providers for the most complex patients (those at highest risk for poor outcomes and adverse medical events). The clinical specialists will also conduct outcome-based reviews of formulary adherence, prescribing practices, treatment guideline implementation, and process improvement. The clinical specialists will work in parallel with the local pharmacy staff rather than as line authority supervisors. Each clinical specialist will serve an assigned region,

working at the institution level. The overall framework is intended to provide an organizational structure and line-of-sight for all members of the CDCR patient care team.

Objective A.1: Establish a central pharmacy services administration, budget and enforcement authority.

Objective A.1.1: Identify and hire leadership and clinical specialists.

Objective A.2: Establish direct lines of authority to all pharmacy services personnel and define linkage to central medical staff.

Objective A.2.1: Define and communicate roles and responsibilities of leadership and clinical specialist to workforce and medical staff.

Objective A.2.2: Meet with pharmacy workforce and outline the road map, identify early adopters and delineate expectations for the pharmacy workforce.

Objective A.3: Update and maintain system-wide pharmacy policies and procedures.

Objective A.3.1: Review existing central P&P; obtain input from institution level P&P to identify best practices.

Objective A.3.2: Create single standardized P&P for all institutions (and care levels).

Objective A.3.3: Roll out standardized P&P to institutions.

Objective A.3.4: Monitor adherence to new standardized P&P.

Objective A.3.5: Implement a continual readiness system for standards, regulations and P&P.

Objective A.4: Establish key performance metrics used to evaluate the performance of the pharmacy services program.

Objective A.4.1: Identify available information sources and establish data reliability.

Objective A.4.2: Define operational targets for pharmacy and institution level teams.

Objective A.4.3: Develop a pharmacy initiative tracking grid (for projects with finite timelines), balanced scorecard (clinical, service, financial and workforce measures), and dashboard (workload measures) to include historical benchmarks, measures, targets and milestones for the program (see Appendix B for examples).

Objective A.4.4: Create institution level dashboards to provide performance benchmarks and comparisons, and set targets to structure improvement (institution level report card for prescribers and pharmacy).

Objective A.4.5: Institute culture in which the balanced scorecard and dashboard are central themes in meetings at every level. Over time, allow institution level scorecards and/or dashboards to become unique to strategic needs locally while assuring alignment with overall program goals and strategies. Future initiatives and operational enhancements will be considered around the agreed upon central strategies indicated on the scorecard.

Objective A.5: Establish standardized monitoring reports and processes designed to continually assess program performance.

Objective A.5.1: (See Objective A.4).

Objective A.5.2: (See Objective A.3.5).

Objective A.5.3: Use an action plan tracking grid to establish timelines and monitor implementation of the road map (see Appendix C for example).

Objective A.5.4: Establish standardized institution audit process to assess adherence to standards of practice and P&P.

Objective A.5.5: Create a stoplight grid to post institution audit results with links to detail reports. Post on website or other shared forum to allow comparison between institutions. Discuss at monthly P&T committee meetings. Require corrective action plans from institutions not meeting requirements (see Appendix D for example).

Objective A.5.6: Develop standardized pharmaco-economic analysis consultations for institutions not meeting overall goals. The analysis will include assessment of scorecards, dashboards, adherence to operational and disease management guidelines, prescribing practices and local issues based on care level and type. The consultation provides detailed recommendations for change to close the performance gap.

Objective A.5.7: Develop a standardized format for identification of needed disease management guidelines, criteria development, data collection, reporting, monitoring and follow-up.

- Objective A.5.8: Develop and implement disease management guidelines and treatment protocols.
- Objective A.5.9: Monitor provider use of the guidelines and provide findings to central medical administration and communicate findings to institution level provider; implement process improvement strategy to meet goal.

Goal B: Implement and enforce clinical pharmacy management processes including formulary controls, P&T committee, disease management guidelines and the establishment of a program of regular prison institution operational audits (using the framework of methodology identified under Goal A)

Uniformity in policies and procedures, formulary development, treatment guidelines and drug use processes including selection, procurement, prescribing, dispensing, administration, inventory, storage and controls will be achieved.

Through the use of interdisciplinary committees and work groups such as the P&T Committee, standardization will be established and maintained for all institutions to optimize patient care and assure safe, rational, cost-effective therapy. Uniformity in policies and procedures, formulary development, treatment guidelines and drug use processes including selection, procurement, prescribing, dispensing, administration, inventory, storage and controls will be achieved. Committees and workgroups comprised of CDCR medical, pharmacy, nursing and administrative leadership, with input and participation from institution level workforce, will develop policies, procedures, processes, formulary and treatment approaches for all to follow. More complex initiatives will be piloted in a representative sample of institutions with targeted patient care needs; initiatives will be improved using standard quality improvement methodology and then implemented statewide. Outcomes and desired measures identified will be monitored and initiatives will be implemented when targets are not realized. The group will develop and disseminate a clear performance-based system of goals, measures and targets, including performance feedback and initiatives to reach goals. Implementation of a system of routine institution level inspections will ensure adherence to procedures, standards of practice, and regulations.

Objective B.1: Revise and reconstitute, as needed, the current P&T committee and implement measures to allow for strong P&T oversight of prescribing and dispensing patterns.

- Objective B.1.1 Develop an interdisciplinary P&T Committee with membership experienced in formulary management. Include central, regional and institution level participation as appropriate.
- Objective B.1.2: Establish a clear committee charter utilizing principles stated in Objectives A3, A4, and A5.
- Objective B.1.3: Assign committee members responsibility for various functions; assign implementation oversight and ownership to gain accountability from all members.
- Objective B.1.4: Methodically work through the formulary categories and various reports and measures identified under Goal A to implement initiatives as identified.

Objective B.2: Establish methodologies and schedules for tracking and monitoring formulary compliance and prescribing behavior.

Objective B.2.1: See Objective A.4 and A.5.

Objective B.3: Develop and implement effective and enforceable peer-reviewed treatment protocols.

Objective B.3.1: See Objectives A4 and A5.

Objective B.4: Develop and implement effective and enforceable institution audit process.

Objective B.4.1: See Objectives A3, A.5.4 and A.5.5.

Goal C: Establish a comprehensive program to review, audit and monitor pharmaceutical contracting and procurement processes to ensure cost efficiency in pharmaceutical purchases.

Contracting will have a direct line of communication with the activities of the P&T committee, so that formulary additions support cost-effective purchasing contracts.

Pharmaceutical contracting and procurement will be centralized within HCSD and standardized to maximize purchase values and market share, as well as to monitor contract compliance. Contracting will have a direct line of communication with the activities of the P&T committee, so that formulary additions support cost-effective purchasing contracts. The central purchasing authority will monitor individual pharmacies to ensure that the right quantities of the right products are purchased at the institution level. Central review, editing, and submission of all purchase orders will assure optimal contract adherence and cost-effective purchasing. 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.

Objective C.1: Monitor wholesaler (vendor) to ensure contract compliance.

Objective C.1.1: Load purchasing contracts in a central data repository to allow for electronic monitoring of contract pricing.

Objective C.1.2: Electronically monitor contract pricing on a continual basis and identify those items for which contract pricing is not being received.

Objective C.1.3: Work with wholesaler account to ensure that the correct contract pricing is loaded.

Objective C.1.4: Reconcile credit processes to ensure that wholesaler credits are received in the amount equal to the loss in contract pricing.

Objective C.2: Develop process to monitor inventory shrinkage.

Objective C.2.1: Implement 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.

Objective C.2.2: Monitor purchases versus dispenses to identify potential shrinkage. Shrinkage identified through either of these processes will be referred to the Receiver for determination of appropriate investigative and corrective action.

Objective C.2.3: Develop trend-analysis procedures to automatically reset stock levels based on current utilization.

Objective C.2.4: Eliminate the use of bulk stock and have institution level pharmacist/pharmacy technician monitor drug use processes across the continuum of care.

Objective C.3: Implement process to insure that the best value contracted item is used.

Objective C.3.1: Establish a direct line of communication between contracting and P&T committee.

Objective C.3.2: Evaluate current formulary as compared to purchasing contracts.

Objective C.3.3: Secure purchasing contracts for those drugs with preferred status on the formulary and eliminate costly non-contracted drugs from the formulary if there are other more cost-effective drugs for which contracts can be obtained.

Objective C.3.4: Mandate the purchase/use of generics and therapeutic interchanges when possible.

Objective C.4: Consolidate and standardize pharmacy purchasing through development of a centralized procurement system.

Objective C.4.1: Obtain purchasing data and establish inventory levels based on historical trends.

Objective C.4.2: Train pharmacy staff on central purchasing procedures and supply system.

Objective C.4.3: Transition all pharmacies to central purchasing.

Objective C.4.4: Ensure that the best value contracted item is stocked by the wholesaler and purchased by the individual pharmacies in the correct quantities to maximize inventory turns.

Objective C.5: Evaluate feasibility of achieving 340 B preferential pricing on all drug purchases.

Objective C.5.1: Explore sub-contracting possibilities with covered 340 B entities.

Objective C.5.2: Conduct a cost-benefit analysis of 340 B pricing potential.

Objective C.5.3: Evaluate potential for contracting with a covered entity to allow for 340 B eligibility.

Objective C.5.4: If contracting opportunities are available, feasible, and cost-effective, contract with a covered entity, establish 340 B status, and obtain pricing.

Goal D: Develop a meaningful pharmacy human resource program that effectively manages staffing, compensation, job descriptions, competency, performance assessment, discipline, training, and use of the workforce including temporary employees and non-pharmacist staff.

A complete skill set inventory of State employees will be conducted to identify knowledge deficits in clinical, operational, and fiscal matters.

Employees will be hired and trained to replace registry personnel. Scheduling and use of floater/PRN positions will be maximized to decrease use of registry personnel to cover vacation and sick leave. Clearly defined criteria, procedures, and processes will be implemented to monitor and reduce the use and cost of registry personnel. A complete skill set inventory of State employees will be conducted to identify knowledge deficits in clinical, operational, and fiscal matters. Required training and in-services will be provided as needed for existing employees to ensure adherence and comprehension of policies. Local, regional, and state-wide meetings, conference calls, and/or visits with pharmacy managers will be conducted on a routine basis to facilitate management, communication and standardization of pharmacy practices. An effective means of documenting and tracking employee training, education, and disciplinary action will be developed and all employee job descriptions and personnel files will be updated to include a current evaluation completed within the last year. The use of pharmacy technicians and clerks will be maximized to allow pharmacist staff to perform needed clinical functions, while delegating clerical and administrative functions to other staff. Staffing patterns will be established for each institution based on prescription volume and personnel will be reassigned as needed.

Objective D.1: Hire and train new employees as needed to replace registry personnel.

Objective D.1.1 Reevaluate staffing pattern versus workload and interim practice model (prior to full system redesign) to

- determine appropriate staffing compliment and numbers.
- Objective D.1.2: Hire employees to fill all vacant pharmacy manager (Pharmacist II) positions.
- Objective D.1.3: Recommend and implement meaningful salary levels as determined by the Receiver.
- Objective D.1.4: Hire employees to fill all other vacant positions.
- Objective D.1.5: Train new employees and define methodologies for monitoring and evaluating employee competence and performance.

Objective D.2: Complete skill set inventory of State and registry employees and provide required training, performance measures, and disciplinary measures as needed for existing personnel.

- Objective D.2.1: Identify knowledge deficits in clinical, operational, and fiscal matters.
- Objective D.2.2: Prioritize in-services and develop time frames for conducting training.
- Objective D.2.3: Assign team leaders and implementation teams to conduct in-services in the identified knowledge deficits.
- Objective D.2.4: Conduct in-services on a monthly or quarterly basis, as needed. Use web-based e-authoring tools to develop "smart," self-paced competency and training system.

Objective D.3: Develop effective means of documenting and tracking employee training, education, performance, and disciplinary action.

Objective D.3.1: See Objective D.1 and D.3.

Objective D.4: Reevaluate previous staffing patterns at each institution in light of the adoption of new technologies to improve efficiency and the transition of volume to the centralized pharmacy.

Objective D.4.1: Track prescription volume, define current staffing levels, and identify ideal staffing patterns.

Objective D.4.2: Maximize use of pharmacy technicians to perform administrative and clerical functions.

Objective D.4.3: Transition excess staff to the central pharmacy and other areas as needed. Eliminate any remaining PRN and registry positions to meet new, lower staffing needs.

Objective D.4.4: Develop a centralized pharmacist intern program to improve the public image of the CDCR HCSD as an employer and to help recruit talented pharmacists and support personnel entering the field.

Goal E: Redesign and standardize overall institution level pharmacy drug distribution operations for inpatient and outpatient needs. Design, construct and operate a centralized pharmacy facility.

An automated centralized pharmacy will be developed to gain advantages of scale related to efficient purchasing, inventory control, volume production, drug distribution, workforce utilization, and increased safety.

To ensure that patient needs are met based on care level and to achieve safety, accountability, efficiency and consistency, institution level operations will be redesigned and standardized. An automated centralized pharmacy will be developed to gain advantages of scale related to efficient purchasing, inventory control, volume production, drug distribution, workforce utilization, and increased safety. A plan created by pharmacy leadership and based on appropriate regulations and best practices, including input from central, regional and institution level medical staff and pharmacists, will be implemented. The plan will consider segmented populations such as preventative care, acute hospital care, ambulatory care, long-term care, chronic care, mental health, and dental care and systems that optimize available technology and identified best practices. Pilots will be used for highly complex changes using goals, measures and targets. Institution level redesign will be defined and implemented while the central pharmacy proposal is under development.

The concept for the majority of patients served includes the eventual use of a prescriber order entry system with clinical tools to promote developed treatment guidelines and prescribing principles. A limited number of on-site pharmacist(s) and technician(s) will provide prospective patient profile review, correct any problems, intervene with prescribers as indicated to optimize therapy, and release the prescription for processing. Acute care medications will be filled at the institution using a bar code checking system. All other medications will be filled and processed at the central pharmacy for subsequent delivery. Institution level pharmacy staff will ensure proper controls are in place and that unused medications are accounted for, returned to inventory and documented. These returns will serve as the inventory for any needed floor stock and acute care

prescriptions filled. Central staff will handle all vendor contracting, purchasing, packaging, and non-acute medication dispensing, as well as support unit level services during staffing shortages.

Objective E.1: Prior to centralization, implement standardized operations in all existing institution level operations to correct problems identified in audits.

Objective E.1.1: Implement best practice for “ambulatory” care distribution model using existing resources and pre-centralization model (correct high risk safety and control issues).

Objective E.1.1.1: Assess if external support or regionalization is needed to bridge the gap between the current system and infrastructure rebuilding and centralization.

Objective E.1.1.1.1 If external support or regionalization is needed, implement on small scale and adjust operational model to meet inmate/patient needs.

Objective E.1.1.1.2 Expand service agreement as appropriate.

Objective E.1.2: Develop straw model for institution level operations (see under Goal E) under centralization plan.

Objective E.1.2.1: While implementing centralization, pilot straw man at institution level, establish measures to evaluate and adjust model.

Objective E.1.2.2: Finalize institution unit level model and spread to all institutions.

Objective E.1.3: Establish best practices for “inpatient” care areas and implement model in all sites.

Objective E.1.3.1: Assess technology and operations to develop optimal model of operations for inpatient care areas.

Objective E.1.3.2: Establish resource needs and create action plan to pilot optimal inpatient model with measures and goals.

Objective E.1.3.3: Finalize model and spread to remaining inpatient areas.

Objective E.2: Design, construct and operate a centralized pharmacy facility.

Objective E.2.1: Develop straw model for centralization concept (see under Goal F).

Objective E.2.2: Finalize model based on available automation and institution level operational technology; assess staffing needs.

Objective E.2.3: Determine general location, survey real estate and identify a suitable location for the centralized pharmacy facility.

Objective E.2.4: Design and complete architectural build out of facility.

Objective E.2.5: Procure and install necessary mechanization, robotics, fixtures, conveyor belts, and electronics.

Objective E.2.6: Relocate, hire and train pharmacy personnel to staff centralized pharmacy.

- Objective E.2.7: Obtain California State Board of Pharmacy and DEA licenses.
- Objective E.2.8: Transition prescription workload from individual institutions to centralized pharmacy.

Goal F: Based on a thorough understanding of redesigned work processes, design and implement a uniform pharmacy information management system needed to successfully operate and maintain the CDCR pharmacy operation in a safe, effective and cost efficient way.

Connectivity will be established and/or upgraded for all 33 institutions to facilitate web-based software access and reporting. An interdisciplinary team of pharmacy experts with clinical, operational, fiscal, and technological backgrounds will comprehensively review the pilot pharmacy system, VistA, to evaluate whether it accommodates CDCR's complex challenges. This team will explore alternative pharmacy systems utilizing comparable analysis techniques before final evaluation and implementation of a suitable software product. Steps will be taken to improve data collection and facilitate management/clinical oversight by assembling a development team to design and implement improved reporting and monitoring capabilities in the interim using the current Prescription Tracking System.

Technology upgrades will include barcode checking and physician order entry to ensure the right medication is administered to the right patient at the right time.

Once conversion to a state-of-the art pharmacy information management system is complete, ancillary software tools will be developed and customized in order to improve patient safety and cost effectiveness. Technology upgrades will include barcode checking and physician order entry, to ensure the right medication is administered to the right patient at the right time. Real-time adjudication of pharmacy claims will perform patient adherence and provider prescribing review based on established guidelines and protocols. An enterprise reporting tool will be developed to allow for customized utilization reports with available data elements such as patient name, age, disease state, therapeutic class, dispense date, drug, institution, and cost per prescription.

Objective F.1: Develop and implement improved reporting and monitoring capabilities with existing pharmacy system.

Objective F.1.1: Create a data repository of all drug names and assign an industry identifier to all drug names.

Objective F.1.2: Develop rudimentary utilization management and pharmacy reports based on standard managed care and pharmacy benefit manager practices.

Objective F.1.3: Establish provider report cards that compliment the goals and clinical initiatives of the P&T function.

Objective F.1.3.1 Develop an effective mechanism for distribution of report cards, performance monitoring, and follow-up with detailed recommendations for change on how to improve performance.

Objective F.2: Identify and propose solutions to connectivity issues throughout all pharmacies to ensure that web-based software, reporting, and data can be easily accessed at each facility.

Objective F.2.1: Conduct site visits to evaluate current connectivity issues.

Objective F.2.2: Procure new hardware as needed to modernize technology in all institutions.

Objective F.2.3: Achieve high-speed connection in as many sites as possible, replacing dial-up and slow connections with sufficient bandwidth to support institutions' needs; implement back-up systems to ensure connectivity in the event that the primary connection is unavailable.

Objective F.3: Procure a state-of-the-art pharmacy dispensing system.

Objective F.3.1: Organize an interdisciplinary team of pharmacy experts with clinical, operational, fiscal, and technological backgrounds to evaluate the current pilot program, VistA.

Objective F.3.2: Establish guidelines for product evaluation using financial, operational, clinical, and technological indicators.

Objective F.3.3: Evaluate VistA and alternate products on the market.

Objective F.3.4: Compile findings based on product evaluation; choose the most suitable pharmacy information management solution.

Objective F.3.5: Install needed hardware and software to support uniform pharmacy information management system.

Objective F.4: Transition each institution to uniform pharmacy information management system.

Objective F.4.1: Conduct inventories at each pharmacy and input inventory in pharmacy system.

Objective F.4.2: Conduct data conversion where possible and input current prescriptions and allergies information for data that cannot be converted.

Objective F.4.3: Introduce transition teams of highly trained staff to train pharmacy employees on new system to minimize implementation time.

Objective F.4.4: With the direct participation and oversight of transition teams, "go live" on uniform pharmacy information management system.

- Objective F.4.5: Withdraw transition teams, monitor progress, and provide retraining and software reconfiguring as necessary.

- Objective F.5:** Develop and implement reporting tools to facilitate clinical, operational, and fiscal management of the CDCR pharmacy operation.
 - Objective F.5.1: Utilize enterprise Pharmacy Benefit Manager reporting experience to develop reporting tools for management, such as Formulary Compliance, Cost per Rx, Top Therapeutic Category, and Top Drug by Cost reports.
 - Objective F.5.2: Develop provider report cards and other unique reports required by correctional environment including reports that compliment outcome-based, patient centered approach.
 - Objective F.5.4: Establish web-based method for distributing reports, communicating information to medical staff and management, and providing follow-up as needed to ensure compliance and improvement.

- Objective F.6:** Integrate pharmacy information management system with auxiliary technologies such as central supply management, physician order entry, electronic MAR, and barcode checking.
 - Objective F.6.1: See Objective C.4
 - Objective F.6.2: Develop physician order entry system that maintains and communicates formulary information to providers to enable them to choose the most clinically-effective therapies, while

ensuring that cost control initiatives are maximized.

Objective F.6.3: Integrate use of electronic MAR and barcode checking to ensure that the right medication is administered to the right patient at the right time.

Goal G: Develop a process to assure CDCR pharmacy meets accreditation standards of the designated healthcare review body (NCCHC or ACA) and assist in obtaining accredited status.

The process of seeking and maintaining accreditation is intended to provide organizations with guidelines and tools to standardize and improve processes for the delivery of health care. As stated by one such accrediting body, The National Commission for Correctional Health Care:

“Standards for Health Services are our recommendations for managing the delivery of medical and mental health care in correctional systems. The Standards have helped the nation’s correctional and detention facilities improve the health of their inmates and the communities to which they return; increase the efficiency of their health services delivery; strengthen their organizational effectiveness; and reduce their risk of adverse legal judgments. Written in separate volumes for prisons, jails and juvenile confinement facilities, the Standards cover the general areas of care and treatment, health records, administration, personnel and medical-legal issues.”

(<http://www.ncchc.org>).

The mission and purpose are similar for other accrediting bodies as are the intended benefits to the organization undergoing accreditation. Furthermore, agencies under court oversight may be required to obtain accreditation as a method of qualifying performance and then be required to maintain the accreditation thereafter, to assure that standards of practice are maintained.

Objective G.1: Establish Receiver and CDCR commitment to pursue accreditation and determine the accrediting organization standards to be followed.

- Objective G.1.1: Assemble an interdisciplinary committee with input from persons experienced in both ACA and NCCHC systems.
- Objective G.1.2: Assess the standards of both ACA and NCCHC to determine the best match for the healthcare and custody system.
- Objective G.1.3: Develop a standards audit readiness team.

- Objective G.2:** Develop a readiness grid identifying the standards and assigning assessment responsibilities to members of the team.
 - Objective G.2.1: Begin the process of mock audits to identify standards in violation.
 - Objective G.2.2: Implement process improvement and procedural change to become compliant with standards in violation.
 - Objective G.2.3: Continue mock audits until violations are resolved.

- Objective G.3:** Complete mock audits using a credentialed auditor for target accrediting body.
 - Objective G.3.1: Complete processes G.2.1 through G3 until confident that the CDCR meets accrediting body standards.

- Objective G.4:** Apply for accreditation at one or more institutions. Expand audits to all institutions on a defined schedule.

PHASE I: CRAWL (0-12 MONTHS)

- Objective A.1: Establish a central pharmacy services administration, budget and enforcement authority.
- Objective A.2: Establish direct lines of authority to all pharmacy services personnel and define linkage to central medical staff.
- Objective B.1: Revise and reconstitute, as needed, the current P&T committee and implement measures to allow for strong P&T oversight of prescribing and dispensing patterns.
- Objective B.2: Establish methodologies and schedules for tracking and monitoring formulary compliance and prescribing behavior.
- Objective C.1: Monitor wholesaler (vendor) to ensure contract compliance.
- Objective C.2: Develop process to monitor inventory shrinkage.
- Objective C.3: Implement process to insure that the best value contracted item is used
- Objective D.1: Hire and train new employees as needed to replace registry personnel.
- Objective D.2: Complete skill set inventory of State and registry employees and provide required training, performance measures, and disciplinary measures as needed for existing personnel.
- Objective D.3: Develop effective means of documenting and tracking employee training, education, performance, and disciplinary action.
- Objective F.1: Develop and implement improved reporting and monitoring capabilities with existing pharmacy system.
- Objective F.2: Identify and propose solutions to connectivity issues throughout all pharmacies to ensure that web-based software, reporting, and data can be easily accessed at each facility.

PHASE II: WALK (12-24 MONTHS)

- Objective A.3: Update and maintain system-wide pharmacy policies and procedures.
- Objective A.4: Establish key performance metrics used to evaluate the performance of the pharmacy services program.
- Objective B.3: Develop and implement effective and enforceable peer-reviewed treatment protocols.
- Objective C.4: Consolidate and standardize pharmacy purchasing through development of a centralized supply procurement system.
- Objective E.1: Prior to centralization, implement standardized operations in all existing institution level operations to correct problems identified in audits.
- Objective F.3: Procure a state-of-the-art pharmacy dispensing system.
- Objective F.4: Transition each institution to a uniform pharmacy information management system.
- Objective F.5: Develop and implement reporting tools to facilitate clinical, operational, and fiscal management of the CDCR pharmacy operation.

PHASE III: RUN (2-3 Years)

- Objective A.5: Establish standardized monitoring reports and processes designed to continually assess program performance.
- Objective B.4: Develop and implement effective and enforceable institution audit process.
- Objective C.5: Evaluate feasibility of achieving 340 B preferential pricing on all drug purchases.
- Objective D.4: Reevaluate previous staffing patterns at each institution in light of the adoption of new technologies to improve efficiency and the transition of volume to the centralized pharmacy.
- Objective E.2: Design, construct and operate a centralized pharmacy facility.
- Objective F.6: Integrate pharmacy information management system with auxiliary technologies such as central supply management, physician order entry, electronic MAR, and barcode checking
- Objective G.1: Establish Receiver and CDCR commitment to pursue accreditation and determine the accrediting organization standards to be followed.
- Objective G.2: Develop a readiness grid identifying the standards and assigning assessment responsibilities to members of the team.
- Objective G.3: Complete mock audit using credentialed audit for target credentialing body.
- Objective G.4: Apply for accreditation audit at one or more institutions. Expand audits to all institutions on a defined schedule.

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APPENDIX A: CDCR PURCHASES VS. DISPENSES ANALYSIS -- 2005 CALENDAR YEAR

Institution	GCN	Drug	Qty		Qty Difference	% Not Dispensed
			Purchased	Dispensed		
California Institution for Women	21414	GABAPENTIN 300 MG CAPSULE	16700	219	16481	98.69
	47563	GEODON 20 MG CAPSULE	3440	1767	1673	48.63
California Medical Facility	41806	GABAPENTIN 800 MG TABLET	24700	200	24500	99.19
	4225	ROXICODONE 5 MG TABLET	186000	5488	180512	97.05
California State Prison, Corcoran	34188	SEROQUEL 100 MG TABLET	20000	15628	4372	21.86
	27961	ZYPREXA 5 MG TABLET	4410	3463	947	21.47
California Rehabilitation Center	46222	PAROXETINE HCL 10 MG TABLET	3960	2403	1557	39.32
Chuckawalla Valley State Prison	27462	PROTONIX 40 MG TAB EC	300	30	270	90.00
	50137	PAXIL CR 12.5 MG TABLET	390	30	360	92.31
Deuel Vocational Institution	4204	HYDROCODONE-APAP 5/500 TAB	9440	3316	6124	64.87
	46484	RENAGEL 400 MG TABLET	360	90	270	75.00
High Desert State Prison	27462	PROTONIX 40 MG TAB EC	90	30	60	66.67
	8361	NAPROXEN 375 MG TABLET	400	178	222	55.50
	21414	GABAPENTIN 300 MG CAPSULE	2000	1056	944	47.20
North Kern State Prison	45652	KEPPRA 750 MG TABLET	480	208	272	56.67

APPENDIX A: CDCR PURCHASES VS. DISPENSES ANALYSIS -- 2005 CALENDAR YEAR

Pelican Bay State Prison	51800	RISPERDAL 2 MG M-TAB	11256	677	10579	93.99
	46228	SERTRALINE 50 MG TABLET	14400	1653	12747	88.52
	34189	SEROQUEL 200 MG TABLET	94300	42544	51756	54.88
	47568	GEODON 80 MG CAPSULE	32320	15279	17041	52.73
Pleasant Valley State Prison	21415	GABAPENTIN 400 MG CAPSULE	5900	416	5484	92.95
Richard J. Donovan Correctional Facility	4000	LITHIUM CARBONATE 150 MG CAP	400	42	358	89.50
	21413	GABAPENTIN 100 MG CAPSULE	6900	946	5954	86.29
California State Prison Sacramento	23381	COZAAR 25 MG TABLET	1330	614	716	53.83
California Medical Facility	47568	GEODON 80 MG CAPSULE	21620	590	21030	97.27
	47563	GEODON 20 MG CAPSULE	1760	50	1710	97.16
	46403	EFFEXOR XR 37.5 MG CAP SA	9800	317	9483	96.77
	47198	SEROQUEL 300 MG TABLET	124020	4720	119300	96.19
	21155	RISPERIDONE 2MG	22300	976	21324	95.62
Sierra Conservation Center		None Outstanding				
California State Prison Solano	24505	OXYCONTIN 20 MG TABLET SA	9175	280	8895	96.95
	46223	PAROXETINE HCL 20 MG TABLET	25220	874	24346	96.53
	47563	GEODON 20 MG CAPSULE	7320	268	7052	96.34
	21155	RISPERIDONE 2MG	41040	2738	38302	93.33
	41027	ZYPREXA 20 MG TABLET	6210	468	5742	92.46
	46401	EFFEXOR 75 MG TABLET	9300	780	8520	91.61

APPENDIX A: CDCR PURCHASES VS. DISPENSES ANALYSIS -- 2005 CALENDAR YEAR

47198	SEROQUEL 300 MG TABLET	63120	5679	57441	91.00
41026	ZYPREXA 15 MG TABLET	7620	711	6909	90.67
46452	MIRTAZAPINE 45 MG TABLET	18000	1699	16301	90.56
4225	ROXICODONE 5 MG TABLET	600	57	543	90.50
46405	EFFEXOR XR 150 MG CAPSULE SA	3000	297	2703	90.10
34189	SEROQUEL 200 MG TABLET	82000	8721	73279	89.36
San Quentin					
50760	LEXAPRO 20 MG TABLET	2100	3	2097	99.86
29077	ZYPREXA 2.5 MG TABLET	1060	11	1049	98.96
46450	MIRTAZAPINE 15 MG TABLET	30390	5888	24502	80.63
46452	MIRTAZAPINE 45 MG TABLET	14450	2850	11600	80.28
34189	SEROQUEL 200 MG TABLET	61900	12853	49047	79.24
Salinas Valley State Prison					
4204	HYDROCODONE-APAP 5/500 TAB	7500	4289	3211	42.81
29928	LEVAQUIN 500 MG TABLET	550	320	230	41.82
27780	TRILEPTAL 600 MG TABLET	4400	2594	1806	41.05
Valley State Prison for Women					
22647	PREMPRO 0.625/5 MG TABLET	588	16	572	97.28
53321	PREMPRO 0.3 MG/1.5 MG TABLET	672	22	650	96.73
4242	METHADONE 5 MG TABLET	200	14	186	93.00
22648	PREMPRO 0.625/2.5 MG TABLET	8400	1052	7348	87.48
Wasco State Prison					
21983	ZERIT 20 MG CAPSULE	240	4	236	98.33
29077	ZYPREXA 2.5 MG TABLET	120	4	116	96.67
46403	EFFEXOR XR 37.5 MG CAP SA	900	31	869	96.56
41286	CELEBREX 200 MG CAPSULE	200	20	180	90.00
21984	ZERIT 30 MG CAPSULE	120	28	92	76.67
27961	ZYPREXA 5 MG TABLET	6540	1882	4658	71.22

APPENDIX B-1: SAMPLE DASHBOARD

Measure	Measure Definitions	Yellow - At risk for not meeting target/off target												Stoplight Status (R/Y/G)	Data Link
		Actual FY 2005	Red - FY 2006 YTD	Jan	Feb	Mar	Apr	May	etc	FY06 Target					
Workload															
Rx Volume Total	Rx Processed/1000 patients														
Rx Volume Central Pharmacy	Rx Processed/1000 patients														
Rx Volume X Institution	Rx Processed/1000 patients														
Returned Drug Institution X	# Rx and \$														
Clinical															
Rx Errors Total	leaving pharmacy control														
Rx Errors Institution X	leaving pharmacy control														
Guidelines Deployed	Disease Management Practice/ Guidelines Deployed														
Staffing Vacancies															
RPh	#(%)														
Tech	#(%)														
Institution X RPh	#(%)														
Institution X Tech	#(%)														
Compliance															
Institution Audits	% passing														
Initiatives (Milestones)															
Central Pharmacy	Milestones														
Procedures Updated & Deployed	Milestones														
Institution level Redesign	Milestones														
Budget															
Drug	% Variance to budget														
Salary/Benefits	% Variance to budget														

APPENDIX B-2: SAMPLE INSTITUTION LEVEL BALANCED SCORE CARD

Green - On target												
Yellow - At risk for not meeting target/off target												
Red - Will not meet target/seriously off target												
Measure	Measure Definitions	Actual		Jan	Feb	Mar	Apr	May	etc	FY06 Target	Stoplight Status (R/Y/G)	Data Link
		FY 2005	FY 2006 YTD									
Service and Finance												
Rx #	Rx # (per Inmate per month)											
Rx \$	Rx \$ (per Inmate per month)											
Nonformulary Rx #	#											
Nonformulary Rx \$	\$											
Internal Process												
Guidelines adherence	% patients treated following target guideline											
Guidelines adherence system Average	% patients treated following target guideline											
Learning & Growth												
RPh	Training modules completed											
Tech	Training modules completed											
Initiatives (Milestones)												
Elimination of floor stock	Milestones											
Implementation of automation	Milestones											

APPENDIX C: ACTION PLAN TRACKING GRID

Goal:	A	Develop meaningful and effective centralized oversight, control and monitoring over the pharmacy services program.	Key Target Date
Objective:	A.1	Establish a central pharmacy services administration, budget and enforcement authority.	Month day, Year
Action Officer:		John Doe (title, contact info here)	
Prior Audit References:		CPR-IRP Report, Chap. 6; Senate Report, p.4; FOX Report Solution Package A,D	

(ROUGH EXAMPLE ONLY)

Action Item ID	Action Step	Assigned	Start Date	Targeted Completion Date	Status /Comments	Expected Outcome or Performance Metric	Key Milestone?
A.1.1	Identify and hire leadership and clinical specialists.	XXX	05-15-06	06-10-06		Central Office Staffing Pattern	Y
A.1.2	Establish written job descriptions and set salary rates.	XXX	05-30-06	06-15-06		Complete set of Position Descriptions; Salary Schedule	N
A.1.3	Prepare Operating Budget for central office.	YYY	05-20-06	06-15-06		Budget Document	N
A.1.4	Select Chief Pharmacist and administrator for Pharmacy Services program	XXX	06-15-06	07-01-06		Chief Pharmacist and Administrator in place	Y

APPENDIX D: SAMPLE UNIT INSPECTION GRID

Unit	Jan	Feb	Mar	Apr	May	Jun	etc	Links to Detail
Unit W								
Unit X								
Unit Y							Problem	
Unit Z								
Percent Passed	75%	75%	100%	75%	100%	100%	75%	

APPENDIX E: E-MAIL CORRESPONDENCE



"Rick Pollard"
<rpollard@maxor.com>
05/24/2006 01:55 PM

To <ASerio@maxor.com>
cc
bcc
Subject email

-----Original Message-----

From: Paul B. Mello [mailto:Pmello@hansonbridgett.com]
Sent: Monday, May 22, 2006 12:11 PM
To: Rick Pollard
Cc: Jon Wolff
Subject: Maxor Audit -- Purchase v. Dispense Questions

Mr. Pollard,

Below (and attached) is a response to your purchase v. dispense questions from Eugene (Gene) Roth, PharmD, Pharmacy Services Manager, Division of Correctional Health Care Services, CDCR:

1. Describe the CDCR policy about entering prescriptions into the pharmacy dispensing system.

Pharmacy Law (California Code of Regulations, Title 16, Division 17 Board of Pharmacy, Article 2, 1707.1) is the requirement for Pharmacies to maintain a Patient Medication Record. This record must be reviewed prior to dispensing (1707.3).

2. If facilities are not required to enter prescriptions into the system, what safeguards exist to insure that pharmacists have complete patient profiles when dispensing.

By producing a label in the Pharmacy Prescription Tracking System (PPTS) the prescription is on file in the patient's profile. Labeling is required by Pharmacy law (Business and Professions Code, Chapter 9, Division 2, Article 4, 4076.) The exception may be floor/ward stock medications that are issued on a separate document, not entered in PPTS at some facilities.

3. Describe procedures used to detect and prevent diversion.

Procedures to prevent diversion vary greatly between facilities. This variance is not only in the existence of a method, but also the methods themselves and the rigor of enforcement. Over the past 3 years there have been 4 Feasibility Study Reports that have included automated tracking of medications from receipt in the Pharmacy to delivery to a patient or return to the Pharmacy. Each of these proposals have been delayed due to lack of funding.

4. Describe any flaws you see in my methodology that may impact the results.

Floor stock, controlled substances (not patient specific), or some similar issue not recorded in PPTS may impact Maxor's results.

Regarding the purchase vs. dispensed numbers (see spreadsheet): I spoke with Rick Pollard and the analyst who produced the numbers this morning. It

APPENDIX E: E-MAIL CORRESPONDENCE

appears that they took the Qty number out of PPTS as the total number of units dispensed. I pointed out the fallacy in this thinking. Psychotropic medications are Direct Observed Therapy (DOT) administered and often have the number of units in one med pass (e.g. Qty=1 for 1 tab twice daily; (so the Medication Administration Record is easily readable) when 60 tabs are actually dispensed). This would cause the difference between purchased and dispensed medication counts to be inflated. Mr. Pollard is reevaluating his information given these new facts.

<<cdc_pvsd_final.xls>> <<cdc_pvsd_final2.xls>>

Please contact us if you have any questions.

Paul Mello

-----Original Message-----

From: Rick Pollard [mailto:rpollard@maxor.com]
Sent: Thursday, May 11, 2006 4:54 PM
To: greg.doe@dgs.ca.gov; Roth, Eugene
Cc: 'Jon Wolff'
Subject: Purchase vs Dispense Questions

Mr. Doe/Mr. Roth

Attached is a copy of a spreadsheet showing a review of purchases vs. dispenses for the various CDCR facilities. To accomplish this review we used the purchase data provided by DGS and compared it to the dispensing data provided by CDCR. We used First Data Bank to establish the generic code for each line item purchased. We then used Maxor resources to assign generic codes to a sampling of the items dispensed, since items are only tracked by drug name within the pharmacy dispensing system. We excluded any facilities that did not have a complete set of a data for the Calendar year 2005.

My first impression of the data is that it shows that not all prescriptions are entered into the pharmacy dispensing system, resulting in incomplete profiles. Or, that there are issues with diversion within the facilities. I have not been able to identify any other potential explanations for the discrepancies.

To further refine these results I would appreciate your response to the following questions.

1. Describe the CDCR policy about entering prescriptions into the pharmacy dispensing system.
2. If facilities are not required to enter prescriptions into the system, what safeguards exist to insure that pharmacists have complete patient profiles when dispensing.
3. Describe procedures used to detect and prevent diversion.
4. Describe any flaws you see in my methodology that may impact the results.

Because of the short time frames involved, I would appreciate a response by the 18th of May 2006, so the responses can be included in the final report to Mr. Sillen.

APPENDIX E: E-MAIL CORRESPONDENCE

Please call if you would like to discuss the data.

Thank you
Rick Pollard

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To ensure compliance with requirements imposed by the IRS, we inform you that any tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

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APPENDIX E: E-MAIL CORRESPONDENCE



"Rick Pollard"
<rpollard@maxor.com>
05/24/2006 01:36 PM

To <ASerio@maxor.com>
cc
bcc
Subject email

From: Jon Wolff [mailto:Jon.Wolff@doj.ca.gov]
Sent: Thursday, May 18, 2006 7:12 PM
To: rpollard@maxor.com
Cc: Greg Doe; Linda.Cabatic@dgs.ca.gov; Ron LaSala; pmello@hansonbridgett.com
Subject: Plata - Responses to Pricing Questions

Mr. Pollard-

Thank you for the opportunity this morning during the conference call to discuss the issues raised in your pricing questions. We hope that Mr. Doe's and Mr. LaSala's responses were of assistance. As requested, the following are Mr. Doe's written responses to your questions regarding pricing. Thank you.

1. What processes are used to verify contract pricing is received?

Contract pricing is loaded into the pharmaceutical prime vendor from Managed Health Care Associates (MHA) on a daily basis. Because of the volume, frequency of change, and available resources, we have not been able to verify MHA pricing changes unless a challenge has been discovered due to billing (such as an add bill). For our state contracts, we notify the prime vendor of contract pricing and issue an effective date for the pricing. We manually confirm pricing has been loaded by going into the prime vendor's computer system.

We have just hired additional resources and are working with our IT department to develop methods for better managing and confirming pricing on contracts.

2. What process is used to notify the Prime Vendor that a credit and re-bill should be initiated on items where contract pricing was not received?

When contract pricing was not received on state contract items, we notify the prime vendor to correct price and credit the agency for any incorrect overages. Price corrections that result from MHA contract pricing are the result of notification from MHA based upon reports received from the prime vendor. Some rebilling may occur based upon late notification of price changes do to contract relationships between MHA and their contract holders.

As we finalize processes to track pricing within the system we will initiate the requests for correction and credit.

3. What procedures are in place to insure that ordering facilities utilize the best contract price available?

The Department of General Services (DGS) mails copies of the current state drug contracts to each pharmacy, and provides internet access to state contracts and revisions. In addition, DGS, through the prime vendor contract, provides electronic ordering systems which identify the contract items and associated pricing. This system also provides pharmaceutical management tools, allowing pharmacies to manage the purchasing of drugs within their

APPENDIX E: E-MAIL CORRESPONDENCE

facilities. DGS cannot force contract compliance over the physicians prescribing habits. DGS works as an agent on behalf of the state agencies to develop pricing contracts for pharmaceuticals. DGS works with a Common Drug Formulary committee and Pharmacy Advisory Board with membership appointed by the Department Directors. The Common Drug Formulary Committee identifies drugs, policies and procedures which will be used at the local level. DGS then develops contracts based on these recommendations. The Pharmacy Advisory Board has the responsibility for implementation and enforcement.

4. Describe any flaws you see in my methodology that may impact the results.

1. Does this sheet take into account the ___ % service fee charged by McKesson?
2. We do not understand why the discount provided in column (R) is calculated at a loss when this is a prompt payment savings.
3. Some of the companies have a single source contract, meaning that the company only allows a contract with MHA or the State. Lilly is one such company. We are working on identifying the other companies with MHA. We would not have contract pricing through MHA on Lilly products because we have a contract for Zyprexa. We sent the pricing files current of 4-17-2006 and 12-13-2005. These files do not contain historical pricing changes. Ron will provide you with the historical pricing changes.
4. We are assuming column (P) is MHA or State contract price when appropriate.
5. We are assuming column (L) is WAC pricing.
6. I am having trouble confirming contract pricing, and will continue to work with Ron on that.

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APPENDIX E: E-MAIL CORRESPONDENCE



"Rick Pollard"
<rpollard@maxor.com>
05/24/2006 02:05 PM

To <ASerio@maxor.com>
cc
bcc
Subject email

From: Paul B. Mello [mailto:Pmello@hansonbridgett.com]
Sent: Monday, May 22, 2006 2:02 PM
To: Rick Pollard
Cc: Jon Wolff
Subject: Maxor -- Zyprexa Rebates

Mr. Pollard,

Per DGS, we believe that this email addresses your questions regarding the Zyprexa Rebates.

Question 1A : All Zyprexa 30 counts were added on October 12, 2005 via letter and the IM dosage form was added July 1, 2004 by amendment.

Question 1B: All Zyprexa products eligible for rebates are on the contract by notification letters and amendments.

Question 2: Rebates are calculated and validated by Lilly through the quarter usage report sent by DGS. A quarterly usage report is generated by DGS using the prime vendor's custom reporting system. DGS identifies the product to the NDC level for each agency. Lilly verifies this information with the Prime Vendor charge backs. To date there has not been any disputes with Lilly on usage.

Question 3: Rebates are only received by crediting to the account.

Questions 4 & 5 : Any rebates received from MHA and the Lilly are provided as credits. MHA and Prime vendor price corrections would appear as credits. Overcharges from manufacturers, errors from other companies, and damages from other parties may appear under this title.

Question 6: DGS is still evaluating this.

Thank you.

Paul Mello

-----Original Message-----

From: Rick Pollard [mailto:rpollard@maxor.com]
Sent: Thursday, May 18, 2006 2:57 PM
To: LaSala, Ron; Doe, Greg
Cc: 'Jon Wolff'; 'Jerry Hodge'; 'Jim Riley'
Subject: FW: Zyprexa Rebates

APPENDIX E: E-MAIL CORRESPONDENCE

Mr. LaSala/Mr. Doe

I am forwarding an email by one of our analysts. He has reviewed the Lilly contract and compared it to the purchasing data received.

His evaluation indicates some issues that need to be clarified before we finalize our evaluation.

1. Reference the products identified as not being listed in the contract:
 - a. Is there an amendment adding those NDC's?
 - b. Were those items eligible for rebates based on some other agreement?
2. What process is used to validate rebates due and reconcile the actual receipts?
3. Other than credits to the account, is there any other way that rebate credits are received?
4. Is our assumption that the credits identified as "THIRD PARTY DEBITS/CREDITS" represent Lilly rebates correct?
5. Are there any credits other than Lilly rebates that would be identified as "THIRD PARTY DEBITS/CREDITS" in the purchase file?
6. Describe any flaws in our evaluation process that may impact the results?

Because we are under severe time constraints in providing the final report to Mr. Sillen combined with the late receipt of the Lilly contract I would appreciate your response by close of business on May 19, 2006 so we can work on the report over the weekend.

Rick

From: Ryan Ahern [mailto:rahern@maxor.com]
Sent: Thursday, May 18, 2006 3:53 PM
To: 'Rick Pollard'
Subject: Zyprexa Rebates

Rick,

Attached is my analysis of the Zyprexa rebates.

I excluded the following Zyprexa NDC's from the Purchase file data as they were not referenced specifically in the Lilly contract:

NDC/UPC
00002411230
00002411530
00002411630
00002411730
00002441530
00002442030
00002759701

In reviewing the credits in the Purchase file, I identified only six Item Descriptions that did not reference an NDC number or a specific drug. I totaled their credits for the five quarters beginning in January 2005:

APPENDIX E: E-MAIL CORRESPONDENCE

Item Description	SumOfCredits
\$0.00 MFG. DENIED CHARGEBACK	-37.44
FLF LOST OR DAMAGED EQUIPMENT	-245.58
MISC ADJUST MENT	-42,098.95
RETURNS OF GM	-1.42
THIRD PARTY DEBITS/CREDITS	-130,168.76
TOTAL SERVICE FEE	-754.3

After reviewing these credits to determine which may be associated with the rebates, I determined that DVI received a "MISC ADJUST MENT" credit of \$41,435.48 on 4/17/06. Since this is far more than the \$15,338.11 they actually earned as a ___% rebate from eligible Zyprexa purchases from Jan 2005 through March 2006, one can only assume that if there are any rebates for Zyprexa, they must be reflected in the "THIRD PARTY DEBITS/CREDITS".

With that assumption in mind, for each "THIRD PARTY DEBITS/CREDITS" credit received, I matched it up to the ___% rebate earned during the previous quarter for each facility. There is not an exact science to pairing the two numbers up as the contract states that every effort will be given to credit the wholesaler within 90 days of the report by the state and local agencies, but does not guarantee it. The end result, however, can not be disputed by the timing of the credits received.

Also, it is interesting to note that no relating credits appear to have been received after the agencies reported their second quarter Zyprexa purchases (credit received in 3Q2005). The contract is not up until August 31, 2006.

As for the credit received that exceed the rebates earned in the attached Excel file, my only guess would be that the excluded NDC's mentioned above may also have been eligible under the contract or the excess credits received were for prior quarters.

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APPENDIX E: E-MAIL CORRESPONDENCE

prohibited. If you have received this communication in error, please immediately notify the sender by telephone or email, and permanently delete all copies, electronic or other, you may have.

To ensure compliance with requirements imposed by the IRS, we inform you that any tax advice contained in this communication (including any attachments) was not intended or written to be used, and cannot be used, for the purpose of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter addressed herein.

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APPENDIX E: E-MAIL CORRESPONDENCE



"Rick Pollard"
<rpollard@maxor.com>
05/24/2006 02:04 PM

To <ASerio@maxor.com>
cc
bcc
Subject email

From: Rick Pollard [mailto:rpollard@maxor.com]
Sent: Friday, May 12, 2006 8:22 AM
To: 'greg.doe@dgs.ca.gov'; 'Ron LaSala'
Cc: 'Jon Wolff'
Subject: RE: Plata v. Schwarzenegger

Please clarify

Any additional information you think might be useful in my evaluation. DGS also has a rebate agreement with Lilly for Zyprexa (___% discount off WAC with a ___% rebate).

These numbers seem to be inconsistent with the contract file provided by Mr. Doe on 4/25/2006. As an example:

ZYPREXA 7.5mg, MHA contract price is \$___ per tab, Lilly contract price (provided by Mr. Doe with the effective date of 12-18-2005) \$___, Current WAC – ___% would be \$___ and after rebate of would net \$___ per unit. The average price paid in the data provided for calendar year 2006 was \$___ and the last price paid on April 24th 2006 was ___.

In my conversations during the site visit, it was my impression that it had been determined that CDCR was not eligible for DGS rebate contracts.

1. Is that not true?
2. Is this an exception?
3. Where would the rebates be received and reconciled?

I am disappointed that I am finding out about this contract at this late date. The first item on my initial data request dated 4/19/2006 was "1. A copy (preferably in PDF format) of all manufacturer pricing contracts used by CDCR." Please provide me a copy of this and any other contracts available to CDCR that have not been previously provided.

Rick

APPENDIX E: E-MAIL CORRESPONDENCE

From: Jon Wolff [mailto:Jon.Wolff@doj.ca.gov]
Sent: Thursday, May 11, 2006 2:01 PM
To: rpollard@maxor.com
Cc: Greg Doe; Laurie.Giberson@dgs.ca.gov; Linda.Cabatic@dgs.ca.gov; Ron LaSala; jschaefer@hansonbridgett.com; Pmello@hansonbridgett.com
Subject: Plata v. Schwarzenegger

Mr. Pollard-

The following are Greg Doe's responses to your questions:

1. The redacted contract with Roche Labs details market baskets and market share requirements for specific pricing. What market share levels were realized? Discounts are being given at the highest market level.
2. Were these market share levels verified by DGS? No.
3. Is this contract related to the ~~Denied Chargebacks~~ in the McKesson purchase data? Do not understand question.
4. If the maximum market share levels were not achieved, what is your opinion as to why the initiative failed? Does not apply. DGS is being paid at the highest market level.
5. What actions were used to increase market share of Pegasys? None have been needed.
6. This appears to be the only market share based contract. Can you tell me if there are plans to enter into more of these types of agreements? If so, are there processes in place (i.e. enforceable treatment protocols) to maximize these contracts? Possibly, enforceable treatment protocols will be developed specific to the procurements.
7. Any additional information you think might be useful in my evaluation. DGS also has a rebate agreement with Lilly for Zyprexa (__ % discount off WAC with a __ % rebate).

Please contact Greg with any questions. Because Greg is on jury duty this week, you may also want to contact Ron La Sala at 916-375-4461 with any questions.

Thank you.

-Jon

Jonathan L. Wolff
Supervising Deputy Attorney General
California Department of Justice
Office of the Attorney General
455 Golden Gate Avenue, Suite 11000

APPENDIX E: E-MAIL CORRESPONDENCE

San Francisco, CA 94102
Direct: 415-703-1113
Fax: 415-703-5843
Email: jon.wolff@doj.ca.gov

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"Jim Riley"
<jriley@maxor.com>
05/24/2006 10:08 AM

To "Angela Serio" <aserio@maxor.com>
cc
bcc
Subject Fw: Pharmacy Series Vacancy--March

----- Original Message -----

From: Sallade, Denny
To: Jim Riley
Sent: Wednesday, April 26, 2006 2:56 PM
Subject: RE: Pharmacy Series Vacancy--March
His name is Dave Salacci and he is a Registry person.

-----Original Message-----

From: Jim Riley [mailto:jriley@maxor.com]
Sent: Wednesday, April 26, 2006 9:02 AM
To: Sallade, Denny
Subject: Re: Pharmacy Series Vacancy--March

GM Denny:

Can you help me with one follow up question? The name of the individual who fills the pharmacist II position at San Quentin?

Thanks,

Jim

----- Original Message -----

From: Sallade, Denny
To: jriley@maxor.com
Sent: Tuesday, April 25, 2006 5:56 PM
Subject: FW: Pharmacy Series Vacancy--March

-----Original Message-----

From: Lieng, Helen
Sent: Tuesday, April 25, 2006 1:50 PM
To: Sallade, Denny
Cc: Grader, Lindsay
Subject: Pharmacy Series Vacancy--March

Denny, this is the latest data we have for Pharmacy Series Vacancy. If this is not what you need, please let me know.

APPENDIX E: E-MAIL CORRESPONDENCE

Helen Lieng
Resource Management Unit
Division of Correctional Health Care Services
Department of Corrections and Rehabilitation
Phone (916) 322-6939
Fax (916) 327-8972

APPENDIX E: E-MAIL CORRESPONDENCE



"Jim Riley"
<jriley@maxor.com>
05/24/2006 10:10 AM

To "Angela Serio" <aserio@maxor.com>
cc
bcc
Subject Fw: Pharmacy Series Vacancy--March

----- Original Message -----

From: Sallade, Denny
To: Jim Riley
Sent: Thursday, May 04, 2006 1:39 PM
Subject: RE: Pharmacy Series Vacancy--March

There is no additional information regarding San Quentin. Apparently the situation is as was indicated in the e-mail.

SCO does not release reports until the 5th so we cannot provide you an update just yet.

-----Original Message-----

From: Jim Riley [mailto:jriley@maxor.com]
Sent: Thursday, May 04, 2006 7:21 AM
To: Sallade, Denny
Subject: Re: Pharmacy Series Vacancy--March

GM Denny:

Have you received any follow up from Ms VanOrnum? I would also appreciate getting the most recent (Arl 2006?) vacancy rate report for Pharmacy staff as a whole and that for just pharmacist positions.

Thanks,

Jim

----- Original Message -----

From: Sallade, Denny
To: jriley@maxor.com
Sent: Wednesday, April 26, 2006 6:52 PM
Subject: FW: Pharmacy Series Vacancy--March

I'm not sure if this helps or just makes you more confused.

-----Original Message-----

From: VanOrnum, Terry
Sent: Wednesday, April 26, 2006 4:35 PM
To: Sallade, Denny
Subject: RE: Pharmacy Series Vacancy--March

I called Tracy McCrary, she is the IPO at SQ, she said it's odd that the Pharmacist II is showing up on the SCO report as being filled. A short history is: the position has been vacant since 12/28/01, they have hired Patricia Ono, a retired annuitant off and on over the years, the latest re-hire for Patricia was in January 06 and her employment will be terminated shortly. Tracy

APPENDIX E: E-MAIL CORRESPONDENCE

noticed that Patricia was never paid so she doesn't really know what happened there.

Dave Salacci has been employed as registry person even though they show Patricia as the retired annuitant, I forgot to ask Tracy when did Dave Salacci start his employment. I faxed Tracy SQ's vacancy report we had for March, so we plan to research a bit more to find out what happened. Tracy did indicate that SCO gets their information from a database, SCO can access and obtain all department vacancies, she believes SCO picked up a wrong number. I looked on our database as far as I could go and it shows the position as being filled. I also called Sadie because she used to track the Pharmacy positions to see if she recalls anything or maybe how to research further.

I'll let you know what I find out.

*Terry Van Ornum, Staff Services Analyst
The Division of Correctional Health Care Services,
Resource Management Unit
Department of Corrections and Rehabilitations
(916) 322-8582 Fax: (916) 327-8972
Terry.VanOrnum@cder.ca.gov*

-----Original Message-----

From: Sallade, Denny

Sent: Wednesday, April 26, 2006 2:51 PM

To: VanOrnum, Terry

Subject: FW: Pharmacy Series Vacancy--March

We provided an SCO report showing that a 1.0 Pharm II was allocated to San Quentin and that the position is filled. This obviously conflicts with our information regarding Mr. Salacci. Could you see if San Quentin can provide clarification? Thanks. It could be that someone is on Administrative Leave/Military Leave or something.

-----Original Message-----

From: Jim Riley [mailto:jriley@maxor.com]

Sent: Wednesday, April 26, 2006 2:36 PM

To: Sallade, Denny

Subject: Re: Pharmacy Series Vacancy--March

Hi Denny:

In your response to my question on the "filled" SQ Pharmacist II position your response was "His name is Dave Salacci and he is a Registry person." Now I am confused. If Helen Lieng's list is only for state employees and does not reflect any registry personnel; and the list shows the SQ Pharm II as filled, wouldn't it have to be filled by someone other than Mr. Salacci? Can you help me understand this issue?

Thanks for taking the time to clarify this for me.

Jim

----- Original Message -----

APPENDIX E: E-MAIL CORRESPONDENCE

From: Sallade, Denny

To: Jim Riley

Sent: Tuesday, April 25, 2006 6:39 PM

Subject: RE: Pharmacy Series Vacancy--March

That is correct. The SCO only reports those EMPLOYEES who have been issued a check. It does not reflect any registry personnel.

-----Original Message-----

From: Jim Riley [mailto:jriley@maxor.com]

Sent: Tuesday, April 25, 2006 4:31 PM

To: Sallade, Denny

Subject: Re: Pharmacy Series Vacancy--March

Thanks Denny!

Am I correct that "filled" positions are State employees and do not include registry employees? For example, of the 86.7 pharmacist I positions allocated, 47 are filled by state employees and 39.7 are vacant and have to be covered by registry pharmacists?

Jim

----- Original Message -----

From: Sallade, Denny

To: jriley@maxor.com

Sent: Tuesday, April 25, 2006 5:56 PM

Subject: FW: Pharmacy Series Vacancy--March

-----Original Message-----

From: Lieng, Helen

Sent: Tuesday, April 25, 2006 1:50 PM

To: Sallade, Denny

Cc: Grader, Lindsay

Subject: Pharmacy Series Vacancy--March

Denny, this is the latest data we have for Pharmacy Series Vacancy. If this is not what you need, please let me know.

Helen Lieng

Resource Management Unit

Division of Correctional Health Care Services

Department of Corrections and Rehabilitation

Phone (916) 322-6939

Fax (916) 327-8972

APPENDIX F-1: INTERNAL AFFAIRS MEMORANDUM

State of California

Department of Corrections and Rehabilitation

Memorandum

Date : June 23, 2006

To : Erin Parker
Senior Special Agent
Internal Affairs-Northern Region

Subject: **RESPONSE TO MAXOR NATIONAL PHARMACY SERVICES CORPORATION
REGARDING NARCOTICS INVENTORY AT CALIFORNIA MEDICAL FACILITY AND
CALIFORNIA STATE PRISON-SOLANO**

In June 2006, Maxor Pharmacy Services Corporation submitted a report (Exhibit A) which included the comparing of the quantity of narcotic doses dispensed by CDCR pharmacies to the quantity of doses purchased during the calendar year (CY) 2005.

The report indicated the dispensing data was provided by the CDCR and the purchasing data was obtained from McKesson, the CDCR drug wholesaler during CY 2005. The drugs compared included some commonly used antipsychotic medications and narcotic controlled substances used for pain control.

Rick Pollard, Maxor's Vice President of Operation Support, was contacted via telephone. Pollard said the dispensed data provided by CDCR was from the Patient Profile Tracking System (PPTS) reports provided by Health Care Services Division (HCSD).

The report indicated that the expectation is drugs purchased should equal the drugs dispensed by the pharmacy plus the amount of medication used for stock and some very small amount of product that expires unused. Stock would be expected to include the inventory within the pharmacy and a small amount of floor stock medication placed in treatment areas for doses needed during emergencies and the hours the pharmacies are closed.

Maxor indicated the highest percentages of discrepancies were at California Medical Facility (CMF), and California State Prison-Solano (SOL) of the narcotic controlled substances with a very high abuse potential. Roxicodone® and Oxycontin®, had a greater than 95% gap between purchases and dispensing.

The report showed that CMF purchased a quantity of 186,000 Roxicodone 5 mg units from McKesson Drug Company during CY 2005. Of the 186,000 units purchased the

APPENDIX F-1: INTERNAL AFFAIRS MEMORANDUM

report indicated only 5,488 units were dispensed or 97.05% of the purchased Roxicodone were not dispensed.

Maxor reported that at SOL, a quantity of 9,175 Oxycontin, 20mg units were purchased from McKesson Drug Company during CY 2005 with only 280 units being dispensed or 96.95% of the purchased Oxicontin were not dispensed.

Also included in the report regarding SOL were the quantities of Risperidone, 2 mg and Seroquel 300 mg purchased during CY 2005. SOL purchased 41,040 units of Risperidone dispensing only 2,738 or 93.33% were not dispensed. SOL purchased 63,120 units of Seroquel dispensing only 5,679 or 91.00% were not dispensed.

Of obvious concern were the differences in the quantities of drugs purchased to the quantities of drugs dispensed during the review period.

On June 19-21, 2006, Special Agents Ballard, Kingston and McCoy, Office of Internal Affairs, Northern Region conducted an emergency audit/inventory of specific narcotics at California Medical Facility (CMF) and California State Prison-Solano (SOL). Specifically, at CMF the accountability of the Roxicodone was reviewed and at SOL the accountability of the Oxycontin, Risperidone and Seroquel were reviewed.

The agents conducted a physical count of the narcotics identified at each of the institutions assuring the units inventoried were accurately reflected on the institutional pharmacy inventory log.

Upon entrance into the pharmacy cage at CMF the inventory log reflected that they currently possessed 6,850 units of Roxicodone 5 mg. All units were accounted for accurately.

A review of the CY 2005 running inventory of Roxicodone 5 mg showed each shipment being received from McKesson Drug Company. The review indicated 186,000 units were ordered by CMF and received from McKesson. The institutional orders were compared to the shipping invoices from McKesson and accurately reflected units ordered to units received.

During the CY 2005, the on hand inventory within the CMF pharmacy cage was at its highest in July at 12,600 units of Roxicodone and in September the institution was at zero units prior to receiving their shipment from McKesson.

Our review of CMF pharmacy records showed 186,000 units of Roxicodone 5 mg were purchased and received in CY 2005. This amount is in agreement with Maxor. The pharmacy records showed a dispensed amount of 185,783 units in 2005. The dispense rate for 2005 is 99.88%. Maxor's report showed a "Not Dispensed" rate of 97.05% or the dispense rate of 2.95%.

APPENDIX F-1: INTERNAL AFFAIRS MEMORANDUM

Upon entrance into the pharmacy cage at SOL the inventory log reflected that they currently possessed 40 units of Oxycontin 20 mg. All units were accounted for accurately.

A review of the SOL CY 2005 running inventory of Oxycontin 20 mg. showed each shipment being received from McKesson Drug Company and indicated 8,975 units were received from McKesson.

Our review of SOL pharmacy records showed 9,474 units of Oxycontin 20 mg. were dispensed from their pharmacy in 2005 which equate to a dispense rate of greater than 100%. Maxor's reported dispensed rate 3.05% or a "Not Dispensed" rate of 96.95%.

During the CY 2005, the on hand inventory within the SOL pharmacy cage was at its highest in September and November at 475 units and at its lowest in June and July at 4 units prior to receiving their shipment from McKesson.

It should be noted that in April 2005 it is noted on the pharmacy log that 100 units of the Oxycontin 20 mg. were missing. The log indicates that the Drug Enforcement Agency (DEA) was notified.

The units of the Risperidone and Seroquel were considered atypical antipsychotic drugs and not accounted for as were the narcotics. Two medical staff members escorted the agents for a review of the H-Dorm med cart on Yard 2 within SOL. The observation revealed that the Risperidone and Seroquel are maintained under a controlled environment, locked within a pharmaceutical cart and distributed to the patients by prescription. A scenario was presented to the two staff members in which two bottles of Risperidone were removed covertly from the cart's working supply drawer. They were then asked how would they be able to prove two bottles were missing from their supply and they replied , they couldn't.

The running inventories at CMF and SOL indicate that upon receipt of the narcotics into the pharmacy cage the narcotics are distributed to the individual clinics, carts, wings, hospice, dental, emergency rooms, hospice, surgery and to individual inmates upon their parole.

A breakdown of the individual carts and a review of the Medical Activity Reports (MAR) for the individual patients are to follow upon request.

The differences between the Internal Affairs and Maxor's findings are in the incomplete electronic data provided to Maxor by HCSD and the manually recorded data located at the individual institutions.

Should you have any further questions or need any additional information please feel free to contact any of the below listed agents at (916)-464-3758.

Bob Ballard
Special Agent
Internal Affairs-North

Bryan Kingston
Special Agent
Internal Affairs-North

Ernie McCoy
Special Agent
Internal Affairs-North

APPENDIX F-2: MAXOR RESPONSE TO INTERNAL AFFAIRS MEMORANDUM



SENT VIA EMAIL

June 27, 2006

Robert Sillen, Court-Appointed Receiver
2457 Golf Links Circle
Santa Clara, CA 95050

Dear Mr. Sillen:

Per our conversation, I am forwarding a copy of a CDCR Internal Affairs Memorandum, dated June 23, 2006, subject: *RESPONSE TO MAXOR NATIONAL PHARMACY SERVICES CORPORATION REGARDING NARCOTICS INVENTORY AT THE CALIFORNIA MEDICAL FACILITY AND CALIFORNIA STATE PRISON-SOLANO.*

The memorandum correctly identifies the issue of comparing the quantity of narcotic doses dispensed by CDCR pharmacies to the quantity of doses purchased for CDCR during CY 2005, and the findings of significant differences in "Not Dispensed" rates. The memorandum concludes that the purchased-dispensed differences are in the electronic data from the official CDCR Patient Profile Tracking System (PPTS) when compared to the manually recorded data located at the individual institutions. The disparity in the records not only creates the opportunity for diversion, but points to serious patient safety concerns as well.

Maxor concurs with the Internal Affairs general finding. The fact that the CMF and SOL pharmacy records are in such wide disparity with the official PPTS, particularly for sensitive, supposedly tightly controlled narcotic medications is a matter of grave concern. Perhaps more alarming are the disparities identified by Maxor in other more expensive non-narcotic medications where less control and oversight exists.

The Maxor report highlighted the inadequacy of inventory controls and high potential for shrinkage and diversion. The Internal Affairs scenario of covertly diverting two bottles of the expensive medication, Risperidone (approximately \$881 per 100-count bottle), clearly illustrates a lack of proper inventory controls and accountability. A systemwide assessment of unaccounted for narcotics, such as those identified as missing in the SOL pharmacy, should be accomplished as soon as possible. Trends developed from frequent assessments would serve as a useful tool for improving accountability and oversight.

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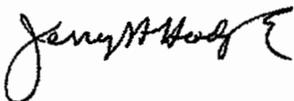
*Robert Sillen
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Based on follow-up discussions with Internal Affairs investigators, the audits did not attempt to verify that a valid physician prescription was written for each narcotic medication dispensed by the pharmacy and relied on a spot audit on a single wing to review inventory and the administration records of eight (8) patients. With the transient nature of inmate housing and difficulty in obtaining inmate records, it would be virtually impossible to audit the controlled substance system full-circle. While there was not a finding of large-scale diversion, the IA audit methods were primarily designed to consider our finding of a disparity between purchases versus dispenses and perhaps identify diversion on a macro-scale. The current pharmacy management system and inventory control processes are markedly antiquated and possess limited or no ability to prevent micro-scale diversion at the prescription level.

As mentioned earlier, the greatest potential for misuse or diversion rests with non-narcotic medication, which can be diverted at any scale, as there are virtually no inventory controls. Individuals with access to medications, with almost no risk of being detected, may divert unlimited medications from the CDCR stock. The value of these lost medications could easily represent millions of dollars per year.

In summary, the findings in the IA report are consistent with Maxor's findings. The PPTS dispense data is inaccurate and unreliable, making diversion extremely difficult to identify. Not all dispenses are entered into the patient profile, which raises serious patient safety concerns, in addition to the obvious accountability issues. Maxor appreciates the efforts of Internal Affairs to further investigate this issue and validate the findings of our report.

Sincerely,



Jerry Hodge, R.Ph.
Chairman

Enclosure