AUDIT OF THE FEDERAL BUREAU OF PRISONS PHARMACY SERVICES

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Audit Division

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EXECUTIVE SUMMARY

The Federal Bureau of Prisons (BOP) is faced with a significant challenge in providing adequate and cost-effective medical care to inmates because of the rising federal inmate population and the increasing cost of prescription medications. The BOP's total health care costs for treating inmates increased from $412.65 million in FY 2000 to $623.52 million in FY 2004, an average annual increase of about 11 percent. During that same period, the BOP's costs for prescription medications and related supplies increased an average of 23 percent annually, from $22.51 million in FY 2000 to $50.73 million in FY 2004. Additionally, the cost of prescription medications and related supplies has continued to account for a growing share of the BOP's total health care costs, rising from 5.5 percent in FY 2000 to 8.1 percent in FY 2004.

The Department of Justice (DOJ) Office of the Inspector General (OIG) conducted this audit to:

- evaluate the BOP's efforts to reduce increasing costs of its prescription medications;
- assess whether the BOP ensures adequate controls and safeguards over prescription medications; and
- assess whether the BOP pharmacies are in compliance with applicable laws, regulations, policies, and procedures.

During the audit, we conducted work at the BOP headquarters and 12 BOP institutions, consisting of 4 Federal Correctional Institutions (FCI), 3 United State Penitentiaries (USP), 1 Federal Prison Camp (FPC), 1 Administrative Maximum Security (ADX), 1 Federal Transfer Center (FTC), and 1 medical center as shown in Figure 1.

FIGURE 1. BOP INSTITUTIONS AUDITED

Institution	Location
Alderson FPC	West Virginia
Atlanta USP	Georgia
Atwater USP	California
Danbury FCI	Connecticut
Florence ADX	Colorado
Florence FCI	Colorado
Florence USP	Colorado
Forrest City FCI (Low)	Arkansas
La Tuna FCI	New Mexico
Oklahoma City FTC	Oklahoma
Oxford FCI	Wisconsin
Springfield Medical Center	Missouri

Background

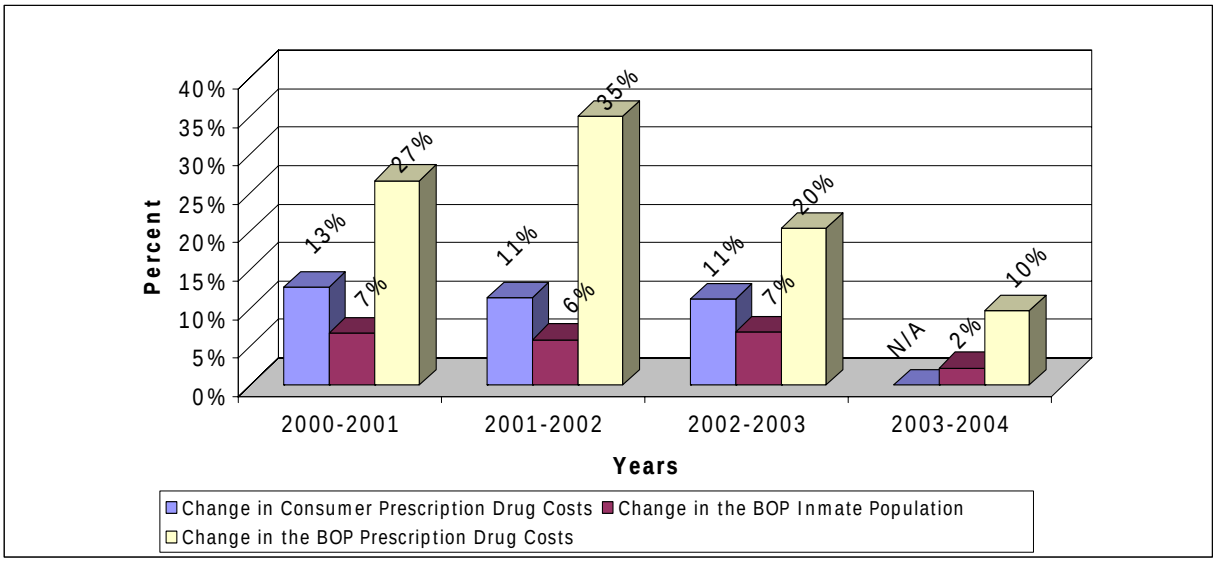
Health care costs consist of many different components. In 2002 the three largest components were hospital care (31 percent), physician and clinical services (22 percent), and prescription medications (11 percent). Of these components, prescription medication costs have grown at the fastest rate, increasing by 167 percent from 1995 to 2002. Two significant factors related to the rise in prescription medication costs are increased price and increased usage. From 1995 to 2002, the Consumer Price Index for prescription medications and medical supplies increased by 35 percent, while the Consumer Price Index for the United States, on average, increased by only 18 percent. Additionally, the number of individuals reporting that they had taken at least one prescription medication in the month prior to the survey increased from 39 percent in 1988 through 1994, to 44 percent in 1999 through 2000.[1]

As of July 2005, the BOP was responsible for the custody and care of approximately 182,000 federal offenders. The BOP consisted of 106 institutions, 6 regional offices, a central office, 2 staff training centers, and 28 community corrections management offices.

[1] Department of Heath and Human Services, National Center for Health Statistics, *Health, United States, 2004*.

The BOP's daily prescription medication cost was $0.92 per inmate in FY 2004, an increase of 5 percent from FY 2003, and 79 percent from FY 2000. The BOP attributes the increase in its prescription medication costs to various reasons, including the: (1) increase in inmate population, and (2) increasing prices of prescription medications as shown in Figure 2.

FIGURE 2. CHANGES IN PRESCRIPTION MEDICATION COSTS AND INMATE POPULATION[2]



Source: Inmate population and prescription medication costs provided by the BOP; consumer costs obtained from the U.S. Statistical Abstract 2004-2005.

In an effort to reduce prescription medication costs, the BOP is planning to or has implemented the following proposals:

- **Levels of Care** – through Levels of Care, BOP institutions will be classified based on the level of medical care required by the inmates. The classification will include four levels based on the severity of inmates' medical needs, with Level 1 consisting of healthy inmates and Level 4 consisting of inmates at one of the BOP's six medical centers. In turn, the BOP plans to reorganize the staffing of its pharmacies to reflect the medical classification of its institutions.

- **Central Fill** – through Central Fill, pharmacists at BOP institutions will review prescriptions to ensure an inmate is not allergic to a medication, and that a medication does not negatively interact with an

[2] Due to the availability of data, the data for the Change in Consumer Prescription Drug Costs is based on the calendar year, while the Change in the BOP Inmate Population and the Change in the BOP Prescription Drug Costs are based on fiscal year.

inmate's current prescriptions or medical condition. The pharmacist will then transmit the prescriptions electronically to the Department of Veterans Affairs (VA) Centralized Mail Outpatient Pharmacy Center in Dallas, Texas. The VA will fill the prescriptions and mail them overnight to the institution.

- **Central Processing** – through Central Processing, institutions that do not have a pharmacist on site will be able to electronically transmit the inmate's prescriptions to a central location, where BOP pharmacists will review them for contraindications and then transmit them electronically to Central Fill.[3]

- **Electronic Medical Records System** – through an electronic medical records system, BOP pharmacists will be able to access the inmate's medical information from any location, thus allowing them to conduct a complete review of inmate prescriptions to check for any contraindications. In addition, the system will allow for prescriber order entry, so that physicians can electronically enter prescriptions into the system.

- **Over-the-Counter (OTC) Policy** – the OTC policy outlines the requirements that each BOP institution, except medical centers, must follow when using OTC medications for the treatment of inmates. The BOP's OTC policy requires that inmates who complain about cosmetic, general hygiene issues, or symptoms of minor ailments should be referred to the commissary where they can purchase OTC medications with their own funds.

Summary of OIG Findings

Our audit concluded that, the BOP has not adequately assessed the budgetary impact of its initiatives to reduce increasing costs for prescription medications. As a result, future initiatives may result in increased, rather than decreased costs. We also found that the BOP's cost-benefit analysis for its Central Fill proposal contained errors and incorrect assumptions that may result in increased prescription medication costs rather than savings. We also found that the BOP needs to improve efforts to reduce prescription medication costs associated with waste and ensure that cost savings initiatives such as the OTC policy are fully implemented.

[3] Contraindications include drug to drug, drug to disease, and drug to food interactions; therapeutic duplications; allergies; therapeutic inappropriateness; inappropriate doses; incorrect duration of therapy; and adverse drug reactions.

Cost Savings Initiatives

The BOP completed a cost-benefit analysis of its Central Fill proposal in March 2004, to estimate the impact on the BOP's prescription medication costs. Based on its cost-benefit analysis, the BOP estimated that Central Fill will result in a savings of $1.14 million per year. However, based on our analysis, we concluded Central Fill may cost the BOP as much as $895,016 more per year, as shown in Figure 3.

FIGURE 3. SUMMARY BOP AND OIG COST-BENEFIT ANALYSIS

	BOP Original	OIG Analysis	Difference
Annual Savings:			
Gross Purchase Savings	$4,943,349	$1,969,371	($2,973,978)
Waste	2,385,786	577,360	(1,808,426)
Vials	173,250	96,277	(76,973)
Labels	239,250	132,954	(106,296)
Total, Annual Gross Savings	**$7,741,635**	**$2,775,962**	**($4,965,673)**
Annual Costs:			
Rx Fee	$5,600,000	$3,111,978	($2,488,022)
Shipping	1,000,000	555,000	(445,000)
Information Technology	4,000	4,000	---
Total, Annual Gross Costs	**$6,604,000**	**$3,670,978**	**($2,933,022)**
NET IMPACT (Savings - Costs)	**$1,137,635**	**($ 895,016)**	**($2,032,651)**

Source: BOP and OIG survey and analysis

As shown in Figure 3, the BOP estimated that Central Fill would result in gross annual savings of $7.74 million, annual costs of $6.6 million, and annual net savings of $1.14 million. Based on our analysis, the BOP may have overstated annual gross savings by $4.97 million and annual gross costs by $2.93 million, resulting in overstated annual net savings of $2.03 million. Specifically, we found that:

- The data used by the BOP to calculate the gross purchase savings of $4.94 million included two errors that resulted in overstated savings of $2.3 million.

- The BOP's analysis used to calculate gross purchase savings also incorrectly assumed that all institutions will use Central Fill for 100 percent of prescription medications, resulting in additional overstated savings of $0.67 million.

- The BOP estimated savings of $2.39 million from the reduction of waste of prescription medications. However, based on our survey of

BOP pharmacists, we estimated savings related to waste of only $0.58 million, resulting in overstated savings of $1.81 million.

- The BOP estimated that Central Fill will reduce the costs related to vials and labels by $0.41 million per year. However, this figure was based on the incorrect assumption that all institutions will use Central Fill for 100 percent of prescription medications, resulting in overstated savings of $0.18 million.

- The BOP estimated that VA fees for filling prescriptions would cost $5.6 million annually. However, this estimate was also based on 100 percent usage of Central Fill for prescription medications, resulting in overstated costs of $2.49 million.

- The BOP estimated costs of $1 million annually for shipping. However, this estimate was based on 100 percent usage of Central Fill for prescription medications, resulting in overstated costs of $0.45 million.

In summary, the BOP's cost-benefit analysis for its Central Fill proposal includes several errors and incorrect assumptions. As a result, the BOP's estimate that Central Fill will result in net annual savings of $1.14 million is incorrect. Based on our analysis, we found that Central Fill may actually increase prescription medication costs by approximately $900,000 per year. Therefore, it is essential that the BOP has an accurate understanding of the budgetary impacts of the Central Fill proposal before proceeding with implementation.

We also concluded that the BOP needs to improve efforts to reduce prescription medication costs associated with waste. Based on the responses to our survey of BOP pharmacists, we found that prescription medication costs associated with waste were estimated at $2.81 million in FY 2004, or 5.54 percent of the BOP's total prescription medication costs.

Based on the results of our pharmacist survey, the transfer of inmates is the largest reason for prescription medication waste, accounting for an estimated $1.05 million in FY 2004. Waste from inmate transfers results from the fact that all inmates who are transferred receive a 7-day supply of their prescription medications regardless of whether or not the inmate already has a sufficient supply. In addition, there is currently no BOP requirement that prescription medications already in the inmate's possession are transferred with the inmate. As a result, when inmates are transferred their prescription medications are often left in the inmate's cell or locker and

must be disposed of because the pharmacy cannot reuse medication once it has been in an inmate's possession.

Confiscations during searches of inmates' cells were the second largest reason for prescription medication waste based on our pharmacist survey, accounting for an estimated $1.02 million in FY 2004. Waste from confiscations was generally related to the BOP's policy prior to January 15, 2005, that prescriptions could only be valid for a total of 90 days (30 days with 2 refills). Therefore, expiration dates on prescription labels indicated 90 days or less, even though the medication may still be valid according to the manufacturer's expiration date. During searches of inmates' cells, if correctional officers find a prescription medication that is past the expiration date on the label, the medication is confiscated and frequently thrown away. In our survey, BOP pharmacists noted that if correctional officers were instructed to return confiscated prescription medications to the pharmacy, some of the medications could be reissued to the same inmates. In addition, this would assist the pharmacists in tracking inmate prescription medication usage.

In an effort to reduce prescription medication waste and save pharmacist time, the BOP issued the OTC Medication Program Statement on November 17, 2004. The BOP's OTC policy requires that inmates who complain about cosmetic, general hygiene issues, or symptoms of minor ailments should be referred to the commissary where they can purchase OTC medications with their own funds. However, based on our review of 12 BOP institutions and our pharmacist survey, we found that the OTC policy has not been fully implemented or consistently applied throughout the BOP institutions. Specifically, our survey found that, as of April 2005, 35 percent of the respondents stated that the OTC policy had not been implemented at their institution. Additionally, 43 percent of the survey respondents stated that they had been told by medical staff to provide OTC medication to an inmate even though it was either not medically necessary or could be obtained from the commissary by the inmate.

Controls and Safeguard over Prescription Medications

Our audit found that, the BOP is not adequately accounting for and safeguarding prescription medications. As a result, the BOP could not account for 1 percent of the controlled substances that should have been on hand at the time of our inventory at the institutions included in our audit. However, unaccounted for controlled substances within institutions identify issues related to internal controls that undermine the accounting and safeguarding of prescription medications. In addition, we noted numerous errors related to controlled substances inventory and administration records. For instance, quarterly inventories submitted to BOP headquarters did not always include all controlled substances. We also found the BOP has not implemented adequate internal controls related to the purchasing, ordering, receiving, payment, and dispensing of prescription medications.

At each of the institutions included in our review, we conducted an accountability audit of controlled substances. The accountability audit consisted of a physical count of controlled substances at the time of our visit and a review of all mainstock and substock records[4] for the 1-year period prior to our audit, including an analysis of documentation related to purchases, disposals, administrations, and transfers.[5] As a result of our audit, we identified 402 unaccounted for doses of controlled substances out of a total of 42,125 that should have been on hand at the time of our inventory at the 12 institutions audited.

Additionally, we found numerous errors in the controlled substances inventory records, which based on the inventory records alone appeared to result in unaccounted-for controlled substances. However, we were able to resolve these discrepancies by reviewing additional documentation. Specifically, we identified approximately 400 inventory recordkeeping errors related to: (1) transfer location was not identified in the mainstock or substock inventory; (2) no amount administered or an incorrect amount administered was entered into the usage column; and (3) the administration was entered as a "floor charge" rather than to a specific inmate, identified by inmate name and number. We also identified approximately

[4] Mainstock consist of the bulk inventory of controlled substances. The mainstock inventory is used to account for all purchases, disposals, and transfer to substocks. The substock consists of a smaller number of controlled substances dispensed from the mainstock and is used to administer medications to inmates on a daily basis.

[5] At the Springfield Medical Center, we judgmentally selected a sample of nine controlled substances, and only reviewed a 7-month period because of the large volume of use at the institution.

800 recordkeeping errors related to missing information, including inmate names, inmate numbers, prescription numbers, dates, and times that medications were administered.

In addition to conducting an accountability audit of controlled substances, we selected a total of 245 controlled substances administered to inmates from the Proof of Use sheets and compared the information to the inmate's Medication Administration Record (MAR) to verify that the inmate received the medication.[6] Based on our review, we found that 25 percent of the controlled substance administrations selected: (1) were not available for review due to missing MARs, (2) were not signed off by the person who administered the medication, (3) included the wrong dosage, or (4) did not include a prescription for the medication administered.

We also found that quarterly inventories submitted by BOP pharmacists to BOP headquarters did not always include all controlled substances. Specifically, we identified controlled substances at three of the institutions that should have been included with the mainstock in the quarterly inventory. We also found that 10 out of 12 institutions audited did not include controlled substances substock in their quarterly inventories. Pursuant to BOP policy, the institutions are only required to include mainstock in the quarterly controlled substances inventories; however, federal regulations require all controlled substances be included in the inventories required by the Drug Enforcement Administration (DEA). Further, given the numerous recordkeeping errors related to controlled substances noted in this report, in our judgment it is important that a complete accounting of all controlled substances is conducted on a quarterly basis.

We identified inadequate internal controls related to purchasing of prescription medications, including ordering, receiving, and payment. At each institution audited, we did not find any evidence of segregation of duties related to purchasing of prescription medications. At most institutions the person who ordered the prescription medications was the same person who received and inventoried the shipment, and signed off on the invoice before it was submitted to the business office for payment. The BOP currently does not have a national policy related to internal controls over the purchasing of prescription medications, and relies on each institution to

[6] Proof of Use sheets are logs that track substock inventory and include an inmate's name and number, quantity issued, date and time, and person administering the medication. MARs are individual inmate records used to track the receipt of medication and include an inmate's name and number, prescription medication name, strength, quantity, date, time, and person who administered the prescription medication.

develop and implement its own policies and procedures. The lack of internal controls resulted in a Chief Pharmacist being able to fraudulently purchase 30,600 doses of prescription medications between July 2002 and February 2004 for his personal consumption.[7] This cost the BOP approximately $1,567, with a retail value of approximately $28,700.

Pharmacy Compliance

We found that the BOP pharmacies were not always in compliance with applicable BOP policies and procedures regarding the dispensing and administering of prescription medications. At the 12 BOP institutions included in our audit, we reviewed 1,107 prescriptions, including 488 prescriptions for controlled substances, and found that 384 (35 percent) of the prescriptions reviewed were not in compliance with BOP policy. Specifically, we found:

- 206 prescriptions for which the pharmacist's review for contraindications was not documented,
- 54 controlled substance prescriptions for which the prescription forms were missing a DEA registration number or required signature,
- 31 prescriptions for non-formulary medications for which the required waiver was not obtained,[8]
- 24 controlled substances prescriptions for which the required separate written prescription forms were not maintained by the institution,
- 20 controlled substances prescriptions that were written for longer than the allowable time period,

[7] In lieu of prosecution, the Western District of Oklahoma offered the pharmacist a 1-year Pretrial Diversion Program and if all conditions are met, the pharmacist will not be prosecuted.

[8] The BOP National Formulary is a list of all prescription medications recommended as essential for inmate care and is used to help provide clinically appropriate, safe, and cost-effective prescription medications. If a non-formulary drug is deemed necessary, the prescriber is required to obtain a Non-Formulary Drug Authorization requesting approval for the use of non-formulary medication to treat a specific inmate need.

- 19 prescriptions for which required information was missing in the inmate's medical file, and

- 30 prescriptions with other miscellaneous errors.

Recommendations

Our report contains 13 recommendations for the BOP to improve the administration of its Pharmacy Services. Specifically, our recommendations seek to ensure that:

- an adequate cost-benefit analysis is conducted for all cost savings initiatives prior to implementation and that the initiatives are implemented consistently throughout all institutions;

- institutions accurately account for and safeguard their prescription medications, especially controlled substances;

- institutions implement controls over ordering and receiving prescription medications that provide for adequate separation of duties; and

- institutions comply with applicable laws and BOP policies.

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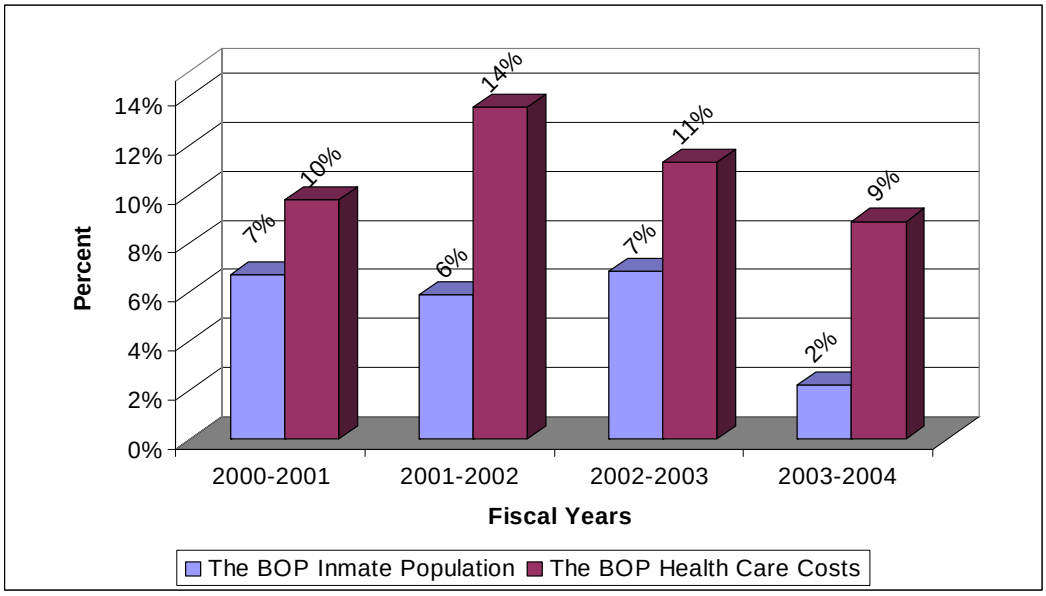
INTRODUCTION

The Federal Bureau of Prisons' (BOP) stated mission is to protect society by confining offenders in the controlled environments of institutions and community-based facilities that are safe, humane, cost efficient, appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. The mission of the BOP Pharmacy Services is to "provide access for inmates to quality, necessary, and cost–effective drug care consistent with community standards."

As of July 2005, the BOP consisted of 106 institutions, 6 regional offices, a central office, 2 staff training centers, and 28 community corrections management offices. The BOP is currently responsible for the custody and care of approximately 182,000 federal offenders.

The BOP is faced with a significant challenge in providing adequate and cost effective medical care to inmates because of the rising federal inmate population the increasing cost of health care, as shown in Figure 1.

FIGURE 1. THE BOP ANNUAL PERCENT INCREASE IN HEALTH CARE COSTS AND POPULATION



Source: Data provided by the BOP

Over the past 5 years, the BOP's inmate population has increased by 23 percent, from 123,141 in FY 2000 to 152,023 in FY 2004. The BOP's total health care costs for treating inmates increased from $412.65 million in

FY 2000 to $623.52 million in FY 2004, an average annual increase of about 11 percent. During that same period, the BOP's costs for prescription medications and related supplies increased an average of 23 percent annually from $22.51 million in FY 2000 to $50.73 million in FY 2004. Additionally, the cost of prescription medications and related supplies has continued to account for a growing share of the BOP's total health care costs, rising from 5.5 percent in FY 2000 to 8.1 percent in FY 2004.

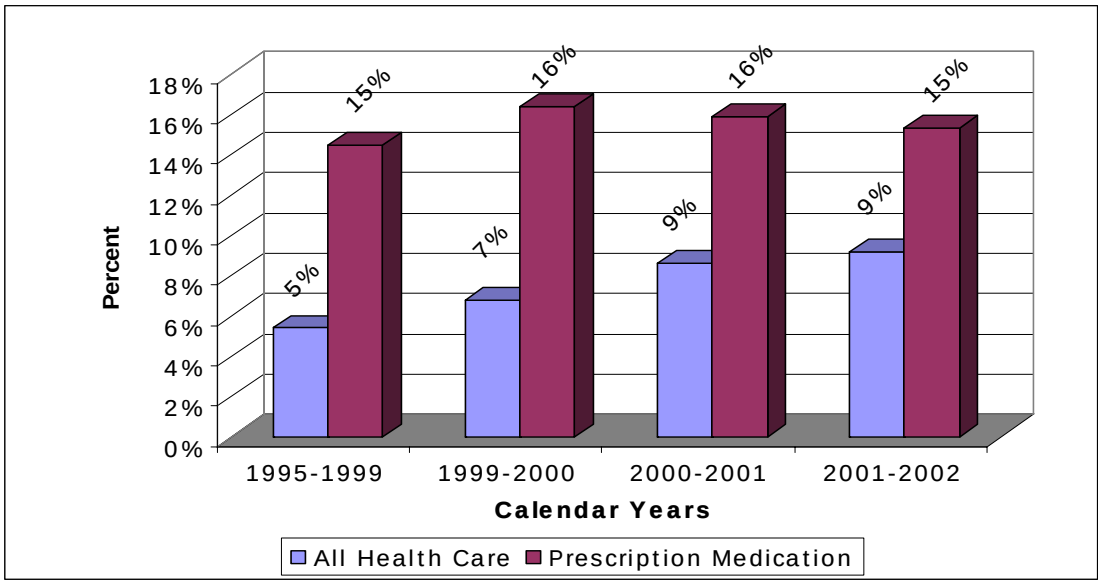
Background

According to a Department of Health and Human Services report, the United States spends more on health care than any other industrialized nation.[1] Health care costs account for a significant and increasing portion of the United States economy. In 1980, health care costs comprised only 9 percent of the Gross Domestic Product; however, by 2002 health care costs had increased to 15 percent. Additionally, from 1999 to 2002, health care costs increased an average of 8 percent annually, while the Gross Domestic Product only increased an average of 4 percent.

Health care costs consist of many different components. In 2002 the three largest components were hospital care (31 percent), physician and clinical services (22 percent), and prescription medications (11 percent). Of all these components, prescription medication costs have grown at the fastest rate, increasing by 167 percent from 1995 to 2002, as illustrated in Figure 2.

[1] Department of Health and Human Services, Center for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2004*.

FIGURE 2. ANNUAL PERCENT INCREASE IN HEALTH CARE COSTS



Source: Department of Health and Human Services, Center for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2004*

Two significant factors related to the rise in prescription medication costs are increased prices and increased usage. From 1995 to 2002 the Consumer Price Index for prescription medications and medical supplies increased by 35 percent, while the Consumer Price Index for the United States as a whole increased by only 18 percent. Additionally, the number of individuals reporting that they took at least one prescription medication in the month prior to the survey increased from 39 percent during the period from 1988 to 1994, to 44 percent during the period from 1999 to 2000. The survey also found that during the same periods, the number of individuals reporting that they took 3 or more prescription medications in the month prior to the survey increased from 12 percent to 17 percent.[2]

The BOP Health Services Division

The BOP Health Services Division consists of over 3,000 health care professionals including physicians, nurses, dentists, pharmacists, and mid-level practitioners, of which 750 are United States Public Health Services Commissioned Officers.[3] The Health Services Division provides a broad

[2] Department of Heath and Human Services, National Center for Health Statistics, *Health, United States, 2004*.

[3] The BOP defines Mid-Level Practitioners as Physician Assistant Certified, Physician Assistant Non-Certified, and Nurse Practitioner.

range of services to inmates, from routine patient care to surgery. These include dental, pharmacy, laboratory, radiological, and psychiatric services. The BOP Pharmacy Services Division is administered under the Health Services Division, whose mission is to "provide necessary medical, dental, and mental health services to inmates by a professional staff, consistent with acceptable community standards."[4]

As of February 2005, the BOP Pharmacy Services Division consisted of over 160 pharmacist positions, of which 133 are currently filled. About 120 BOP pharmacists are Public Health Services Commissioned Officers.

The responsibilities of the BOP pharmacists include:

- tracking the controlled substances inventory;
- safeguarding controlled substances;
- ordering and receiving prescription medications;
- reviewing prescriptions for contraindications (e.g., potential negative interactions with other prescriptions and an inmate's medical condition);
- providing fellow practitioners with drug information, such as drug recalls, and drug interactions;
- filling prescriptions;
- monitoring an inmate's prescription medication usage to minimize waste and providing practitioners with information that helps treat inmates effectively, thereby ensuring that an inmate is taking the medication as prescribed;
- counseling patients;
- conducting clinics on diabetes, hypertension, mental health, and monitoring the treatment of infectious diseases;

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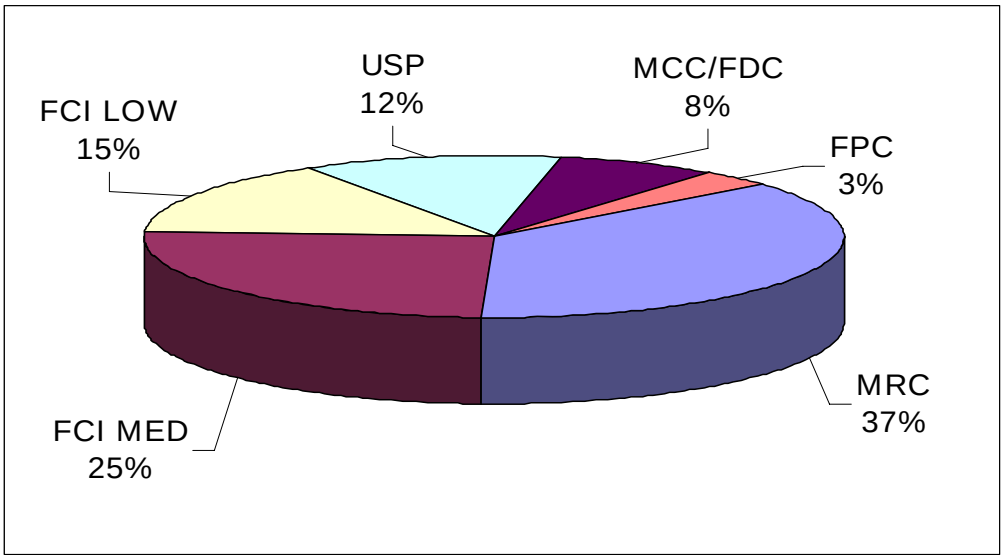
[4] BOP Program Statement No. 6000.05, *Health Services Manual*, updated February 11, 2000.

- attending rounds with physicians; and

- providing discharge counseling.

The BOP is comprised of six major types of institutions, each of which generally have pharmacies: (1) Medical Referral Centers (medical centers), (2) Federal Correctional Institutions (FCIs), (3) United States Penitentiaries (USPs), (4) Metropolitan Correctional Centers (MCCs), (5) Federal Detention Centers (FDCs), and (6) Federal Prison Camps (FPCs). The BOP medical centers provide acute medical services, including surgery, cancer treatment, and long-term care. Although there are only seven BOP medical centers, they account for the largest amount (37 percent) of the BOP's total prescription medication costs, as shown in Figure 3.[5]

FIGURE 3. THE BOP PRESCRIPTION MEDICATION COSTS BY INSTITUTION TYPE FOR FY 2004

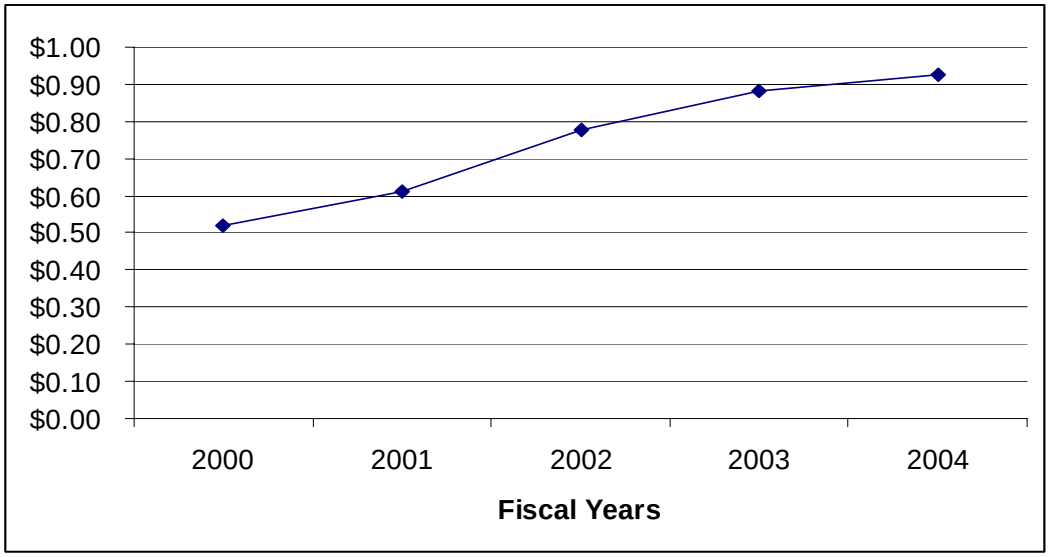


Source: The BOP Prescription Medication Cost Report

In FY 2004, the BOP spent $50.73 million on prescription medications and related supplies, representing an increase of 10 percent over the prior fiscal year. On average, there has been a 23-percent annual increase in the BOP's prescription medication costs since FY 2000. Furthermore, in FY 2004 the BOP spent a daily average of $0.92 per inmate on prescription medications. On average, the daily prescription cost per inmate has increased annually by 16 percent since FY 2000, as shown in Figure 4.

[5] As of September 2005, the BOP was in process of reclassifying the medical center in Fort Worth, TX, to an FCI. As a result, when discussing the BOP's future actions we refer to six, rather then seven, medical centers.

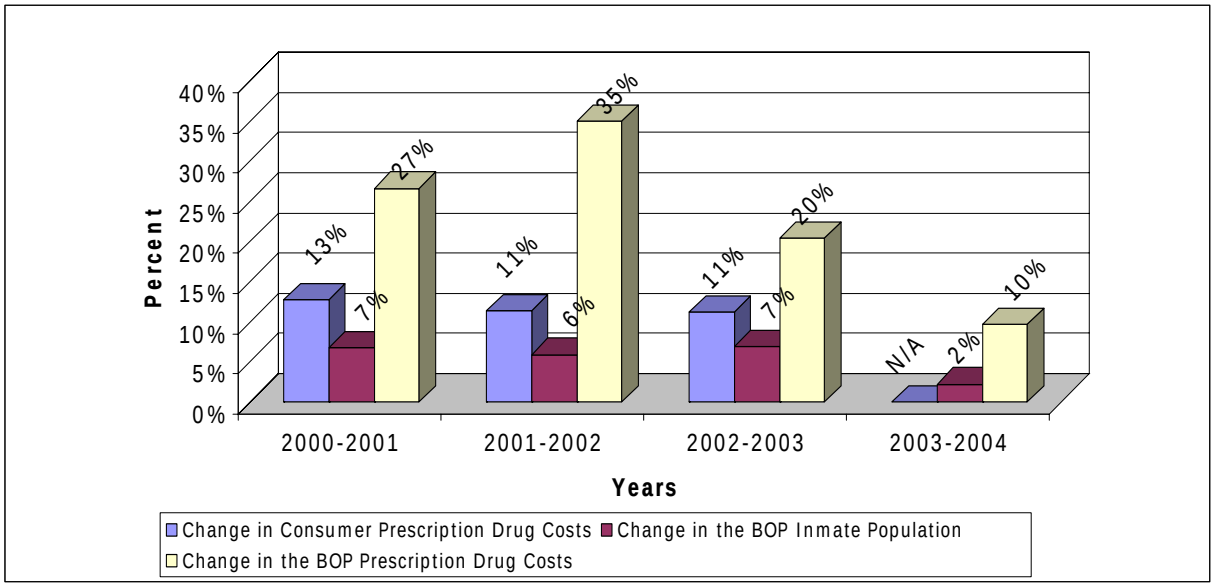
FIGURE 4. BOP DAILY PRESCRIPTION MEDICATION COSTS PER INMATE



Source: Data provided by the BOP

The BOP attributes the increase in its prescription medication costs to the: (1) aging of inmates serving longer mandatory sentences, (2) increase in inmate population, and (3) increasing prices of prescription medications. However, we found that the average inmate age increased by 0.4 years from FY 2001 to FY 2004, which does not appear to support the BOP's assertion that the increase in prescription medication costs is caused, in part, by an aging inmate population. On the other hand, from FY 2000 to FY 2003 the increase in inmate population and consumer drug prices accounted for about 70 percent of the total increase in the BOP's prescription medication costs. From FY 2000 to FY 2003 the inmate population increased on average by 6 percent annually, while consumer prescription medication costs increased on average by 12 percent annually, as shown in Figure 5.

FIGURE 5. CHANGES IN PRESCRIPTION MEDICATION COSTS AND INMATE POPULATION[6]



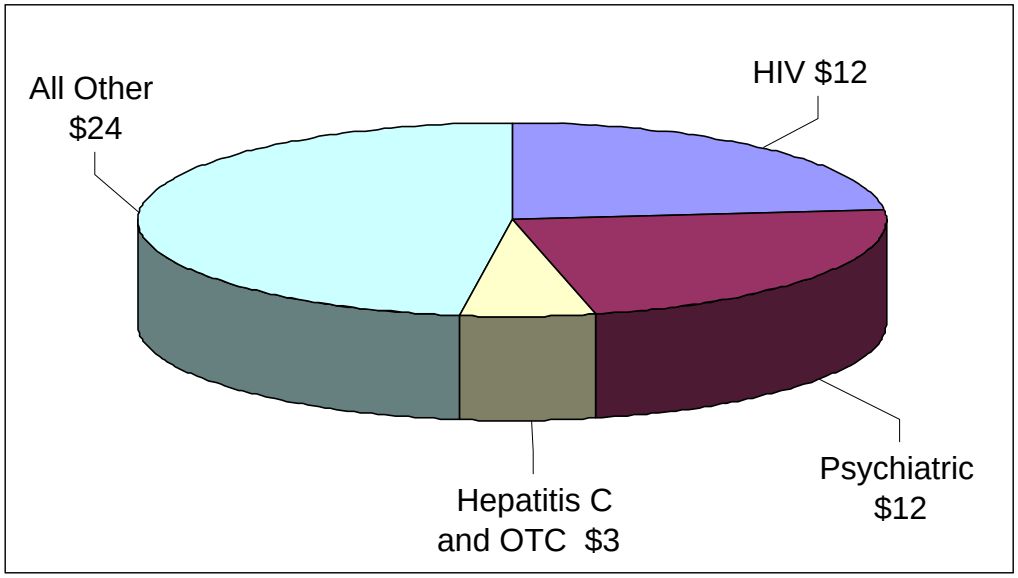
Source: Inmate population and prescription medication costs provided by the BOP; consumer costs obtained from the U.S. Statistical Abstract 2004-2005.

Treating inmates who test positive for Human Immunodeficiency Virus (HIV) and inmates requiring psychiatric care account for a significant portion of the BOP's total prescription medication costs. While the BOP reported that 1,677 inmates (or 1 percent) are HIV-positive, including 639 inmates with Acquired Immunodeficiency Syndrome (AIDS), the cost of prescription medications to treat HIV-positive inmates comprised 23 percent of the BOP's prescription medication costs in FY 2004. Additionally, the cost of HIV prescription medications increased by 14 percent from FY 2003 to FY 2004, while the HIV positive inmate population increased by only 5 percent. Prescription medication costs for treating inmates for psychological conditions also comprised 23 percent of the BOP's total prescription medication costs in FY 2004. As of March 2005, there were a total of 6,910 inmates who were being treated with one or more psychiatric medications within the BOP.[7] In FY 2004, $23.49 million of the $50.73 million in total BOP prescription medication costs were related to HIV and psychiatric medications, as shown in Figure 6.

[6] Due to the availability of data, the data for the Change in Consumer Prescription Drug Costs is based on the calendar year, while the Change in the BOP Inmate Population, and the Change in the BOP Prescription Drug Costs is based on fiscal year.

[7] This number does not include data from the Oklahoma FTC, the Rochester Medical Center, and the Beaumont Federal Correctional Complex because they do not use the same tracking program as the other BOP institutions.

FIGURE 6. THE BOP PRESCRIPTION MEDICATION COSTS BY TYPE FOR FY 2004 (in millions)



Source: Prescription medication costs provided by the BOP

The BOP utilizes the Federal Supply Schedule (FSS) for the majority of its prescription medication purchases. The FSS is a price catalog of over 23,000 prescription medications that are available for purchase by federal agencies. In addition to the FSS, the BOP utilizes specific contracts with prescription medication companies administered by the Veterans Administration (VA). The BOP purchases over 40 prescription medications through "Mandatory National Contracts" administered by the VA, which require that each institution buy specific prescription medication brands. These contracts provide the BOP with prices lower than the FSS, and include some frequently used medications, such as Tylenol®, Advil®, Aleve®, and Zocor®.

Current BOP Proposals to Reduce Prescription Medication Costs

According to the BOP, in an effort to reduce prescription medication costs, the BOP has implemented or plans to implement several changes to its health care and pharmacy programs including: (1) classifying institutions by the level of medical care required by inmates, (2) Central Fill and Central Processing of prescription medications, (3) use of an electronic medical records system, and (4) requiring inmates to pay for nonprescription medications.

Medical Level of Care Classifications

The BOP is reclassifying its institutions based on a four-level tier of medical care required by inmates. The BOP also plans to reorganize the staffing of its pharmacists to reflect the medical classification of its institutions.

- **Level of Care 1** – Includes inmates who are generally healthy but may have limited medical or mental health conditions that can be easily managed by semi-annual clinical evaluations. This level consists of 10 institutions, of which 9 will not have an on site pharmacist. The BOP plans to restructure staffing for this level between January 2008 and December 2008.

- **Level of Care 2** – Includes inmates who are stable but have chronic medical conditions requiring at least quarterly clinical evaluations but can still perform activities of daily living. This level consists of at least 60 institutions that will have 1 pharmacist on site, except for the Oklahoma Federal Transfer Center (FTC) which will continue to maintain 3 pharmacists.[8] The BOP plans to restructure staff for this level between January 2009 and December 2011.

- **Level of Care 3** – Includes inmates who are fragile outpatients requiring at least monthly clinical evaluations and who may have limitations in their ability to perform activities of daily living but do not require daily nursing care. The BOP has not decided the number of institutions or pharmacist staffing allocation for this level of care. The BOP plans to restructure staff for this level between January 2009 and December 2010.

- **Level of Care 4** – Include inmates who require the services available at the six medical centers and who may require daily nursing care. The BOP has not decided the pharmacist staffing allocation for this level. The BOP plans to restructure staff for this level between January 2009 and December 2010.

[8] The Oklahoma FTC will not use Central Fill for its prescription medications because of the constant turnover of inmates at the facility. Consequently, there will be no change in its pharmacist staffing levels.

Central Fill and Central Processing

To address concerns related to the rising cost of prescription medications, the BOP created the Pharmacy Workgroup (Workgroup). The Workgroup is comprised of 11 members representing many departments within the BOP, headed by the BOP Chief Pharmacist. Pursuant to an Executive Staff Paper dated April 30, 2004, the objectives of the Workgroup are to:

- control costs by consolidating prescription medications into a main inventory and buying the least expensive brand of generic medications; and

- establish an automated prescription medication fulfillment system that provides medications in a timely manner for all BOP institutions.

The Workgroup recommended that the BOP establish an Interagency Agreement with the Department of Veterans Affairs Centralized Mail Outpatient Pharmacy Center in Dallas, Texas, to fill prescription medications for BOP institutions. Through Central Fill, the onsite pharmacists at BOP institutions would review prescriptions for the following contraindications, as required by BOP policy:[9]

- drug to drug interactions,

- drug to disease interactions,

- drug to food interactions,

- therapeutic duplications,

- allergies,

- therapeutic appropriateness,

- appropriate dose,

- duration of therapy,

- adverse drug reactions, and

[9] BOP Program Statement No. P6360.01, *Pharmacy Services*, dated January 15, 2005.

- final check of the prescription to ensure it contains the correct medication.

The pharmacists would then electronically transmit prescriptions to the VA. Once the order is received, the VA would fill the prescription via its automated system and mail it overnight to the BOP institutions. The institutions would receive the prescription medication the following morning and administer or dispense it to inmates.

The October 25, 2004, draft Interagency Agreement between the BOP and the VA states that Central Fill will "improve the cost efficiencies through economies of scale and clinical effectiveness of BOP Pharmacists." The BOP expects the Level of Care 1, 2, and 3 institutions to use Central Fill for 95 percent of their prescriptions. Conversely, the BOP expects the Level 4 institutions and FDCs to use Central Fill for 50 percent of their prescriptions because of the unique missions of these institutions.

The Workgroup cited several benefits related to its Central Fill proposal, including improving drug inventory management, reducing redundancies, eliminating the majority of bulk stock from institutions, reducing errors through the use of barcode labels on prescriptions, and increasing the use of pharmacists in a clinical capacity. According to the BOP, increasing the use of its pharmacists in a clinical capacity would improve inmate medical care, reducing overall health care costs. Clinical pharmacy would require BOP pharmacists to:

- assist doctors with continuity of care to improve medication management;

- monitor, modify, and discontinue prescription medication therapy, as needed;

- order, perform, and evaluate laboratory tests; and

- conduct clinics to help inmates manage diseases, including diabetes, HIV, Hepatitis C, asthma, and others.

The BOP provided several reports illustrating the benefits of clinical pharmacy. According to a 2002 report in the *American Journal of Health System Pharmacy,* HIV clinics conducted by pharmacists improved patient compliance and care.[10] The report also stated that the vast majority of pharmacists working in the clinics improved treatment effectiveness by

[10] *American Journal of Health-System Pharmacy,* Issue 59(8) (2002).

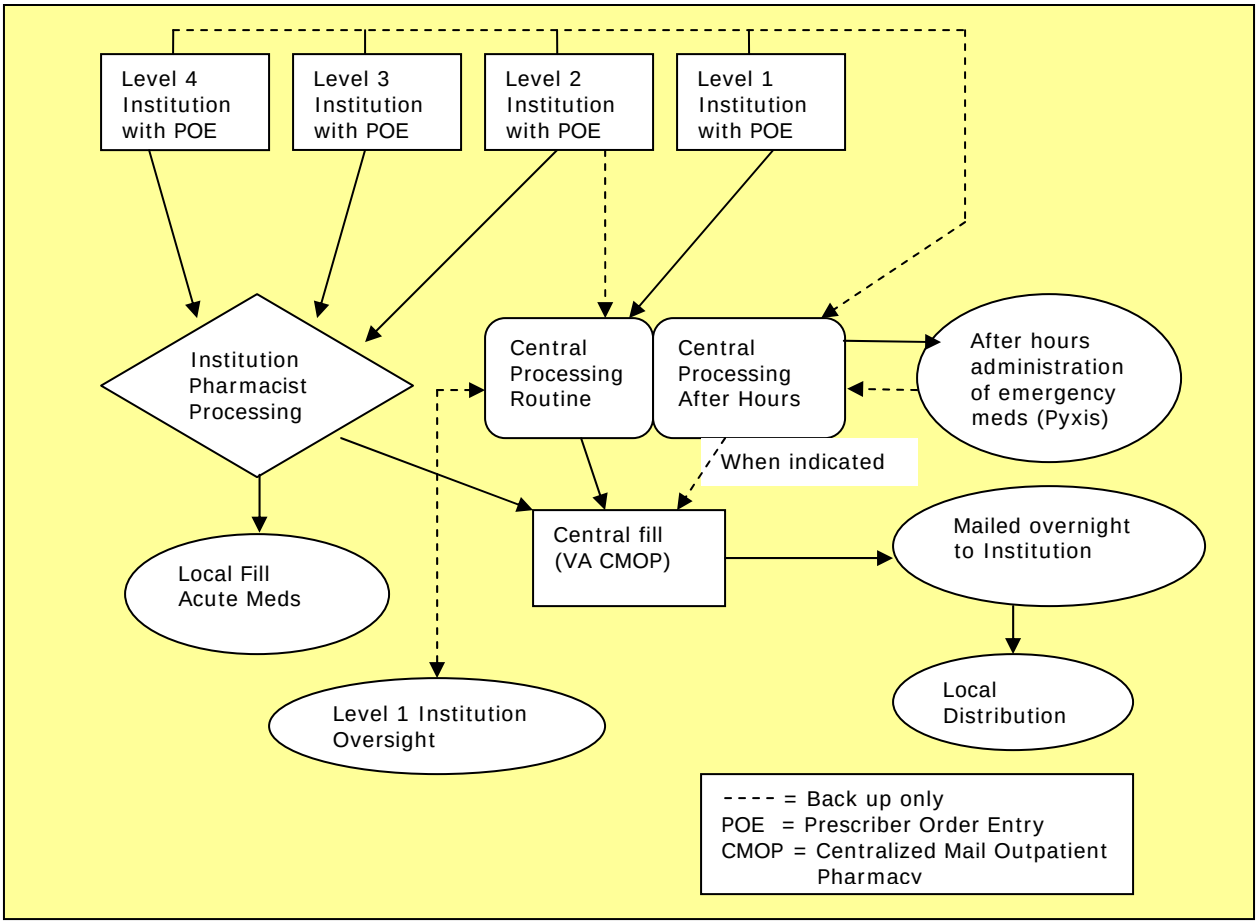
62 percent. Furthermore, according to a 2003 report in the *Journal of American Pharmacists Association,* a diabetes clinic run by pharmacists reduced the average direct medical cost per patient from $1,872 to $1,200 per year.[11]

The Workgroup also proposed the development of Central Processing, whereby institutions lacking an on site pharmacist could electronically transmit inmates' prescriptions to a central location where the BOP's pharmacists would review prescriptions for contraindications, and in turn, transmit them electronically to Central Fill. All BOP institutions would use Central Processing as a backup or during periods when an on site pharmacist was not available. BOP officials noted that one benefit from this proposal would be to reduce the need to hire contract pharmacists to assist when staff is on leave. The BOP estimates that Central Processing would save about $2 million a year, assuming that an average of 65 institutions use a contract pharmacist for 50 days a year at a rate of $80 per hour. However, the BOP has not conducted a formal cost-benefit analysis of the Central Processing proposal.

Figure 7 illustrates the relationships between the BOP's Levels of Care, Central Fill, and Central Processing proposals.

[11] *Journal of American Pharmacists Association,* Issue 43(2) (2003).

FIGURE 7. THE CENTRAL FILL AND CENTRAL PROCESSING



Source: BOP Pharmacy Staff

- **Level of Care 1 Institutions** – The institution would transmit prescriptions to the Central Processing center using prescriber order entry. This is an electronic method by which prescriptions are entered into a computer system by the prescriber and sent to a central location for processing. A pharmacist at the Central Processing center would review the prescription for contraindications and then transmit the prescription electronically to Central Fill.

- **Level of Care 2, 3, and 4 Institutions** – The on site pharmacist at the institution would review prescriptions for contraindications during normal business hours and then transmit the prescriptions electronically to Central Fill. If the prescription is for an acute medication, the institution's pharmacist would order it directly from the prime vendor. During periods when the onsite pharmacist is not available, the institution would transmit prescriptions via prescriber order entry to Central Processing, which would then transmit the prescription electronically to Central Fill.

The BOP plans to implement Central Fill and Central Processing over the next 6 years. The BOP estimates that it will sign the Interagency Agreement for Central Fill with the VA by June 2006. Once the agreement is signed, the BOP estimates that it will take more than 3 years to fully implement the changeover to Central Fill. The BOP plans to implement Central Fill for the Level 1 institutions by December 2007, with all other institutions being implemented by December 2009.

Electronic Medical Records System

The development of an electronic medical records system is included as an objective in the BOP's 2005 Strategic Plan, which states, "Implement an electronic medical records system which incorporates all medical, psychiatric, psychological, and disability information about individual inmates. The electronic medical records system will incorporate information currently maintained separately in paper medical records, the Psychology Data System, the Correctional Institution Pharmacy System, and the SENTRY data base."[12] In conjunction with the Central Fill and Central Processing proposals, the BOP is in the planning and development stages of implementing an electronic medical records system.

The electronic medical records system would provide pharmacists with the ability to access an inmate's medical information from any location, thus providing them with the ability to conduct a complete review of inmate prescriptions to check for any contraindications. In addition, the system would provide the capability for prescriber order entry, allowing other physicians to enter prescriptions into the system electronically. A recent study published by the *Journal of the American Medical Association* showed that computerized physician prescribing reduced errors by 80 percent.[13]

If the proposed electronic medical records system is not implemented, we would be concerned with the feasibility of implementing Central Processing, because it is unclear which level of information would be provided to pharmacists to conduct their review of the prescriptions for contraindications.

[12] SENTRY is the BOP's primary on-line information system.

[13] *Journal of the American Medical Association,* "Leading Patient Safety Advocates Assess Progress in Reducing Medical Error Five Years After Landmark IOM Report," (May 18, 2005).

Over-the-Counter (OTC) Medications

In an effort to reduce the costs of prescription medications, the BOP issued the OTC Medication Program Statement on November 17, 2004.[14] This statement outlines the requirements that each institution – other than medical centers – must follow when using OTC medications for the treatment of inmates. The BOP's OTC policy requires that inmates who complain about cosmetic, general hygiene issues, or symptoms of minor ailments should be referred to the commissary where they can purchase OTC medications with their own funds. If an inmate is considered indigent, that is, having less than a $6 average balance in their account for the last 30 days, then the institution can provide two OTC medications per week to the inmate.

Prior Reviews

In 2000, the Government Accountability Office (GAO) conducted a review of the health care costs at the BOP.[15] It found that from FY 1990 to FY 1999 the average annual increase in BOP health care costs was about 8.6 percent. The GAO noted several BOP initiatives to help reduce health care costs, including cooperative agreements using VA contracts to purchase prescription medications. In the report, the BOP stated that this resulted in a $0.76 million annual savings for health care costs. The GAO report also stated that the BOP made progress in containing health care costs, but additional proposals would help to contain increasing costs. These proposals included the BOP implementing a co-payment for inmates and negotiating more cost-effective contracts with community hospitals.

[14] BOP Program Statement No. 6541.01, *Over-the-Counter Medications*, issued November 17, 2004.

[15] Government Accountability Office, *Federal Prisons: Containing Health Care Costs for an Increasing Inmate Population* (2000).

Audit Objectives

The Department of Justice (DOJ) Office of the Inspector General (OIG) conducted this audit to evaluate the BOP Pharmacy Services. Our objectives were to:

- evaluate the BOP's efforts to reduce its increasing costs of prescription medications;
- assess whether the BOP ensures adequate controls and safeguards over prescription medications; and
- assess whether the BOP pharmacies are in compliance with applicable laws, regulations, policies, and procedures.

During the audit we conducted work at BOP headquarters and the 12 institutions shown in Figure 8.[16]

FIGURE 8. BOP INSTITUTIONS AUDITED

Institution	Location
Alderson FPC	West Virginia
Atlanta USP	Georgia
Atwater USP	California
Danbury FCI	Connecticut
Florence Administrative Maximum Security (ADX)	Colorado
Florence FCI	Colorado
Florence USP	Colorado
Forrest City FCI (Low)	Arkansas
La Tuna FCI	New Mexico
Oklahoma City Federal Transfer Center	Oklahoma
Oxford FCI	Wisconsin
Springfield Medical Center	Missouri

At each of the above institutions, we:

- reviewed documentation from FY 2002 to FY 2005 related to costs of prescription medications, lost or stolen controlled substances, investigations pertaining to the pharmacy and its staff, program and operational reviews, and access to the pharmacy;

[16] We also visited the Englewood FCI, Colorado, to obtain background information; however, the Englewood FCI is not included in our audit results.

- analyzed selected samples related to purchases, prescriptions, inventory, and disposal of controlled and noncontrolled substances from FY 2004 and FY 2005; and

- interviewed BOP officials, analyzed the use of OTC medications, and obtained information impacting the BOP's proposals to reduce the cost of prescription medications.

In addition, we analyzed the BOP's Central Fill and Central Processing proposals and conducted a survey of all BOP Pharmacists.

The details of the results of our audit are contained in the Findings and Recommendations section of this report. Additional information related to our audit appears in the Objectives, Scope, and Methodology section.

FINDINGS AND RECOMMENDATIONS

I. BOP EFFORTS TO REDUCE PRESCRIPTION MEDICATION COSTS

The BOP has not correctly assessed the budgetary impact of its planned initiatives to reduce increasing costs for prescription medications. As a result, future initiatives may result in increased rather than decreased costs. In our judgment, the estimated costs and savings of the BOP's proposal to move to a Central Fill pharmacy are inaccurate. The BOP estimated that when Central Fill is fully implemented it will save $1.14 million annually; however, we found that Central Fill may actually increase costs by approximately $900,000 annually. We also found that the BOP wastes over 5 percent of its prescription medication costs due to inmate transfers, confiscations, expiration of medication, and other reasons. We estimated the waste to be approximately $2.81 million in FY 2004. Finally, we found that the BOP's OTC policy has not been consistently applied and implemented across all BOP institutions.

As noted in the Background section of this report, the BOP is concerned about the increasing cost of prescription medications, the difficulty in recruiting trained professionals, and the safety of administering increasingly complex medication regiments. To reduce costs and address other concerns, the BOP has proposed several changes to its pharmacy services. These include the planned realignment of institutions based on levels of care, Central Fill, Central Processing, electronic medical records system, and an OTC policy.

Central Fill Cost-Benefit Analysis

Through the BOP's Central Fill proposal, pharmacists at BOP institutions would review prescriptions for contraindications and then transmit the prescriptions electronically to the VA Centralized Mail Outpatient Pharmacy Center in Dallas, Texas. The VA would fill the prescriptions and mail them overnight to the institution.

In March 2004, the BOP completed a cost-benefit analysis of its Central Fill proposal to estimate the impact on the BOP's prescription medication costs. Initially, the BOP developed three different estimates of savings, ranging from $1.14 to $6.42 million annually, as shown in Figure 9.

FIGURE 9. BOP's CENTRAL FILL COST SAVINGS ESTIMATES

	Gross Purchasing Savings	Gross Savings	Gross Cost	Net Savings
Estimate 1 - VA only	$10,230,250	$13,028,536	($6,604,000)	$ 6,424,536
Estimate 2 - VA/Perry Point/FSS	$ 7,925,581	$10,723,867	($6,604,000)	$ 4,119,867
Estimate 3 - VA/FSS	$ 4,943,349	$ 7,741,635	($6,604,000)	$ 1,137,635

Source: BOP analysis

The difference in savings for each estimate is based on whether the BOP can access pricing related to Pub. L. No. 102-585 (1993), which provides a discount known as the Federal Price Ceiling (FPC) on brand name prescription medications for which there are no generic equivalents. This discount was granted to the four federal agencies that are the largest purchasers of prescription medications: the VA, the Department of Defense, the Department of Health and Human Services, and the Coast Guard. As a result, the FPC discount is commonly known as "Big 4" pricing. Based on a legal opinion provided by the VA, it is a violation of Pub. L. No. 102-585 (1993) for an agency to pass on its Big 4 pricing to any other entity; therefore, Big 4 pricing is not available to the BOP.

As shown in Figure 9, the BOP Workgroup calculated the three estimates based on different assumptions of prescription medication prices charged by the VA.

- **Estimate 1 –** The net projected savings of $6.42 million is based on the BOP's ability to buy all prescription medications from the VA using Big 4 pricing. However, the estimated savings of $6.42 million is not attainable since Big 4 pricing is not available to the BOP.

- **Estimate 2 –** The net projected savings of $4.12 million is based on restocking the VA facility for Big 4 prescription medications purchased through the Department of Health and Human Services Supply Services Center, located in Perry Point, Maryland. During the audit, we determined that the Supply Services Center was passing on its Big 4 savings to the BOP, in violation of Pub. L. No. 102-585 (1993). As a result, the Supply Services Center has discontinued this practice. Therefore, the estimated savings of $4.12 million also is not attainable.

- **Estimate 3 –** The net projected savings of $1.14 million is based on the BOP purchasing prescription medications through the FSS at non-Big 4 prices to restock the VA facility for Big 4 prescription medications. This process could avoid any legal issues related to the BOP receiving Big 4 pricing on prescription medications, and results in the only feasible estimate. However, as described below, we believe that this estimate is also not accurate.

According to BOP officials, they are planning to request that Congress amend Pub. L. No. 102-585 (1993) to make the BOP eligible for Big 4 pricing. Given the potential for savings by the BOP in its prescription medication costs, we believe this is an important strategy, and we recommend that the BOP aggressively pursue this effort. However, at the time of our audit, Estimate 3 appeared to be the only feasible estimate. Consequently, we based our analysis on it.

The BOP based its net savings of $1.14 million for Estimate 3 on estimated gross savings of $7.74 million, minus estimated costs of $6.6 million. The $7.74 million estimated gross savings consists of $4.94 million from gross purchase savings, $2.39 million from the reduction of waste, and $0.41 million from labels and vials that will no longer be used. The estimated $6.6 million cost consists of $5.6 million in VA fees, $1 million in shipping fees, and $4,000 in information technology. A detailed breakdown of how the BOP reached Estimate 3 is shown in Figure 10.

FIGURE 10. BOP COST-BENEFIT ANALYSIS

Annual Savings:	
Gross Purchase Savings:	
Total Prescription Medication Costs	$47,715,720
Percent Savings	10.36%
Total, Gross Purchase Savings	**$4,943,349**
Waste:	
Total Rx Costs	$47,715,720
Recent Waste	5.00%
Total, Waste	**$2,385,786**
Vials:	
Number of Vials per year	2,750,000
Price per Vial	$ 0.063
Total, Vials	**$ 173,250**
Labels:	
Number of Labels per year	5,500,000
Price per Label	$ 0.0435
Total, Labels	**$ 239,250**
Total, Annual Savings	**$7,741,635**
Annual Costs:	
Prescription Medication fees:	
Number of Prescriptions per year	5,000,000
VA Fee Per Prescription	$ 1.12
Total, Prescription Medication Fees	**$5,600,000**
Shipping:	
Cost per Institution per year	$ 10,000
Number of Institutions	100
Total, Shipping	**$1,000,000**
Information Technology:	
Scanners and Barcodes	$ 2,000
Number of Institutions (new per year)	2
Total, Information Technology	**$ 4,000**
Total, Annual Costs	**$6,604,000**
NET TOTAL	**$1,137,635**

Source: BOP analysis

We reviewed the BOP's cost-benefit analysis for Estimate 3 and determined that the savings related to the Central Fill proposal are overstated. As shown in Figure 10, the BOP estimated that a fully implemented Central Fill would save $1.14 million per year. However, our analysis shows that Central Fill could actually cost the BOP as much as approximately $900,000 per year.

Analysis of Gross Purchase Savings

As previously stated, the BOP estimated a savings of $4.94 million on prescription medications purchased through the VA by using Central Fill. The estimated-gross-purchase savings were based on a BOP survey of six institutions over a 1-year period.[17] The BOP compared the costs of prescription medications purchased by the six institutions to prices paid by the VA for the same medication. Based on this analysis, the BOP calculated that Central Fill would save the six institutions $0.33 million, or 10.36 percent of their total prescription medication costs per year. The BOP then projected the 10.36 percent savings to the total BOP prescription medication costs for the same time period. Accordingly, the BOP calculated savings for all institutions at an estimated $4.94 million (10.36 percent of $47.71 million).

However, based on our analysis of the BOP's estimate, we found several errors and incorrect assumptions that resulted in gross purchase savings being overstated by $2.97 million. Specifically, we found that the: (1) data used to calculate the 10.36 percent savings, from the analysis of the six institutions, included two errors resulting in an overstatement of savings; (2) the savings estimate incorrectly assumed 100-percent usage of Central Fill by all BOP institutions; (3) analysis of the six institutions did not include all prescription medications purchased during the 1-year period; and (4) analysis compared the BOP and VA prices for different time periods.

Specifically, we found that the data used by the BOP to calculate the 10.36 percent estimated gross purchase savings included an error related to Ribavirin, a Hepatitis C medication, which resulted in an 1,803-percent difference. The BOP calculated savings for Ribavirin by using costs of $0.22 million for the six institutions divided by an estimated 17,486 pills purchased. This resulted in an estimated average price per pill for Ribavirin of $12.45. However, based on our analysis the number of pills purchased was actually 51,086, a difference of 33,600 pills. Using the adjusted number of pills, we estimated the average price of Ribavirin to be $4.26 per pill, a difference of $8.19, as shown in Figure 11.

[17] The six institutions were Forrest City FCI, Arkansas; Atlanta USP, Georgia; Petersburg FCI (Medium), Virginia; Oxford FCI, Wisconsin; Lompoc USP, California; and Fort Dix West FCI, New Jersey, from March 1, 2003, to February 28, 2004.

FIGURE 11. DETAIL ON IMPACT OF RIBAVIRIN ERROR

	Original BOP	OIG First Adjustment	Difference
Calculation of BOP Price Per Pill			
Total BOP Ribavirin Costs	$ 217,713	$ 217,713	---
Number of Pills	÷ 17,486	÷ 51,086	33,600
BOP Price Per Pill	**$ 12.45**	**$ 4.26**	**($ 8.19)**
Savings From Using Central Fill for the Six Institutions			
BOP Price Per Pill	$ 12.45	$ 4.26	($ 8.19)
VA Price Per Pill	(4.11)	(4.11)	---
Difference	**$ 8.34**	**$ 0.15**	
Number of Pills	× 17,486	× 51,086	
Total Ribavirin Savings	**$ 145,833**	**$ 7,663**	**($ 138,170)**
Total Savings Excluding Ribavirin	$ 182,495	$ 182,495	---
Total Ribavirin Savings	145,833	7,663	(138,170)
Total Savings	$ 328,328	$ 190,158	($ 138,170)
Total Rx Costs	÷ 3,170,327	÷ 3,170,327	---
Savings as Percent of Total Rx Costs	**10.36 %**	**6.00 %**	**(4.36 %)**
Impact on Gross Purchase Savings on All BOP Institutions			
Total Rx Costs	$47,715,720	$47,715,720	---
Percentage Savings	× 10.36 %	× 6.00 %	(4.36 %)
Total Gross Purchase Savings	**$ 4,943,349**	**$ 2,862,943**	**($2,080,406)**

Source: BOP and OIG analysis of data provided by the BOP and the VA

Based on our estimate, the percentage gross purchase savings for the six institutions is reduced from 10.36 percent to 6 percent. When we project the new percentage savings to all BOP institutions, we estimate gross purchase savings to be $2.86 million, compared to the original BOP calculation of $4.94 million. We brought this error to the attention of BOP management, who concurred with the OIG calculation and the recommended adjustment.

We also found that the BOP gross purchase savings estimate included two prescription medications, Videx® 200 milligrams (mg) chewable and Sular® 20 mg tablets, for which a VA price was not available for comparison. Instead of excluding these prescription medications from the gross purchase savings analysis, the BOP included $14,558 as a cost savings for the six

institutions. Based on our analysis, the savings of the six institutions should be reduced by 0.46 percent, resulting in a 5.54 total estimated percent savings instead of 6 percent.

FIGURE 12. DETAIL ON IMPACT OF VIDEX® AND SULAR® ERROR

	First Adjustment	OIG Second Adjustment	Difference
Savings from Using Central Fill for the Six Institutions			
Total Rx Savings	$ 190,158	$ 190,158	---
Removal of Videx®	---	(6,278)	($ 6,278)
Removal of Sular®	---	(8,280)	(8,280)
Adjusted Total Rx Savings	**$ 190,158**	**$ 175,600**	**($ 14,558)**
Total Rx Costs	÷ 3,170,327	÷ 3,170,327	---
Savings as Percent of Total Rx Costs	**6.00 %**	**5.54 %**	**(0.46 %)**
Impact on Gross Purchase Savings on All BOP Institutions			
Total Rx Costs	$47,715,720	$47,715,720	---
Percentage Savings (Adjusted)	× 6.00 %	× 5.54 %	(0.46 %)
Total Gross Purchase Savings	**$ 2,862,943**	**$ 2,643,451**	**($219,492)**

Source: OIG analysis of data provided by the BOP and the VA

As shown in Figure 12, we used the adjusted percent to project gross purchased savings to all institutions, and calculated the savings to be $2.64 million (5.54 percent x $47.72 million), rather than the BOP's estimate of $4.94 million, a difference of $2.3 million.

We also found that the BOP based its estimate of gross purchase savings on the assumption that all prescription purchases would occur through Central Fill. The BOP used the total prescription costs for all institutions of approximately $47.72 million during the 1-year period of its analysis to calculate estimated savings. However, the BOP expects that medical centers and FDCs will only purchase 50 percent of their prescription medications through Central Fill. We also noted that the Oklahoma FTC will not use Central Fill, and all other institutions will use Central Fill for 95 percent of their prescription medications. As a result, the BOP will use Central Fill to purchase only 74.5 percent of its total prescription

medications.[18] We applied the adjusted usage of 74.5 percent to the prescription medication costs used in the BOP's analysis, and found the total cost affected by Central Fill is reduced to $35.55 million, a difference of $12.17 million, as shown in Figure 13.

FIGURE 13. ADJUSTMENT TO TOTAL COST ESTIMATE

Impact on Gross Purchase Savings on All BOP Institutions	Second Adjustment	OIG Third Adjustment	Difference
Total Rx Costs	$47,715,720	$35,548,211	($12,167,509)
Percentage Savings (Adjusted)	× 5.54 %	× 5.54 %	---
Adjusted Total Gross Purchase Savings	**$ 2,643,451**	**$ 1,969,371**	**($ 674,080)**

Source: OIG analysis of data provided by the BOP and the VA

This adjustment further reduces the BOP's estimated gross purchase savings to $1.97 million, a difference of $2.97 million from the BOP's original estimate of $4.94 million.

Finally, we found that the BOP did not include all prescription medications in its analysis of gross purchase savings for the six institutions. Instead, the BOP estimated the savings on just tablets and capsules, and excluded any other types of prescription medications. According to BOP officials, liquids and ointments were excluded to simplify the calculation. However, without estimating the costs or savings for all medications, the BOP could be overstating or understating the estimated total gross purchase savings. In addition, the time periods used for BOP and VA prices are not consistent. BOP prices were derived using the average price paid by the six institutions over a 1-year period from March 2003 through February 2004. The VA prices were based on a specific date during the time of the analysis. As a result, some BOP estimated gross purchase savings may be the result of timing differences in prescription prices.

[18] To arrive at the 74.5 percent calculation we used the BOP's FY 2004 expenditures of $50.73 million and reduced this amount by: (1) 50 percent of the medical centers' and FDCs' costs ($11.00 million); (2) the entire FTC's costs ($0.51 million); and (3) 5 percent of the remaining BOP's costs ($1.41 million), which equal $37.81 million, or 74.5 percent ($37.81 million/ $50.73 million) of the total FY 2004 BOP prescription medication costs.

Analysis of Waste Savings

The BOP's Central Fill proposal estimated savings of $2.39 million from the reduction of waste of prescription medications. The BOP based this savings on informal discussions with several BOP pharmacists, who indicated that the BOP could save about 5 percent of its total prescription medication costs through reduced waste. The 5 percent savings relies on the assumption that Central Fill will provide better inventory management, by preventing expiration of prescription medications and improving the ordering of crash cart medications.[19]

During our audit, we found many different causes of prescription medication waste, such as expired medicines, transfers of inmates, and confiscations. For example, the BOP does not ensure that prescription medications are transferred with inmates when they are moved to new facilities. Waste from confiscations is also caused by correctional officers seizing prescription medications during searches of inmates' cells. Central Fill would only reduce waste associated with expired prescription medications. With Central Fill, most institutions only maintain an inventory of emergency prescription medications, such as antibiotics and pain relievers, which, in theory, reduce waste caused by medications that expire before they are used.

Based on our analysis, the BOP overstated the estimated savings of $2.39 million due to the reduction of waste. We conducted a survey of all BOP pharmacists and had a response rate of 84 percent (106 responses out of 126 questionnaires sent). The results of our survey found that BOP pharmacists estimated that only 1.21 percent of waste is associated with expired medications rather than the 5 percent figure used by the BOP in its calculation.

FIGURE 14. ADJUSTMENT TO WASTE ESTIMATE

	BOP Original	OIG Adjustment	Difference
Impact on Gross Purchase Savings on All BOP Institutions			
Total Rx Costs	$47,715,720	$47,715,720	---
Percent Reduction in Expired Waste	× 5.00 %	× 1.21 %	(3.79 %)
Adjusted Total Rx Savings	**$ 2,385,786**	**$ 577,360**	**($1,808,426)**

Source: BOP and OIG analysis of costs and percentage of estimated waste

[19] Crash carts contain urgent care prescription medications, including controlled substances that are used for emergency purposes only.

As shown in Figure 14, we estimate savings from Central Fill related to a reduction in waste of $0.58 million (1.21 percent x $47.72 million), a difference of $1.81 million from the BOP's estimate.[20] In addition, the BOP's analysis does not include the partial refunds that many BOP institutions receive when they return expired prescription medications, which would further reduce the estimate savings.

Analysis of Vials and Labels

The BOP estimated that by switching to Central Fill it would reduce vial and label purchases and save an estimated $0.41 million per year. The BOP based this estimate on the assumption that 5 million prescriptions were filled during a 1-year period, requiring 2.75 million vials for 55 percent of prescriptions, and 5.5 million labels for 110 percent of prescriptions.[21] However, from data we gathered for FY 2003 and FY 2004, the BOP only dispensed an average of 3.33 million prescriptions per year during the period. Therefore, based on our analysis, we estimated that the BOP will only use Central Fill for 83.4 percent or 2.78 million prescriptions.[22] Using the same percentages for vials and labels estimated by the BOP, the number of vials used is reduced to 1.53 million and the number of labels used is reduced to 3.06 million, as shown in Figure 15.

[20] The calculation uses $47.72 million in cost because the Central Fill proposal affects all inventories of prescription medications within the BOP, not only the portion of prescription medication costs that will use the Central Fill ($35.55 million).

[21] The BOP assumes that institutions will use more labels than the actual number of prescriptions due to mistakes and various other reasons.

[22] To arrive at the 83.4 percent calculation we used the BOP's FY 2004 and FY 2003 average prescription of 3.33 million and reduced this amount by: (1) 50 percent of the medical centers' and FDCs' average prescriptions (0.43 million); and (2) 5 percent of the remaining BOP's prescriptions (0.12 million), which equal 2.78 million, or 83.4 percent (2.78 million/3.33 million). Note that the total BOP prescription numbers provided by the BOP did not include the prescriptions issued at the Oklahoma FTC.

FIGURE 15. ADJUSTMENT TO VIALS AND LABELS SAVINGS ESTIMATE

	BOP Original	Adjustment	Difference
Number of Prescriptions sent to Central Fill			
Total Number of Prescriptions	5,000,000	3,331,597	(1,668,403)
Percent of Prescriptions being sent to Central Fill	× 100 %	× 83.4 %	(16.6 %)
Total Number of Prescriptions sent to Central Fill	**5,000,000**	**2,778,552**	**(2,221,448)**
Vials			
Number of Vials sent to Central Fill	2,750,000	1,528,204	(1,221,796)
Price Per Vial	× $ 0.063	× $ 0.063	---
Total Savings from Vials	**$173,250**	**$ 96,277**	**($ 76,973)**
Labels			
Number of Labels sent to Central Fill	5,500,000	3,056,407	(2,443,593)
Price Per Labels	× $ 0.0435	× $ 0.0435	---
Total Savings from Labels	**$239,250**	**$132,954**	**($106,296)**
Total, Vials and Labels Savings	**$412,500**	**$229,231**	**($183,269)**

Source: BOP and OIG analysis of number of prescriptions, vials, and labels

As shown in Figure 15, we estimate that the BOP would save $229,231 in vials and labels by using Central Fill rather than its estimate of $412,500.

Analysis of Annual Costs

The BOP estimated that it will spend $6.6 million annually related to Central Fill. Of this total amount, $5.6 million would come from VA fees, $1 million from shipping, and $4,000 from information technology. Our analysis revealed that the BOP overstated prescription fees and shipping costs.

The BOP estimated that the fees paid to the VA for filling prescriptions would average $5.6 million annually. We found that this estimate is based on an assumed fee of $1.12 per prescription that the VA will charge to fill an estimated 5 million prescriptions per year. Because we determined that the BOP will more likely use the Central Fill for about 2.78 million prescriptions per year, the cost associated with VA fees would be $3.11 million as opposed to $5.6 million, shown in Figure 16.

FIGURE 16. ADJUSTMENT TO PRESCRIPTION FEE COST

	BOP Original	Adjustment	Difference
Impact on Prescription fee Cost for All Institutions			
Number of Prescriptions sent to Central Fill	5,000,000	2,778,552	(2,221,448)
VA Prescription fee	x $ 1.12	x $ 1.12	---
Total Prescription fee Paid by the BOP	**$5,600,000**	**$3,111,978**	**($2,488,022)**

Source: BOP and OIG analysis of the number of prescriptions using Central Fill

The BOP's estimated cost also included a $1 million charge for annual prescription shipping costs from the VA facility in Dallas, Texas, to 100 BOP institutions. The BOP estimated shipping cost is based on an assumption of 200 prescriptions per day, per institution, for 250 shipping days per year. This results in a total of 5 million prescriptions shipped per year. However, as stated previously, we estimated that the BOP will only use the Central Fill for about 3 million prescriptions per year. As a result, the number of prescriptions shipped per day, per institution, is reduced from 200 to 111, resulting in a $0.45 million reduction in the total shipping cost, as shown in Figure 17.

FIGURE 17. ADJUSTMENT TO SHIPPING COST

	BOP Original	Adjustment	Difference
Prescriptions Per Day Per Institution			
Number of Prescriptions sent to Central Fill	5,000,000	2,778,552	(2,221,448)
Number of Shipping Days in a Year	÷ 250	÷ 250	---
Number of Prescriptions Per Day	20,000	11,114	(8,886)
Number of Institutions	÷ 100	÷ 100	---
Number of Prescriptions Per Day Per Institution	**200**	**111**	**(89)**
Impact on Shipping Cost for All Institutions			
Weight Per Day (4 ounces per prescription)	5,000 lbs	2,775 lbs	(2,225) lbs
Price Per Pound	$ 0.80	$ 0.80	---
Total Shipping Cost Per Day	$ 4,000	$ 2,220	($ 1,780)
Number of Shipping Days in a Year	× 250	× 250	---
Total Shipping Cost	**$1,000,000**	**$555,000**	**($445,000)**

Source: BOP and OIG analysis of costs related to shipping

Summary of BOP and OIG Central Fill Cost-Benefit Analysis

During our review of the BOP's cost-benefit analysis for its Central Fill proposal, we found several errors and incorrect assumptions concerning the accuracy of the BOP's estimated savings. The BOP estimated savings of $1.14 million annually, which based on our analysis, is overstated by as much as $2.03 million. As a result, Central Fill may cost the BOP as much as $895,016 per year, as shown in Figure 18.

FIGURE 18. SUMMARY BOP AND OIG COST-BENEFIT ANALYSIS

	BOP Original	OIG Analysis	Difference
Annual Savings:			
Gross Purchase Savings	$4,943,349	$1,969,371	($2,973,978)
Waste	2,385,786	577,360	(1,808,426)
Vials	173,250	96,277	(76,973)
Labels	239,250	132,954	(106,296)
Total, Annual Gross Savings	**$7,741,635**	**$2,775,962**	**($4,965,673)**
Annual Costs:			
Rx Fee	$5,600,000	$3,111,978	($2,488,022)
Shipping	1,000,000	555,000	(445,000)
Information Technology	4,000	4,000	---
Total, Annual Gross Costs	**$6,604,000**	**$3,670,978**	**($2,933,022)**
NET IMPACT (Savings - Costs)	**$1,137,635**	**($ 895,016)**	**($2,032,651)**

Source: BOP and OIG survey and analysis

In our judgment, it is important that the BOP has an accurate understanding of the budgetary impacts of its Central Fill proposal before proceeding. Therefore, we recommend that it conduct a complete and accurate cost-benefit analysis considering the monetary and non-monetary impacts of the proposal before deciding if it should proceed with the implementation of this proposal.

Additional Concerns about the Central Fill Cost-Benefit Analysis

In addition to the concerns related to the specific dollar estimates, we identified several other concerns related to the BOP's Central Fill cost-benefit analysis. These include: (1) the representation of the six institutions used to estimate savings, as compared to the BOP as a whole; (2) whether pharmacists ensure that the lowest-cost prescription medications are purchased; (3) the static nature of the analysis which does not include any assumptions of growth in inmate population or changes in prescription

medication costs; and (4) the increase in clinical work conducted by pharmacists.

In our judgment, the six institutions used by the BOP to estimate prescription medication costs may not represent the average institution. The BOP stated that it picked six institutions at random; however, no sampling methodology was used to ensure that the sample was representative of all institutions. Although we could not verify the validity of the sample, we found several factors that cause concern. The average amount spent on prescription medications by the six institutions was 23 percent higher than the average for all other BOP institutions. Further, 47 percent of the FY 2004 prescription medication costs for one of the six institutions were for Hepatitis C medications, compared to an average of 3 percent for all BOP institutions. These issues raise concerns about the BOP's ability to project analyses of these six institutions to all BOP institutions.

According to the Workgroup, Central Fill would allow the BOP to utilize VA staff to research manufacturer prices and purchase prescription medications at the lowest cost. The BOP asserts that using the Central Fill would result in cost savings because BOP pharmacists currently do not have the time to conduct price research. However, we found that it is possible for BOP pharmacists to research the lowest prescription medications prices. We reviewed prescription medication purchases at several BOP institutions and found significant price differences for identical medication during the same time period. For example, one institution purchased Nasalide® 25 mcg nasal spray on October 14, 2003, for $0.98 each, while another institution purchased the same item on October 21, 2003, for $0.21 each, for a difference of $0.77 per item. This demonstrates that BOP pharmacists can research the lowest prescription medication prices. Thus, in our judgment the BOP should implement a policy that would require staff to search for the lowest possible price within the FSS.

We also found that the BOP's cost-benefit analysis was based on the number of BOP institutions, number of prescriptions, inmate population, and prescription medication costs in FY 2004, without taking into account future changes. Based on the current implementation plan for Central Fill, the BOP does not anticipate full implementation until December 2009. As a result, many of the factors used to compile the analysis may change and should be incorporated to develop a complete and accurate cost estimate. For example, cost estimates do not include information regarding inmate population growth, changing demographics of the inmate population, increasing prescription medication costs, and BOP staffing levels, since each of these factors impact the estimated savings. We recommend that they

should be included in the cost analysis if the BOP is to accurately project the proposal's future impact on the prescription medication costs.

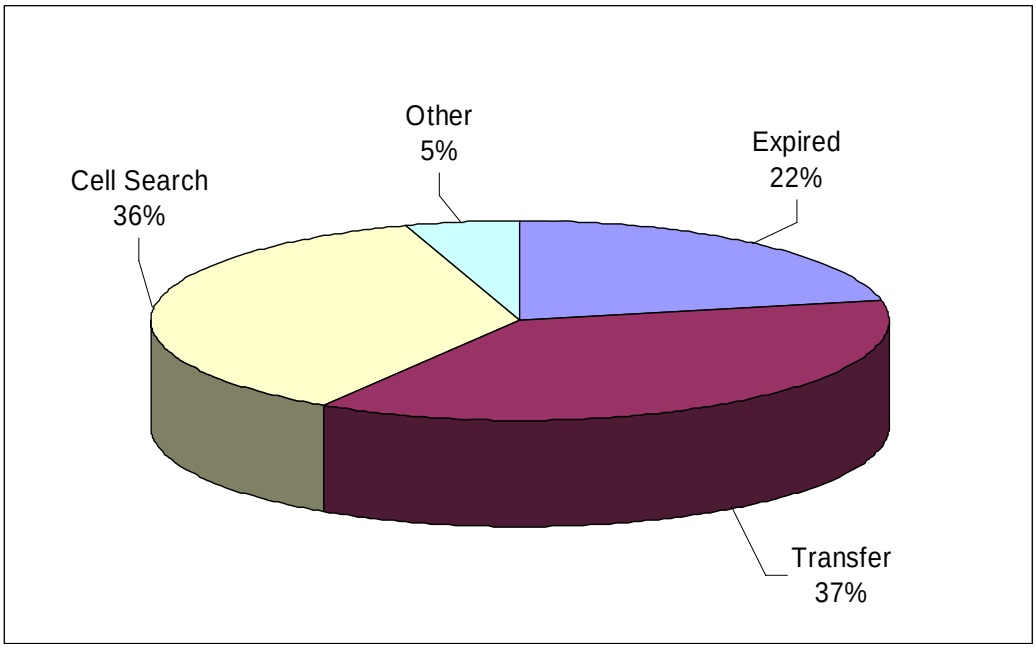
In addition, as stated in the Introduction section of this report, the BOP Workgroup asserts the Central Fill proposal will increase pharmacists' ability to conduct clinical work. The BOP asserts that the proposal frees time, allowing pharmacists to hold clinics to better manage disease and medication through education and examinations. The free time occurs because pharmacists will no longer have to fill prescription bottles manually. We believe that the BOP may be overestimating the amount of time Central Fill will actually save pharmacists. Out of the 12 institutions visited, 10 would use the Central Fill for the majority of their prescriptions. Of these 10, 8 had at least 1 pharmacy technician, who usually filled prescription bottles manually. By eliminating the need to fill the prescriptions at the institution, the BOP is reducing the workload of the pharmacy technicians rather than the pharmacists. The pharmacists currently spend much of their time reviewing prescriptions for contraindications and effectiveness, which will still be completed by the BOP pharmacists under Central Fill, resulting in little reduction of their workload.

In sum, the BOP's cost-benefit analysis overstates the savings related to the Central Fill proposal and fails to consider other important issues. The BOP estimated that a fully implemented Central Fill would save $1.14 million per year, while our analysis shows that Central Fill could actually cost approximately $900,000 per year. It is important that the BOP fully consider the monetary and non-monetary impacts of the proposal before deciding if it should proceed with the implementation of this proposal.

Prescription Medication Waste

We found that the BOP needs to improve efforts to reduce prescription medication costs associated with waste. Based on the responses to our pharmacist's survey, we found that the BOP pharmacist estimated prescription medication costs associated with waste at $2.81 million in FY 2004, or 5.54 percent of the BOP's total prescription medication costs. Most often, the survey found that prescription medication waste is the result of inmate transfers and confiscations. As shown in Figure 19, waste from transfers and confiscations during searches of inmates' cells comprise approximately 74 percent of total waste, an estimated $2.07 million per year.

FIGURE 19. DISTRIBUTION OF PRESCRIPTION MEDICATION WASTE BY TYPE



Source: OIG Survey of BOP Pharmacists

The results of our pharmacist survey showed that the transfer of inmates is the largest cause of prescription medication waste, accounting for an estimated $1.05 million annually. Waste from inmate transfers results from the BOP's policy requiring that all transferred inmates receive a 7-day supply of prescription medications, regardless of whether or not the inmate already has a sufficient supply. This policy was established to ensure enough prescription medication is available to the inmate during the transfer and to give the new institution time to purchase the medication if it is not currently in the institution's inventory. There is currently no BOP requirement that prescription medications already in the inmate's possession be transferred with the inmate. As a result, when inmates are transferred, their prescription medications are often left in their cell or locker. In turn, these medications must be disposed of since the pharmacy cannot reuse them for another inmate once it has been in an inmate's possession.

In response to our survey, pharmacists offered several suggestions to reduce waste from transfers. Out of 81 pharmacists who responded to this question, 37 (46 percent) suggested that the BOP require medications to be transferred with the inmates. Other suggestions include: (1) limiting the amount of medication dispensed to inmates; (2) requiring correctional officers to return medication to the pharmacy prior to transfer; and (3) shortening the number of days of medication required for intra-system transfers from 7 to 3 days.

Our pharmacist survey responses indicated that confiscations during searches of inmates' cells were the second largest reason for prescription medication waste. Confiscations from waste totaled an estimated $1.02 million in FY 2004. Waste from confiscations was generally related to the BOP's policy prior to January 15, 2005, that prescriptions could only be valid for a total of 90 days (30 days with 2 refills). Therefore, the expiration date on the prescription label was for no more than 90 days, even though the medication may still be valid per the manufacturers' expiration date and still valid for use by the inmate. During searches of inmates' cells, if correctional officers found prescription medications that were past the expiration date per the label, the medications were confiscated and frequently thrown away.

Based on our survey, BOP pharmacists noted that if correctional officers were required to return confiscated prescription medications to the pharmacy, there was a possibility that the medication could be reissued to the same inmate. In addition, this would assist the pharmacists in tracking inmate prescription medication usage. The BOP revised its policy on January 15, 2005, and extended the length of time for a valid prescription from 90 to 180 days (a 30-day prescription with 5 refills), which may reduce waste resulting from confiscations.

In conclusion, prescription medication waste represents a significant cost to the BOP, representing about 5 percent of total prescription medication expenditures. The BOP has made some progress addressing these issues by extending the expiration date, which may help to reduce the waste associated with confiscations. However, we recommend the BOP implement policies and procedures ensuring the transfer of prescription medications with inmates, and that confiscated prescription medications are returned to the pharmacy for reissuance or disposal.

Over-the-Counter Medication Program Statement

In an effort to reduce the cost of prescription medications, the BOP issued the OTC Medication Program Statement, on November 17, 2004 . This statement outlines the requirements that each institution – other than the medical centers' inmates who are classified as in-patient status – must follow when using OTC medications for the treatment of inmates. The BOP requires that inmates who complain about cosmetic, general hygiene, or symptoms of minor ailments should be referred to the commissary, where they can purchase OTC medications with their own funds. If an inmate is considered indigent, that is, having less than a $6.00 average balance in their account for the last 30 days, then the institution must provide two OTC

medications per week to the inmate, as needed. The following OTC medications are available to BOP inmates, as shown in Figure 20.

FIGURE 20. THE BOP OTC MEDICATIONS

- Tylenol® 5 grain Tablets
- Bayer® 5 grain Tablets
- Aller-Chor® 4 mg Tablets
- Cortaid® 0.5%
- Mylanta® II or Maalox® Plus Liquid
- Ex-Lax® Milk of Magnesia Liquid
- Fiberall® Muciloid Powder SF
- Selsun Blue® 1% Shampoo
- Mylanta® 40 mg Tablets
- Tinactin® 1% Cream

Source: BOP Program Statement No. 6541.02, *Over-the-Counter Medications*, issued November 17, 2004

However, based on our review of 12 BOP institutions and our pharmacist survey, we found that the BOP has not fully implemented OTC policy throughout BOP institutions. Specifically, 35 percent of the respondents stated on our survey that the OTC policy had not been followed at their institution. Additionally, 43 percent of respondents stated that medical staff directed them to provide OTC medication to an inmate even though it was either not medically necessary or could be obtained from the commissary.

The savings generated from implementing the OTC policy relates to time, instead of dollar savings. OTC medication comprises only 2.7 percent, or $1.36 million, of the BOP FY 2004 medication costs. As a result, lowering the amount of OTC medication issued has a small impact on the total costs. However, the larger savings from this policy relates to pharmacists' time. We found pharmacists and their staff spend much of their day reviewing and filling prescriptions for all medications. By shifting the OTC medication from the pharmacy to the commissary, the BOP will reduce the number of prescriptions the pharmacy staff has to review and fill on a daily basis. This will allow pharmacists more time to complete other required tasks.

Recommendations

We recommend that the BOP:

1. Conduct a complete and accurate cost-benefit analysis of the Central Fill proposal before deciding whether to proceed with implementation.

2. Pursue efforts to request that Congress amend Pub. L. No. 102-585 (1993) to provide the BOP with eligibility for Big 4 pricing.

3. Ensure BOP pharmacy staff search for the lowest possible prescription medication prices within the FSS.

4. Implement a system that would ensure that prescription medications are transferred with the inmates, by taking into account security issues.

5. Ensure that prescription medication confiscated from an inmate is returned to the pharmacy for reissuance to the same inmate or is disposed of properly.

6. Ensure that all BOP institutions comply with the OTC policy.

II. CONTROLS AND SAFEGUARDS OVER PRESCRIPTION MEDICATIONS

The BOP is not adequately accounting for and safeguarding prescription medications. As a result, the BOP could not account for 402 controlled substances at the institutions included in our audit. In addition, we noted numerous errors related to controlled substances inventory and administration records. Furthermore, quarterly inventories submitted to BOP headquarters did not always include all controlled substances. We also found the BOP has not implemented adequate internal controls related to the purchasing, ordering, receiving, payment, and dispensing of prescription medications.

BOP policy requires that necessary medical, dental, and mental health services be provided to inmates by professional staff.[23] Sick or injured inmates may be seen during routine appointments or through sick calls at the institution. If an inmate needs a prescription medication, the health service practitioner prepares a written order, which can sometimes include controlled substances.

Controlled Substances

Controlled substances are prescription medications that fall under the jurisdiction of federal and state laws regulating their manufacture, sale, distribution, use, and disposal. The federal government separates controlled substances into five schedules as defined by the Controlled Substances Act § 202 (21-USC-812), as follows:

- Schedule I – controlled substances that have no accepted medical use in the United States.

- Schedule II – controlled substances that have accepted medical uses but a high potential for abuse, with severe psychological or physical dependency.

[23] BOP Program Statement No. 6000.05, *Health Service Manual*, updated February 11, 2000.

- Schedule III through V – controlled substances that have accepted medical uses for which the potential for abuse is in decreasing levels of dependency.

The Drug Enforcement Agency (DEA) is the primary agency responsible for enforcing the Controlled Substances Act. In order to prescribe and administer controlled substances, institutions and physicians must register and obtain a DEA Controlled Substance Registration Certificate. The DEA requires registrants to comply with regulatory requirements related to security, records accountability, and other specific standards for controlled substances. Specifically, the DEA requires that registrants conduct biennial inventories of all controlled substances and maintain records of all purchases, disposals, and administration of controlled substances for at least 2 years. Registrants must also have a written prescription for controlled substances that include the physician's signature and applicable DEA registration number. Each BOP institution is registered with the DEA to prescribe, dispense, and administer controlled substances.[24]

The BOP places further requirements on the use and accounting for controlled substances.[25] BOP policy requires that the mainstock of controlled substances be stored in a safe or vault and that only the Chief Pharmacist or designee should have access.[26] Each institution is required to maintain a perpetual inventory for all controlled substances stored in the mainstock. The inventory for controlled substances is used to record all purchases, transfers, and disposals of controlled substances in and out of the mainstock.

BOP policy also requires that any substocks of controlled substances be stored in a stationary, approved steel cabinet with overlapping steel doors that are separately locked or in a safe with a key padlock. Several institutions use an automated system, such as a Pyxis or OmniCell system, to store controlled substances substock. These systems allow for improved electronic tracking and recordkeeping through inventory records. The only staff members who generally have access to the substock are pharmacists,

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[24] "Prescribing" is defined as writing or giving medical directions, or indicating remedies. "Dispensing" is defined as providing multiple doses in a properly labeled container for use over a period of time. "Administration" is defined as providing one dose of medication to be applied or consumed immediately.

[25] The Chief Pharmacist is responsible for procurement, storage, distribution, product selection, and security of all controlled substances.

[26] BOP Program Statement No. 6000.05, *Health Service Manual*, updated February 11, 2000.

pharmacy technicians, and mid-level practitioners. According to BOP policy, institutions should maintain a perpetual inventory of controlled substances in any substock. In addition, institutions are required to count controlled substances at each shift change.

Each time a controlled substance is administered to an inmate from the substock, the BOP requires it to be recorded on the Proof of Use sheet as well as the inmates' Medication Administration Record (MAR). The Proof of Use sheet is the substock inventory record and includes the inmate's name and number, date issued, strength, quantity, signature of the person administering the medication, and balance on hand. The MAR should include the prescription medication name, strength, quantity, date, time, and person who administered the prescription medication. The information on the Proof of Use sheet and the MAR should agree.

At the 12 institutions included in our audit, we identified 22 different types of controlled substances that were being used to treat inmates. (See Appendix I for the medical uses of each type of controlled substance.) Tylenol® with Codeine and Phenobarbital were the most commonly used controlled substances throughout the institutions. The types of controlled substances identified in our audit, the number of institutions using each type, and the DEA Schedule classification, are shown in Figure 21.

FIGURE 21. CONTROLLED SUBSTANCES IDENTIFIED AT THE 12 BOP INSTITUTIONS AUDITED

Controlled Substance	Number of Institutions	DEA Schedule
Tylenol® with Codeine	12	III
Phenobarbital	12	IV
Ativan®	11	IV
Klonopin®	9	IV
Valium®	9	IV
Morphine	9	II
Andro®	7	III
Demerol®	6	II
Percocet®	6	II
Xanax®	3	IV
Dolophine®	3	II
Roxicodone®	3	II
Codeine	2	II
Lomotil®	2	V
Duragesic®	2	II
Ritalin®	2	II
Android-10®	2	III
Stadol®	1	IV
Lorcet®	1	III
Darvon®	1	IV
Provigil®	1	IV
Versed®	1	IV

Source: OIG analysis of BOP institutions' inventory records

At each institution audited, we reviewed all relevant documents for controlled substances to account for every dose. We conducted an accountability audit consisting of a physical count of controlled substances during our review, and a review of all mainstock and substock records for a 1-year period. This included a review of documents related to purchases, disposals, administrations, and transfers. At the Springfield Medical Center we judgmentally selected a sample of nine controlled substances, and reviewed at least a 7-month period because of the large volume of use at the institution.[27]

Based on the results of our accountability audit, we found that BOP institutions did not always adequately account for and safeguard controlled substances. Specifically, we identified 402 unaccounted for doses of controlled substances out of a total of 42,125 that should have been on hand at the time of our inventory as shown in Figure 22.

[27] The Springfield Medical Center had 12 types of controlled substances consisting of 36 different strengths and forms (liquid vs. tablet).

FIGURE 22. UNACCOUNTED FOR CONTROLLED SUBSTANCES BY BOP INSTITUTION

Institution	Tablets	Others[28]	Total
Springfield Medical Center	**159.00**	**4.00**	**163.00**
Percocet®	*69.00*		*69.00*
Tylenol® with Codeine	*43.00*		*43.00*
Ativan®	*43.00*		*43.00*
Codeine	*2.00*		*2.00*
Phenobarbital	*2.00*		*2.00*
Duragesic®		*4.00*	*4.00*
La Tuna FCI	**98.00**	**1.50**	**99.50**
Tylenol® with Codeine	*60.00*		*60.00*
Klonopin®	*35.00*		*35.00*
Valium®		*3.00*	*3.00*
Andro®		*1.50*	*1.50*
Atwater USP	**46.00**	**39.00**	**85.00**
Lomotil®	46.00		46.00
Liquid Tylenol® with Codeine Elixir		39.00	39.00
Danbury FCI	**23.00**	**1.00**	**24.00**
Phenobarbital	*19.00*		*19.00*
Tylenol® with Codeine	*4.00*		*4.00*
Stadol®		*1.00*	*1.00*
Forrest City FCI (Low)	**11.00**		**11.00**
Tylenol® with Codeine	*10.00*		*10.00*
Phenobarbital	*1.00*		*1.00*
Oklahoma FTC	**5.00**		**5.00**
Percocet®	*4.00*		*4.00*
Phenobarbital	*1.00*		*1.00*
Atlanta USP	**4.00**		**4.00**
Percocet®	*2.00*		*2.00*
Klonopin®	*2.00*		*2.00*
Florence USP	**4.00**		**4.00**
Phenobarbital	*3.00*		*3.00*
Lomotil®	*1.00*		*1.00*
Florence FCI	**3.00**	**1.00**	**4.00**
Percocet®	*2.00*		*2.00*
Morphine	*1.00*		*1.00*
Valium®		*1.00*	*1.00*
Alderson FPC	**2.25**		**2.25**
Tylenol® with Codeine	*2.00*		*2.00*
Klonopin®	*0.25*		*0.25*
Florence ADX	**0**	**0**	**0**
Oxford FCI	**0**	**0**	**0**
Total	**352.25**	**49.50**	**401.75**

Source: OIG analysis of BOP Institutions

[28] "Others" category includes, liquid doses in milliliters, injectables, and patches.

A summary of our findings related to the missing controlled substances by institution is included in Appendix I.

Controlled Substance Recordkeeping Errors

Additionally, we found numerous errors in the controlled substances inventory records, which based on the inventory records alone, appeared to result in unaccounted controlled substances. We were able to resolve all of these discrepancies by reviewing additional documents. Although, these errors did not result in missing controlled substances, errors in the inventory records for controlled substances weaken the ability of the BOP to accurately account for and safeguard the controlled substances.

At the 12 institutions included in our audit, we reviewed the controlled substances records for the mainstock perpetual inventory and substock Proof of Use sheets to determine if the required information was complete and accurate.[29] As a result of our review, we identified two different types of errors relating to the records used to account for controlled substances: (1) errors that resulted in discrepancies in the controlled substances balance that could be resolved using inmates' MARs, and (2) missing or incomplete information in the mainstock and substock records, such as date, time, inmate number or name, and signature of person administering the medication. These errors were generally related to substock Proof of Use sheets, which are maintained by health services staff administering the controlled substances, and not the pharmacist. We noted many errors had been identified previously as deficiencies during the institutions' Operation and Program Reviews.

Specifically, we identified approximately 400 recordkeeping errors on the controlled substances inventories that appeared to result in unaccounted-for controlled substances. However, we were able to account for the controlled substances using additional documentation. The following types of errors comprise the majority of these issues.

- Transfer location not identified – we noted 133 instances where the transfer location was not identified in the mainstock or substock inventory;

- Incorrect number in the usage column – we noted 52 instances where the incorrect amount was entered into the usage column on the Proof of Use sheet;

[29] We sampled 9 of the 36 controlled substances at the Springfield Medical Center.

- "Floor charge" entries – we noted 46 instances where a prescription medication was removed from the OmniCell and shown as a "floor charge" rather than as an administration to a specific inmate, which would include the inmate's name and number; and

- Missing entry or amount in the usage column – we noted 77 instances where the amount administered was not entered in the usage column on the Proof of Use sheet.

We also noted the following errors on the inventory records for controlled substances:

- incorrect beginning inventory balance,

- incorrect dose subtracted from the balance column,

- doses administered that were not recorded,

- duplicate entries,

- incorrect strength shown for medication,

- inventory overstated,

- purchase not recorded in mainstock,

- disposal not recorded in mainstock,

- transfer not recorded in mainstock,

- incorrect transfer amount recorded in mainstock, and

- substock records show administered to pill line rather than to inmate.

In addition to these recordkeeping errors, we noted our physical count of controlled substances sometimes exceeded the balance on the inventory records. For example, at one institution we identified 32 extra Phenobarbital tablets from mainstock records that may have been caused by an unrecorded transfer of controlled substances with an inmate who transferred into the institution. There were also instances where the Proof of Use sheet had incorrect information, resulting in a physical count that exceeded the balance per the inventory record.

We also identified approximately 800 instances for which required information was not entered in the mainstock and substock inventory records, including the following:

- missing inmate name and, or number;
- missing inmate prescription medication number;
- missing date and time the prescription medication was administered; and
- missing signature of the person administering the prescription medication.

As stated previously, these errors weaken the ability of the BOP to adequately account for and safeguard controlled substances, which can result in missing or stolen medication. For example, as a result of inadequate recordkeeping, there was a theft of controlled substances from the Springfield Medical Center. According to an OIG Investigation, between June and December 2003, a Licensed Practical Nurse stole approximately 1,300 Percocet®, which the DEA labels a Schedule II controlled substance. The nurse was convicted in the United States District Court, Springfield, Missouri, for violation of Title 21, USC 844(a), Possession of Controlled Substances and sentenced to 3-years probation.

The investigation found that the nurse concealed the theft by altering and destroying various records for the controlled substances, because of poor recordkeeping at the facility. In fact, she concealed the theft for approximately 6 months. The nurse identified several factors that also contributed to her ability to steal the controlled substances. She noted that there were no supervisors or other independent persons that verified the controlled substances log sheets. In addition, the Proof of Use sheets were not routinely returned to the pharmacy in a timely manner, and when they were returned, the nurse did not believe that pharmacy staff reviewed the sheets to check for errors.

Controlled Substance Inventory

The DEA requires that each registrant conduct a biennial inventory of all controlled substances. In addition, the BOP requires that the mainstock is inventoried quarterly with results submitted to BOP headquarters, and that the substock is inventoried at each shift change, unless the institution is using an automated system.

According to federal regulations, "Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken . . . . Controlled Substances shall be deemed to be 'on hand' if they are in the possession of or under the control of the registrant, including substances returned by a customer."[30] We found quarterly inventories submitted to BOP headquarters did not always include all controlled substances. Specifically, we identified controlled substances at three institutions that should have been listed on the mainstock in the quarterly inventory:

- Atwater USP – 70 Lomotil® tablets located within a lock box in the pharmacy were not included in any inventory;

- La Tuna FCI – 53 Klonopin® tablets that were transferred in with an inmate but not included in the institution's quarterly controlled substances inventory; and

- Florence FCI – 7.2 milliliters of Andro® that were transferred in with an inmate but not included in the institution's quarterly controlled substances inventory.

We also found that 10 out of 12 institutions audited did not include controlled substances in substock quarterly inventories.[31] Pursuant to BOP policy, the institutions are only required to include mainstock in the quarterly controlled substances inventories. However, federal regulations require all controlled substances to be included in the inventories required by the DEA. Given the numerous recordkeeping errors related to controlled substances noted in this report, in our judgment, we believe it is important for the BOP to conduct a complete accounting of all controlled substances on a quarterly basis.

Administration of Controlled Substances

According to BOP policy, health service staff members, including mid-level practitioners, and medical and pharmacy technicians who have completed a Pharmacy Services Training Program can administer doses of controlled substance medications to inmates. The staff member administering the medication is required to record it on the Proof of Use

[30] Code of Federal Regulations, 21 C.F.R. (2004) § 1304.11.

[31] These institutions are, Florence FCI, Florence USP, Alderson FPC, Atlanta USP, Atwater USP, Danbury FCI, Forrest City FCI (Low), Oklahoma FTC, Oxford FCI, and Springfield Medical Center.

sheet and the MAR, immediately following administration of the controlled substance. Information recorded on the Proof of Use sheet must include the inmate's name, inmate number, date, time, dosage administered, and signature of the person who administered the controlled substance. The information recorded on the MAR, which is located in the inmate's medical file, should include the name, quantity, and strength of the controlled substance issued, as well as the date, time, and name of the person who administered the controlled substance.

At each of the 12 institutions included in our audit, we generally selected a sample of 20 controlled substances administered to inmates from the Proof of Use sheets except for Oklahoma FTC during the period September 2003 through April 2005. Our sample included a total of 245 administrations of controlled substances to inmates based on the information recorded on the Proof of Use sheets. We then compared the information recorded on the Proof of Use sheet to the inmate's MAR to verify that the inmate received the medication, and we determined if the institutions were in compliance with the BOP's requirements.

As shown in Figure 23, we found that the institutions did not always comply with the BOP's requirements for administering controlled substances to inmates.

FIGURE 23. ADMINISTRATION OF CONTROLLED SUBSTANCES REVIEW

Institution	Controlled Substance Reviewed	Missing MAR	MAR Not Signed	Other Issues
Alderson FPC	30	4	2	0
Atlanta USP	20	3	5	0
Atwater USP	20	3	0	15
Danbury FCI	20	3	2	0
Florence ADX	20	0	0	0
Florence FCI	21	0	0	0
Florence USP	20	0	0	2
Forrest City FCI (Low)	20	0	0	0
La Tuna FCI	24	4	6	0
Oklahoma FTC	10	0	0	0
Oxford FCI	20	2	2	0
Springfield Medical Center	20	7	1	0
Total	**245**	**26**	**18**	**17**

Source: OIG analysis of the BOP's review of the administration of controlled substances

Specifically, we found:

- for 26 controlled substance administrations, we were unable to locate the MAR in the inmate's medical file that covered the period during which the controlled substances were recorded as being administered; as a result, there are no assurances that the inmate received the medication;

- for 18 controlled substance administrations, the date of the administration per the inmate's MAR did not match the date recorded on the Proof of Use sheet; and

- for 17 controlled substance administrations, incorrect information was recorded on the Proof of Use sheet, including the inmate's name, or the information recorded on the MAR including prescription information and the dose administered did not match the Proof of Use sheet, or the inmate was given a medication without obtaining the required non-formulary waiver.

It is important that the required administration information of controlled substances is complete and accurate on the Proof of Use sheet and the MAR. Without accurate documentation the institution has no assurance that the medication was administered to the correct inmate or in

the correct dose. This weakens the institution's ability to account for or to detect theft of controlled substances.

Prescription Medications Purchasing

The BOP purchases its prescription medications through a "prime vendor" contract that is administered by the VA. During our audit, we identified inadequate internal controls related to purchasing, ordering, receiving, and paying for prescription medications. At each institution included in our audit, we found that there was no evidence of any segregation of duties related to purchasing of prescription medications. At 4 of the 12 institutions, either the Health Services Administrator (HSA) or the contracting officer signed a blanket purchase agreement for the entire year and delegated all responsibilities for ordering, receiving, and approving invoices for payment to the pharmacist. In addition, 5 of the 12 institutions audited, there was no documentation that the pharmacist verified the prescription medications received to the invoice. Furthermore, in 5 of the 12 institutions the person who ordered and received prescription medications was also the individual who signed off on the invoice before it was submitted to the business office for payment.

The lack of internal controls over the purchasing of prescription medications at BOP institutions allowed a Chief Pharmacist at the El Reno FCI to illegally purchase four different brands of non-formulary prescription medications. An OIG investigation found that he stole a total of 30,600 doses between July 2002 and February 2004, for his personal consumption. This individual's purchases included Fioricet®, Soma®, Ultram®, and Mobic®, and cost the BOP approximately $1,567 with a retail value of approximately $28,700. In lieu of prosecution, the Western District of Oklahoma offered the pharmacist a 1-year Pretrial Diversion Program and if all conditions are met, he will not be prosecuted. Adequate segregation of duties for purchasing and receiving of controlled substances would likely have prevented this theft.

Recommendations

We recommend the BOP:

7. Ensure all documentation related to controlled substances is accurate and complete.

8. Require all controlled substances, including those in the substock, crash cart, and other locations, are included in the quarterly inventories.

9. Develop and implement policies and procedures requiring the Health Service Administrator or an authorized designee to approve each prescription medication purchase order and verify the items received to each vendor invoice.

10. Develop and implement policies and procedures requiring adequate segregation of duties for ordering and receiving prescription medications.

III. PHARMACY COMPLIANCE

We found that the BOP pharmacies were not always in compliance with applicable BOP policies and procedures. At the 12 BOP institutions included in our audit, we found that 384 (35 percent) of the prescriptions reviewed were not in compliance with BOP policy. Specifically we found prescriptions for which: (1) the pharmacist's or physician's signature was not documented; (2) the separate written prescription form for controlled substances was not maintained; (3) required information was missing in inmates' medical files; (4) controlled substance prescription forms were missing a DEA registration number or required signature; and (5) the prescription time period exceeded the BOP policy for controlled substances. We also found 31 prescriptions (84 percent) for non-formulary medications and 14 purchases (47 percent) of non-formulary medications for which the required waivers were not obtained.

Prescription Review

In assessing compliance with BOP policies and procedures, we judgmentally selected a sample of about 100 prescriptions written from October 2003 through July 2005 at each institution audited, with the exception of the Oklahoma FTC.[32] Our sample generally consisted of 50 controlled and 50 noncontrolled substances prescriptions. If an institution did not have 50 prescriptions for controlled substances during the period, we increased our sample of noncontrolled substances for a total combined sample of about 100 prescriptions. Additionally, if the prescription selected from our sample was for an inmate that had been transferred or released, we verified the inmate's location by using the BOP's SENTRY system and replaced the sample with a new prescription since medical files are transferred with the inmates.

At the 12 institutions included in our audit, we selected a total of 1,107 prescriptions, including 488 prescriptions for controlled substances. For each prescription in our sample, we reviewed the inmate's medical file to ensure that the appropriate information such as prescription name, dosage, and instructions were recorded, and that the pharmacist's review was

[32] Over 80,000 inmates transfer through the Oklahoma FTC annually. Generally, the inmates are at the facility for an average of 14 to 30 days, and some inmates are at the facility for less than 24 hours. Therefore, we only reviewed a sample of 18 prescriptions at FTC Oklahoma because the medical files are transferred with inmates.

documented. In addition, we reviewed prescriptions for controlled substances to determine if separate prescription forms were completed, including all required information, and that the prescription was written for the allowable time period. We also reviewed prescriptions for non-formulary medications to determine if the required waivers had been obtained.

As shown in Figure 24, we found that 384 (35 percent) of the 1,107 prescriptions reviewed were not in compliance with applicable policies and procedures.

FIGURE 24. PRESCRIPTION REVIEW

Institutions	Controlled Substances Reviewed	Noncontrolled Substances Reviewed	Total Number of Findings[33]
Alderson FPC	50	50	2
Atlanta USP	50	50	101
Atwater USP	50	50	45
Danbury FCI	39	61	9
Florence ADX	11	79	3
Florence FCI	43	51	52
Florence USP	50	55	33
Forrest City FCI (Low)	50	50	24
La Tuna FCI	43	57	63
Oklahoma FTC	2	16	0
Oxford FCI	50	50	4
Springfield Medical Center	50	50	48
Total	**488**	**619**	**384**

Source: OIG analysis of the BOP's prescription review

We found 206 prescriptions for which the pharmacist's review for contraindications or physician's signature was not documented in the inmate's medical file. The majority of these prescriptions (93) were at the Atlanta USP. Officials there stated that pharmacists review prescriptions for contraindications but do not annotate their review in the inmate's medical chart because of a staffing shortage. At several other institutions, the pharmacist's review for contraindication was not documented because the prescription was faxed to the pharmacy. For example, at the Springfield Medical Center we found about 40 prescriptions that were faxed to the pharmacy from a nursing station and the faxed copy with the pharmacist's signature could not be retrieved. We also noted that as a result of faxing the prescriptions for contraindications, the pharmacist does not have the

[33] The total number of findings may include multiple errors for the same prescription.

inmate's medical chart, as required, to conduct a review of the prescription for contraindications.

Generally, at each of the 12 institutions, we found that the written prescriptions were included in the inmate's medical files and that the prescriptions contained the required information; however, we noted that 19 prescriptions were not in the inmate's medical file or lacked required information such as prescription name, dosage, and instructions.

As stated previously, our sample included 488 prescriptions for controlled substances. According to federal regulations, all prescriptions for controlled substances are required to include the physician's name, address, signature, and DEA registration number.[34] In addition, BOP policy requires that prescriptions for Schedule II controlled substances should be written for no more than 72 hours and that prescriptions for Schedule III through V controlled substances should not be written for more than 30 days, with up to 2 refills, not to exceed a total of 90 days.[35] Based on our review of 488 controlled substance prescriptions, we found:

- 54 controlled substance prescriptions for which the prescription forms were missing a DEA registration number or required signature;

- 24 controlled substances prescriptions for which the required separate written prescription forms were not maintained by the institution; and

- 20 prescriptions that were written for periods exceeding 72 hours for Schedule II controlled substances or 90 days for Schedule III through V controlled substances.[36]

On February 10, 2005, the Director of BOP Pharmacy Services distributed an e-mail to BOP pharmacists stating that separate prescription forms are no longer required for non-receiving and discharging controlled substance medication orders. Instead, prescriptions for controlled substances can be filled directly from the inmate's medical file since all BOP pharmacies are licensed with the DEA as a hospital or clinic, which was

[34] Code of Federal Regulations, 21 C.F.R. § 1306.05 (2004).

[35] BOP Program Statement No. 6000.05, *Health Services Manual*, updated February 11, 2000.

[36] Schedule II controlled substances can be written for 30 days if the medication is used in cases of chronic or terminal illness resulting in unremitting pain not likely to abate in the short term, or if it is used to treat narcolepsy.

verified with the DEA. However, the written prescription in the inmate's medical file must still contain the information required by federal regulations. In addition, BOP institutions are required to keep logs for prescription of controlled substances.

Non-Formulary Waivers

The BOP National Formulary (formulary) is a list of all prescription medications recommended as essential for inmate care and is used to help provide clinically appropriate, safe, and cost-effective prescription medications. The BOP Pharmacy and Therapeutics Committee, comprised of pharmacists and physicians from the institutions and the Central Office, develops and maintains the formulary. Physicians and pharmacists are generally required to limit prescriptions to those medications listed in the formulary. If a non-formulary prescription medication is deemed necessary for the treatment of an inmate, the prescriber is required to obtain a non-formulary Drug Authorization (waiver) requesting approval for the use of non-formulary medication to treat a specific inmate's needs.[37] The non-formulary waiver must be approved by the BOP Medical Director.

For each of the 1,107 prescriptions included in our sample, we determined whether or not the medication was included in the BOP formulary. For any non-formulary medications, we determined whether the required non-formulary waiver had been obtained. Our sample of 1,107 prescriptions included 37 prescriptions that were for non-formulary medications. Of the 37 non-formulary prescriptions identified from our sample, we found that for 31 prescriptions (84 percent) the required non-formulary waiver had not been obtained.[38]

In addition to reviewing the prescription sample to identify any non-formulary prescription medications for which the required waivers were not obtained, we also reviewed a sample of medications purchased. At each institution included in our audit, we obtained invoices for prescription medications purchased from October 2003 through July 2005 and selected a sample of at least 100 individual medications. Our total sample consisted of 1,198 prescription medications purchased during the period of October 2003

[37] BOP Program Statement No. 6501.06, *Pharmacy Technical Reference Manual*, updated February 28, 2001.

[38] This analysis includes prescriptions for each separate non-formulary prescription. For example, we found 23 instances where the same non-formulary medication was prescribed to the same inmate without the required waiver and this was counted as 23 separate non-formulary prescriptions without the required waiver.

through July 2005. We reviewed each prescription medication in our purchase sample to identify any non-formulary medications that were purchased and determined whether the required waiver had been obtained. Generally, the institutions included in our sample were in compliance with the BOP's requirements for non-formulary prescription medications; however, we found a total of 30 purchases for non-formulary medications, of which 14 purchases (47 percent) did not obtain the required non-formulary waiver.

Although we found that the institutions included in our audit were generally in compliance with the BOP's non-formulary medication requirements, we did identify an issue related to the non-formulary waivers that should be addressed. The BOP's current requirements allow non-formulary waivers to be issued for an indefinite period, which does not take into consideration changes in the inmate's medical condition or the availability of newer prescription medications. Therefore, in our judgment, the BOP should require that non-formulary waivers be renewed annually to ensure that the inmate's prescription is still medically necessary. In addition, since the BOP formulary is updated annually, this practice would allow the BOP to determine if another medication in the updated formulary may fulfill the need of the non-formulary prescription.

Recommendations

We recommend that the BOP:

11. Implement a policy that requires pharmacist reviews for contraindications are documented in the inmates' files.

12. Ensure that written prescriptions include all required information.

13. Ensure that non-formulary waivers are obtained and required to be renewed annually.

OBJECTIVES, SCOPE, AND METHODOLOGY

The DOJ OIG conducted this audit to evaluate the BOP Pharmacy Services. The objectives of our audit were to:

- evaluate the BOP's efforts to reduce its increasing costs of prescription medications;
- assess whether the BOP ensures adequate controls and safeguards over prescription medications; and
- assess whether the BOP pharmacies are in compliance with applicable laws, regulations, policies, and procedures.

We conducted our audit in accordance with the *Government Auditing Standards*. We included such tests as were considered necessary to accomplish the audit objectives. The audit generally covered, but was not limited to, the period of October 2003 through July 2005. We conducted audit work at the sites shown in Figure 25.[39]

FIGURE 25. BOP INSTITUTIONS VISITED

Institution	Location
Alderson FPC	West Virginia
Atlanta USP	Georgia
Atwater USP	California
Danbury FCI	Connecticut
Florence ADX	Colorado
Florence FCI	Colorado
Florence USP	Colorado
Forrest City FCI (Low)	Arkansas
La Tuna FCI	New Mexico
Oklahoma City FTC	Oklahoma
Oxford FCI	Wisconsin
Springfield Medical Center	Missouri

To evaluate the BOP's efforts to reduce its increasing costs of prescription medications, we analyzed the BOP's Central Fill proposal. Our

[39] We also visited the Englewood FCI, Colorado, to obtain background information; however, Englewood FCI is not included in our results.

analysis included a comprehensive review of the cost-benefit analysis conducted by the BOP in support of the Central Fill proposal. We analyzed purchasing data for the six institutions included in the BOP's analysis during the period of March 2003 to February 2004, and compared it to pricing information provided by the VA, in order to determine estimated gross purchase savings. In addition, we analyzed the BOP's estimate of savings from the elimination of waste by conducting a survey of all BOP pharmacists to determine the percentage of waste that would be reduced by Central Fill. We also analyzed the number of prescriptions and percentage of prescription medication costs that would use Central Fill and determined their impact on the cost-benefit analysis.

To determine estimated prescription medication costs related to waste and other issues, we surveyed all 126 BOP pharmacists. We received responses to 106 (84 percent) surveys. The survey consisted of 40 questions and covered the following topics: (1) training and assessment; (2) access and security; (3) purchasing and receiving; (4) OTC medication; (5) waste and returns; (6) Central Fill; (7) Central Processing; and (8) other areas.

To determine whether the BOP's OTC program statement had been fully implemented, we reviewed OTC medications prescribed at the institutions to ensure that inmates were being referred to the commissary. When appropriate, we also conducted interviews of staff and included questions in our survey to determine the progress towards implementation of the policy throughout the BOP.

To determine whether the BOP ensures adequate controls and safeguards over controlled substances, we reviewed all controlled substances at 11 of the 12 sites included in our audit and identified deficiencies related to the records used to account for controlled substances. Specifically, we performed an accountability audit of controlled substances, which compared the physical inventory that we conducted on site, to an inventory conducted at least 1-year prior to our audit. At the Springfield Medical Center, we judgmentally sampled a selection of 9 of the 12 controlled substances maintained, and conducted an accountability audit that included at least 7 months of data. The accountability audit consisted of:

- conducting a physical inventory;
- adding prescriptions, disposals, and transfers out;
- subtracting out the beginning inventory balance; and

- subtracting out purchases and transfers in.

All controlled substances were accounted for if the result of the calculation was equal to zero. If the total was not equal to zero, we reviewed additional documentation to attempt to account for all controlled substances. During the accountability audit we reviewed the following records:

- mainstock perpetual inventory, which includes purchases, transfers in from the substock, transfers out to the substock, and disposal of controlled substances;

- substock Proof of Use sheets, also known as certificates of disposition, which are used to record the transfers in from the mainstock, the administration of controlled substances to inmates, and transfers back to the mainstock;

- inmates' MARs, which are used to record the administration of a controlled substance to an inmate;

- DEA 222 form for the disposal and purchase of controlled substances;

- controlled substance invoices from the prime vendor; and

- disposal records provided to the institution by the returns company.

To determine whether the BOP had adequate controls over prescription medication purchases, we reviewed five purchases from the prime vendor and ensured that documentation was maintained and signed off by a supervisor. In addition, we reviewed up to 10 purchases from sources other than the prime vendor to ensure proper documentation. During interviews with pharmacists and the HSA, we asked for detailed descriptions of how the ordering, approving, receiving, and paying processes worked.

To determine whether the BOP pharmacies were in compliance with applicable laws, regulations, policies, and procedures, we selected a sample of approximately 100 prescriptions written from October 2003 through July 2005 at each institution we audited, with the exception of the Oklahoma FTC. Our prescription sample generally consisted of 50 controlled and 50 noncontrolled substances. If an institution did not have 50 prescriptions for controlled substances during the period, we increased our sample of noncontrolled substances for a total sample of about 100 prescriptions. Additionally, if the prescription selected from our random sample was for an inmate that had been transferred or released, we verified

the inmate's location by using the BOP's SENTRY system and replaced the sample with a new prescription, because medical files are transferred with the inmates.

For each prescription included in our sample, we reviewed the inmate's medical file to ensure that the appropriate information, such as prescription name, dosage, and instructions were recorded, and that the pharmacist's review was documented. In addition, we reviewed prescriptions for controlled substances to determine if separate prescription forms were completed – including the required information – and to determine if the prescription was written for the allowable time period. For each of the prescriptions included in our sample, we determined whether or not the medication was included in the BOP formulary. For any non-formulary medications, we determined whether the required non-formulary waiver had been obtained.

At each institution included in our audit, we also obtained invoices for prescription medications purchased from October 2003 through July 2005 and selected a sample of at least 100 individual medications. We reviewed each prescription medication in our purchase sample to identify any non-formulary medications that were purchased and determined whether the required waiver had been obtained.

In addition, at each site, except Oklahoma FTC, we judgmentally selected at least 20 administrations of controlled substances and ensured that the information on the Proof of Use sheets and MARs agreed. At Oklahoma FTC we only reviewed 10 administrations due to the constant transferring of inmates and their records. We selected our sample based on the Proof of Use sheet and then obtained the inmate's MAR from their medical file and ensured that the MAR agreed with all the information, including drug name, strength, date, time, and quantity.

STATEMENT ON COMPLIANCE WITH LAWS AND REGULATIONS

As required by the *Government Auditing Standards,* we tested the BOP's records and documents pertaining to Pharmacy Services and prescription medications to obtain reasonable assurance that the BOP complied with laws and regulations that, if not complied with, in our judgment could have a material effect on the BOP's administration of Pharmacy Services. Compliance with laws and regulations related to prescription medications is the responsibility of BOP management. An audit includes examining, on a test basis, evidence about compliance with laws and regulations. At the time of our audit, the pertinent legislation and the applicable regulations were:

- Code of Federal Regulations, 21 C.F.R. (2004)
- BOP Program Statement No. 6000.05, *Health Services Manual*, updated February 11, 2000
- BOP Program Statement No. 6501.06, *Pharmacy Technical Reference Manual,* updated February 28, 2001
- BOP Program Statement No. 6541.02, *Over-the-Counter Medications,* dated November 17, 2004
- BOP Program Statement No. 6360.01, *Pharmacy Services,* dated January 15, 2005
- BOP *Health Services National Formulary 2003*, dated January 8, 2003
- BOP *Health Services National Formulary 2004*, dated February 17, 2004

Except for the issues discussed in the Findings and Recommendations section of this report, nothing came to our attention that caused us to believe that BOP management was not in compliance with the laws listed above.

STATEMENT ON INTERNAL CONTROLS

In planning and performing our audit of the BOP's Pharmacy Services, we considered the BOP's internal controls for the purpose of determining our auditing procedures. The evaluation was not made for the purpose of providing assurance on the internal control structure as a whole; however, we noted certain matters that we consider reportable conditions under generally accepted government auditing standards.[40]

Finding II

- The BOP did not ensure that records for controlled substances, including the mainstock and substock inventory, Proof of Use sheets, and quarterly inventories, were accurate and complete.

- The BOP did not ensure that the Health Services Administrator or an authorized designee approved and verified all purchase orders and verified items received to the vendor invoices for all prescription medications.

- The BOP did not ensure that the administration of controlled substances was properly documented on inmates' Medication Administration Records.

- The BOP did not ensure that there was adequate segregation of duties for ordering and receiving of prescription medications.

Finding III

- The BOP did not ensure that its institutions were in compliance with regulations related to prescriptions for controlled substances.

- The BOP did not ensure that prescriptions in inmates' medical files contained the required information, including documentation of the pharmacists' reviews for adverse interactions.

[40] Reportable conditions involve matters coming to our attention relating to significant deficiencies in the design or operation of the internal control structure that, in our judgment, could adversely affect the ability of the BOP to administer its Pharmacy Services.

Because we are not expressing an opinion on the BOP's overall internal control structure, this statement is intended solely for the information and use of the BOP in managing its Pharmacy Services.

APPENDIX I

DETAILS OF UNACCOUNTED FOR CONTROLLED SUBSTANCES

Springfield Medical Center

We were unable to account for 69 Percocet® tablets, 43 Tylenol® with Codeine tablets, 43 Ativan® 1 mg tablets, 2 Codeine 30 mg tablets, 2 Phenobarbital 30 mg tablets, and 4 Duragesic® 75 mg patches. The 69 Percocet tablets were related to 39 errors on the substock Proof of Use sheets that could not be resolved using the inmates' MARs. These errors include:

- Twenty transactions that showed a decrease in the balance column, for which a corresponding amount administered was not recorded in the usage column, for a difference of 38 tablets; and

- Nineteen transactions recorded in the usage column that did not match the change in the balance column, for a difference of 31 tablets.

The 43 missing Tylenol® with Codeine tablets were related to 19 errors on the substock Proof of Use sheets that could not be reconciled with the inmates' MARs. These errors include:

- Eleven transactions that showed a decrease in the balance column, for which a corresponding amount administered was not recorded in the usage column, for a difference of 22 tablets;

- Seven transactions recorded in the usage column that did not match the change in the balance column, for a difference of 19 tablets; and

- One transaction of a return to substock that was not added to the inventory balance, for a difference of 2 tablets.

For the 43 missing Ativan® tablets, we found:

- The mainstock records showed a transfer out of 140 tablets to the substock, in January 2005. However, the corresponding substock records only showed a transfer in of 122 doses, resulting in 18 unaccounted for tablets;

- Two decreases in the substock inventory that could not be accounted for with an inmate's MAR, for a difference of 11 tablets;

- The mainstock records showed 1 transfer out of 10 tablets to the substock in December 2004. We were unable to account for the medication being transferred in on the corresponding substock records, resulting in 10 unaccounted for tablets; and

- Three transactions recorded in the usage column did not match the change in the balance column, for a difference of 4 tablets.

The remaining 8 missing controlled substances (2 Codeine 30 mg tablets, 2 Phenobarbital 30 mg tablets, and 4 Duragesic® 75 mg patches) resulted from several transactions errors.

La Tuna FCI

We were unable to account for 60 Tylenol® with Codeine tablets, 35 Klonopin® tablets, 3 Valium® vials, and 1.5 milliliters of liquid Andro®.

- For the 60 missing Tylenol® with Codeine tablets, the mainstock records showed transfers out totaling 122 tablets to the camp between June and August 2004. The corresponding substock records at the camp, however, only showed total transfers in of 62 tablets, resulting in 60 unaccounted for tablets.

- For the 35 missing Klonopin®, we found the institution received a total of 58 tablets that were transferred to the facility with an inmate. Using the inmate's MAR, we were able to determine that 23 of the 58 tablets were administered to the inmate during June and July 2004. However, we were unable to account for the remaining 35 tablets. In addition, we noted that the Klonopin® tablets were not recorded as part of the institution's quarterly controlled substances inventory.

- For the three missing Valium® , we found the substock records at the Federal Satellite Location in El Paso, Texas, showed a transfer out of three vials to La Tuna FCI in March 2004. However, La Tuna FCI did not have a record of receiving the medication, resulting in three unaccounted for vials.

Atwater USP

We were unable to account for 46 Lomotil® tablets and 39 doses of Liquid Tylenol® with Codeine Elixir.

- The mainstock records showed 3 transfers of 100 tablets to one inmate between January and February 2005. We examined the inmate's corresponding MAR and were able to verify the administration of 254 tablets, leaving 46 unaccounted tablets. We noted that the 300 tablets were not recorded in the substock.

For the 39 missing Liquid Tylenol® with Codeine Elixir:

- The mainstock records showed 3 transfers of 10 doses each to the OmniCell between September and December 2004. We reviewed the OmniCell records and were unable to account for the medication being transferred, resulting in 30 unaccounted-for doses;

- The mainstock record showed a transfer out of 20 doses to the OmniCell in February 2005. However, the corresponding OmniCell records only showed a transfer in of 12 doses, resulting in 8 unaccounted-for doses; and

- The mainstock records showed a transfer out of 10 doses to the substock, in August 2004. However, the corresponding substock records only showed a transfer in of 9 doses, resulting in 1 unaccounted-for dose.

Initially, our tests were unable to account for 1,391 controlled substances. Subsequent to our review, the staff at USP Atwater provided additional documents showing the existence of a second substock that we were not aware of during our initial visit. The additional information helped to account for the majority of missing controlled substances. Nevertheless, we were still unable to account for the 46 Lomotil® tablets and the 39 doses of Liquid Tylenol® with Codeine Elixir.

Danbury FCI

We were unable to account for 19 Phenobarbital tablets, 4 Tylenol® with Codeine tablets, and 1 milliliter of liquid Stadol®. These missing drugs were related to decreases in the balance column on the substock Proof of Use sheets, for which no amount was recorded in the corresponding usage column. On each occasion, the substock records

identified the inmate's name and number; however, we were unable to verify the administration of the tablets using the inmate's MAR.

Forrest City FCI (Low)

We were unable to account for 10 Tylenol® with Codeine tablets and 1 Phenobarbital tablet. For the 10 missing Tylenol® with Codeine, the mainstock records show a transfer out of 10 tablets to the medium security facility in September 2004. We were unable to account for the medication as being transferred in, on the corresponding records for the Forrest City FCI medium security facility. For the missing Phenobarbital tablet, the mainstock records show a transfer out of 30 tablets to the camp in October 2004, and a return transfer of 29 tablets from the camp on December 2004, resulting in 1 unaccounted for tablet. The camp did not maintain records showing either transfer or that the missing tablet was given to an inmate.

All Other Institutions

At the remaining seven institutions, controlled substances were generally accounted for; however, we found some minor issues at the following five institutions:

- **Oklahoma FTC –** We were unable to account for four Percocet® tablets, and one Phenobarbital tablet because errors in the usage column of the substock Proof of Use sheet could not be resolved using the inmates' MARs.

- **Atlanta USP –** We were unable to account for two Percocet® tablets, and two Klonopin® tablets because errors in the usage column of the substock Proof of Use sheet could not be resolved using the inmates' MARs.

- **Florence USP –** We were unable to account for three Phenobarbital tablets and one Lomotil® tablet because errors in the usage column of the substock Proof of Use sheet could not be resolved using the inmates' MARs.

- **Florence FCI –** We were unable to account for two Percocet® tablets, one Morphine tablet, and one Valium® injectable because errors in the usage column of the substock Proof of Use sheet could not be resolved using the inmates' MARs, and discrepancies in the disposals reported by the institution and the returns company.

- **Alderson FPC –** We were unable to account for two Tylenol® with Codeine tablets and a quarter tablet of Klonopin® 1 mg because errors in the usage column of the substock Proof of Use sheet could not be resolved using the inmates' MARs.

CONTROLLED AND NONCONTROLLED SUBSTANCES

Brand Name	Generic Name for Controlled Substance	Usage
Ativan®	Lorazepam	Anxiety
Andro®	Depo-Testosterone	Testosterone Hormone
Android-10®	Methyltestosterone	Hormone
Darvon®	Propoxyphene	Pain
Demerol®	Meperidine	Moderate to Severe Pain
Dolophine®	Methadone	Narcotic Addiction
Duragesic®	Fentanyl	Pain
Klonopin®	Clonazepam	Seizure
Lorcet®	Propoxyphene with Acetaminophen	Mild to Moderate Pain
Lomotil®	Diphenoxylate and Atropine Sulfate	Anti-Diarrheal
MSIR®	Morphine	Severe Pain
Percocet®	Oxycodone with Acetaminophen	Moderate Pain
Provigil®	Modafinil	Sleep Apnea
Ritalin®	Methylphenidate	Attention Deficit Hyperactivity Disorder
Roxicodone®	Oxycodone	Moderate to Severe Pain
Stadol®	Butorphanol	Pain
Solofton®	Phenobarbital	Seizure
Tylenol® with Codeine	Acetaminophen with Codeine	Moderate Pain
Tylenol® with Codeine Elixir	Acetaminophen with Codeine	Moderate Pain
Valium®	Diazepam	Anxiety
Versed®	Midazolam	Sedative
Xanax®	Alprazolam	Anxiety
(None)	Codeine	Pain

Brand Name	Generic Noncontrolled Substance	Usage
Advil®	Ibuprofen	Anti-Inflammatory
Aleve®	Naproxen Sodium	Anti-Inflammatory
Aller-Chor®	Chlorpheniramine	Allergies/Allergic Reaction
Bayer®	Aspirin	Fever, Pain, Inflammation
Copegus®	Ribavirin	Hepatitis C
Cortaid®	Hydrocortisone Cream	Skin Irritations
Ex-Lax® Milk of Magnesia	Magnesium Hydroxide	Constipation
Fiberall®	Psyllium	Diarrhea or Constipation
Fioricet®	Butalbital	Mild to Moderate Pain
Maalox®	Simethicone	Excess Gas
Mobic®	Meloxicam	Arthritis
Mylanta®	Aluminum with Magnesium Hydroxide	Antacid
Nasalide®	Flunisolide	Nasal Congestion
Selsun Blue®	Selenium	Dandruff
Soma®	Carisoprodol	Muscle Relaxer
Sular®	Nisoldipine	Blood Pressure
Tinactin®	Tolnaftate	Skin Infections
Tylenol®	Acetaminophen	Mild to Moderate Pain
Ultram®	Tramadol	Pain Relief
Videx®	Didanosine	HIV
Zocor®	Simvastatin	Cholesterol

U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director

Washington, DC 20534

October 24, 2005

MEMORANDUM FOR GUY K. ZIMMERMAN
ASSISTANT INSPECTOR GENERAL FOR AUDIT
OFFICE OF THE INSPECTOR GENERAL

FROM: Harley G. Lappin, Director

SUBJECT: Response to the Office of Inspector General's (OIG) Report: Audit of the Federal Bureau of Prisons Pharmacy Services

The Bureau of Prisons (BOP) appreciates the opportunity to comment on and respond to the recommendations from the OIG's report entitled Audit of the Federal Bureau of Prisons Pharmacy Services.

Twelve BOP institutions were selected for on-site visits as part of the audit. It was explained each was selected simply to ensure all types of facilities would be included (i.e., USP, FCI, FPC, FCC, MCC, MDC, and FTC), and that the institutions were not randomly selected. Although no major findings were identified it may not be appropriate to extrapolate the findings to all BOP institutions. The 12 selected institutions may not be a true representation of all BOP institutions in regards to institution type, region, size, Program Review findings, Joint Commission on Accreditation of Health Organization (JCAHO) review scores, American Correctional Association (ACA) findings, staffing levels, staffing shortages, etc. As such, selection bias may have a role in the findings.

Page iii of the Executive Summary states, "The BOP attributes the increase in its prescription medication costs to various reasons, including the: (1) increase in inmate population, and (2) increasing prices of prescription medications as shown in

Figure 2." Other major and more specific contributing factors for increased medication costs, within and outside the BOP, should be referenced and include: new drug modalities for diseases such as HIV (e.g., Fuzeon™) and hepatitis C (e.g., interferon and ribavirin), atypical antipsychotics, advances in chemotherapy treatments; lack of community resources for persons with mental illness resulting in incarceration; increased vigilance and aggressive therapy by national guidelines such as the National Cholesterol Education Program (NCEP) and lipid levels, American Diabetes Association and glycosylated hemoglobin levels, and increased diagnosis and expanded treatment recommendations of chronic hepatitis C treatment; HIV patients are living longer and hence taking many medications for longer periods of time; need for the utilization of the newer HIV medications for BOP patients as these patients often come into the system heavily treatment experienced, accompanied with significant HIV resistance patterns; increased duration of release medications to improve continuity of care and transition into the community. It should be noted that appropriate medication therapy and monitoring, while possibly increasing medication expenditures, often play a role in reducing healthcare expenditures by improving overall patient outcomes.

OIG assessed the pharmaceutical per capita cost increase from 2000 to 2002 which BOP agrees is the most appropriate means to evaluate trends related to pharmaceutical expenditures. As noted, there was a 79 percent increase during this period which translates into a 15.8 percent per capita per year increase. This is consistent with the United States Department of Health and Human Services statistics for prescription medication cost increases of 15 to 16 percent from 1995 to 2002 represented by Figure 2, page 3 of the report. However, we do not concur with the appropriateness of the comparison between BOP prescription drug costs and the change in Consumer Prescription Drug Costs represented in Figure 2, page iii, and Figure 5, page 7. This comparison does not take into account any covariables between the data such as age, population growth, and gender. The BOP population is not identical to the U.S. population in relation to these covariables. Severely mentally ill and hepatitis C infected individuals are represented at a much higher prevalence within the BOP and correctional agencies in general, than in the population at large. As such, this comparison may graphically inflate any differences between BOP purchases and Consumer Prescription Drug Costs. We believe a better comparison is made by utilization of per capita costs as referenced above.

We have undertaken several initiatives to reduce overall healthcare costs, as well as improve patient care, which were not

addressed in the report. One such initiative is the BOP National Formulary which was cited as a model program on pages 138 and 392 of the June 2002 publication Criminal Justice/Mental Health Consensus Project. Other initiatives include the BOP Clinical Practice Guidelines and the Inmate Copayment Program Policy.

Please find the Bureau's response to each individual recommendation below:

Recommendation #1: Conduct a complete and accurate cost-benefit analysis of the Central Fill proposal before deciding whether to proceed with implementation.

Response: We agree with your recommendation. As pointed out in your cost adjustments, many of which were based upon differing assumptions between BOP and OIG, we realize that there will always be some variables. Taking into consideration your cost adjustments in relation to the BOP analysis and how Central Fill is inextricably linked to an overall pharmacy transformation, our final review of the entire process to include further analysis of our plan, has confirmed a need to centralize this function; and I have made the decision to move forward with our plans to implement Central Fill, Central Processing, and increased Clinical Pharmacy Services. We believe this is supported and consistent with ongoing initiatives within other government agencies as well as the private sector. We will keep you apprized of our progress in this endeavor and provide updates as we reach milestones in our strategic plans for this initiative.

Recommendation #2: Pursue efforts to request that Congress amend Pub. L. No. 102-585 (1993) to provide the BOP with eligibility for Big 4 pricing.

Response: We agree with this recommendation. This proposal was one of the BOP's internal legislative initiatives prior to the commencement of the OIG audit. Our intentions, to coordinate with the Department of Justice and pursue this initiative, were shared with the OIG at the beginning of the audit. The BOP will continue to work with the Department regarding this proposal.

Recommendation #3: Ensure BOP pharmacy staff search for the lowest possible prescription medication prices within the FSS.

Response: We agree with this recommendation. The following statement is now included in the 2005 BOP National Formulary: "The least expensive generic equivalent is to be utilized when available, otherwise non-formulary approval is required." Additionally, page 6 of the Pharmacy Services Program Statement

6360.01, dated January 15, 2005, states: "All institutions will use the least expensive A/B rated generic when possible." The Health Services Program Review Guidelines will be revised to incorporate a review step to assess pharmacists compliance with this requirement by December 31, 2005.

Recommendation #4: Implement a system that would ensure that prescription medications are transferred with the inmates, by taking into account security issues.

Response: We agree with this recommendation. There have been generalized discussions concerning this specific issue for some time. It should be recognized that application of any such policy is extraordinarily difficult because of security and safety concerns of the staff assisting with transfer, as well as the inmate. This was most recently discussed during the Health Services Division and National Union's policy development workgroup. Appropriate Union concerns and security issues were discussed including the fact inmates are not aware of when they are moving, so medications cannot be obtained from their possession prior to preparing for transfer. This is imperative for the safety of BOP staff. Inmates are often prepared for transfer after normal working hours when a pharmacist is not onsite to verify appropriateness or identity of medications. This can risk patient safety as the potential exists for adulteration or mislabeling of medications by the inmate while they are in their possession. Lastly, this creates a mechanism for the potential smuggling of contraband. We will revise policy by June 30, 2006.

Recommendation #5: Ensure that prescription medication confiscated from an inmate is returned to the pharmacy for reissuance to the same inmate or is disposed of properly.

Response: We agree with this recommendation. It is agreed, we should always strive to reissue chronic medications when appropriate and not confiscate them when inappropriate. It should also be noted some waste is unavoidable due to therapy changes, patient non-compliance, non-use of "as needed" medications, or medications associated with treatment of an acute condition which are not taken as directed. The current Pharmacy Services Program Statement 6360.01, dated January 15, 2005, page 22, includes the following direction:

- **Medications for Inmates in Special Housing Units**
  - Local procedures will be developed and negotiated to retrieve the inmate's confiscated medication.

Health Services staff will determine if the medication should be administered or redistributed to the inmate, if appropriate.

- Under no circumstances will medication be locked up with the inmate's property, thrown in "hot trash," or distributed or administered to an inmate by anyone other than a health care provider.

Additionally, on page 7 it states, "Discontinued and outdated drugs and containers with worn, illegible, or missing labels will be returned to the pharmacy for proper disposition."

We will revise policy by June 30, 2006. In addition, the Health Services Program Review Guidelines will be revised to incorporate a review step to evaluate compliance with this procedure by December 31, 2005.

Recommendation #6: Ensure that all BOP institutions comply with the OTC policy.

Response: We agree with this recommendation. Since completion of the audit this specific issue has been addressed through revision of the Health Services Program Review Guidelines. The revised steps are 1.5.11.d and 1.7.14. (See attached.) We request this recommendation be closed.

Recommendation #7: Ensure all documentation related to controlled substances is accurate and complete.

Response: We agree with this recommendation. We understand OIG is evaluating us based on our own policy; however, the acceptable compliance rate or threshold of OIG is unclear. The Bureau has much higher standards regarding accountability of controlled substances, per our policy, than expected in the community or as required by law. While we strive for an error rate of zero, this may not be realistic in a paper driven or even electronic medium as human administrative errors will always exist. The report insinuates only a 100 percent compliance rate is acceptable. Pages iii and 40 of the report refer to 402 unaccounted for doses, which represents less than a 1 percent error rate (402 doses/42,125 doses = 0.95 percent). There were no trends or outliers identified within the report.

Documentation and accountability of controlled substances within an institution are thoroughly reviewed through the BOP Program Review process. Several steps (1.7.1.a - e, 1.7.4 through 1.7.12) within the Health Services Program Review Guidelines

address this specific issue. (See attached.) We will continue to review potential electronic processes to assist in decreasing documentation and accountability errors. Based on our own internal review process and the extremely low percentage of non-compliance identified by OIG, we request this recommendation be closed.

Recommendation #8: Require all controlled substances, including those in the substock, crash cart, and other locations, are included in the quarterly inventories.

Response: We agree with this recommendation. It should be noted the intent and type of data collected for the quarterly inventory for substock is different from what is needed for the quarterly inventory for main stock. The Quarterly Controlled Substance Inventory for Main Stock is a mechanism for trending controlled substance use by Central Office. The purpose of the DEA biennial inventory is different than that of the Quarterly Controlled Substance Inventory for Main Stock. The DEA biennial inventory is required by the DEA to obtain a snapshot of all controlled substances within the institution. This results in a reference point which can be analyzed against all invoices, administrations, substock transfers, etc., in the event the DEA audits a DEA licensed institution.

As a trending tool, the Quarterly Controlled substance inventory is concerned with movement through the main stock. Adding substocks to the Quarterly Controlled Substance Inventory would add no value for this trending by Central Office. Having a separate substock quarterly inventory, however, could potentially provide further control and oversight at the institution level above those already in place by the required perpetual substock inventory and shift inventories.

It is hopeful the Electronic Medical Record (EMR) Pharmacy Module initiative will eventually result in the ability to completely automate the controlled substance main stock, substock, administration disposition sheets, and the medication administration records. This would create the ability to monitor controlled substance activities by tying an electronic inventory system with the administration of the medication. This may result in the ability to monitor electronically, negating the need for the labor intensive Quarterly Controlled Substance reports. Discussion with the EMR vendor in this regard is ongoing.

In the interim, we will revise the pharmacy policy to address completion of a separate Quarterly Controlled Substance Inventory

for Substock. We anticipate completing the policy revision by June 30, 2006.

Recommendation #9: Develop and implement policies and procedures requiring the Health Service Administrator or an authorized designee to approve each prescription medication purchase order and verify the items received to each vendor invoice.

Response: We agree with this recommendation. We are hopeful the EMR Pharmacy Module initiative will result in the ability to assist with medication monitoring activities by tying an electronic inventory system and the dispensing activity through the pharmacy module. This has been discussed with the EMR vendor. However, we believe this would be best accomplished by someone other than the Health Services Administrator (HSA). As administrators, many HSA's will not know formulary status, or be familiar with medication names to provide appropriate oversight.

It should be noted our current system does not vary with the standard mechanism found within the community. Additionally, if one or more pharmacy personnel are present, peer oversight would be inherent because of the physical proximity, overlapping duties, and oversight of the Chief Pharmacist.

Central Fill and associated centralized inventory will greatly assist in this area.

We will review potential processes for inclusion in policy until such time as the EMR Pharmacy Module can accommodate this function. We anticipate completing revisions to the pharmacy policy by June 30, 2006.

Recommendation #10: Develop and implement policies and procedures requiring adequate segregation of duties for ordering and receiving prescription medications.

Response: We disagree with this recommendation. This recommendation is in essence a redundancy of recommendation #9. If a new procedure is appropriately found and implemented, this recommendation will not be necessary. Segregation of duties would be very difficult as this is a primary responsibility of the pharmacy department with little knowledge by anyone outside of the pharmacy department. Central Fill and associated centralized inventory will greatly assist in this area. We request this recommendation be closed based on the planned corrective actions identified for recommendation #9.

Recommendation #11: Implement a policy that requires pharmacist reviews for contraindications are documented in the inmates' files.

Response: We agree with this recommendation. The pharmacy policy will be revised to require a pharmacist's signature indicating the review of contraindications. We anticipate the policy revision will be completed by June 30, 2006.

Recommendation #12: Ensure that written prescriptions include all required information.

Response: We agree with this recommendation. Pharmacy Services Program Statement 6360.01, dated January 15, 2005, on pages 27-28 states, "Medication orders written in the health record and inpatient record, must be complete and will include:

- drug name;
- route and site of administration;
- dosage form;
- dose;
- strength;
- frequency of administration;
- duration of therapy; and
- prescriber's name."

On page 19 it states, "**DEA Controlled Substances.** The physician or dentist will initiate or countersign the medication order in the health record which will include:

- controlled substance;
- DEA number;
- strength;
- directions; and
- duration of therapy."

The Health Services Program Review Guidelines will be revised to evaluate compliance with this requirement by December 31, 2005.

Recommendation #13: Ensure that non-formulary waivers are obtained and required to be renewed annually.

Response: We agree with this recommendation. We agree the clinical status of patients may change which may necessitate further evaluation of a non-formulary medication.

Efforts are underway to ensure implementation of annual review with the EMR Pharmacy Module application. It is hopeful the EMR Pharmacy Module will electronically force formulary compliance through the electronic Prescriber Order Entry and Non-Formulary Request moieties rather than relying on manual tracking and audits.

It should be noted only 31 out of 1107 prescriptions reviewed did not have non-formulary approval (2.8 percent) and that 23 of these instances were for the same drug for the same inmate.

We will revise the pharmacy policy, by June 30, 2006, to require all non-formulary waivers be renewed annually.

If you have any questions regarding this response, please contact Michael W. Garrett, Senior Deputy Assistant Director, Program Review Division, at (202) 616-2099.

OFFICE OF THE INSPECTOR GENERAL COMMENTS ON THE BOP RESPONSE TO THE DRAFT REPORT

The OIG has identified several issues in the BOP response to our draft report (see Appendix III) that we believe should be addressed. Before addressing each response to the OIG recommendations in turn, we are providing the following comments on the BOP response to the draft report.

In Appendix III, page 69, the BOP provided the following general statement in response to the audit:

> *The 12 selected institutions may not be a true representation of all BOP institutions in regards to institution type, region, size, Program Review findings, Joint Commission on Accreditation of Health Organization (JCHO) review scores, American Correctional Association (ACA) findings, staffing levels, staffing shortages, etc. As such, selection bias may have a role in the findings.*

The OIG disagrees with the BOP suggestion that selection bias may have a role in the findings. We solicited the BOP's input when selecting the 12 BOP institutions for on-site visits. In addition, we provided pharmacists at all BOP facilities with the opportunity to complete an anonymous questionnaire that included questions about many of the issues addressed in the OIG recommendations. We received responses from 84 percent of the BOP pharmacists (106 responses out of 126 questionnaires sent), which, in our judgment, is a fair representation of all BOP institutions.

In Appendix III, page 70, the BOP provided the following general statement in response to the audit:

> *Other major and more specific contributing factors for increased medication costs, within and outside the BOP, should be referenced. . . It should be noted that appropriate medication therapy and monitoring, while possibly increasing medication expenditures, often play a role in reducing healthcare expenditures by improving overall patient outcomes.*
>
> *OIG assessed the pharmaceutical per capita cost increase from 2000 to 2002 which BOP agrees is the most appropriate means to evaluate trends related to pharmaceutical expenditures. . . However, we do not*

concur with the appropriateness of the comparison between BOP prescription drug costs and the change in Consumer Prescription Drug Costs represented in Figure 2, page iii, and Figure 5, page 7. . . As such, this comparison may graphically inflate any differences between BOP purchases and Consumer Prescription Drug Costs.

It should be noted that the information referred to by the BOP was included in the report as background information to help provide context to understand the report. These facts were not used to develop a finding or recommendation related to the BOP's prescription medication costs. Rather, the information was intended to demonstrate that prescription medication costs were not only increasing within the BOP, but throughout the entire United States, and that those increases can be partially explained by some of the factors we detailed in the background section of the report. We agree that these are not the only factors found explaining the increases.

In Appendix III, pages 70 and 71, the BOP provided the following general statement in response to the audit:

We have undertaken several initiatives to reduce overall healthcare costs, as well as improve patient care, which were not addressed in the report. One such initiative is the BOP National Formulary which was cited as a model program on pages 138 and 392 of the June 2002 publication Criminal Justice/Mental Health Consensus Project. Other initiatives include the BOP Clinical Practice Guidelines and the Inmate Copayment Program Policy.

Again, the information referred to by the BOP was cited by the OIG for background purposes to provide basic information regarding some of the major initiatives that may have a direct impact on BOP pharmacy services. On page 53 of the report, the OIG refers to the National Formulary and states that "The BOP National Formulary (formulary) is a list of all prescription medications recommended as essential for inmate care and is used to help provide clinically appropriate, safe, and cost-effective prescription medications." In regards to the BOP Clinical Practice Guidelines, the BOP did not provide any documentation to demonstrate how it impacted the overall health care costs or the BOP pharmacy services. Lastly, the Inmate Copayment Program Policy was not implemented at the time of our field work so we were not able to review its impact on BOP pharmacy services, and thus it was not included in our report.

In Appendix III, page 71, the BOP provided the following statement in response to recommendation 1:

1. Conduct a complete and accurate cost-benefit analysis of the Central Fill proposal before deciding whether to proceed with implementation.

We agree with your recommendation. As pointed out in your cost adjustments, many of which were based upon differing assumptions between BOP and OIG, we realize that there will always be some variables. Taking into consideration your cost adjustments in relation to the BOP analysis and how Central Fill is inextricably linked to an overall pharmacy transformation. . . I have made the decision to move forward with our plans to implement Central Fill. . .

Although the BOP stated that it agrees with the recommendation, it nevertheless states that it decided to move ahead with the implementation of the Central Fill proposal without conducting a complete and accurate cost-benefit analysis. The OIG report sites several concerns with the BOP's existing cost-benefit analysis that can only be resolved by conducting a new analysis prior to deciding whether to proceed with the implementation of the Central Fill proposal. The concerns related to the BOP's cost-benefit analysis identified in the report include:

- Page 30 of the report states that, "The BOP estimated savings of $1.14 million annually, which based on our analysis, is overstated by as much as $2.03 million. As a result, Central Fill may cost the BOP as much as $895,016 per year. . ."

- Page 25 of the report states that, "we found that the BOP did not include all prescription medications in its analysis of gross purchase savings for the six institutions. Instead, the BOP estimated the savings on just tablets and capsules, and excluded any other types of prescription medications. According to BOP officials, liquids and ointments were excluded to simplify the calculation. However, without estimating the costs or savings for all medications, the BOP could be overstating or understating the estimated total gross purchase savings."

- Page 25 of the report states that, "the time periods used for BOP and VA prices are not consistent. BOP prices were derived using the average price paid by the six institutions over a 1-year period from March 2003 through February 2004. The VA prices were based on a specific date during the time of the analysis. As a result, some BOP

estimated gross purchase savings may be the result of timing differences in prescription prices."

- Page 31 of the report states that, "In our judgment, the six institutions used by the BOP to estimate prescription medication costs may not represent the average institution. The BOP stated that it picked six institutions at random; however, no sampling methodology was used to ensure that the sample was representative of all institutions. Although we could not verify the validity of the sample, we found several factors that cause concern."

In Appendix III, page 73, the BOP provided the following statement in response to recommendation 7:

7. Ensure all documentation related to controlled substances is accurate and complete.

We understand OIG is evaluating us based on our own policy; however, the acceptable compliance rate or threshold of OIG is unclear. . . Pages iii and 40 of the report refer to 402 unaccounted for doses, which represents less than a 1 percent error rate.

Documentation and accountability of controlled substances within an institution are thoroughly reviewed through the BOP Program Review Process.

The OIG believes that in the secured environment provided by BOP facilities, that it is important that all controlled substances are properly accounted for and documented. In addition, the OIG disagrees with the BOP assertion that documentation of controlled substances is thoroughly reviewed through the BOP Program Review process to ensure that records are accurate and complete. The report refers to numerous recordkeeping errors in addition to the 402 unaccounted for doses that show the need for the BOP to ensure all documentation related to controlled substances is accurate and complete. Page 42 of the report states that "Specifically, we identified approximately 400 recordkeeping errors on the controlled substances inventories that appeared to result in unaccounted-for controlled substances." As stated in the report, the OIG had to use supplemental documentation to account for these controlled substances that appeared to be missing. In addition, page 44 of the report states that "We also identified approximately 800 instances for which required information was not entered in the mainstock and substock inventory records." As a result, we found at least 1,600 doses for which the information on the controlled substances records was not complete or accurate.

It should also be noted that the BOP Program Review Process does not include any steps that require individuals conducting the review to check the accuracy of the data entered into the controlled substances inventory. Further, these same review processes were in place during the time of our audit; however, the Program Reviews at the sites we visited did not find the errors related to controlled substances documentation we identified during our audit. Therefore, we believe the BOP needs to develop and implement additional procedures to ensure the accuracy and completeness of the controlled substances records.

In Appendix III, page 75, the BOP provided the following statement in response to recommendation 10:

10. Develop and implement policies and procedures requiring adequate segregation of duties for ordering and receiving prescription medications.

We disagree with this recommendation. This recommendation is in essence a redundancy of recommendation #9. If a new procedure is appropriately found and implemented, this recommendation will not be necessary.

The OIG agrees with the BOP assertion that this recommendation may be addressed by developing new procedures in response to recommendation 9. However, we disagree with the BOP conclusion that the recommendation is not necessary or that it is a redundancy of recommendation 9. Recommendation 10 addresses the broader issue of segregation of duties compared to recommendation 9 which looks only at the approval process for purchasing and receiving. Page 48 of the report states that "During our audit, we identified inadequate internal controls related to purchasing, ordering, receiving, and paying for prescription medications. At each institution included in our audit, we found that there was no evidence of any segregation of duties related to purchasing of prescription medications." In addition, on page 48 the report provides an example of how inadequate segregation of duties provided a pharmacist with the opportunity for theft from a BOP pharmacy. Specifically, "The lack of internal controls over the purchasing of prescription medications at BOP institutions allowed a Chief Pharmacist at the El Reno FCI to illegally purchase four different brands of non-formulary prescription medications. An OIG investigation found that he stole a total of 30,600 doses between July 2002 and February 2004, for his personal consumption."

APPENDIX V

ANALYSIS AND SUMMARY OF ACTIONS NECESSARY TO CLOSE THE REPORT

1. **Unresolved.** This recommendation can be resolved when the BOP conducts an additional and more accurate cost-benefit analysis of the Central Fill proposal before deciding whether to proceed with implementation. The BOP response states that it agrees with the recommendation; however, it has decided to proceed with the implementation of the Central Fill proposal without conducting a new cost-benefit analysis that addresses the concerns identified in the report.

2. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has pursued efforts to request Congress amend Pub. L. No. 102-585 (1993).

3. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has revised the Health Services Program Review Guidelines to incorporate a review step to assess if pharmacists are in compliance with the new requirements placed in the 2005 BOP National Formulary.

4. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy that would ensure that prescription medications are transferred with the inmates.

5. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy that would require prescription medication confiscated from inmates to be returned to the pharmacy for reissuance to the same inmate or for proper disposal.

6. **Closed.**

7. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy to ensure all controlled substance documentation is accurate and complete.

8. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy that requires all controlled substances to be included in the quarterly inventories.

9. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented policies and procedures requiring Health Services Administrators or their authorized designees to approve prescription medication purchase orders and verify the items received to vendor invoices.

10. **Unresolved.** This recommendation can be resolved when the BOP provides a plan that addresses the recommendation to develop and implement policies and procedures requiring adequate segregation of duties for ordering and receiving prescription medication. The BOP response disagrees with this recommendation because it asserts it can be addressed by developing new procedures in response to recommendation 9. While the OIG agrees that the BOP can incorporate adequate segregation of duties in its procedures developed in response to recommendation 9, the OIG disagree with the BOP conclusion that the recommendation is not necessary.

11. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy requiring pharmacist reviews for contraindications to be documented in the inmates' file.

12. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has updated the Health Services Program Review Guidelines to ensure that written prescriptions include all required information.

13. **Resolved.** This recommendation can be closed when we receive documentation supporting that the BOP has implemented a policy to ensure that non-formulary waivers are obtained and required to be renewed annually.