

State of California • Arnold Schwarzenegger, Governor State and Consumer Services Agency

DEPARTMENT OF GENERAL SERVICES

Procurement Division

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The Annual Report to the Legislature on Procurement of Pharmaceuticals

January 2009

INTRODUCTION

Assembly Bill 139 (Chapter 74, Statutes of 2005) requires the Department of General Services (DGS) to report annually to the Chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature on any joint activities of the DGS, the University of California (UC) and the Public Employees' Retirement System (CalPERS) in connection with procurement of pharmaceuticals and any resulting cost savings. This legislation also requires the DGS to develop an annual work plan describing the DGS' annual activities to reduce the State's costs for pharmaceuticals and estimate of cost savings.

Attachment A summarizes the annual work plan for 2009.

THE DGS PHARMACEUTICAL PROGRAM BACKGROUND

The DGS Procurement Division (PD) Pharmaceutical Section (Rx Section) implements and administers the Statewide Pharmaceutical Program (SPP) established by Government Code (GC) Sections 14977-14982. Attachment B illustrates the relationships among the stakeholders participating in the SPP.

The Rx Section has five positions dedicated to it, which include three Contract Administrators, one Pharmaceutical Consultant II, and one Pharmaceutical Program Consultant.

The Rx Section coordinates contracts supporting the SPP. These contracts provide for the purchase, distribution, reimbursement, and reverse distribution and destruction of pharmaceuticals and other medical and surgical supply products. Pricing for products through these contracts is established by:

- Discounts through the Pharmaceutical Wholesaler
- Group Purchasing Organization (GPO)
- Direct negotiations with pharmaceutical manufacturers, distributors and suppliers
- Competitive bidding processes such as an Invitation for Bid (IFB) or Request for Proposal (RFP)

The Department of Corrections and Rehabilitations (CDCR)¹, the Department of Mental Health (DMH), the Department of Developmental Services (DDS), and other State agencies under the DGS' authority are mandated to participate in this program. Additionally, the DMH operates two correctional programs, Salinas Valley Psychiatric Program and Vacaville Psychiatric Program, which purchase through the CDCR.

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¹ In February 2006, the CDCR healthcare system was placed under federal receivership, pursuant to federal court order in the case of *Plata vs. Schwarzenegger* (U.S. District court, Northern District of California, Case No. C-01-1351 TEH). CDCR, under the direction of Federal Receiver, Clark Kelso (Receiver), and his agent for pharmaceutical purchases, Maxor National Pharmacy Services Inc. (MAXOR), may or may not make purchases of products on the DGS contracts. The Receiver and MAXOR will provide direction and instruction to CDCR Procurement personnel on pharmaceutical related purchases.

Other State, district, county, city, and municipal or public agency governmental entities may elect to participate in this program. The DGS works with entities to facilitate their participation in the SPP. Other entities participating in the SPP include:

The California State University (CSU) System - The 22 campus pharmacies and three of the clinics located within the CSUs elect to purchase through the SPP. The CSU spent \$5.4 million through the SPP in Fiscal Year (FY) 2007-2008.

California Highway Patrol (CHP) Office of Air Operations - The CHP purchases about \$40,000 worth of drugs annually through the Pharmaceutical Wholesaler.

Emergency Preparedness - The Rx Section works with the Office of Emergency Service (OES), Emergency Medical Services Authority (EMSA), and the California Department of Public Health (CDPH) Emergency Preparedness Office to procure products and services, such as the Antiviral Supply Program and drug caches, which support the State's emergency preparedness efforts.

CDPH Immunization Branch - The CDPH participates in the Vaccine Program associated with the SPP. CDPH purchases Influenza Vaccine, Diphtheria, Tetanus & Pertussis (DTaP) Vaccine, Tetanus, Diphtheria & Acellular Pertussis (TDaP) Vaccine, and Hepatitis B Vaccine through this program.

California Department of Veterans Affairs (CDVA) - Public Law 103-210 HR 2535 authorizes State veterans' facilities to participate in federal Department of Veterans Affairs (VA) contracts accessing Federal Supply Schedule (FSS) pricing on pharmaceuticals. Accessing the contracts requires an agreement between the VA and the CDVA. The CDVA Yountville and Chula Vista facilities signed sharing agreement contracts (CDVA #06YS0061 and #07CS0035) with the VA. The DGS established the agreement (Contract No. 1-08-65-50-B that allows the CDVA to purchase pharmaceuticals at the FSS pricing through the VA's contractor, McKesson Corporation.

The DGS refers to these agreements as the CDVA Drug Distribution Program. The CDVA has five facilities planned or under construction that will access the CDVA Drug Distribution Program in the coming years. The CDVA spends about \$10 million annually through this program. FSS pricing averages about 30 percent below the pricing available to the SPP.

The SPP has the following goals:

- Control costs to the State
- Develop and implement Drug Utilization Reviews (DURs) and Step Therapies to control drug costs and ensure appropriate drug therapies for patients
- Work through the Common Drug Formulary (CDF) Committee to conduct Therapeutic Category Reviews on drugs accounting for the top 80 percent of the drug spend
- Expand participation in the SPP to local governmental entities
- Identify contracts necessary to improve the SPP

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- Establish baselines and reporting requirements for the SPP
- Implement strategies identified by UC System and CalPERS
- Identify and inform on issues which may affect the SPP
- Develop policies, procedures and guidelines to support the SPP
- Contract for biologicals, which include a wide range of medicinal products such as vaccines, blood and blood components

The DGS achieves these goals through the following methods:

1. Pharmacy Advisory Board (PAB)

The DGS established a central PAB, which implements and administers the SPP through a coordinated effort among State agencies, local governmental entities, and the DGS. Directors of each entity participating in the SPP appoint membership to the PAB. The PAB:

- Provides oversight to the CDF Committee
- Coordinates the efforts among the DGS, other State agencies, and local governmental entities to identify goals and objectives for the SPP
- Exchanges information and identifies opportunities among the participating entities to work together to improve upon the SPP
- Identifies opportunities within additional State agencies and local governmental entities for participation in the SPP
- Develops and implements a management system for the administration of the SPP
- Coordinates the efforts of State and local governmental entities to develop guidelines, policies and procedures for the administration of the SPP
- Identifies and coordinates discussions relating to relevant practice management issues that will improve upon the SPP

The PAB has identified the following issues as directions for future study and action:

- Qualify for 340B pricing for pharmaceutical purchases. 340B pricing is U.S.
 Public Health Service Act (PHSA) pricing on pharmaceuticals available to
 qualified public pharmaceutical purchasers. The benefits of this pricing have not
 been realized by any entities participating in the SPP as no agencies have
 qualified as (a) Disproportionate Share Hospitals, or b) serving clients classified
 as indigents.
- Implement Electronic Drug Pedigree (e-pedigree) requirements. Chapter 713, Statutes of 2008 (SB 1307 Ridley-Thomas), establishes an implementation schedule for the e-pedigree law, beginning January 1, 2015, through July 1, 2017. It requires drug manufacturers to have 50 percent compliance by 2015, and the remaining by 2016, and prohibits starting July 1, 2017, the sale, repackaging, trading, transferring, etc., of any drug without a pedigree. The e-pedigree may impact the individual pharmaceutical pricing agreements, the GPO Agreement, the Pharmaceutical Wholesaler Agreement, and the Reverse Distribution & Destruction Agreement.

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- Establish data-sharing arrangements constant with the Health Insurance Portability and Accountability Act (HIPAA) regulations. The DGS contract with HealthTrans (Contract No. 1S-05-65-51), a Pharmacy Benefit Manager (PBM), requires agencies to exchange individuals' Protected Health Information (PHI) with the contractor and the DGS. However, the DGS does not currently receive utilization data on the HealthTrans contract due to the HIPAA provisions.
- Implement federal rebate and discount reporting requirements.

Current workload in the Rx Section may limit the activities the Rx Section will be able to undertake in the coming year to make progress on these longer-term issues.

2. The CDF Committee

The CDF Committee is a subcommittee of the PAB established in response to GC Section 14982(b)(3). The CDF Committee membership is appointed by the Directors of the participating entities or the PAB. The CDF Committee meets the third Wednesday of each month to:

- Develop, maintain, and implement a CDF system for entities participating in the SPP
- Develop information on the relative effectiveness of pharmaceuticals
- Investigate and implement options and strategies to achieve the greatest savings on pharmaceuticals with pharmaceutical manufacturers, suppliers, and wholesalers
- Communicate with department and local Pharmaceutical and Therapeutic (P&T)
 Committees within the entities participating in the SPP

The CDF represents a common commitment to pharmaceuticals, relevant guidelines and protocols for drugs prescribed in entities participating in the SPP, while leveraging the buying power of the State. The CDF Committee considers efficacy, essential need, misuse potential, safety and cost when evaluating pharmaceuticals for the CDF.

A goal of the CDF Committee is to conduct Therapeutic Category Reviews for the top 80 percent of the pharmaceutical expenditures through the SPP over the next three years. The CDF Committee reviews local P&T Committee(s) and nationally established clinical guidelines, and protocols, when making decisions on drugs.

In FY 2007-2008 the CDF Committee completed the following Therapeutic Category Reviews:

- HMG-CoA Reductase Inhibitors
- Proton Pump Inhibitors
- Short, Intermediate and Long Acting Insulins
- Nasal Corticosteroids
- Fluoroquinolone antibiotics
- Extended Release Vaginal Insert Contraceptive

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The Rx Section Staff is in the final stages of contracting and/or providing guidance for the drugs in these Therapeutic Categories. The DGS estimates an annual savings of \$1.5 million through this effort.

Though there are significant benefits to the program, it is recognized that a particular program may not always have common interests with other State entities. Therefore, participation is voluntary and individual agencies are not required to participate. The DGS will work with any agency that identifies individual needs to create separate and unique contracts.

The CDF is published on the DGS Website: http://www.pd.dgs.ca.gov/contracts/pharma/CDF.htm

3. Contracts Supporting the SPP

Entities participating in the SPP access pricing agreements for pharmaceuticals through the Pharmaceutical Wholesaler Agreement with AmerisourceBergen Drug Corporation (ABDC) (Contract No. 1S-05-65-50). These pricing agreements are established through:

A Group Purchasing Organization. The DGS entered into a MOU with the Multi-State Alliance with the Commonwealth of Massachusetts and is a member of the Massachusetts Alliance for State Pharmaceutical Buying (MASPB). Through the MASPB the DGS accesses the GPO Managed Healthcare Associates, Inc. (MHA). The GPO leverages the buying power of numerous public and private sector entities through a purchasing consortium to negotiate pricing agreements with pharmaceutical manufacturers.

The GPO pricing agreements are essential when the State does not purchase in sufficient volumes to entice manufacturers to engage in direct price negotiations. In addition, direct negotiations take time and a planned approach. The GPO provides the State discounted pricing for areas which either cannot be or have not yet been the subject of direct negotiations.

The Pharmaceutical Wholesaler reports, in FY 2007-2008, 3,798 of the 5,174 unique drugs purchased by the State were through the GPO pricing agreements.

• The IFB process. The DGS establishes pricing agreements for pharmaceuticals with manufacturers through the IFB process that demonstrate a savings over the GPO and other contracting options. Prior to the GPO relationship, the DGS established pharmaceutical pricing agreements for nearly 600 unique drugs through the IFB process. Because of the savings achieved though the GPO, the DGS now establishes pricing agreements for about 200 unique drugs through a single IFB. These pricing agreements expired in November of 2008; the Rx Section does not have the resources to conduct an IFB this year.

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Direct negotiations between the DGS and pharmaceutical manufacturers. To
gain the best discount from pharmaceutical manufacturers, the DGS works with
the CDF Committee to develop criteria for drug selection. The DGS uses these
criteria when negotiating with pharmaceutical manufacturers. Working with the
CDF Committee, the DGS is systematically pursuing further negotiations from the
top 80 percent of spending on pharmaceuticals.

The CDCR entered into their own Pharmaceutical Wholesaler Agreement, on February 4, 2008, to service the CDCR Division of Adult Operations (DAO). The DGS Pharmaceutical Wholesaler Agreement was implemented March 1, 2006 and, will expire November 2009. The DGS is evaluating the following for the next Pharmaceutical Wholesaler Agreement for the SPP:

- Leveraging the CDCR Pharmaceutical Wholesaler Agreement
- Accessing a Pharmaceutical Wholesaler Agreement through the Minnesota Multi-State Contracting Alliance for Pharmacy
- Conducting a solicitation to establish a new Pharmaceutical Wholesaler Agreement

Reports available through the Pharmaceutical Wholesaler show entities (excluding the CDCR DAO) participating in the SPP spent \$45.6 million through this agreement, with a savings of \$17 million. Savings consisted of the following:

- 1.2 percent off the wholesale acquisition cost (WAC)
- Discounted price available through ABDC's ProX® program. The Pharmaceutical Wholesaler reports agencies participating in the SPP purchased 1,154 unique drugs through this program for a savings of \$2.4 million
- A savings of \$11.1 million on pharmaceuticals purchased through the GPO
- A savings of \$3.4 million on pharmaceuticals purchased through pricing agreements established by the DGS

Additional savings realized through the Pharmaceutical Wholesaler result from:

- A prompt payment discount of 2.5 percent if payment is postmarked within 20 days
- No service fee charged by ABDC; the previous Pharmaceutical Wholesaler Agreement charged a 0.05 percent service fee

Table 1 summarizes the total products purchased, source of pharmaceutical pricing, and savings as reported by ABDC.

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Table 1
Spend Through Pharmaceutical Wholesaler FY 2007-2008
for Entities Participating in the SPP
(Excluding CDCR DAO)
Reported by ABDC

Brand Pharmaceuticals

Contract Type	Unique Count of NDC	Total Volume (units)	Total Wholesale Cost\$	Total \$ Purchase Price	Savings from Wholesale Cost	Percent Savings
ABC	19	472	\$182,373.53	\$112,362.44	\$70,011.09	38.39%
GPO	695	63,563	\$14,654,246.03	\$13,477,905.35	\$1,176,340.68	8.03%
DGS	56	36,820	\$22,939,944.10	\$19,794,577.58	\$3,145,366.52	13.71%
Total	770	100,855	\$37,776,563.66	\$33,384,845.37	\$4,391,718.29	11.63%

Generic Pharmaceuticals

Contract Type	Unique Count of NDC	Total Volume (units)	Total Wholesale Cost\$	Total \$ Purchase Price	Savings from Wholesale Cost	Percent Savings
ABC	1,135	63,465	\$4,517,330.82	\$2,157,993.19	\$2,359,337.63	52.23%
GPO	3,103	486,428	\$19,726,952.88	\$9,775,339.66	\$9,951,613.22	50.45%
DGS	166	18,417	\$506,401.40	\$168,148.29	\$338,253.11	66.80%
Total	4,404	568,310	\$24,750,685.10	\$12,101,481.14	\$12,649,203.96	51.11%

4. Utilization of Generic Drugs

Table 2 summarizes the percentage of Brand vs. Generic pharmaceuticals purchased through the Pharmaceutical Wholesaler Agreement.

Table 2
AGENCY PURCHASE OF BRAND/GENERIC PHARMACEUTICALS
FY 2007-2008

Purchaser	Brand Name % of Total Units Purchased	Brand Name % of Total Dollars Purchased	Generic % of Total Units Purchased	Generic % of Total Dollars Purchased
CDCR DJJ	27%	77%	73%	23%
DMH	37%	93%	63%	7%
DDS	28%	88%	72%	12%
CSU	17%	67%	83%	33%
OTHER	40%	80%	60%	20%
Total	29%	89%	71%	11%

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5. Pharmacy Benefit Manger

The DGS PBM contract (Contract No. 1S-05-65-51), with HealthTrans, enables the CDCR Division of Adult Parole Operations (DAPO) parolee pharmaceutical dispensing program to cover the dispensing of mental health medications required as a condition of parole. Prior to this contract, the CDCR DAPO's purchased these medications through a contract with Rite Aid, a retail pharmacy chain. According to reports from HealthTrans, State agencies spent \$23.9 million through the PBM in FY 2007-2008, with a savings of \$9 million. The DGS is currently amending this Agreement to include the CDCR Division of Juvenile Justice (DJJ) Parole Operations (Contract No. 1-08-65-51-A) and emergency prescription fills for CDCR DAO (Contract No. 1-08-65-51-C).

6. Vaccine Program

The DGS procures the following vaccines through the Vaccine Program.

2008-2009 Season Influenza Vaccine. Each year the DGS procures influenza vaccine for the upcoming flu season. The DGS combined the volumes for the CDPH Immunization Branch, the CDCR DAO, and other state entities purchasing through the SPP into one competitively bid procurement.

Influenza Vaccine procured for the 2008-2009 Season covers all five risk groups identified by the federal Centers for Disease Control and Prevention (CDC). The procurement was designed to follow CDC, the Food and Drug Administration (FDA), and the American Pharmacists Association (APHA) recommendations to provide Influenza Vaccine through multiple vendors. This recommendation helps secure a supply chain, should a manufacturer fail to produce the Influenza Vaccine. The DGS has "booking as available" period, enabling agencies to obtain additional Influenza Vaccine, at reduced pricing, throughout the flu season.

The State purchased 763,660 doses of the 2008-2009 Season Influenza Vaccine through the DGS' contracts with a savings of \$1.2 million or 16 percent over last year. The State saved about \$850,000 over the CDC contracts.

Diphtheria Tetanus & Pertussis (DTaP) Vaccine. The DGS competitively bid the DTaP Vaccine for the CDPH Immunization Branch and received pricing equal to the previous year and \$2.85 per dose less than the CDC contracts. The CDPH Immunization Branch purchased 45,000 doses for a total spend of \$468,000 with a savings of \$128,250.

Tetanus, Diphtheria \$ Acellular Pertussis (TDaP) Vaccine. The DGS competitively bid the TDaP Vaccine for the CDPH Immunization Branch and received pricing equal to the previous year and \$2.25 per dose less than the CDC contracts. The CDPH Immunization Branch purchased 19,000 doses for a total spend of \$541,500, with a savings of \$42,750.

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Hepatitis B Vaccine. The DGS competitively bid the Hepatitis B Vaccine for CDPH Immunization Branch for a price \$0.75 per dose less than the CDC contracts. The CDPH Immunization Branch purchased 58,500 doses for total spend of \$511,875, with a savings of \$43,875.

7. Antiviral Supply Program

The DGS works in conjunction with the CDPH to implement the Antiviral Supply Program for response to a pandemic flu. This program allows the DGS to purchase on behalf of State agencies and Local Health Departments (LHDs), from the Federal supply schedule for Pandemic Response, a savings of nearly 75 percent. The federal government provides a subsidy of an additional 25 percent for California's federally allotted ("subsidized") purchases. This federal contract is currently expired. Federal contract extensions should be completed after new federal regulations regarding the program are published.

JOINT ACTIVITIES OF THE DGS, UC AND CaIPERS

The DGS, the UC System and CalPERS identified significant differences among each organization's pharmacy models including:

- Populations served (i.e. age, economic demographics, inpatient vs. outpatient)
- Disease states being treated (i.e. cancer vs. psychosis)
- Grant opportunities with pharmaceutical manufacturers
- Pharmaceuticals purchased (about 6 percent of the top 50 drugs purchased by the UC and SPP are similar)
- Method in which patients access health care, such as through insurance plans
- Method by which healthcare is provided and contracted

Despite these differences, the DGS will work with the UC System and CalPERS developing the following plan to explore opportunities to consolidate purchases or derive savings through the DGS:

1. The CDF System

- Evaluate the structure of the CDF System to determine if improvements can be made to the current structure
- Identify ways for the UC System and CalPERS to participate in the CDF
 Committee for the purpose of sharing information regarding drug effectiveness
- Explore opportunities with the UC San Diego Pharmacoeconomics program

2. Drug Contracting

Identify the feasibility of entities within the UC System accessing the pharmaceutical contracts entered into between the DGS and manufacturers of Atypical Antipsychotics and oral typhoid vaccine.

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3. Coordinating Programs Offered by Pharmaceutical Manufacturers Providing Pharmaceuticals Free or at Reduced Cost

- Identify programs offered by pharmaceutical manufacturers providing pharmaceuticals free or at reduced costs within the DGS, UC System and CalPERS
- Determine if these programs can be accessed by other agencies

4. GPO

Evaluate the GPO contracted by the UC System in the process of contracting for a new GPO to support the SPP.

5. PBM

Through the procurement planning for a new PBM agreement, to replace the current contract with HealthTrans, the DGS will:

- Identify State and local governmental entities accessing PBM Agreements
- Identify pros and cons to expanding the PBM's role with State agencies using other pharmaceutical models
- Identify pros and cons for consolidating State and local governmental entities into a single PBM
- Identify limitations and solutions for accessing CalPERS' PBM
- Explore opportunities to contract with a consultant through Health Actuarial and Benefits Consultant Services Pool established by CalPERS; to work with the DGS to develop and award the DGS solicitation for a new PBM

6. Pharmaceutical Wholesaler

Through the procurement planning for a new Pharmaceutical Wholesaler agreement, to replace the current contract with ABDC, the DGS will:

- Identify UC entities which use a Pharmaceutical Wholesaler Agreement
- Evaluate Pharmaceutical Wholesaler Agreements with the UC System
 Pharmaceutical Wholesaler, the CDCR DAO Pharmaceutical Wholesaler, the
 Minnesota Multi-State Contracting Alliance for Pharmacy (MMCAP), and other
 pharmaceutical wholesalers as identified through continuing research
- Identify State and local governmental entities accessing Pharmaceutical Wholesaler Agreements, and the pharmaceutical services provided through these agreements
- Identify limitations, solutions, and potential for additional savings and services involved in consolidating the UC System, State and local governmental entities into a single Pharmaceutical Wholesaler Agreement

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7. Other Collaborative Efforts

Consistent with the requirements of GC Section 14982(b)(3), the DGS collaborates with the UC System through the California Mental Health Care Management (CalMEND) program. CalMEND is a consortium of publicly-funded providers and purchasers of mental health services dedicated to improve the quality and reduce the cost of mental health services to persons served by these entities. CalMEND coordinates resources among organizations to develop clinical practice guidelines, algorithms, policies and procedures that are integrated with patients, families, and caregivers.

The DGS will work with the Pharmacy Advisory Board and the CDF Committee to incorporate results from these efforts into the policy, procedures, and contracts supporting the SPP.

8. Pharmacy Information Management System (PIMS)

The DGS is developing the PIMS Project. The PIMS will allow the DGS to perform in-depth analysis regarding pharmaceutical pricing and improve price verification. This project chartered on March 27, 2007, is designed to address the full range of the SPP data storage, data analysis, and reporting needs. PIMS is organized into three phases.

Phase I. Consolidates the purchase history data obtained from ABDC into a central database. This phase of the project is completed. The DGS is able to conduct basic reporting regarding price comparisons on pharmaceuticals, Generic vs. Brand purchases, and formulary and contract purchases. The DGS continues to develop enhancements to the reporting through this phase on contract spend reporting and formulary compliance.

Phase II. Implements the solutions recommended by the Feasibility Study Report developed by Public Sector Consultants. This phase of the project will incorporate State contract pricing, GPO Pricing, and industry standardized pharmaceutical pricing available from subscription services into the central pharmaceutical database. Completion of this phase of the project will enable the DGS to generate the following types of reports:

- Reports mandated by GC Section 14982 (b)(6)(A-F)
- Contractually Required Reports These reports are required by specific contracts entered into by the DGS and include:
 - Contract Compliance Reports used to determine if entities participating in the SPP are complying with the terms and conditions of the DGS contract
 - Rebate Reports Track rebates or other discounts associated with a product
 - Market Share Reports Compares contracted product to total purchases in a defined market basket over a given period of time
- Contract Management Reports Internal reports that allow the DGS to ensure the contracts are performing to their best value. These reports include:
 - Reconciliation Reports Allow Rx Section staff to reconcile data against information reported by contractor or other third party sources

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- Data Validation Reports Allow Rx Section staff to validate pricing, and determine if the product is at the best available pricing for the State
- *CDF Reports* Reports required by the CDF Committee, which include:
 - Cost Comparison Reports These reports are used by the Rx Section staff to analyze and make cost comparisons among pharmaceuticals within identified therapeutic classes. These reports also provide the basis for more specific analysis as needed. These reports utilize drug purchase data available through the Pharmaceutical Wholesaler and other therapeutic data related to the pharmaceuticals
 - Formulary Compliance Reports These reports are used to determine if entities participating in the SPP are compliant to the CDF
- Historical Purchase Reports These reports allow the DGS to predict drug trends, track savings, and develop contract and formulary strategies
- Ad Hoc Reports enabling the DGS to respond to requests from the Legislature, management, customers, the public, and industry
- *DGS Reports* Reports required by the DGS to conduct its business practices. These reports include:
 - Usage Reports Purchases made through contracts for a specific period of time to ensure proper pricing and calculate savings
 - Billing Reports Used by the DGS to bill and/or validate the appropriate DGS fees charged to purchasers
 - No- Contract Purchase Reports The DGS monitors non-contracted pharmaceutical purchases made by State agencies to improve upon the contracting needed through the SPP
- Phase III: Future steps involve a project that incorporates all the DGS PD pharmaceutical vendors' transactional data, related pricing data, and customer information. The comprehensiveness of this data will allow the DGS staff to perform analysis and matrix reporting comparing information from multiple sources

FUTURE PLANS

The DGS will work through the PAB and the CDF Committee to increase the participation of other State entities and explore options to increase value-based purchasing. Such purchasing will require the coordination of resources among organizations and other State entities to develop or adopt clinical practice guidelines, algorithms, procedures, and policies.

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Attachment A The DGS Workplan 2009

Pharmacy Advisory Board (PAB)

Definition: Create an interagency organizational structure to support the Statewide

Pharmaceutical Program (SPP)

Savings: Undetermined

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Develop invitation letter from the DGS Director to departments participating in the SPP.	Completed
Schedule Regular Meetings for the PAB. • Fourth Thursday of January, April, July, and October	Workload of Rx Section does not allow for regular meetings of PAB.
Review the PAB Guiding Principles.	Adopted
Develop Agendas for the PAB Meetings. • January	Ongoing – The general workflow has been developed.
Approve Charter for Common Drug Formulary (CDF) Committee.	developed.
April	
Receive CDF Strategic Plan.	
• July	
Confirm appointed representatives to the CDF committee. Authorizes CDF Strategic Plan.	
October	
PAB confirms representation to CDF Committee. Receives proposed changes, revisions and amendments to CDF Committee Charter.	
Identify contracts necessary to maintain or improve the SPP.	Ongoing - The DGS
Pharmaceutical Wholesaler	provides the PAB
Group Purchasing Organization (GPO)	regular updates on the
 Individual Drug Contracts with Manufacturers 	status of these
Reverse Distribution and Destruction of Pharmaceuticals Pharmacy Benefit Manager (PBM)	contracts.
Identify and inform on issues which may affect the SPP.	The PAB will address
Electronic Drug Pedigree Implementation (e-Pedigree)	these issues as DGS is
Health Insurance Portability and Accountability Act of 1996, Public Law 104 101 as amended, and the regulations.	able to provide
Public Law 104-191 as amended, and the regulations promulgated thereunder ("HIPAA")	resources.
Rebate and Discount Reporting Requirements	
Develop Policies, Procedures and Guidelines to support the SPP.	TBD
Expand membership for PAB. The DGS is working with:	The DGS is working
Sacramento County	with these local
Orange County	governmental entities
Santa Clara County	to include them in the SPP.

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Common Drug Formulary Committee

Definition: Serves as a steering committee to consolidate the formularies of participating entities into one CDF system.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Recruit Membership – Current membership includes: • Department of Mental Health (DMH) • Department of Developmental Services (DDS) • California State University (CSU) • California Department of Corrections and Rehabilitation (CDCR) Division of Juvenile Justice (DJJ) • CDCR Division of Adult Parole Operations (DAPO)	Ongoing – The DGS is working with Local governmental entities that have expressed interest in the SPP
Schedule regular CDF meetings. • Third Wednesday of each Month	Ongoing
Develop the CDF meeting agendas focusing on: Important disease and therapeutic issues High cost therapeutic categories	Ongoing – The DGS solicits Agenda Topics from the CDF Committee monthly.
Maintain the CDF. Revise CDF to a more concise format.	Ongoing - The CDF is published on the DGS Website
 Enforce CDF Monitoring non-formulary purchases for Atypical Antipsychotics Developing Formulary Compliance Report to monitor Therapeutic Categories 	Ongoing – The DGS shares non-formulary purchases with the CDF Committee on a monthly basis. The CDF Committee has been successful in changing purchasing patterns on drugs.
 Develop Guidelines, Protocols and Procedures to support the CDF. CDF Adherence Protocol – Adopted (Next Review Aug 2009) CDF Pharmaceutical Review Process for Status on CDF Update Formulary Addition/Deletion Notification Procedures California Protocol for the Selection of Antipsychotic Medications Hypercholesterol Therapeutic Category Review Asthma Therapeutic Category Review Seizure Medication Therapeutic Category Review 	 Completed Under Review Under Review Statins completed (6/18/2008) – remainder Under Review Inhaled corticosteroid Completed – remainder Under Review TBD

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OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
The following Therapeutic Categories are identified by the CDF Committee for review. Psychosis (Schizophrenia/Mania) Atypical Antipsychotic Medications Butyrophenones Phenothiazines Thioxnthenes Miscellaneous Antipsychotics Seizure Medications Barbiturates Benzodiazepines Hydantoins Oxazolidinediones Succinimides Miscellaneous Anticonvulsants Hypercholesterolemia Bile Acid Sequestrants Fibric Acid Derivatives HMG-CoA Reductase Inhibitors Miscellaneous Antilipemic Agents Asthma Bronchodilators Corticosteroids Inhaled Adrenal Corticosteroid Meter Dose Inhalers (MDI) Nasal Corticosteroid inhalers Adrenals Inhalant Solution Miscellaneous Therapeutic Agents Sympathomimetic (Adrenergic) Agents Respiratory Smooth Muscle Relaxants Gastroesophageal Reflux Disease (GERD)/Peptic Ulcer Disease (PUD) Proton Pump Inhibitors (PPIs) Diabetes Short acting insulin Intermediate acting insulin Long acting insulin Long acting insulin Pain and Inflammation Nonsteroidal Anti-Inflammatory Agents (NSAID) Cyclooxygenase-2 (Cox-2) Inhibitors Infectious Disease Fluoroquinolone Antibiotics Contraception Extended Release Vaginal Insert Oral Contraceptives Depression Selective-serotonin Reuptake Inhibitors	The CDF Committee is reviewing the drugs in the following Therapeutic Categories: Completed:

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OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE	
Develop pharmaceutical models for Therapeutic Category Reviews • Phase I of the Pharmaceuticals Information Management System (PIMS) Project • Phase II of PIMS Feasibility Study Report	Ongoing – The DGS is mapping data elements and developing the necessary databases and reports to support CDF Committee. The DGS contracted with Public Sector Consulting to develop an	
(FSR) to address data and reporting needs	FSR for the second phase of the PIMS project.	

The DGS, University of California (UC), and the Public Employees' Retirement System (CalPERS) Meetings

Definition: Mandated by Government Code (GC) Section 14982(a) for the DGS, UC & CalPERS to regularly meet and share information regarding each agency's procurement of pharmaceuticals in an effort to identify and implement opportunities for cost savings in connection with this procurement.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Improve upon the CDF Committee. • Evaluate the structure of the CDF System to determine if: - Can improve upon current structure - Identify protocols, procedures and guidelines which may need to be developed to improve functioning of the CDF Committee • Identify ways for the UC system and CalPERS to participate in the CDF Committee for the purpose of sharing information regarding pharmaceutical effectiveness • Explore opportunities with the UC San Diego Pharmacoeconomics Program	Ongoing
Coordinate programs offered by pharmaceutical manufacturers providing pharmaceuticals free or at reduced cost. • Identify if the UC system or CalPERS is taking advantage of any of these programs • Determine if these programs can be accessed by other agencies	TBD
Improve pricing through the GPO.	Ongoing – The DGS is working with CDCR to develop a new contract for the GPO. The DGS will include the UC GPO in the IFB process.

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OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
 Improve pricing through the PBM. Identify State and local agency governmental entities accessing a PBM and the pharmaceutical services provided through their agreements Review CalPERS' Pharmacy Carve-Out Study and RFP for their PBM for their Self-Funded Health Plans Pharmacy Program to determine differences between contracts Identify pros and cons for expand the PBM's role with the State agencies using other pharmaceutical models Identify pros and cons for consolidating State and local governmental entities into a single PBM Identify limitations and solutions for accessing CalPERS PBM 	Ongoing – The DGS is evaluating contracting with a consultant from the CalPERS Health Actuarial and Benefits Consultant Services Pool for the procurement development for a new PBM.
Improve upon drug distribution. Identify UC entities which use a Pharmaceutical Wholesaler Agreement Evaluate Pharmaceutical Wholesaler Agreements with the: UC System Pharmaceutical Wholesaler CDCR Pharmaceutical Wholesaler Minnesota Multi State Contracting Alliance for Pharmacy (MMCAP) Other pharmaceutical Wholesaler Agreements as identified in our research Identify State and local governmental entities accessing Pharmaceutical Wholesaler Agreements Identify business needs of State and local governmental entities accessing Pharmaceutical Wholesaler Agreements, and the pharmaceutical services provided through these agreements Identify limitations and solutions for consolidating the UC system, State and local governmental entities into a single Pharmaceutical Wholesaler Agreement	TBD
 Improve upon drug contracting. Determine feasibility and potential savings of consolidating drug contracting for: Atypical Antipsychotics Other therapeutic drug categories as identified by the comparison of top drug expenditures 	Ongoing. – The DGS is developing contracts with Atypical Antipsychotic and vaccine manufacturers to explore access by the UC system for purchasing product.

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Explore Additional Strategies for Managing the Increasing Cost of Pharmaceuticals

Definition: Identify and Implement other strategies as permitted under State and federal law aimed at managing escalating pharmaceutical prices consistent with GC Section 14980.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Coordinate programs offered by pharmaceutical manufacturers providing pharmaceuticals free or at reduced cost. (GC Section 14980(a). • Working with the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS) to certify California agencies exempt from the limitations on sales at nominal price • Identify nominal pricing agreements from the pharmaceutical manufacturers with the largest pharmaceutical spend	Ongoing, The DGS is in contact with CMS and has begun contacting pharmaceutical Manufacturers and including language in contracts to access nominal pricing. Manufacturers have not yet been willing to enter into nominal pricing agreements.
Study the feasibility and appropriateness of including in the bulk purchasing program entities in the private sector, including employers, providers, and individual consumers. (GC Section 14980(b).	TBD

Expansion of the State of California Prescription Drug Bulk Purchasing Program

Definition: Expand the SPP to State, district, county, city, municipal or public agency governmental entity, other than those required to participate in the Statewide Pharmaceutical Program, consistent with GC Section 14977.5

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
 Develop contracts that allow other governmental agencies to access pharmaceutical pricing agreements and contracts: Develop Memorandum of Understanding between the State and local governmental entities Develop contract with pharmaceutical wholesalers used by local governmental entities to allow access of the DGS Pricing Agreements Develop Nondisclosure Agreements between the DGS and local governmental entities 	Ongoing. The DGS developed the nondisclosure agreements and is working with Orange County to allow access to DGS Drug Pricing Agreements.
 Identify other governmental agencies to expand the SPP Sacramento County Orange County Corrections Santa Clara County 	Ongoing. These entities have expressed interest in exploring a relationship with the DGS.

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OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
 Promote contracts which other governmental agencies may access: Pharmaceutical Wholesaler Group Purchasing Organization Contract Reverse Distribution & Destruction Contract Pharmacy Benefit Manager Contract 	Ongoing – working with local agencies identifying themselves to the DGS.
 Develop contracts which allow for other governmental entities to access. Eli Lilly & Company, Antidepressant - Cymbalta® Eli Lilly & Company, Atypical Antipsychotic - Zyprexa® and Zydis® AstraZeneca, Atypical Antipsychotic - Seroquel® Bristol Myers Squibb, Atypical Antipsychotic - Abilify® Berna, Oral Typhoid Vaccine – Vivotif Berna® Eli Lilly & Company, Short, Intermediate and Long Acting Insulins Schering-Plough, Contraceptive Extended Release Vaginal Insert, Bronchodilator, and Fluoroquinolone Antibiotics - NuvaRing®, Proventil® HFA, and Avelox® 	Ongoing. 14 local governmental entities expressed interest in purchasing through the Oral Typhoid Vaccine Contract.

Program Measurement and Reporting

Definition: The Pharmaceuticals Information Management System (PIMS) under development by the DGS will address the full range of the SPP data storage, data analysis and reporting needs.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Phase I of PIMS allows the DGS to conduct analysis of:	Ongoing – the DGS is developing additional reports to enhance the current system.
Phase II of PIMS implements the solutions recommended by the Feasibility Study Report (FSR) developed by Public Sector Consultants. This phase of the project will incorporate State contract pricing, GPO Pricing and industry standardized pharmaceutical pricing available from subscription services into the central pharmaceutical database. Completion of this phase of the project will enable the DGS to perform complex analysis and reporting including the items listed on the following page.	Ongoing – The DGS awarded a contract to Public Sector Consultants to develop an FSR. The DGS is in the approval phase of the final draft of the FSR. Implementation of the FSR recommendations should begin in FY 2009-2010.

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- Reports mandated by GC § 14982 (b)(6)(A-F)
- Contractually Required Reports These reports are required by specific contracts entered into by the DGS and include:
 - Contract Compliance Reports used to determine if entities participating in the SPP are complying with the terms and conditions of the DGS contract
 - Rebate Reports Track rebates or other discounts associated with a product
 - Market Share Reports Compares contracted product to total purchases in a defined market basket over a given period of time
- Contract Management Reports Internal reports allowing the DGS to ensure the contracts are performing to their best value. These reports include:
 - Reconciliation Reports Allows Rx Section staff to reconcile data against information reported by contractor or other third party sources
 - Data Validation Reports Allows Rx Section staff to validate pricing, and determine if the contract is the best available pricing for the State
- *CDF Reports* Reports required by the CDF Committee, which include:
 - Cost Comparison Reports used by the Rx Section staff to analyze and make cost comparisons of pharmaceuticals within identified therapeutic classes. These reports also provide the basis for more specific analysis as needed. These reports utilize drug purchase data available through the Pharmaceutical Wholesaler and other therapeutic data related to the pharmaceuticals
 - Formulary Compliance Reports used to determine if entities participating in the SPP are compliant to the CDF
- Historical Purchase Reports These reports allow the DGS to predict drug trends, track savings and develop contract and formulary strategies
- Ad Hoc Reports enabling the DGS to respond to requests from the Legislature, management, customers, the public, and industry
- DGS Reports Reports required by the DGS to conduct its business practices. These reports include:
 - Usage Reports Purchases made through contracts for a specific period of time to ensure proper pricing and calculate savings
 - Billing Reports Used by the DGS to bill and/or validate the appropriate DGS fees are charged to purchasers
 - Non Contract Purchase Reports The DGS monitors non-contracted pharmaceutical purchases made by State agencies to improve upon the contracting needed through the SPP

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Pharmaceutical Benefit Manager Contract

Definition: Contract entered into with Health Trans enabling the CDCR's parolee pharmaceutical dispensing program to cover the dispensing of mental health medications which are required as a condition of parole.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
 Identify ways to increase savings. Review CalPERS' Pharmacy Carve-Out Study and Request for Proposal for their PBM for their Self-Funded Health Plans Pharmacy Program Contract with a consultant available through the CalPERS Health Actuarial and benefits Consultant Services Pool 	Ongoing – Current savings are reported to be \$9 million on \$23.9 million spend for FY 2007-2008. The DGS is exploring opportunities to contract with a CalPERS consultant to identify additional savings as part of the solicitation development for a new PBM contract.
Maintain updated pharmaceutical formularies:	Ongoing. New formulary format accepted by CDCR DAPO. Formulary updates as identified by CDCR DAPO and CDCR DJJ.
 Expand contract to other entities CDCR DJJ Parole Operations CDCR Division of Adult Operations (DAO) for emergency fills 	Ongoing – The CDCR DJJ Parole Operations is awaiting signature and CDCR DAO is in its final review. Fresno County expressed an interest in accessing the PBM contract; however, they decided to bid it out themselves.

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Pharmaceutical Wholesaler Contract

Definition: The Current Pharmaceutical Wholesaler Agreement is with AmerisourceBergen Drug Corporation (ABDC). The Pharmaceutical Wholesaler provides State agencies with access to the pharmaceutical supply chain. The Pharmaceutical Wholesaler purchases pharmaceuticals from individual manufacturers, warehouses & distributes to State agencies.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
 Identify ways to increase savings Improve contract loads to reduce re-billings to agencies Review contract deliverables (as contract terms and conditions allow) for the: MMCAP CDCR Pharmaceutical Wholesaler UC System Pharmaceutical Wholesaler Other Pharmaceutical Wholesalers as identified through continuing research. Work with individual State agencies, Pharmacy Advisory Board (PAB) and CDF Committee to identify and explore 	Ongoing – Savings is reported to be \$2.4 million on \$45.6 million spend for FY 2007-2008.
other options for savings	

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Pharmaceutical Pricing Agreements

Definition: Pharmaceutical Pricing Agreements allow State agencies to purchase pharmaceuticals through the Pharmaceutical Wholesaler at discounts below those offered by the Pharmaceutical Wholesaler. These discounts may include both up-front discounts from the price and rebates.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Develop cost effective pharmaceutical pricing agreements to provide a discount on pharmaceuticals. Invitation for Bid process Develop & award contracts from an IFB by December 2008 Leverage CDCR Pharmaceutical Pricing Agreements Direct Negotiations with pharmaceutical manufacturers Develop contracts as identified by CDF committee Develop contracts for pharmaceuticals identified by individual State or local governmental entities Develop contract for vaccines	Due to workload the DGS was not able to conduct the IFB. In FY 2007-2008 State agencies purchased about \$20 million from 222 line items with a savings of over \$3.5 million. The DGS will leverage CDCR Pharmaceutical Pricing Agreements as resources become available. The DGS is currently working on leveraging an insulin agreement.
 Identify additional options for savings. Non-contract pharmaceutical purchasing reported by State agencies CDF requests State and local governmental entity requests Evaluating pharmaceuticals purchased through Pharmaceutical Wholesaler which are not receiving discounts through pricing agreements entered into directly with the State or through the GPO 	Ongoing –The DGS is in various stages of negotiations on contracts supporting the CDF.

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Group Purchasing Organization Agreement

Definition: The DGS entered into the Commonwealth of Massachusetts and is a member of the Massachusetts's Alliance for State Pharmaceuticals Buying (MASPB). Through the MASPB the DGS accesses the Group Purchasing Organization (GPO) Managed Healthcare Associates, Inc. (MHA). The GPO Leveraging the buying power of numerous public and private sector entities through a purchasing consortium to negotiate pricing agreements with pharmaceutical manufacturers. State agencies access the pricing agreements established by the GPO through the Pharmaceutical Wholesaler.

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Improve savings on contracts through the GPO. Work with the GPO and pharmaceutical manufacturers to improve pricing by qualifying State agencies and local governmental entities into lower pricing tiers available though the GPO agreements with pharmaceutical manufacturers. Identify contracts which the State is not taking advantage of, which are available through MHA. The following Contracts were identified on October 17, 2008: B-Braun Baxter Purdue	In FY 2007-2008 State agencies and local governmental entities purchased about \$23.3 million from 3,798 individual line items with a savings of \$11.1 million. The DGS will qualify State Agencies out for appropriate tiered pricing directly with manufacturers in conjunction with the solicitation for the new GPO contract. The DGS will work on accessing additional contracts available through MHA as
	resources become available.
Develop solicitation for new GPO agreement supporting the SPP. • Evaluate UC's GPO • Evaluate MMCAP	The DGS is working with CDCR to develop a new GPO agreement for award in 2009.

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Savings through Generic Pharmaceuticals

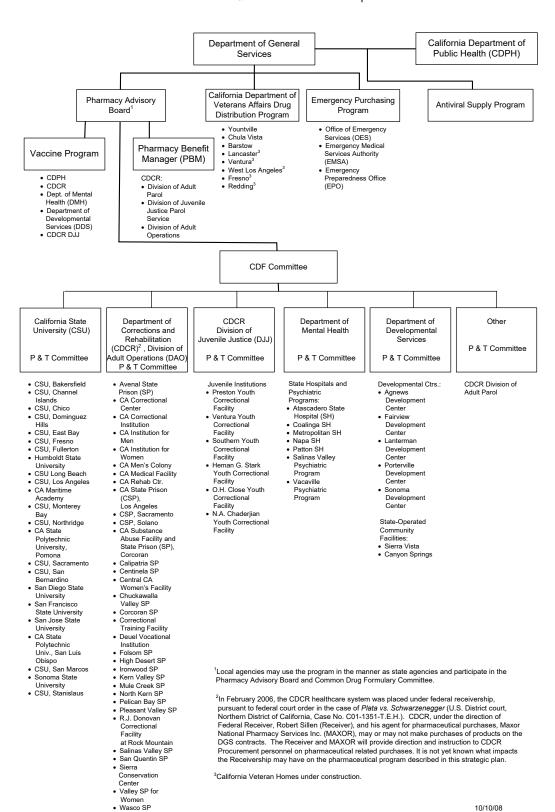
Definition: Develop strategies, in consultation with the affected agencies, for the State to achieve saving though the greater use of generic pharmaceuticals consistent with GC Section 14983 (4).

OBJECTIVE	STATUS AND/OR ESTIMATED COMPLETION DATE
Baseline generic pharmaceutical spending and report on agency purchases of Brand/Generic pharmaceuticals by volume and cost at: • Monthly CDF Committee meetings. - Previous months report presented to CDF Committee. • Quarterly PAB Meetings. - October 1 through December 31 for January PAB Meeting - January 1 through March 31 for April PAB Meeting - April 1 through June 30 for July PAB Meeting - July 1 through September 30 for October PAB Meeting.	Ongoing – about 71% of the volume purchased and 11% of the dollars are from Generic Pharmaceuticals. Resources have not been available to prepare monthly reports, however the CDF Committee continues to monitor new generic entries into the market, and recommend switching of brand purchases to generic.
 Identify generic pharmaceutical substitution. Quarterly Present and discuss reports on Summary of Brand/Generic Pharmaceutical Purchases for each agency in the Therapeutic Categories being reviewed at CDF Committee meetings and PAB Meetings to identify potential savings on changing brand to generic pharmaceuticals and generic pharmaceuticals availability in market. October 1 through December 31 for January CDF and PAB Meeting. January 1 through March 31 for April CDF & PAB Meeting. April 1 through June 30 for July CDF & PAB Meeting. July 1 through September 30 for October CDF & PAB Meeting. 	Ongoing – The DGS does not have resources to prepare these reports for presentation.
Identify therapeutic pharmaceutical substitutions. Work with the CDF Committee to identify lower cost Therapeutic Substitutions in Therapeutic Categories being reviewed.	Ongoing – Working with CDF Committee at monthly meetings.

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Attachment B

Statewide Pharmaceutical Program Structure & Stakeholder Relationship



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