

Office of the Inspector General U.S. Department of Justice

OVERSIGHT ★ INTEGRITY ★ GUIDANCE



Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs and Procurement



Executive Summary

Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs and Procurement

Introduction

As part of its mission, the Federal Bureau of Prisons (BOP) provides federal inmates with medical care, including pharmaceutical drugs (drugs) when needed. The BOP primarily purchases drugs through the U.S. Department of Veterans Affairs (VA) Pharmaceutical Prime Vendor (PPV) Program, which consists of several different types of contracts through which the BOP and other federal agencies can purchase drugs at a discount. Between fiscal year (FY) 2012 and FY 2018, the BOP's reported drug purchases increased from \$74 million to \$126.9 million (71 percent) while the BOP's inmate population decreased during the same period by approximately 7 percent.

The U.S. Department of Justice (Department) Office of the Inspector General (OIG) conducted this review to examine the BOP's drug procurement process, the prices it pays for drugs, and its efforts to control drug costs. Our review also included an evaluation of the BOP's management of Hepatitis C testing and treatment because Hepatitis C treatment alone accounted for roughly 20 percent of the BOP's drug spending during FY 2018 and because of the significant health risks of not effectively managing Hepatitis C.

Results in Brief

We identified several issues related to the BOP's drug procurement process and its ability to control drug costs, including its lack of access to some of the lowest government pricing; certain practices that lack sufficient oversight and risk the BOP paying more than necessary; and lack of complete data and analysis that could help identify strategies to control costs and reduce waste. While the BOP has taken some steps that could improve the efficiency of drug procurement, system upgrades and additional use of data are needed to achieve their full benefits. We also found that managing Hepatitis C is a particular challenge for the BOP and that its efforts to manage and prevent Hepatitis C have been hampered by inconsistent testing and treatment of inmates.

Recommendations

In this report, we make nine recommendations to improve the BOP's pharmaceutical procurement process and save on drug costs.

The BOP Has Made Efforts to Obtain Big 4 Pricing to Control Drug Costs, but the Department Has Not Prioritized This Objective

The prices that the BOP pays for drugs is a major factor affecting its overall drug costs. We found that the BOP does not have access to the "Big 4" price, which is a discounted government price that, by law, is available to only four government agencies: (1) the U.S. Department of Defense; (2) the VA; (3) the U.S. Public Health Service, specifically the Indian Health Service; and (4) the U.S. Coast Guard. The BOP has estimated that if it had had access to the Big 4 price in FY 2017 it could have reduced its total drug spending by approximately \$13.1 million (11 percent).

We found that, while the BOP has made some efforts to obtain Big 4 pricing, the Department is not actively pursuing Big 4 pricing on behalf of the BOP or its other components. Similarly, a 2016 OIG report on the BOP's spending for outside medical services found that the BOP was paying more for certain medical services than other federal agencies. In that instance, federal law set a cap on the price that other federal agencies paid for these medical services. However, we found that the Department, as with Big 4 drug pricing, had not fully explored options to obtain this favorable pricing for the BOP or its other components. We believe that the similarity between these two issues—Big 4 pricing and the medical services pricing cap—presents an opportunity for the Department to explore possible solutions for both issues in tandem.

The BOP Is Not Ensuring that Institutions Are Procuring Pharmaceutical Drugs in the Most Cost-Efficient Way

We found that institutions' drug procurement practices sometimes create a risk that the BOP could pay more than necessary because institutions do not consistently follow the BOP's drug ordering hierarchy and do not always search for the lowest available price when they should. Further, we found that the BOP does not ensure that drug prices are competed when required. These challenges are exacerbated by the outdated Health Services Program Review Guidelines for Pharmacy Services, which do not include sufficient criteria to monitor institutions' use of cost-efficient procurement practices, meaning that the BOP is not requiring institutions to follow cost-efficient procurement practices, nor is the BOP determining the extent to which they are.



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The BOP Does Not Collect Complete and Accurate Data on Its Drug Purchases or Effectively Analyze Pharmaceutical Data

We found that the BOP lacks a complete picture of its pharmaceutical purchasing data, which may impede its ability to control drug costs. Specifically, not all BOP institutions consistently and accurately report certain drug purchases to the BOP's Central Office and, until March 2018, the Central Office did not store or analyze historical purchase-level data. As a result, the BOP does not have complete and accurate data about current or historical drug purchasing. We believe that collecting additional data and analyzing its existing data more thoroughly would assist the BOP in its efforts to control costs, seek more favorable drug prices, and reduce waste resulting from unused drugs.

The BOP Has Taken Several Steps That Could Improve Drug Procurement and Control Costs, but Achieving the Full Benefits from These Steps Would Require Additional System Upgrades and Enhanced Use of Data

We identified areas in which further system upgrades and use of data could improve the BOP's pharmaceutical procurement and its ability to control costs. First, the BOP implemented a Pharmacy Inventory Management System to track the quantity and price of drugs that institutions are dispensing, as well as institutions' current drug inventory; however, the system requires updates to achieve optimal functionality. Second, although some institutions conduct pharmacy clinics, which can improve inmate health and reduce medical and drug costs, in FY 2018 only 38 out of 98 BOP-managed institutions had agreements in place to conduct them. In addition, limited staffing and data to demonstrate the clinics' value have prevented institutions from conducting more. Third, the BOP has obtained Temporary Price Reductions (TPR) on particular drugs, but we believe that enhanced data collection and analysis could help the BOP realize more cost savings through TPRs.

Case Study: The BOP's Efforts to Prevent and Manage Hepatitis C Are Hampered by Inconsistent Testing and Treatment

We found that managing Hepatitis C within the inmate population and the associated costs of treatment has been a particular challenge for the BOP. A critical component of the BOP's management of Hepatitis C is identifying the prevalence of Hepatitis C within its inmate population so that it can determine treatment priorities and anticipate costs. However, we found that not all inmates in the BOP's custody are tested for Hepatitis C due to variations among institutions' testing protocols and that the BOP does not track treatment needs systematically.

In FY 2017, the BOP established a centralized fund intended to remove cost as a deciding factor for treating Hepatitis C at the institution level. We found that this initiative did not fully accomplish the goal of ensuring that Hepatitis C treatment was provided consistently. However, results from the initiative's first year indicate that centralizing funding may be an effective way for the BOP to help ensure that its institutions' treatment decisions are not driven by cost, as long as the funding is readily available to institutions.

Based on this case study, and in light of the high cost of Hepatitis C treatment and the health risks that untreated cases pose to inmates and staff, we believe that it is essential for the BOP to implement protocols that ensure that it identifies cases of Hepatitis C in a timely fashion through testing and that it systematically tracks the treatment needs of inmates. This information can help the BOP prevent the spread of Hepatitis C to other inmates or staff; ensure that inmates receive appropriate treatment; and assist the BOP in projecting, requesting, and allocating the funds needed for treatment.

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INTRODUCTION

Background

The Federal Bureau of Prisons (BOP) provides medical care to federal inmates as part of its mission to confine inmates in environments that are safe, humane, cost-efficient, and appropriately secure. In providing medical care to inmates, the BOP procures pharmaceutical drugs (drugs) to treat inmates' acute and chronic medical conditions and provide preventive care. The U.S. Department of Justice (Department, DOJ) Office of the Inspector General (OIG) conducted this review to examine the BOP's process for drug procurement, the prices it pays for drugs, and the efforts it makes to control rising drug costs.

This review is a continuation of previous OIG reviews examining the BOP's medical spending.¹ In this Introduction, we describe trends we identified in the BOP's drug spending, some of the drug pricing available to the BOP and other federal government agencies, BOP institutions' sources for procuring drugs, and the BOP's management of pharmacy services.

The BOP's Increasing Pharmaceutical Costs

As detailed below, BOP institutions have different sources by which they can procure drugs; however, because not all institutions report their purchases from all sources, the BOP is unable to report the total amount that it collectively spends on drugs. The BOP does know the total amount that its institutions spend on drug purchases from the prime vendor, which makes up most of BOP drug spending.² As shown in Figure 1 below, between fiscal year (FY) 2012 and FY 2018 the amount of the BOP's reported drug purchases through the prime vendor increased 71 percent (\$74 million to \$126.9 million) while the BOP's inmate population decreased during that same period by approximately 7 percent.³

¹ See DOJ OIG, <u>The Impact of an Aging Inmate Population on the Federal Bureau of Prisons</u>, Evaluation and Inspections (E&I) Report 15-05 (May 2015), www.oig.justice.gov/reports/2015/e1505.pdf, and DOJ OIG, <u>The Federal Bureau of Prisons' Reimbursement Rates for Outside Medical Care</u>, E&I Report 16-04 (June 2016), www.oig.justice.gov/reports/2016/e1604.pdf (both accessed February 12, 2020).

² Our review focused on 98 BOP-managed institutions and excluded BOP contract prisons and Residential Reentry Centers. There were 122 BOP-managed institutions as of September 2019, but the BOP considers correctional complexes (multiple institutions co-located) to be a single institution when making and reporting drug purchases.

³ The U.S. Department of Veterans Affairs' (VA) Pharmaceutical Prime Vendor (PPV) contract defines the pharmaceutical prime vendor as "the major provider of a broad range of pharmaceutical products." We discuss the PPV Program in more detail below.

Total Population

Figure 1

BOP Annual Prime Vendor Drug Spending and Inmate Population,
FY 2012-FY 2018

Note: The population figures pertain only to the BOP-managed institutions.

■ Total Prime Vendor Drug Spending

Source: BOP data

This 71 percent increase in spending through the prime vendor was a far greater increase than the BOP's 35 percent increase in overall medical spending during the same period (\$891 million in FY 2012 to \$1.2 billion in FY 2018). As a result of the increased prime vendor spending, pharmaceutical costs composed an increasingly larger portion of medical spending each year, rising from 8 percent to 11 percent of overall medical spending.

Between FY 2012 and FY 2018, as the BOP's inmate population decreased overall, the BOP's annual pharmaceutical cost per inmate increased by 84 percent (from \$450 to \$828). The BOP told us that one major reason for its increasing pharmaceutical costs has been the cost of Hepatitis C drugs, which increased by approximately 471 percent, from \$4.4 million in FY 2012 to \$25 million in FY 2018.⁴

(Cont'd)

⁴ We used the non-rounded numbers to calculate percent change. In this instance, the percentage calculation based on the actual number is different from the calculation based on the rounded number.

In addition to Hepatitis C drugs, the BOP has attributed its increasing pharmaceutical costs to the increase in overall pharmaceutical industry prices and the aging inmate population. The U.S. Department of Health and Human Services reported that pharmaceutical costs in the United States are rising faster than overall health spending, due in large part to increased drug prices. See U.S. Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, "ASPE Issue Brief:

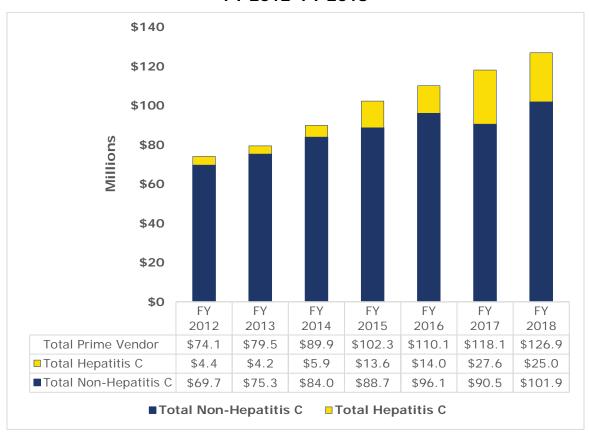
Observations on Trends in Prescription Drug Spending," March 8, 2016, www.aspe.hhs.gov/system/

A BOP Central Office Pharmacy Services official attributed the increase in Hepatitis C drug spending to two primary factors between FY 2012 and FY 2017. First, a new class of Hepatitis C drugs became available. Initially, the drugs were very expensive, with some treatment regimens costing as much as \$85,000 for a single inmate. ⁵ Second, when the drug prices decreased, the BOP increased the number of inmates to whom it provided Hepatitis C treatment.

As shown in Figure 2, Hepatitis C spending grew to nearly 20 percent of the BOP's total drug spending in FY 2018.

Figure 2

The BOP's Prime Vendor and Hepatitis C Drug Spending, in Millions,
FY 2012-FY 2018



Note: The numbers in the table have been rounded.

Source: BOP data

files/pdf/187586/Drugspending.pdf (accessed February 12, 2020). In our previous report on the BOP's aging inmate population, we found that inmates age 50 and older are more costly to incarcerate than their younger counterparts due to increasing medical needs. See DOJ OIG, *Impact of an Aging Inmate Population*.

⁵ According to the Centers for Disease Control and Prevention (CDC), these new treatments "usually involve just 8–12 weeks of oral therapy (pills) and cure over 90% of people with few side effects." See CDC, "<u>Hepatitis C Questions and Answers for the Public</u>," November 2, 2018, www.cdc.gov/hepatitis/hcv/cfaq.htm#A4 (accessed February 12, 2020).

The BOP's Drug Pricing

The BOP, along with many federal government agencies, purchases most of its drugs at the Federal Supply Schedule (FSS) price.⁶ All federal agencies are eligible for this price, which the U.S. Department of Veterans Affairs (VA) negotiates on behalf of the General Services Administration. In doing so, the VA aims to obtain Most Favored Commercial Customer prices (the lowest price that drug manufacturers report that purchasers have paid for a drug) or lower for federal agencies. The VA lists FSS prices publicly on the FSS for drugs. Agencies purchase drugs at FSS prices through contracts that provide for an indefinite quantity of drugs over a fixed period of time.⁷ For details on drug types and descriptions, see Appendix 2.

A discounted FSS price to which the BOP does not have access is the "Big 4" price. This price is available by statute to four agencies: (1) the U.S. Department of Defense; (2) the VA; (3) the U.S. Public Health Service (PHS), specifically the Indian Health Service; and (4) the U.S. Coast Guard. The federal ceiling pricing program established the Big 4 price, which is statutorily calculated and by law cannot exceed the previous year's regular FSS price. The Big 4 price is also the highest price that a drug manufacturer may charge the four agencies. According to a VA official, as well as a 2005 estimate of the Congressional Budget Office (CBO), the Big 4 agencies' purchases account for about 95 percent of all FSS drug purchases.

The BOP's Sources for Drug Procurement

BOP pharmaceutical procurement occurs at the institution level, and institutions have three types of sources for purchasing drugs:

1. The VA's Pharmaceutical Prime Vendor (PPV) Program. BOP institutions purchase most of their drugs through the VA's PPV Program, in which the BOP has participated since 1996. As the implementer of the PPV Program, the VA negotiates a contract with the prime vendor, currently McKesson Corporation. The PPV Program contract consists of multiple types of manufacturer contracts from which several agencies, including the BOP, purchase drugs. The VA

⁶ FSS drug purchases accounted for 80 percent of all of the BOP's PPV Program expenditures in FY 2017. Other PPV Program expenditure types included VA National Contracts, FSS restricted (Temporary Price Reduction), and blanket purchase agreements. The BOP also purchases generic drugs called Wholesale Acquisition Cost Based Priced Generics.

⁷ These contracts are known as indefinite delivery, indefinite quantity contracts.

⁸ 38 U.S.C. § 8126 is the federal statute that sets limits on the Big 4's drug prices based on amendments to the Veterans Health Care Act of 1992. The statute generally prohibits drug manufacturers who do not offer Big 4 pricing or list certain drugs on the FSS from participating in Medicaid and selling drugs to the Big 4 agencies.

⁹ The Big 4 price is a type of FSS price and therefore is also listed publicly on the FSS. See also CBO, <u>Prices for Brand-Name Drugs Under Selected Federal Programs</u> (June 2005), www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-16-prescriptdrug.pdf (accessed February 12, 2020).

decides whether to add or remove an agency from the PPV Program contract, and an agency may withdraw from the contract at any time.

Through the PPV Program, the prime vendor maintains a supply of drugs and provides next-day delivery to BOP institutions, which place orders according to inmate needs. Institutions use their prime vendor account to purchase all PPV Program drugs, and they report these purchases to the BOP's Central Office using a specific code in their financial reporting system.

An important feature of the PPV Program is the discount, known as a negative distribution fee, which the BOP receives for PPV Program drug purchases. Each drug manufacturer that agrees to participate in the PPV Program helps fund this discount by paying a fee to the prime vendor. The PPV contract in effect during the scope of our review was set to expire in August 2020.

- 2. **Prime Vendor Open Market Account.** Institutions can use this source to order from the prime vendor drugs that are unavailable through the PPV Program.¹¹
- 3. **Non-Prime Vendor Sources.** Institutions can also purchase drugs from other sources such as drug manufacturers, local retail pharmacies, and the pharmaceutical "gray market." Drugs purchased at local retail pharmacies and through the gray market are typically more expensive than those purchased through the PPV Program, while drugs purchased from manufacturers at FSS prices may be less expensive. ¹³

Institutions are required to use the PPV Program to purchase drugs unless the drugs are not included in it or are out of stock.

Pharmacy Services at the BOP Central Office and Institution Levels

The BOP's Central Office and institutions have separate responsibilities for implementing the BOP's pharmacy program. At the Central Office, the Chief

The BOP's Chief of Pharmacy Logistics Support told us that drug manufacturers that choose not to participate in the PPV Program typically do so because they do not want to pay the prime vendor fee. Therefore, while a drug may be available at an FSS price, it may not be available through the PPV Program.

The current PPV Program contract excludes open market drugs. Throughout this report, "prime vendor open market" refers to the BOP's non-PPV Program contract drug purchasing through a separate account with the prime vendor, McKesson Corporation.

Institutions pay no shipping costs for PPV Program or prime vendor open market purchases. However, they incur a 0.25 percent recovery fee on all prime vendor purchases, which the prime vendor collects and then uses to reimburse the VA for costs related to the negotiation, award, and administration of the PPV Program.

¹² The pharmaceutical gray market consists of secondary wholesalers purchasing drugs from primary wholesalers and typically selling them at a higher price during drug shortages.

¹³ Purchasing non-PPV Program drugs creates a risk that the BOP could pay more than necessary if institutions do not compete them or if they do not purchase them at FSS prices, which have already been competed according to federal acquisition regulations.

Pharmacist and Chief of Pharmacy Logistics Support oversee Pharmacy Services. These two officials advise institution pharmacy staff regarding pharmacy operations, but they do not have authority over institutions' pharmacy staff or operations, including how the institutions procure drugs.

Most institutions maintain a pharmacy that, typically, a Pharmacist directs. Institution pharmacy staff, among other things, process and fill prescriptions; manage the pharmacy's drug inventory; and conduct clinical work, which involves educating inmates on disease management and specific drug use. The number of staff in institution pharmacies varies. BOP policy states that a sufficient number of trained personnel should staff each institution pharmacy according to the size of the institution and the medical services provided. During the scope of our review, the number of approved pharmacy positions increased, from 238 in FY 2012 to 253 in FY 2017, but the number of pharmacy staff decreased, from 221 to 214.¹⁴

All but 17 BOP-managed institutions process and fill prescriptions for their own inmates. Those 17 institutions, whose pharmaceutical purchasing is relatively low, receive their drug shipments from 6 "Remote Fill" institutions through a program called Central Processing Pharmacy Services. Central Processing Pharmacy Services eliminates the need to employ a Pharmacist and maintain an in-house pharmacy in these institutions.

BOP officials reported that before and during the scope of our review the BOP was in the process of shifting from manual to electronic methods for managing pharmacy inventories. In May 2012, the BOP began to implement the Pharmacy Inventory Management System (PIMS), which is a pharmacy inventory software intended to increase the efficiency and cost-effectiveness of ordering drugs. For example, when a Pharmacist searches for a drug in PIMS, PIMS is programmed to identify drugs that institutions must purchase and, if those are unavailable, the lowest price drug that is available. PIMS also ensures that institutions maintain an adequate supply of drugs by signaling whenever a drug's supply falls below the predetermined minimum quantity, or par level. Shortly after the beginning of our fieldwork, in November 2017, 51 out of 98 BOP-managed institutions were using PIMS to manage their pharmacy inventory while the others were managing their inventory manually. As of February 2019, a BOP official reported that all institutions with the exception of a Federal Transfer Center were using PIMS.

The BOP's Pharmacy Services Policy

In 2005, the BOP developed a formal policy, known as the Pharmacy Services Program Statement, to guide its pharmaceutical operations, including standards of operation, staffing, training, and drug dispensing. The policy requires each institution to use the BOP National Drug Formulary to procure drugs through

BOP pharmacies are staffed with a combination of civil service and PHS positions, both of which we included in our pharmacy staffing data. The U.S. Surgeon General leads the PHS, which is an agency of the U.S. Department of Health and Human Services.

the PPV Program and to order generic drugs whenever possible.¹⁵ To ensure that institutions are complying with Pharmacy Services policy, the BOP conducts program reviews based primarily on the provisions in this program statement.

Prior Work Related to Federal Drug Spending

During the 15 years prior to our review, the CBO and the U.S. Government Accountability Office (GAO) examined the prices that federal agencies paid for drugs, trends in federal drug spending, and methods that federal agencies use to control drug costs. In 2005, the CBO issued a report that included a brand name price comparison for various federal drug prices and found that they varied based on negotiations and rebates. In 2007, a GAO report examined how different federal programs acquired drugs and negotiated their prices. The GAO found that these processes varied and that drug spending in the United States increased faster than overall medical spending between 1998 and 2005. A 2009 GAO report examining how federal programs controlled drug spending found that strategies included use of formularies, statutorily established prices such as the FSS, pharmacy networks, discounts, drug substitution, and prime vendors.

Scope of the OIG Review

The OIG initiated this review to examine the BOP's drug prices and spending from FY 2012 through FY 2018, as well as its drug procurement process. We focused our analysis on the various ways that institutions obtain drugs for their inmate populations. We examined BOP policies and procedures related to pharmaceutical procurement, federal laws, regulations, and proposed legislation. Our fieldwork, conducted from June 2017 through April 2019, included data collection and analyses, document reviews, and interviews. We interviewed officials from the Office of the Attorney General, the Office of the Deputy Attorney General, the BOP Central Office, BOP institutions, the BOP Field Acquisition Office, the VA, and several state departments of corrections. A more detailed description of the methodology is in Appendix 1.

¹⁵ The BOP National Drug Formulary is the approved list of drugs that institutions may order. Institutions may order outside of the formulary with advance approval.

¹⁶ See CBO, Prices for Brand-Name Drugs.

¹⁷ See John E. Dickens, Director, Health Care, GAO, before the Committee on Finance, U.S. Senate, concerning "<u>Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs</u>," GAO-07-358T (January 11, 2007), www.gao.gov/assets/120/115135.pdf (accessed February 12, 2020).

¹⁸ See John E. Dickens, Director, Health Care, GAO, before the Subcommittee on Federal Workforce, Postal Service, and the District of Columbia, Committee on Oversight and Government Reform, House of Representatives, concerning "Prescription Drugs: Overview of Approaches to Control Prescription Drug Spending in Federal Programs," GAO-09-819T (June 24, 2009), www.gao.gov/assets/130/122832.pdf (accessed February 12, 2020).

RESULTS OF THE REVIEW

The BOP Has Made Efforts to Obtain Big 4 Pricing to Control Drug Costs, but the Department Has Not Prioritized This Objective

As described in the <u>Introduction</u>, there is no single federal government price available for drug purchases. Rather, different federal agencies often pay different prices to purchase the same drug.

For most drug purchases that federal government agencies make from the Federal Supply Schedule (FSS), the best price available is the Big 4 price, which by law is available to just four federal agencies: (1) the U.S. Department of Defense; (2) the U.S. Department of Veterans Affairs (VA); (3) the U.S. Public Health Service (PHS), particularly the Indian Health Service; and (4) the U.S. Coast Guard. ¹⁹ A VA official told us, and a 2005 report of the Congressional Budget Office (CBO) estimated, that the Big 4 agencies account for at least 95 percent of FSS drug purchases. ²⁰

Accounting for the remaining 5 percent are the drug purchases of several agencies, including the BOP, that do not have access to the Big 4 price. ²¹ This lack of access to the Big 4 price has had a substantial effect on the BOP: in FY 2017 alone, the BOP estimated that it would have saved approximately \$13.1 million, or 11 percent of its total drug spending, if it had been able to use Big 4 pricing. Much of these savings would have been realized on certain high cost specialty drugs, some of which significantly contributed to the increases in BOP drug spending that occurred during the scope of our review. For example, we found that the BOP would have saved \$2.4 million on a single Hepatitis C drug in FY 2017 if it could have purchased the drug at the Big 4 price. ²²

For the BOP to obtain access to Big 4 pricing, it would first need to coordinate with Department officials, who would then need to coordinate with federal agencies whose interest could be affected by the BOP being added as an

¹⁹ See the Veterans Health Care Act of 1992, as amended, Pub. L. No. 102-585.

The 95 percent figure is a 2005 CBO estimate, which is the most recent data available. See CBO, <u>Prices for Brand-Name Drugs Under Selected Federal Programs</u> (June 2005), www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-16-prescriptdrug.pdf (accessed February 12, 2020).

²¹ The Big 4 agencies purchase drugs at the lower of either the Big 4 or the regular FSS price. Therefore, when a manufacturer does not offer Big 4 pricing the BOP pays the same price as the Big 4 agencies (i.e., the regular FSS price).

In FY 2017, the BOP's price for this drug decreased because a manufacturer offered the BOP a Temporary Price Reduction (TPR), allowing BOP to save 67 percent more than it would have at the Big 4 price. A TPR is an agreement between a drug manufacturer and a government agency that temporarily reduces a drug's price to increase the manufacturer's drug sales. While the price offered through a TPR can be lower than the Big 4 price, a drug manufacturer may revoke a TPR at any time. Therefore, only access to Big 4 Pricing would ensure that the BOP would continue to save on one of its most expensive drugs.

agency eligible for such pricing. BOP and Department officials emphasized to us that pursuing Big 4 pricing for the BOP would also require the Department to help coordinate proposals to and discussions with Congress, particularly since other DOJ components, notably the U.S. Marshals Service, also purchase drugs.²³

We found that, while the BOP has taken some actions to obtain Big 4 pricing, the Department has not prioritized obtaining Big 4 pricing for the BOP or its other components. Specifically, we found that the BOP has made several unsuccessful attempts to obtain Big 4 pricing. For example, the BOP's Assistant General Counsel told us that, in 2006, following an OIG audit in 2005 that recommended that the BOP ask Congress to make the BOP eligible for Big 4 pricing, the BOP proposed that Congress pass a statutory amendment that would give the BOP access to Big 4 pricing. But Congress did not act on the proposal and Department and BOP officials told us that they did not know what, if any, action the Department took to seek other avenues for obtaining Big 4 pricing following Congress's inaction.

In 2017 the BOP again proposed to the Department that it pursue a statutory amendment giving the BOP access to Big 4 pricing, and in April 2018 the Department submitted the BOP's proposal to Congress as one of several proposed amendments to the FIRST STEP Act of 2018, a bill related to prison reform. ²⁵ However, a Department official told us that Congress did not view the proposal as being related to prison reform and therefore did not act on it. Further, a BOP official told us that in August 2018 he discussed with a VA official extending Big 4 pricing to the BOP based on the BOP's use of PHS officers in its institutions. However, the VA official responded that the BOP's arrangement with the PHS was not a sufficient basis for the BOP to obtain access to Big 4 pricing and the BOP did not pursue this further.

With respect to the Department's more recent efforts, an Office of the Deputy Attorney General (ODAG) official told us that, as of October 2018, she was unaware of the ODAG having engaged directly with officials from the VA, the agency responsible for negotiating and managing the pharmaceutical contracts that offer Big 4 pricing, to discuss the feasibility of the BOP or other DOJ components obtaining Big 4 pricing. An ODAG official also told us that in 2018 the ODAG directed the BOP to contact the VA to discuss the prospects of adding the BOP to the Big 4 statute. However, the ODAG did not participate in this meeting and a BOP official who did participate told us that the VA official who attended the meeting did not have the authority to take the regulatory or administrative actions that would be necessary to address the pricing discrepancies, nor was he able to

The OIG is also reviewing the U.S. Marshals Service's pharmaceutical drug procurement process. The review will examine the U.S. Marshals Service's spending on drugs for its detainees as well as its efforts to control rising drug costs. Two additional DOJ components, the Federal Bureau of Investigation and Drug Enforcement Administration, also purchase drugs.

²⁴ DOJ OIG, <u>Audit of the Federal Bureau of Prisons Pharmacy Services</u>, Audit Report 06-03 (November 2005), www.oig.justice.gov/reports/BOP/a0603/final.pdf (accessed February 12, 2020).

The President signed H.R. 5682, known as the FIRST STEP Act, into law in December 2018. See <u>FIRST STEP Act</u>, H.R.5682, 115th Cong. (2017–2018), www.congress.gov/bill/115th-congress/house-bill/5682/text (accessed February 12, 2020).

speak to the VA's position on the BOP gaining access to Big 4 pricing. Department and BOP officials told us that they were not aware of any current activities or future plans to pursue Big 4 pricing for DOJ components, including the BOP.

Department and BOP officials told us that pursuing an amendment to the Big 4 pricing statute could create an opportunity for the pharmaceutical industry to lobby to end the federal ceiling pricing program, which would eliminate Big 4 pricing for all agencies. These officials also told us that they had not formally assessed that concern, had never asked the VA or any other stakeholder for such an assessment, and had not reached out to congressional staff for input into whether this concern was founded. We note, however, that the Veterans Health Care Act of 1992 requires drug manufacturers, in order to receive payment for drug purchases from the Big 4 agencies and under the Medicaid program, to offer FSS and Big 4 prices for brand name drugs. We believe that these provisions create a strong incentive for drug manufacturers to continue offering Big 4 pricing. In our view, the potential savings to the BOP are substantial enough to merit a robust and formal effort by both the BOP and the Department to obtain access to Big 4 pricing.

In a 2016 review, the OIG identified a similar instance in which the BOP was paying more for certain medical services than other federal agencies because it did not have statutory authority to cap its reimbursements to outside medical providers at the Medicare rate. We found that neither the BOP nor the Department had fully explored options for obtaining the authority that was available to these other agencies. We calculated that in FY 2014 the BOP spent at least \$100 million more on these medical services than it would have if it had had access to the Medicare rate, and we concluded that the Department and the BOP should explore options to obtain access for the BOP (see the text box for more information).

Seeking Big 4 pricing and the outside medical services price cap would necessitate the Department

The Department Has Not Fully Explored Options That Could Substantially Reduce the BOP's Spending on Outside Medical Care

A 2016 OIG report on the BOP's spending for outside medical services identified a possible way for the BOP to substantially reduce such costs when providing outside medical care to inmates. Specifically, we found that the BOP consistently paid outside doctors and hospitals 1.7 times more to treat federal inmates than Medicare would pay for the same services. As a result, in FY 2014 the BOP spent at least \$100 million more for medical care than it would have if it had paid Medicare rates.

The OIG also found that, among federal agencies that pay for medical care, the BOP is the only agency that is not covered by a statute or regulation under which the government sets the reimbursement rate, usually at the Medicare rate. The OIG recommended that the BOP "convene a working group of officials from the Department, the BOP, and other federal agencies, as necessary, to consider potential legislative options to improve the BOP's ability to manage reimbursement rates for medical care, including potential amendments to the Social Security Act [of 1935, 42 U.S.C. § 1395cc]." In October 2017, the BOP reported that it had convened a working group and that the working group had drafted proposed legislation to expand the Social Security Act's provider agreement to include the BOP. However, the OIG subsequently learned that the Department did not take further action on this proposal and, as a result, the issue has not been addressed and this cost-saving measure has not been fully explored.

Source: DOJ OIG, <u>Review of the BOP's Reimbursement</u> <u>Rates for Outside Medical Care</u>, E&I Report 16-04 (June 2016), www.oig.justice.gov/reports/2016/e1604.pdf (accessed February 12, 2020)

coordinating among its components and with other stakeholder agencies to consider possible legislative changes to save taxpayer dollars. We believe that the Department should pursue reasonable options—legislative or otherwise—to ensure that its components are included in cost-saving programs available to other federal agencies. We further believe that the similarities between these two issues and their possible solutions may present an opportunity for the Department to explore them in tandem.

We therefore recommend that the ODAG, in consultation with the appropriate DOJ components and other federal stakeholders, formally assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate, for the Department and all of its components, and, if warranted by the assessments, develop a plan to obtain such pricing and/or authority, including timeframes and assignments of responsibility for pursuing the plan.

The BOP Is Not Ensuring that Institutions Are Procuring Pharmaceutical Drugs in the Most Cost-Efficient Way

As discussed above, each BOP institution is responsible for purchasing its own drugs based on the needs of its inmates. We found that institutions' pharmaceutical procurement practices are inconsistent and not always costefficient. Further, we found that the BOP does not ensure that institutions compete non-Pharmaceutical Prime Vendor (PPV) Program purchases that are equal to or greater than the micro-purchase threshold.²⁷ We also found that the BOP's current Pharmacy Services Program Statement is outdated and that its oversight and review process does not thoroughly evaluate cost-efficient procurement practices because it lacks the criteria to do so. This reduces the effectiveness of the BOP Central Office's pharmaceutical procurement oversight. We explain each of these findings in detail below.

Although the BOP Central Office is responsible for managing the BOP's participation in the PPV Program, pharmaceutical purchasing is exclusively an institution function. As described in the <u>Introduction</u>, there are three types of sources that institutions have for purchasing drugs: the PPV Program, the prime vendor open market, and non-prime vendor sources such as retail pharmacies and the gray market. Purchasing non-PPV Program drugs creates a risk that the BOP

Report 18-04451-06 (October 2016), www.va.gov/oig/pubs/VAOIG-18-04451-06.pdf (accessed February 12, 2020).

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²⁶ In October 2019, the VA's Office of Inspector General issued a report that relates to federal agencies not receiving the same price for drugs. The VA OIG found that, because the VA negotiates and awards FSS contracts for drugs on behalf of all federal agencies, it should not award TPRs that benefit only certain agencies. Rather, the VA OIG noted that all federal agencies should receive the same price reductions for drugs. See VA OIG, <u>The Impact of VA Allowing Government Agencies to Be Excluded from Temporary Price Reductions on Federal Supply Schedule Pharmaceutical Contracts</u>,

The Federal Acquisition Regulation established \$3,500 as the "micro-purchase threshold." This means that any purchase equal to or greater than \$3,500 must be competed. In 2018, the National Defense Authorization Act for Fiscal Year 2018 (Section 806) increased the limit to \$10,000 for purchases made since the beginning of FY 2018.

could pay more than necessary because, unless institutions purchase them at FSS prices, non-PPV Program sources do not necessarily offer drugs at favorable prices like the PPV Program does. Ensuring that institutions are following cost-efficient practices is especially important because recent drug shortages in the PPV Program have increased the need for institutions to make purchases from non-PPV Program sources. As discussed later in the report, the BOP does not have a complete reporting of non-PPV Program purchases, but an official told us anecdotally that they are increasing. Because of incomplete reporting, the BOP does not know the percentage of drug procurement from each type of source.

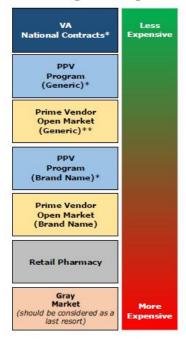
Institutions Do Not Always Follow Cost-Efficient Pharmaceutical Procurement Practices

During our interviews with staff from six BOP institutions, we found that drug procurement practices vary by institution and are not consistently cost-efficient.²⁸ Specifically, we found that institutions do not always follow the "hierarchy" that BOP Central Office Pharmacy Services has recommended to help institutions purchase the least expensive drugs. We also found that institutions do not always search for an FSS price when drugs are unavailable through the PPV Program. Later in this report, we discuss the fact that institutions must seek the lowest price through competition of purchases at or above \$3,500, as required by BOP policy and the Federal Acquisition Regulation (FAR); however, we found that the BOP does not ensure that its institutions do so.

The BOP Does Not Require Institutions to Seek the Lowest Price for Non-PPV Program Drugs, and Institutions Do Not Consistently Do So

We found that Pharmacy Services has informally communicated to institutions a drug ordering hierarchy that should generally result in institutions identifying the lowest price source for drugs (see Figure 3). However, the BOP does not require institutions to follow the hierarchy, nor does the BOP ensure that institutions are aware of it. Following the drug ordering hierarchy could help institutions identify the lowest price source for drugs; therefore, the BOP needs to formalize and disseminate the hierarchy for it to be fully effective.

Figure 3
The BOP's Drug Ordering Hierarchy



^{*} These sources are mandatory.

Source: OIG analysis based on interviews with BOP Pharmacy Services and a Health Services Division memorandum

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^{**} During the scope of our review, BOP policy required institutions to purchase PPV Program drugs if VA National Contract drugs were unavailable. In August 2019, the BOP issued guidance, based on clarification from the VA, that advised institutions that they may purchase prime vendor open market generic drugs instead of PPV Program brand name drugs if the generic drugs are less expensive.

 $^{^{28}\,}$ As discussed in the Methodology (see Appendix 1), our fieldwork involved interviewing staff at six BOP-managed institutions via teleconference.

According to the BOP, as a PPV Program participant, it is required to order drugs, if they are available, through the PPV Program, starting with VA National Contracts. If needed drugs are unavailable through these contracts, according to the hierarchy, institutions should purchase generic drugs from the PPV Program. If PPV Program and prime vendor open market drugs are also unavailable, institutions have the discretion to decide where to purchase the needed drugs. When this occurs, the hierarchy indicates which sources are generally more cost-effective.

While Pharmacy Services does not have the authority to mandate that institutions follow the hierarchy, it can issue guidance recommending this practice. However, we found that Pharmacy Services has not issued written guidance recommending the use of the hierarchy to help institutions identify the lowest price source. Rather, a Pharmacy Services official told us that the BOP verbally communicates required and preferred purchase sources to institution staff during drug procurement training. However, staff at only two of our six select institutions said that they compare prices to determine the lowest price drug and none of the institution staff members we interviewed mentioned the hierarchy. A Chief Pharmacist in one institution told us that she is unsure what to do when specialty drugs are unavailable through the prime vendor, and, similarly, a Health Services Administrator told us that she is unaware of any polices or requirements for purchasing outside of the prime vendor.

We believe that giving institution pharmacy staff guidance—in the form of a hierarchy or otherwise—to assist them in making purchasing decisions would increase the efficiency of drug procurement across BOP institutions and reduce the risk of the BOP paying more than necessary. Because Pharmacy Services officials do not have the authority to mandate specific practices, we further believe that the BOP should ensure that institutions are following Pharmacy Services' guidance. For example, the BOP could establish requirements in policy or work with Wardens and the BOP's six Regional Directors to mandate specific practices. For the guidance to be fully effective, the BOP should also consider developing an appropriate oversight mechanism to ensure that institutions routinely seek the lowest price.²⁹

Some Institutions Do Not Seek FSS Prices for Drugs That Are Unavailable Through the PPV Program

We identified a procurement practice—purchasing drugs directly from manufacturers at the FSS price—that Pharmacy Services told us can be costefficient; but we found that some institutions do not follow this practice and thus risk paying more than necessary for some drugs.

We found that even though prime vendor open market purchases are only a fraction of prime vendor purchases, when institutions use this source instead of buying directly from the manufacturer at a lower FSS price it can result in the BOP paying more than necessary. We analyzed the BOP's prime vendor open market drug purchases from FY 2017 and found that they accounted for approximately

²⁹ Later in this report, we discuss limitations to the effectiveness of the BOP's current pharmaceutical procurement-related policy and oversight mechanisms.

\$3.8 million (3.2 percent) of the \$118 million that the BOP spent on all drugs purchased through the prime vendor during that period. We also examined the BOP's purchases of its 100 costliest prime vendor open market drugs in FY 2017 and found 5 drugs that were not available through the PPV Program. Of these five, it may have been less expensive for institutions to purchase four of them directly from the manufacturer at the FSS price instead of through the prime vendor open market. We estimated that the BOP could have saved \$278,000 (or 43 percent of what it actually spent) on those four drugs had institutions purchased them directly from the manufacturer at the FSS price. As an example of not seeking FSS prices, the BOP's Chief of Pharmacy Logistics Support said that institutions regularly purchase syringes (which fall under drug purchases) through the prime vendor open market even though purchasing them from the manufacturer at the FSS price would have been half the cost.

We identified three factors that may contribute to institutions not seeking the FSS price. First, the BOP's Chief of Pharmacy Logistics Support told us that there are no BOP policies requiring (or guidance advising) institutions to price check drug purchases to determine whether the drug is available from a manufacturer at the FSS price. Second, one institution's Chief Pharmacist told us that the institution's staff values the convenience of ordering drugs unavailable through the PPV Program from the prime vendor open market. Echoing this sentiment, the BOP's Chief of Pharmacy Logistics Support told us that institutions order from the prime vendor open market because it is often faster for them to use it than to work with their respective business offices to process an order from another source even if it could yield additional savings. Further, the BOP told us that the prime vendor will ship the drug to the institution at no cost, which we believe may also create an incentive for institutions to order drugs from the prime vendor open market. Third, the BOP's Chief of Pharmacy Logistics Support told us that institutions do not always know when drugs could be available at the FSS price and may not know how to compare these prices.³⁰

The BOP's Chief of Pharmacy Logistics Support told us that he was aware that institutions did not always seek the FSS price and that he had begun to take action to address this concern. He also told us that he recently started identifying and bringing to institutions' attention purchases made using open market accounts when a lower FSS price was available from the manufacturer. We believe that institutions would benefit if Central Office Pharmacy Services took a more active role in identifying the specific instances in which purchasing drugs from manufacturers at the FSS price is less expensive than the prime vendor open market and routinely shared this information with institutions. We encourage Pharmacy Services to continue to build upon its initial efforts to help institutions obtain drugs at the lowest price available.

³⁰ We found that institution staff have access to the VA's National Acquisition Center (NAC) public catalog search tool to look for an FSS price but the BOP does not require them to do so. The BOP's Chief of the Field Acquisition Office said that his office encourages institutions to use the NAC catalog to determine whether a non-PPV Program drug price is fair and reasonable.

The BOP Is Not Ensuring that Institutions Are Competing Non-PPV Program Purchases Equal to or Greater than the Micro-Purchase Threshold

The BOP's acquisition policy and the FAR require that the BOP compete non-PPV Program purchases (not from the FSS) that are at or above \$3,500 (the micropurchase threshold) or that the BOP document a justification that shows why purchases were not competed.³¹ However, we found that the BOP is not ensuring that institutions compete these purchases, which presents another risk of paying more than necessary for drugs.

We were unable to confirm that BOP institution drug purchases had followed BOP policy and FAR requirements for two reasons. First, because the BOP does not have unique identifiers to link non-PPV Program purchases to institution documentation, we were unable to determine whether particular non-PPV Program purchases had been competed. Second, the BOP's Field Acquisition Office (FAO), which oversees institution purchases, could not provide documentation showing that it had reviewed drug purchases for that purpose when we requested it.³²

Similarly, we believe that these impediments have also prevented the BOP from confirming that its institutions follow BOP policy and FAR requirements. The FAO reviews samples of purchase card and purchase order transactions that exceed the micro-purchase threshold for competition. The FAO Chief, who oversees the FAO's review process, told us that, if an institution does not compete a purchase at or above the micro-purchase threshold, staff must document why competition was not available. However, because when sampling purchases the FAO does not differentiate between drug purchases and other purchases, its records could not demonstrate that institutions competed drug purchases or explain why competition was unavailable. The FAO Chief told us that, in order to determine whether purchases equal to or greater than the micro-purchase threshold were competed, the FAO would have to request documentation separately from each institution. Further, we found that staff at only one of our six select institutions cited the requirement to compete purchases as part of its drug procurement process.

Because the BOP is not ensuring that its institutions are following the FAR's competition requirements when making purchases at or above the micro-purchase threshold from non-PPV Program sources, the BOP cannot ensure that it is obtaining the lowest drug prices and is at risk of violating federal procurement regulations.

The BOP's Health Services Program Review Guidelines for Pharmacy Services Are Outdated and Do Not Thoroughly Evaluate Cost-Efficient Procurement Practices

The BOP uses program reviews as an evaluative tool to assess an institution's internal controls, programs, and operations and to monitor institution compliance

³¹ FAR 13.106. The VA has already competed PPV Program drugs, and therefore the BOP needs to compete non-PPV Program drug purchases only.

³² The FAO Chief told us that information indicating whether drug purchases were included in its sampling is maintained at institutions and not readily retrievable by the FAO.

with policy. 33 The BOP's Program Review Division (PRD) develops the criteria for compliance based on existing BOP policy, which, in the case of pharmacy-related policy, is the Pharmacy Services Program Statement. The criteria are compiled into Program Review Guidelines, which play an important practical role in directing the BOP's pharmacy-related services. The BOP's Chief of Pharmacy Services told us that, unless a requirement is included in the Program Review Guidelines, getting institutions to adhere to it is difficult.

We found that the BOP Health Services Program Review Guidelines related to Pharmacy Services in effect at the time of our review did not thoroughly evaluate cost-efficient pharmaceutical procurement practices. As a result, we believe that the BOP is missing an important opportunity to monitor and control drug spending. Specifically, we found that the Health Services Program Review Guidelines related to Pharmacy Services do not thoroughly evaluate cost-efficient pharmaceutical procurement practices because they lack the criteria to do so. We reviewed the current Health Services Program Review Guidelines and found that out of 11 review criteria only 1 criterion, if used to evaluate an institution's pharmacy services, could help ensure that institutions procure drugs cost-efficiently. This criterion requires the PRD to select five drugs from the National Drug Formulary to determine whether an institution purchased generic equivalents when they were available.

The PRD Section Chief over Health Services for Program Review told us that the PRD meets with divisions once every 3 years to conduct a management assessment and reevaluate the Program Review Guidelines. However, she also said that the PRD and the Health Services Division have not discussed pharmacy-related elements in the guidelines during management assessments and would not do so unless the Central Office had identified national deficiencies that affect most institutions. Because the Program Review Guidelines lack sufficient criteria related to cost-efficient pharmaceutical procurement, we believe that it is unlikely that the BOP would be able to identify such deficiencies through its program reviews.

One reason that the BOP has not updated its Health Services Program Review Guidelines as they relate to Pharmacy Services is because it does not have an updated program statement to serve as the basis for it. The BOP has not updated its Pharmacy Services Program Statement since 2005. The PRD Section Chief over Health Services for Program Review told us that most Program Review Guidelines stem from BOP policy as established in the relevant BOP program statement and that the PRD only rarely updates criteria based on other guidance, such as a memorandum from a senior BOP official. We found that although BOP

The BOP Health Services Program Review Guidelines, in which Pharmacy Services guidelines are a subcategory, cover five main areas: (1) Administration, (2) Infectious Diseases, (3) Quality Improvement (Assurance), (4) Credential Verification/Clinical Privileges/Practice Agreements/Peer Review, and (5) Climate.

³⁴ PRD officials produce a report upon completing their evaluation of institutions' compliance with program review criteria. Unless a deficiency is identified, these reports do not indicate what criteria the evaluators used.

³⁵ As of September 2019, the BOP told us that an updated version of the Pharmacy Services Program Statement is currently awaiting necessary approvals, including approval by the BOP union.

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officials have issued four pharmacy-related guidance memoranda, a senior official wrote only one and it did not result in changes to the Program Review Guidelines.

We believe that the BOP's oversight of its institutions' pharmaceutical procurement practices would be greatly enhanced, and the risk of paying more than necessary for drugs correspondingly decreased, if the BOP were to (1) establish in policy certain cost-efficient procurement practices and (2) incorporate into its Program Review Guidelines additional criteria designed to ensure that BOP institutions are following these practices. At the end of this report, we make several recommendations for enhancing the BOP's oversight of institutions' pharmaceutical procurement practices, which we believe will help the BOP control drug costs.

The BOP Does Not Collect Complete and Accurate Data on Its Drug Purchases or Effectively Analyze Pharmaceutical Data

We found that the BOP lacks a complete picture of its pharmaceutical purchasing, which may impede its ability to control drug costs. Specifically, the BOP has not compiled complete and accurate data on current or historical drug purchasing. Without complete and accurate drug purchase data, the BOP cannot conduct analysis that would assist it in determining how much it is spending on drugs, particularly for those purchased outside of the prime vendor. However, we did identify some analyses that the BOP could conduct with data that it already collects, which we believe could help it control its drug costs.

The BOP Has Not Compiled Complete and Accurate Data on Its Current or Historical Drug Purchasing

We found that the BOP lacks a comprehensive and accurate picture of its current and historical drug purchasing because not all institutions report, or report correctly, their non-prime vendor purchases to the Central Office. In addition, until March 2018, the Central Office did not store or analyze historical purchase-level data; instead the Central Office used summary reports of historical prime vendor purchases that incorrectly grouped drugs from the prime vendor. As a result, the BOP does not have insight into its complete drug spending and purchase volume, both of which could help the BOP negotiate drug prices and identify other cost control strategies. For example, the BOP's Chief of Financial Management for the Health Services Division told us that the BOP has been unable to determine its purchase volume for individual drugs, which has prevented it from obtaining more favorable pricing through blanket purchase agreements (BPA). He said that, because the BOP does not have comprehensive purchase data, some vendors have declined to enter into BPAs with the BOP that would give the BOP lower drug prices.

One of the primary reasons that the BOP lacks complete and accurate drug purchasing data is that BOP institutions have not consistently captured and shared this information with the Central Office. As explained previously, BOP institutions

³⁶ The BOP can negotiate BPAs, which are agreements between the BOP and contractors or vendors based on purchase volume and performance that require commitment from the BOP to purchase certain drugs in exchange for better pricing.

order drugs through the PPV Program, prime vendor open market, or non-prime vendor sources. Data for purchases that institutions make through the prime vendor (either through the PPV Program or their prime vendor open market account) is automatically accessible to Pharmacy Services officials, while data for purchases from non-prime vendor sources is accessible to them only if institutions record it correctly in the BOP's financial reporting system. However, we found that many institutions do not consistently or correctly record this data and Pharmacy Services told us that institutions vastly underreport their overall non-prime vendor purchasing. As a result, Pharmacy Services does not readily have access to comprehensive and accurate drug purchase data.

To increase their insight into institutions' non-prime vendor drug purchasing, in October 2015 Pharmacy Services officials advised all institutions to begin using specific codes to track nonprime vendor purchases in the financial reporting system. However, as of FY 2017, only 57 of the 98 institutions (58 percent) that the BOP manages reported spending on non-prime vendor purchases, even though all institutions would necessarily have had spending to report.³⁷ In addition to underreporting the non-prime vendor purchases they made, some institutions have not reported these purchases using the correct codes, thereby making it impossible for Pharmacy Services to identify the purchases. (See the text box for an example of how the BOP could enhance its ability to ensure institutions are

Tracking and Reporting of Non-Prime Vendor Purchases

We found that the BOP's program reviews do not assess whether institutions use the correct code to track non-prime vendor purchases. We believe that adding this assessment to program reviews would provide a way for Pharmacy Services officials to identify institutions that are inefficiently purchasing drugs from non-prime vendor sources so that they could take corrective action if needed.

The BOP's Chief of Pharmacy Logistics Support told us that, even though this data would be particularly helpful for the Central Office, he could not require institution staff to report it. He said that, because Pharmacy Services officials are in advisory positions only, they do not have the authority to mandate or enforce policy and procedure. Therefore, including the proper tracking and reporting of non-prime vendor purchases in Program Review Guidelines—at least for high volume or high cost drugs—could be an effective way for the BOP to ensure that institutions are consistently and accurately tracking and reporting such purchases.

Source: OIG interviews with BOP Pharmacy Services officials and OIG analysis of BOP program reviews

Our review focused on 98 BOP-managed institutions and excluded BOP contract prisons and Residential Reentry Centers. There were 122 BOP-managed institutions as of September 2019, but the BOP considers correctional complexes (multiple institutions co-located) to be a single institution when making and reporting drug purchases.

As an example of the degree to which non-prime vendor purchases are underreported, the BOP's Chief of Pharmacy Logistics Support told us that the Central Office received reports of flu shot purchases from only some institutions, even though all institutions ordered them from non-prime vendor sources, meaning that only some institutions correctly recorded their purchases in the financial reporting system. Further, the actual spending on flu shots alone would have exceeded what institutions reported in total non-prime vendor spending in FY 2017.

following cost-efficient practices through better tracking of non-prime vendor drug purchases.)

A BOP official also told us that, even when institutions reported non-prime vendor purchases using the correct codes, the reporting did not capture key details such as the source of purchase and, of particular importance, whether that source was the gray market.³⁸ Gray market purchases are one of the options institutions have when a needed drug is unavailable from the prime vendor. However, according to the BOP's Chief of Pharmacy Logistics Support, they are exorbitantly expensive, sometimes "as much as tenfold" what the companies paid before selling them to the BOP.

Although the BOP's Chief Pharmacist stated that institutions should avoid gray market purchases, the BOP's Chief of Pharmacy Logistics Support told us that he believes that most non-prime vendor purchases that are not purchased through a contract are from the gray market.³⁹ However, without detailed non-prime vendor purchase data that shows the source of each purchase, the BOP cannot determine the magnitude of these purchases to decide what, if any, cost control measures are needed.

An isolated example that highlights the risk of having incomplete non-prime vendor purchase data occurred during a recent natural disaster, when there was a manufacturer shortage of intravenous (IV) fluid bags and institutions started purchasing them from the gray market. The Chief of Pharmacy Logistics Support told us that he became aware of the gray market purchases only because he convened an ad hoc group to address the BOP's IV fluid bag shortage and the group reported all IV fluid bag purchases that institutions had made during the shortage. We believe that, if Pharmacy Services officials had non-prime vendor purchase data that showed gray market purchases, they could have identified these instances earlier and facilitated reallocating IV fluid bags between institutions, before additional institutions resorted to the gray market.

Another example of Pharmacy Services' incomplete purchase data relates to out-of-stock drugs. When generic drugs are out of stock through the prime vendor, institutions must find another source, which can result in purchasing more expensive, brand name drugs. 40 If Pharmacy Services has information about when shortages occur, it can inform the prime vendor and thereby trigger the prime

³⁸ As discussed in the <u>Introduction</u>, the gray market for pharmaceuticals involves secondary wholesalers purchasing drugs from primary wholesalers and selling them at a higher price during drug shortages. When institutions make gray market purchases, they are usually purchasing at a much higher than usual price.

³⁹ The BOP purchases some non-prime vendor drugs such as flu shots and specialty drugs through contracts other than the PPV Program contract.

In FY 2017, the BOP's brand name drug purchases accounted for 21.5 percent of total drug purchases but 88 percent of total drug spending. A Pharmacy Services official told us that sometimes institutions order brand name drugs when generic drugs are out of stock or on long-term backorder through the PPV program.

vendor to increase inventory at distribution centers, which will reduce the likelihood of future drug shortages and paying more than necessary for non-PPV Program drugs. However, we found that the prime vendor's online portal does not currently capture when institutions need an out-of-stock drug unless institution staff, after learning that the drug is out of stock, nevertheless process the order and leave the order in the system. A Pharmacy Services official told us that, because processing an order for an out-of-stock drug adds work to the procurement process, institution staff rarely do it; instead, when they realize that a drug is out of stock through the prime vendor, they cancel the order and the out-of-stock event is not captured in the system. 41

The incomplete information about out-of-stock drugs can also cause the BOP to miss credits to which it is contractually entitled but which it cannot claim without a record of the institution's attempt to purchase an out-of-stock VA National Contract drug. We believe that the BOP should ensure that institutions place orders for out-of-stock VA National Contract drugs through the prime vendor or otherwise document out-of-stock events in a manner that allows the BOP to claim all credits to which it is contractually entitled. The BOP may also explore establishing a simpler method for institutions to signal to the prime vendor when a needed drug is out of stock. Further, we believe that having accurate information about out-of-stock events would likely benefit the prime vendor in its efforts to maintain optimal inventory levels.

In addition to the BOP's lack of complete data on its current pharmaceutical purchasing, we found that prior to 2018 the BOP did not capture and store historical purchase-level data from the prime vendor. ⁴² Instead, the BOP relied on prime vendor summary reports that were prone to error in that they incorrectly grouped drugs and the BOP therefore could not use them for accurate analysis of its drug purchasing. ⁴³ After we completed our fieldwork, BOP officials told us that the BOP had begun using a pharmaceutical purchase database that would automatically extract data from the prime vendor portal and, in the future, analyze it. We believe that compiling a complete picture of its purchasing data would assist the BOP in understanding and controlling its drug costs.

One Health Services Administrator told us that his institution's non-PPV Program spending increased 123 percent, from \$126,000 in FY 2015 to \$281,000 in FY 2017. Specifically, in FY 2017, his institution had to purchase drugs from 14 different companies because the prime vendor did not have the drugs in stock. He told us that his institution started to track non-PPV Program purchases because it wanted to determine how much it was spending on drugs outside the PPV Program, especially after receiving an influx of inmates who required specialty drugs.

⁴² Prior to 2018, the BOP had access to aggregate data for only the previous 2 years. Therefore, neither the BOP nor the OIG is able to analyze purchase-level data prior to 2016.

⁴³ For example, the BOP's Chief of Pharmacy Logistics Support told us that the BOP's Hepatitis C drug usage reports were inaccurate in that data from the summary reports did not include one of the BOP's commonly used Hepatitis C drugs. Further, the BOP provided us multiple versions of purchase-level data from FYs 2016 and 2017 showing differing amounts of total spending.

Analysis Using Data That the BOP Already Collects Could Help Control Drug Costs

BOP officials acknowledged that the BOP must improve its data collection and analysis in order to purchase drugs more cost-efficiently. To this end, we identified two types of analysis that could help the BOP control its drug costs using data that it already collects but is not currently analyzing. First, the BOP could analyze all prime vendor purchase data that the BOP National Pharmacy and Therapeutics (P&T) Committee compiles. Second, the BOP could monitor and analyze purchases of drugs that institutions do not ultimately use. We discuss each of these strategies below.

We believe that one possible source of data that could assist the BOP in analyzing drug purchases is the BOP National P&T Committee's compiled reports. According to the BOP's Chief of Pharmacy Logistics Support, this committee compiles data on prescribing patterns and non-formulary drug spending, as well as other drug purchasing statistics. 44 For example, the National P&T Committee reported that between FY 2012 and FY 2016 the BOP's spending on human immunodeficiency virus (HIV) drugs increased 40 percent (\$21.2 to \$29.7 million) and that its spending on Hepatitis C drugs increased 218 percent (\$4.4 to \$14.0 million). 45 At the time of our review, the BOP used this committee's data for informational and historical record-keeping purposes only; according to the BOP's Chief Pharmacist, the committee's purpose is to make clinical decisions about drugs and not to identify ways to control drug costs. However, we believe that using the readily available data that the National P&T Committee compiles may assist the BOP in analyzing its drug spending. Such an analysis could be helpful in identifying areas in which the BOP could pursue cost savings, such as seeking to negotiate reductions in drug prices through BPAs and other means.

Another type of data that the BOP could analyze relates to drugs that institutions purchase but do not use. When BOP institutions return expired or unused drugs to the prime vendor, the prime vendor issues credits, which are refunds for less than the price that the BOP originally paid. We analyzed BOP data on credits issued from FY 2014 through FY 2018 and found that the BOP's credits ranged from \$2.2 million to \$5.1 million per year. However, we found that the BOP does not make a practice of monitoring or analyzing the credits it receives, even though doing so would allow it to develop a fuller picture of over-ordering BOP-wide and to develop strategies to reduce waste and control costs. In addition, credits from the prime vendor are returned to the U.S. Treasury Department unless BOP institutions can match the credit invoice to the original obligation within the same fiscal year; the BOP's Chief of Pharmacy Logistics Support told us that institutions are rarely able to do so. We note that the taxpayer receives the benefit of these credits whether or not the BOP retains them; however, if the BOP were able to

⁴⁴ In 1994, to facilitate its efforts to efficiently manage its pharmacy program, the BOP established a National P&T Committee to, among other things, maintain its national list of drugs approved for inmate use (National Drug Formulary) and report on BOP-wide trends in the types and costs of drugs prescribed for inmates.

 $^{^{\}rm 45}$ We do not report FY 2017 spending because the National P&T Committee could provide only estimates for that fiscal year.

retain more of the credits, these funds would help alleviate its budgetary constraints.

We also found that some institutions have started a promising practice of analyzing their own drug purchase data in a way that Pharmacy Services officials may be able to replicate on a larger scale. Specifically, a Health Services Administrator at a BOP federal medical center told us that she tracks spending on high cost drugs and the number of inmates taking them, which has created a baseline of historical pricing data that has helped her create more accurate budget projections. On a larger scale, data such as this could help the BOP better project its future drug spending and assist it in effectively managing its funds.

The BOP Has Taken Several Steps That Could Improve Drug Procurement and Control Costs, but Achieving the Full Benefits from These Steps Would Require Additional System Upgrades and Enhanced Use of Data

We found that while the BOP has taken steps that could improve the efficiency of pharmaceutical procurement and help control drug costs, several of these steps need to be expanded or enhanced to realize their full potential. First, in May 2012 the BOP implemented the Pharmacy Inventory Management System (PIMS) to facilitate drug procurement and waste reduction at the institution level. However, as of March 2019 PIMS was not fully compatible with certain existing drug dispensing machines used in some institutions and required updates to achieve optimal functionality. Second, some BOP institutions provide "pharmacy clinics," which can improve inmate health and reduce drug and medical costs. However, we found that institutions have limited staffing and insufficient data to demonstrate the clinics' value, which may be an obstacle to increasing institutions' use of clinics. Third, Temporary Price Reductions (TPR) have helped the BOP save on drug costs, but we believe that enhanced data collection and analysis would improve the BOP's negotiating position for these TPRs and allow the BOP to be more strategic when seeking additional TPRs. Below, we describe these three steps that the BOP has taken and the additional work needed to achieve their full benefits.

The BOP Recently Implemented PIMS, but Opportunities for Improvement Remain

The BOP uses PIMS, an electronic drug inventory management system, to improve drug procurement and the cost-efficiency of its pharmacy program. We did not fully assess its benefits and capabilities because not all BOP institutions had implemented PIMS before our fieldwork was complete.

PIMS is intended to facilitate cost-efficient drug procurement by tracking the quantity and price of most drugs that BOP institutions are dispensing, as well as institutions' current drug inventories. Using this information, PIMS indicates when an institution's pharmacy should place a new order so that it will maintain a predetermined minimum quantity (par level) of a given drug. PIMS also helps the BOP control costs by identifying the lowest price drug available. This makes it less likely that pharmacy staff will order the more expensive drug when they have an option. However, we identified two issues that have limited the system's usefulness so far. Specifically, we found that upgrades were needed to fully realize

PIMS's benefits and that PIMS was not compatible with the drug-dispensing machines that some institutions use.

While PIMS has the potential to assist the BOP in managing its drug costs, we found that as of March 2019 opportunities remained for the BOP to improve PIMS to ensure optimal functionality and value. Specifically, PIMS cannot show the drug usage rates of all institutions simultaneously. The BOP's Chief of Pharmacy Logistics Support told us that, if the BOP upgraded PIMS to show institution drug usage rates, it would help Pharmacy Services know when to reallocate drugs from one institution to another to prevent drug shortages and waste. We believe that the reallocations may also reduce the instances in which institutions make costlier purchases from the gray market. The Chief of Pharmacy Logistics Support also told us that additional upgrades would allow PIMS to automatically monitor and adjust par levels with minimal user intervention from institution staff. He cited insufficient funding as the chief impediment to making these upgrades.

We also found that PIMS is not compatible with certain drug dispensing machines that some institutions use in that it does not have an interface to communicate with these machines about their drug dispensing. As a result, PIMS does not currently collect comprehensive data about drug inventory quantities for some institutions and institution staff must consult both PIMS and the dispensing machines to obtain accurate inventory levels.

Additional Pharmacy Clinics Could Help the BOP Control Its Drug and Medical Costs

One aspect of BOP Pharmacists' work includes meeting with individual inmates to discuss the use of drugs to manage their ongoing health conditions. Through these "pharmacy clinics," Pharmacists educate inmates on how to prevent and manage diseases such as diabetes, HIV, and tuberculosis; how to manage pain; and how to properly use specific drugs. BOP officials at the Central Office and at institutions described to us several potential benefits of pharmacy clinics, including that they can reduce drug and medical costs; improve inmate health outcomes; and increase the desirability of BOP pharmacy jobs, thereby helping with recruitment and retention of Pharmacists. However, in FY 2017, only 38 of the 98 institutions (39 percent) had the required agreement between a Pharmacist and the appropriate Physician to conduct these clinics. 46 Further, the BOP's Chief Pharmacist told us that some of the 38 institutions that have conducted these clinics are conducting fewer than they did in the past. The BOP has identified two reasons for this decrease and for the overall limited number. First, the BOP lacks sufficient staffing to conduct them and, second, Pharmacy Services lacks the necessary data to demonstrate their benefits, including potential cost savings.

The BOP uses collaborative practice agreements between the Clinical Director or other Physician and a Pharmacist at a BOP institution, which gives the Pharmacist the prescribing and laboratory ordering rights needed to conduct clinics.

Pharmacy Clinics Have Several Potential Benefits

A Pharmacy Services official told us that, based on the available research, he estimates that clinics have a four to one return on investment, meaning that for every dollar spent on clinics there is a 4-dollar reduction in overall medical costs. The BOP's Chief Pharmacist told us that, although pharmacy clinics can increase pharmaceutical costs by increasing the number of drugs ordered, they can decrease overall medical spending by improving inmate medication compliance and health outcomes. BOP staff told us that clinics are a deliberate drug cost-saving initiative that results in better disease management, that having a Pharmacist consult with inmates helps prevent prescription drug abuse, and that clinics can prepare inmates to manage their medical conditions upon release. A Pharmacist emphasized that clinics allow institution pharmacy staff to better use their specialized training and knowledge. BOP Physicians noted that having Pharmacists conduct clinics allows Physicians more time for other clinical activities.

<u>Staffing Constraints Have Limited the Number of Pharmacy Clinics that Institutions Conduct</u>

Despite the potential benefits of pharmacy clinics, Pharmacy Services and regional and institution staff told us that staffing constraints have prevented Pharmacists from conducting more of them. Pharmacy clinics require that Pharmacists meet with inmates to provide education and counseling and sometimes conduct laboratory work. However, BOP staff told us that there is often not enough time for these activities because their other duties, such as managing inventory, handling prescriptions, and assisting other healthcare staff with less skilled tasks such as working pill lines, consume their time. We believe that this problem may be more acute in Remote Fill institutions, which assist other institutions in filling prescriptions in addition to their regular pharmaceutical duties. 48

⁴⁷ The BOP already collects some clinical outcome data from its diabetes clinics. Notably, in 2016 the *Journal of the American Pharmacists Association* studied BOP pharmacy clinic data and found that "pharmacist-run clinics have been shown to be successful at achieving a productive lowering of A1C"—a positive result for inmates with diabetes and an example of the potential advantages of clinics. See J.T. Bingham and J.J. Mallette, "Federal Bureau of Prisons Clinical Pharmacy Program Improves A1C," *Journal of the American Pharmacists Association* 56 (2016): 173–177, www.japha.org/article/S1544-3191(16)00077-7/pdf (accessed February 12, 2020).

The BOP's Chief of Pharmacy Logistics Support told us that the Central Office did not provide more staff for the additional workload that Remote Fill institutions took on because having the institutions remotely fill prescriptions was supposed to be temporary until the BOP could implement the BOP Mail Order Pharmacy. However, the Mail Order Pharmacy initiative is currently on hold due to staffing and funding limitations. In 2016, the OIG issued a report examining the BOP's medical staffing challenges and its use of Public Health Service officers to address those challenges. See DOJ OIG, *Review of the Federal Bureau of Prisons' Medical Staffing Challenges*, Evaluation and Inspections (E&I) Report 16-02 (March 2016), www.oig.justice.gov/reports/2016/e1602.pdf (accessed February 12, 2020).

Through our review of BOP data, we identified two instances in which a planned pharmacy clinic did not take place due to staffing constraints; however, BOP data did not show the number of institutions that would have planned and held such clinics were additional resources available to them.

We identified three promising initiatives already under consideration by the BOP that, if implemented, could help institutions with limited staffing conduct pharmacy clinics. One is a virtual clinic, or teleclinic, which the National Program Coordinator for the BOP's Regional Hepatitis Clinical Pharmacist Consultant Program told us she is planning to conduct for one institution that has chronic understaffing issues. She told us that the expanded use of teleclinics would allow her to assist institutions that have less experience treating Hepatitis C cases. Two other initiatives would focus on consolidating pharmacy work: the BOP Mail Order Pharmacy would automate and centralize the process of refilling prescriptions, and Central Fill and Distribution would consolidate all Remote Fill institutions into one site. BOP staff told us that these latter two initiatives, if implemented, could give Pharmacists more time to conduct clinics. However, they depend on additional funding and certain staffing allocations and the BOP does not have a timeline for implementing either of them. 49

The BOP Lacks Data to Demonstrate Pharmacy Clinics' Value

Central Office Pharmacy Services told us that better data demonstrating the health-related benefits and potential cost savings of pharmacy clinics could support their expanded use across BOP institutions. In particular, the BOP's Chief Pharmacist told us that assigning a dollar amount to pharmacy work through data collection and analysis might help Wardens recognize and appreciate the value of pharmacy work and ensure adequate staffing for it. For example, the BOP's Chief Pharmacist told us that he would like to compare costs for inmates that participate in diabetes clinics to those that do not to determine whether diabetes clinics can reduce pharmaceutical and medical costs. However, doing so would require the BOP to track inmate-specific pharmaceutical and medical costs that it currently does not track. He said that the new pharmaceutical purchase database that Pharmacy Services developed will not track the necessary drug dispensing data per inmate. He also stated that the U.S. Department of Defense has been able to associate dollar amounts to interventions to demonstrate savings from pharmacy clinical interventions.

⁴⁹ Pharmacy Services told us that the BOP Mail Order Pharmacy would pay for itself in 4 years by eliminating most refill responsibilities for BOP institutions, but that the BOP does not have the \$40 million necessary for its implementation despite having requested the funds from Congress.

In a previous OIG report, we identified several potential benefits related to Central Fill and Distribution, including improved drug inventory management and more time for Pharmacists to serve in a clinical capacity, which can improve medical care and reduce overall costs. DOJ OIG, *Audit of the Federal Bureau of Prisons Pharmacy Services*.

⁵⁰ Wardens have the authority to make staffing decisions in institutions. They determine the number of staff assigned to the pharmacy and can temporarily reassign pharmacy staff to corrections posts through a practice known as augmentation. We do not know how often augmentation affects pharmacy staffing because the BOP does not track augmentation.

⁵¹ The Chief Pharmacist told us that tracking inmate-specific drug costs would also allow the BOP to identify those inmates with the highest pharmaceutical costs to enable targeted intervention.

We believe that, before considering whether to expand the use of pharmacy clinics, it would be helpful for the BOP to collect the data necessary to evaluate whether past and existing clinics have in fact been as cost-efficient and beneficial for inmates as Central Office and pharmacy staff believe. This data would assist Central Office staff in making resource decisions across the institutions and in demonstrating the value of such clinics to Wardens and other institution-level staff as they make resource and staffing decisions at their institutions.

The BOP Has Recently Started Seeking TPRs, but Additional Data and Analysis Could Help the BOP Realize More Cost Savings from Them

To help contain pharmaceutical costs, the BOP uses TPRs, nonbinding agreements between drug manufacturers and government agencies to temporarily reduce a drug's price to increase the manufacturer's drug sales. ⁵² For approximately 10 years, drug manufacturers have offered TPRs to give the BOP prices that are lower than the Federal Supply Schedule (FSS) price for specific drugs. ⁵³ In 2012, the BOP started seeking TPRs from drug manufacturers on its own initiative.

We found that TPRs have helped the BOP save money on its drug purchases. As shown in Table 1, the BOP's data analysis indicated that it saved \$8.3 million in FY 2016 and \$23.3 million in FY 2017 by using TPRs to purchase drugs at prices lower than FSS prices.⁵⁴

Table 1

BOP Cost Savings, in Millions, for Purchasing Drugs through TPRs
Rather than at FSS Prices, FY 2016 and FY 2017

	FY 2016	FY 2017
Total FSS Cost	\$34.8	\$39.4
Total TPR Cost	\$26.5	\$16.1
Total Savings through TPRs	\$8.3	\$23.3
Percent Savings through TPRs	24%	59%

Note: The numbers in the table have been rounded.

Source: BOP data

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TPRs have been especially beneficial in reducing the cost of certain specialty drugs, such as those used to treat Hepatitis C. For example, in FY 2017 the BOP's savings on purchases of five Hepatitis C drugs accounted for 83 percent (\$19.4 of \$23.3 million) of the BOP's savings under TPR agreements (see Table 2 below).

 $^{^{52}\,}$ TPRs typically last for 1 year, but they can expire or be renewed, revoked, or modified at any time.

⁵³ When a drug manufacturer issues the BOP a TPR to lower a drug's price, it has to inform the NAC of the price change. The NAC notifies the prime vendor, and the prime vendor inputs the TPR to the prime vendor online portal.

⁵⁴ In FY 2016, the BOP started collecting data on drug purchases made through TPRs.

Table 2
Cost Savings, in Millions, for Purchasing Hepatitis C Drugs through TPRs Rather than at FSS Prices, FY 2017

Hepatitis C Drug	Total FSS Cost	Total TPR Cost	TPR Savings
Drug A	\$15.2	\$6.6	\$8.6
Drug B	\$10.6	\$3.7	\$6.9
Drug C	\$6.4	\$3.1	\$3.3
Drug D	\$0.8	\$0.2	\$0.6
Drug E	\$0.026	\$0.016	\$0.011
Total	\$33.1	\$13.7	\$19.4

Note: The numbers in the table have been rounded.

Source: BOP data

Specifically, a TPR for Drug A resulted in the BOP saving \$8.6 million compared to what it would have spent had it paid the FSS price. Additionally, we note that a TPR reduced the unit price of Drug D by 75 percent. Pharmacy Services Officials told us that the price reductions realized through TPRs have helped the BOP treat more inmates with Hepatitis C.

BOP Pharmacy Services officials told us that additional data collection and analysis could allow the BOP to strategically seek additional TPRs. Specifically, the BOP's Chief of Pharmacy Logistics Support told us that, by better tracking information such as potential TPR savings, the BOP's purchase volume for specific drugs and drug classes, and drugs for which other federal agencies have TPRs and the BOP does not, the BOP could more effectively identify opportunities to request a TPR from a drug manufacturer. The BOP's Chief Pharmacist told us that the new pharmaceutical purchase database could improve the BOP's bargaining position by identifying potentially beneficial TPRs by drug class rather than individual drug, which could be more valuable to both manufacturers and the BOP. We believe that an additional benefit of collecting this data is that the BOP could share it with other DOJ components, and with other federal agencies, in a collaborative effort to leverage their collective market share for greater TPR savings. ⁵⁵

Case Study: The BOP's Efforts to Prevent and Manage Hepatitis C Are Hampered by Inconsistent Testing and Treatment

Our broader review of the BOP's drug costs and procurement also encompassed a more specific evaluation of the BOP's management of costs related to Hepatitis C, a liver infection that ranges from a mild illness that lasts a few

 $^{\rm 55}$ The OIG is also reviewing the U.S. Marshals Service's pharmaceutical drug costs.

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weeks to a serious, lifelong disease that can be fatal.⁵⁶ We specifically looked into the BOP's management of Hepatitis C, including the health risks of not effectively managing this infectious disease and the high cost of Hepatitis C treatment, which accounted for nearly 20 percent of the BOP's total drug spending in FY 2018. We found that these issues have been a particular challenge for the BOP, in part because, as discussed in the <u>Introduction</u>, the BOP's spending for Hepatitis C drugs has increased by approximately 471 percent in recent years, from \$4.4 million in FY 2012 to \$25 million in FY 2018.⁵⁷

We believe that a critical component of the BOP's management of Hepatitis C is knowing both the overall prevalence of Hepatitis C in its inmate population and the treatment needs of inmates with Hepatitis C.⁵⁸ This information can help the BOP prevent the spread of Hepatitis C to other inmates or staff; ensure that inmates receive appropriate treatment; and assist the BOP in projecting, requesting, and allocating the funds needed for treatment.⁵⁹ However, we found that the BOP lacks this information because not all institutions test all inmates for Hepatitis C or classify those that have tested positive into one of the BOP's three treatment priority levels so that they can be considered for treatment. 60 Further, we found that the availability of resources at the institution level has at times driven Hepatitis C treatment decisions, resulting in inconsistent treatment for inmates and thereby hampering the BOP's efforts to effectively manage Hepatitis C and control pharmaceutical and medical costs. In addition to its importance for inmate health, treating all inmates that the BOP's Hepatitis C Clinical Guidance identifies as needing treatment can be cost-effective in the long run. 61 The BOP's Chief Pharmacist told us that, while treating Hepatitis C can be costly, it can prevent the development of even costlier health conditions.

⁵⁶ According to the Centers for Disease Control and Prevention (CDC), acute Hepatitis C infection occurs within the first 6 months after exposure. Hepatitis C can be short-term, but most acute infections lead to chronic infection. Chronic Hepatitis C can cause liver damage, cirrhosis, liver cancer, and death.

⁵⁷ We used the actual numbers to calculate percent change. In this instance, the percentage calculation based on the actual number is different from the calculation based on the rounded number.

⁵⁸ According to the CDC, new available Hepatitis C treatments "usually involve just 8–12 weeks of oral therapy (pills) and cure over 90% of people with few side effects." See CDC, "Hepatitis C Questions and Answers for the Public," November 2, 2018, www.cdc.gov/hepatitis/hcv/cfaq.htm#A4 (accessed February 12, 2020).

 $^{^{59}}$ According to the CDC, Hepatitis C is transmitted by the blood of an infected person entering the body of another person. See CDC, "Hepatitis C Questions and Answers for the Public."

 $^{^{60}}$ A Hepatitis C test is a blood test that checks for the presence of antibodies that indicate exposure to the Hepatitis C virus.

⁶¹ According to the BOP's Hepatitis C Clinical Guidance, inmates with chronic Hepatitis C infection are eligible for treatment. The BOP considers all inmates with chronic Hepatitis C to need treatment and makes them eligible by assigning a priority level. The Hepatitis C Clinical Guidance recommends ongoing monitoring for those with acute Hepatitis C infection.

The BOP Does Not Know the Prevalence of Hepatitis C in Its Inmate Population Because It Does Not Test All Inmates for Hepatitis C

We found that the BOP does not know the prevalence of Hepatitis C in its inmate population. The BOP's Medical Director estimated, based on one BOP institution that has tested all inmates, that the BOP's overall Hepatitis C prevalence is 10 to 15 percent; however, we found that this cannot be verified because not all institutions test all inmates. We learned that the BOP's Hepatitis C Clinical Guidance recommends but does not require institutions to test all inmates for Hepatitis C. As a result, medical staff at each BOP institution have discretion to determine the criteria for testing their inmates. We found that testing practices vary across institutions.

We spoke with medical staff in eight BOP institutions and identified three different testing practices. Only three institutions followed the BOP's recommended testing practice, which would result in all inmates being tested (except for those who opt out). Specifically, these institutions offer Hepatitis C testing to all inmates, including incoming inmates as they arrive at the institution, as well as to those already in custody who have not previously been tested. In contrast, three institutions test all incoming inmates but do not routinely test inmates already in custody and two institutions test inmates only if they exhibit signs of Hepatitis C infection.

According to a 2014 American Correctional Association (ACA) survey, 13 percent (7 out of 53) of all responding correctional systems in the United States provided opt-out Hepatitis C testing to all inmates. While the BOP is not alone among correctional systems in not testing all inmates for Hepatitis C, the ACA and a public health organization have noted important benefits of doing so. For example, the ACA concluded: "Due to the great variability in the screening practices across the various correctional jurisdictions, it is difficult to accurately assess prevalence. Without accurate prevalence information, it is very challenging to estimate costs of treating this population group." In addition, the American Association for the Study of Liver Diseases noted that, while universal opt-out Hepatitis C testing is

⁶² A BOP official told us that Hepatitis C disproportionately affects the BOP's inmate population because inmates' rates of previous IV drug use are higher than the general population's. In addition, inmates are susceptible to Hepatitis C transmission and reinfection through receiving tattoos in prison.

In August 2018, the BOP updated its Hepatitis C Clinical Guidance to recommend voluntary opt-out testing for all inmates, regardless of sentencing status, including new intakes and inmates in custody that the BOP has not tested. This is an expansion of the guidance issued in May 2017 that recommended institutions test only sentenced inmates.

The ACA issued the survey to the health authorities from all 50 state departments of corrections, the country's 6 largest jail systems, and the BOP. Ninety-three percent of these agencies responded to the survey. ACA Coalition of Correctional Health Authorities, <u>Hepatitis C in Correctional Settings: Challenges and Opportunities</u> (April 2015), www.aca.org/ACA_PROD_IMIS/Docs/OCHC/HCVinCorrectionalSetting_Final.pdf (accessed February 12, 2020).

infrequent in prisons, it can reduce Hepatitis C transmission and subsequent advanced liver disease.⁶⁵

We interviewed officials from five state correctional systems to learn more about their Hepatitis C testing practices and the reasons for them. We found that three systems tested all inmates for Hepatitis C and two did not. A medical official from a state that tests all inmates (except those who opt out) told us that knowing the prevalence of Hepatitis C by testing all inmates is assisting the Department of Corrections in its goal to eradicate Hepatitis C within its inmate population. He said, "You cannot eradicate something without finding it first." Comparatively, an official from a state system that does not test all inmates told us that this correctional system does not know its Hepatitis C prevalence because it relies on inmate self-reports during intake to identify inmates with Hepatitis C. We believe that the findings from the ACA study and our research from the states—in light of inmates' higher risk of infection and the potential high costs of untreated Hepatitis C, which we discuss below—suggest that there is potential value in the BOP testing all inmates who have not yet been tested to determine the prevalence of Hepatitis C within its inmate population. In addition to determining the full scope of its Hepatitis C-related challenges, testing inmates and determining the exact prevalence of Hepatitis C would enhance the BOP's ability to identify inmates with the greatest need for treatment.

In the next section, we discuss the priority level treatment system that the BOP uses to determine which inmates should be prioritized for Hepatitis C treatment. We found that the BOP has not assessed and assigned all Hepatitis C-positive inmates to a treatment priority level so that they can be considered for treatment.

The BOP Does Not Systematically Classify Inmates Diagnosed with Hepatitis C into a Treatment Priority Level

In July 2015, the BOP updated its Hepatitis C Clinical Guidance to include a three-tiered priority level system that classifies inmates according to their need for treatment based on risk of complications and disease progression. ⁶⁶ By requiring institutions to treat inmates in Priority Level 1 first before moving on to Level 2 and then Level 3, this system is intended to ensure that Hepatitis C-positive inmates with the greatest need are identified and receive the treatment they need. A BOP

The American Association for the Study of Liver Diseases adopted this statement from T. He et al., "Prevention of Hepatitis C by Screening and Treatment in U.S. Prisons," Annals of Internal Medicine 164, Issue 2 (2016): 84–92, www.hcvguidelines.org/references/he-2016 (accessed February 12, 2020).

⁶⁶ The BOP's Hepatitis C Clinical Guidance states, "Certain cases are at higher risk for complications or disease progression and may require more urgent consideration for treatment." Inmates at Priority Level 1 have the highest priority for treatment.

The BOP issued guidance in May 2014 that established criteria for prioritizing treatment for Hepatitis C-positive inmates "who have a more urgent need for intervention" but did not classify them into priority levels.

official told us that the system is also intended to help the BOP manage the high cost of Hepatitis C treatment. Even though the decision to request treatment is made at the institution level, the BOP's Central Office plays an important role in managing Hepatitis C treatment BOP-wide. ⁶⁷ Central Office officials write the BOP's Hepatitis C Clinical Guidance, define the boundaries of each of the treatment priority levels, and determine the priority levels that each institution is authorized to treat. ⁶⁸

We found that the BOP has not assigned every Hepatitis C-positive inmate a priority level, and we identified some reasons. First, as discussed above, because the BOP does not test all inmates, it is likely that not all Hepatitis C-positive inmates have been identified so that they can be assigned a priority level. Second, we found that even when BOP institutions test and diagnose inmates with Hepatitis C, institutions are not always using the BOP's system to prioritize inmates who have the greatest need for treatment. A BOP institution official told us that insufficient staffing may prevent institutions from systematically using the treatment priority level system. Specifically, a Physician from a Federal Correctional Institution told us that his institution has not assigned all of its Hepatitis C-positive inmates a treatment priority level because he does not have enough staff to perform the work needed to do so. We believe that, by failing to assign each inmate diagnosed with Hepatitis C a treatment priority level, the BOP is at risk of allocating its resources inefficiently, as well as failing to provide inmates treatment commensurate with their needs.

In 2018, the BOP began implementing a system, known as the Hepatitis C dashboard, intended to increase the Central Office's and institutions' visibility into the number of Hepatitis C-positive inmates and their priority levels BOP-wide and within individual institutions. BOP officials told us that, although the dashboard is still undergoing some development, as of December 2018 all institutions have access to it. Prior to its implementation, institutions had to manually track the relevant data points and calculate the information needed to classify inmates into priority levels, which took a significant amount of time. The dashboard aims to alleviate some of this manual work, and it allows the BOP to aggregate Hepatitis C testing, priority levels, and treatment information nationally and regionally; before the dashboard, the Central Office did not have a way to track this information BOPwide. Similarly, the dashboard gives all institutions a way to identify inmates that have been tested for Hepatitis C, their assigned priority levels, and whether they have received treatment. During our fieldwork, and before the dashboard was implemented, a Clinical Director told us that his institution had to create a spreadsheet to manually track inmates' priority levels because at that time there was not a BOP system that could accomplish this. The BOP's Medical Director told us that the BOP intends to use the dashboard to identify individual institutions whose testing and treatment rates are lower and then work with them to raise

⁶⁷ Within the parameters that the Central Office established, and in consideration of institutions' respective budgets, institutions request approval from the Central Office to treat inmates.

⁶⁸ The BOP determines an inmate's treatment priority level based on the presence of Hepatitis C symptoms, including the degree of fibrosis of the liver, which is measured by the aminotransferase-to-platelet ratio index, known as APRI.

these rates with the overall goal of increasing Hepatitis C testing and treatment BOP-wide. He also told us that, ultimately, the BOP plans to develop the dashboard further so that it can calculate priority levels using data points from inmate health records.

While the Hepatitis C dashboard may assist the BOP in monitoring, testing, and capturing the treatment priority levels of Hepatitis C-positive inmates, its utility will depend on institutions consistently testing inmates for Hepatitis C and classifying diagnosed inmates into the appropriate priority level. We believe that these efforts, if done systematically, would improve the BOP's understanding of the prevalence of Hepatitis C, likely improve its ability to manage Hepatitis C among its inmate population, and help protect inmates and staff. However, improvements to Hepatitis C testing and priority level categorization are not enough to address every issue we found with the BOP's management of Hepatitis C. We discuss issues that we found related to the BOP's treatment of Hepatitis C in the next section.

The BOP's Treatment of Hepatitis C-Positive Inmates Was Inconsistent During Our Review

BOP Central Office Pharmacy Services told us that the BOP's goal is to treat every Hepatitis C-positive inmate that the Hepatitis C Clinical Guidance identifies as needing treatment. We found that, across institutions, treatment of Hepatitis C-positive inmates was inconsistent during the scope of our review. Pharmacy Services and institution staff told us that the staffing requirements associated with Hepatitis C treatment, as well as the cost of Hepatitis C drugs, has prevented the BOP from treating all inmates who needed treatment. ⁶⁹ Central Office Pharmacy Services recognized that institutions were withholding Hepatitis C treatment due to budget constraints. In response, in FY 2017 the Central Office established a centralized reimbursement fund. We believe that centralizing funding may be an effective way for the BOP to ensure that treatment decisions are not driven by cost, as long as adequate funding is readily available to institutions.

BOP officials told us that one impediment to treating all inmates who need Hepatitis C treatment was the staffing requirements for administering treatment. The BOP's Chief Pharmacist told us that, even if the BOP was able to pay for treatment for every inmate that needed it, the BOP still would not be able to administer their treatment due to staffing challenges. One Clinical Director cited this concern as the reason why his institution's spending on Hepatitis C treatment decreased 16 percent between FY 2016 and FY 2017: at that institution, 2 Physicians oversee the care of 7,000 inmates, which he says is insufficient for the follow-up care that Hepatitis C treatment necessitates. Another Clinical Director echoed this concern, telling us that due to time constraints his staff must prioritize treating inmates with more immediately life-threatening conditions such as cancer,

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⁶⁹ A Pharmacy Services official told us that obtaining TPRs, as discussed above, has allowed the BOP to treat Hepatitis C at a lower cost and thereby treat more inmates.

diabetes, and congestive heart failure because Hepatitis C treatment is timeintensive. 70

BOP officials also told us that the cost of Hepatitis C drugs has impeded institutions' ability to treat all inmates that require Hepatitis C treatment. The BOP's Chief of Pharmacy Logistics Support told us that some institutions were not treating inmates because of the high cost of the medications. He told us that in the past Hepatitis C treatment was paid for through institutions' budgets. Even though institutions can request additional funding from the BOP regional offices, they are hesitant to do so because exceeding the institution's budget generally does not reflect well on the institution. For this reason, they may have at times not provided treatment. Indeed, several institution pharmacy staff indicated that availability of funds has affected their institutions' treatment decisions. For example, one Chief Pharmacist told us that, because of the high drug costs, his institution must treat Hepatitis C cases in order of severity until the treatment budget is exhausted. Another Chief Pharmacist expressed his perception that Hepatitis C treatment was limited by funding, stating that his institution does not have "an open checkbook" to treat all Hepatitis C-positive inmates.

We believe that the potential cost—both to inmates' health and to the BOP financially—of untreated Hepatitis C highlights the importance of the BOP identifying inmates with Hepatitis C and ensuring that those who need treatment receive it as soon as possible. A Pharmacy Services official told us that the BOP has not conducted a Hepatitis C treatment cost-benefit analysis. Based on our own analysis, we concluded that as of FY 2019 the BOP's average treatment cost per inmate (about \$10,500) is significantly lower than estimates for more serious conditions that can result from untreated Hepatitis C. For instance, the U.S. Department of Health and Human Services cited an article with cost estimates over 30 years for serious conditions resulting from untreated Hepatitis C, including \$81,096 for cirrhosis; \$267,986 for liver failure; and \$648,147 for liver cancer. 72

⁷⁰ The treatment process includes monitoring laboratory results and the inmates themselves to ensure that they are tolerating the drugs.

In contrast, a Physician from a Federal Medical Center told us that he does not think that Hepatitis C treatment is staff-intensive. However, he acknowledged that other BOP Physicians who do not have the same level of experience that he has working at a Federal Medical Center may disagree.

⁷¹ The BOP's Chief of Pharmacy Logistics Support said that some inmate health records indicate instances wherein Hepatitis C treatment was deferred due to cost of medication. Reviewing individual inmate health records was not within the scope of this review, so we did not seek to verify this statement or determine how often this occurred or whether inmates' health had been adversely affected as a result.

Tost estimates are based on annual Medicaid costs for treatment starting in 2014, and then adjusting for discounting, inflation, and growing Medicaid costs each year. The article also stated that the average liver transplant cost in 2012 was \$188,000. See Mathematica Policy Research, <u>The Costs and Benefits of Expanding Hepatitis C Screening in the Indian Health Service</u> (September 2018), www.aspe.hhs.gov/system/files/pdf/260026/HepC.pdf, and Z. Younossi et al., "<u>Treating Medicaid Patients with Hepatitis C: Clinical and Economic Impact</u>," *American Journal of Managed Care* 23, no. 2 (2017), www.ajmc.s3.amazonaws.com/_media/_pdf/AJMC_02_2017_Younossi %20(final).pdf (both accessed February 12, 2020).

In contrast, the authors of the article found that treating all Hepatitis C-positive study patients and thereby preventing more serious conditions and fatalities resulted in a 39.4 percent savings over their lifetimes.

The Centers for Disease Control and Prevention reports that:

- over 20 to 30 years, 10 to 20 percent of Hepatitis C-infected persons will develop cirrhosis, and
- each year that passes, 3 to 6 percent of Hepatitis C-positive persons with cirrhosis will develop liver failure and 1 to 5 percent of Hepatitis C-positive persons with cirrhosis will develop liver cancer.⁷³

Our analysis indicates that, while it would cost the BOP about \$1.05 million to treat 100 inmates diagnosed with Hepatitis C, leaving them untreated could cost \$15.33 million. Our estimate assumes that:

- over 10 to 20 years, the BOP would pay nearly \$811,000 to treat 10 inmates who develop cirrhosis, and
- over 10 years, about \$8.04 million to treat 30 inmates with liver failure and more than \$6.48 million to treat 10 inmates who develop liver cancer.⁷⁴

While we found no evidence indicating that the BOP is not treating Hepatitis C-positive inmates before they develop cirrhosis, if the BOP does not systematically test all inmates for Hepatitis C and classify those who test positive into priority levels, the BOP risks that inmates' Hepatitis C will go untreated and that they will subsequently develop cirrhosis or other more serious conditions. As a result, the BOP could incur significant, unnecessary medical costs. Further, the future cost burden to the tax payer could be significant if former inmates develop a more serious condition as a Medicaid or Medicare beneficiary after release from custody.

In FY 2016, the BOP's Central Office began an initiative that Pharmacy Services told us was intended to remove cost as a deciding factor for treating Hepatitis C at the institution level and to encourage institutions to treat as many Hepatitis C-positive inmates as possible. Specifically, the Central Office withheld \$25 million from institutions' medical budgets and used it to establish a centralized fund to reimburse institutions after they administered Hepatitis C treatment. The

⁷³ Further, the CDC reports that males age 50 years or older are more likely to develop cirrhosis. See CDC, "Hepatitis C Questions and Answers for the Public." According to the BOP, the overwhelming majority (93 percent) of BOP inmates are male. The OIG reported that 19 percent of BOP inmates were age 50 or older in 2013. See DOJ OIG, <u>The Impact of an Aging Inmate Population on the Federal Bureau of Prisons</u>, E&I Report 15-05 (May 2015), www.oig.justice.gov/reports/2015/e1505.pdf (accessed February 12, 2020).

The BOP's Central Office told us that, due to fluctuations in pricing for treatment by geographic location, it cannot calculate the total cost per inmate for these conditions. Therefore, for our calculations we used the Medicaid estimates that the U.S. Department of Health and Human Services cited.

We calculated this estimate based on the lower end of the CDC's prevalence statistics above.

BOP's Chief of Pharmacy Logistics Support told us that, by disconnecting funding from an institution's decision to treat Hepatitis C, the BOP would be less likely to be the subject of lawsuits from inmates claiming that the BOP denied them treatment. We believe that litigation based on failure to treat Hepatitis C is an ongoing risk for correctional agencies, including the BOP.

The Chief of Pharmacy Logistics Support told us that he compared month-to-month availability of money in the centralized fund with institution treatment approvals and concluded that there was a direct relationship between them. He therefore believed that funding availability drove increases in treatment. He identified and explained to us specific points at which he observed this relationship during FY 2017. First, he said that the number of Hepatitis C treatment approvals was relatively low from October 2016 through February 2017, which was after the BOP established the fund but before money was available to reimburse institutions (Congress had not yet enacted a budget). Once Congress passed a continuing resolution in March 2017 and money became available to immediately reimburse institutions, he observed that treatment levels increased at least five-fold. He told us that when the fund started to deplete in July 2017 Hepatitis C treatment approvals also decreased.

When the Hepatitis C reimbursement fund is depleted, institutions are responsible for covering Hepatitis C treatment costs unless the BOP's Health Services Division requests additional funding. A Chief Pharmacist told us that when the Central Office could not reimburse his institution for Hepatitis C treatment his institution had to reallocate money from its overall budget to ensure that Hepatitis C-positive inmates continued to receive treatment. The Chief of Pharmacy Logistics Support's analysis above leads us to conclude that, as long as adequate funding is readily available in the Hepatitis C reimbursement fund, centralizing funding may be an effective way for the BOP to ensure that treatment decisions are not driven by cost.

We also found that one institution has implemented two promising practices that we believe may help other institutions avoid running out of funding for Hepatitis C drugs. First, the institution's Health Services Administrator told us that the institution allocates a certain amount of the institution's funds for Hepatitis C

⁷⁵ Before treating a given Hepatitis C-positive inmate, an institution must request and receive approval from the BOP Central Office. The Chief of Pharmacy Logistics Support used the number of treatment approvals to support his observation that the number of Hepatitis C-positive inmates treated increases when there is enough money in the Hepatitis C reimbursement fund to immediately reimburse institutions.

The patitis C treatment, the Chief of Pharmacy Logistics Support told us that he continued to communicate to institutions that reimbursement would be forthcoming and that they should provide treatment accordingly. However, some institutions were still reluctant to treat Hepatitis C during these times.

BOP data indicated that Hepatitis C treatment approvals decreased 57 percent, from 115 inmates approved for Hepatitis C treatment in June 2017 to just 49 inmates approved for Hepatitis C treatment in July 2017.

drugs when it receives its budget to ensure that it has enough to continue providing Hepatitis C treatment if Central Office reimbursement funds become unavailable. Second, she told us that she tracks pricing for Hepatitis C drugs, which has created a baseline of historical pricing data and spending, both of which help with her budget projections. We believe that this practice demonstrates the importance of BOP institutions having reliable baseline data on their management of Hepatitis C.

One area that the BOP may explore to improve the consistency of its Hepatitis C treatment is a central billing system whereby the Central Office is responsible for all Hepatitis C drug payments. According to the Chief of Pharmacy Logistics Support, this approach would remove the funding barrier to treatment at the institution level, which we believe would make institutions less likely to make treatment decisions based on drug costs and therefore improve the consistency with which institutions provide Hepatitis C treatment. Whether the BOP adopts this approach or another, the BOP must find a way to ensure that institutions have the funding and staffing required to provide Hepatitis C treatment consistently to inmates who need it. If the BOP does not ensure consistent treatment for Hepatitis C-positive inmates, the heath of inmates and staff may be jeopardized and long-term costs may increase.

CONCLUSION AND RECOMMENDATIONS

Conclusion

We concluded that the BOP's ability to control drug spending is impeded by its inability to obtain drugs at the some of the lowest government pricing, by its drug procurement practices and lack of sufficient oversight of those practices, and by its insufficient collection and analysis of pharmacy data. We believe that the BOP can and must take additional actions to control its increasing drug spending.

With respect to drug prices, we found that the BOP is paying more for drugs than the federal government agencies that have access to Big 4 pricing. Further, we found that the Department has not prioritized efforts to obtain Big 4 pricing for its components, including the BOP, even though the BOP estimated that having access to Big 4 pricing would have saved approximately \$13.1 million, or 11 percent of its total drug spending, in FY 2017 alone. Moreover, this is similar to a 2016 OIG finding that the Department had not fully explored options for reducing BOP spending on outside medical care. We believe that the similarity between how these two issues could be addressed presents an opportunity for the Department to address them in tandem, on behalf of all of its components.

In terms of the BOP controlling drug costs at the institution level, we found that institutions risk paying more than necessary because they do not always search for the lowest price when purchasing drugs. Specifically, we found that institutions do not consistently follow the BOP's drug ordering hierarchy for pharmaceutical purchasing, nor do they always search for a Federal Supply Schedule price when purchasing drugs from non-Pharmaceutical Prime Vendor Program sources. Therefore, institutions risk buying drugs at prices that are higher than necessary. These challenges are exacerbated by deficiencies related to the BOP's Health Services Program Review Guidelines for Pharmacy Services. Specifically, the Guidelines do not include sufficient criteria to monitor institutions' use of cost-efficient procurement practices, meaning that the BOP is not requiring or determining the extent to which institutions are following cost-efficient procurement practices.

We also determined that the BOP does not have comprehensive pharmaceutical data because it does not have complete current and historical drug purchase-level data. As a result, the BOP does not have a clear picture of its total drug spending and cannot perform critical data analysis that could help identify strategies to reduce waste and control costs.

Although the BOP has taken several steps to control drug costs, we found that it must do more. Implementing the Pharmaceutical Inventory Management System and seeking Temporary Price Reductions may improve the cost-efficiency of the BOP's pharmaceutical procurement, and conducting pharmacy clinics has the potential to help reduce drug spending and medical costs. However, these steps alone are not sufficient to stem the BOP's rising drug costs. For the BOP to more effectively control its drug costs, stakeholders from both the Central Office and

institutions BOP-wide must take additional actions to develop a complete picture of BOP drug spending, ensure cost-efficient pharmaceutical procurement, and identify ways to save on increasing drug costs.

Finally, our broader review of the BOP's drug costs and procurement also included an evaluation of the BOP's management of Hepatitis C. In our case study, we found that the BOP's inconsistent testing and treatment weakens its ability to prevent the spread of Hepatitis C, provide treatment to all inmates that the BOP Hepatitis C Clinical Guidance identifies as needing it, and control high medical and pharmaceutical costs related to the disease.

Recommendations

To help the BOP control drug costs, we recommend that the Department:

1. In consultation with the appropriate Department components and other federal stakeholders: formally assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate, for the Department and all of its components, and, if warranted by the assessments, develop a plan to obtain such pricing and/or authority, including timeframes and assignments of responsibility for pursuing the plan.

To help the BOP ensure that institutions follow cost-efficient procurement practices and seek the lowest price when purchasing drugs, to improve data collection and analysis, and to maximize its efforts to control drug costs, we recommend that the BOP:

- 2. Establish and issue to institutions purchasing guidelines to help identify the lowest price drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable, and consider including the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services.
- 3. Ensure that institutions follow federal procurement regulations to compete all drug purchases equal to or greater than the micro-purchase threshold.
- 4. Ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review.
- 5. Ensure that institutions track and report to the Central Office all of their drug purchases, particularly those from non-prime vendor sources, and capture details such as source, purchase date, quantity, and price.
- 6. Require that institutions place orders for out-of-stock drugs through the prime vendor, or otherwise implement a method for notifying the prime vendor when needed drugs are unavailable that also ensures that the BOP is receiving all credits to which it is contractually entitled.
- 7. Assess the costs and benefits of the programs that are on hold or limited due to resources, including pharmacy clinics, Central Fill and Distribution, and the

- BOP Mail Order Pharmacy, and determine whether expansion or initiation of these programs would be helpful to control long-term costs.
- 8. Complete and implement the Hepatitis C dashboard that will allow the BOP to accurately track and report Hepatitis C testing, diagnoses, priority levels, and treatment, and require institutions to maintain it.
- 9. Assess the costs and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing, and determine whether implementing this policy would be appropriate.

PURPOSE, SCOPE, AND METHODOLOGY

Standards

The OIG conducted this review in accordance with the Council of the Inspectors General on Integrity and Efficiency's *Quality Standards for Inspection and Evaluation* (January 2012).

Purpose and Scope

The OIG conducted this review to examine the BOP's drug prices and spending from FY 2012 through FY 2018, as well as its drug procurement process. We analyzed the BOP's pharmaceutical drug purchase data, as well as policies, memoranda, and program reviews. We focused our analysis on how much the BOP was spending on drugs and whether institutions were purchasing drugs in the most effective and cost-efficient manner possible. Our broader review of the BOP's drug costs and procurement also encompassed a more specific evaluation of the BOP's management of costs related to Hepatitis C. Our review focused on 98 BOP-managed institutions and excluded BOP contract prisons and Residential Reentry Centers.

Methodology

Our fieldwork, conducted from June 2017 through April 2019, included data collection and analysis, interviews, and policy and document review.

Data Collection and Analysis

To understand trends in the BOP's pharmaceutical costs, we analyzed overall medical and drug spending from FY 2012 through FY 2018. We note that the BOP provided us with aggregate drug spending from FY 2012 through FY 2015 only. We received three different versions of the BOP's FY 2017 aggregate drug spending data. Additionally, we analyzed BOP population data to determine the average drug cost per inmate from FY 2012 through FY 2018. To determine the frequency and amount of the BOP's drug purchases outside the Pharmaceutical Prime Vendor (PPV) Program, we analyzed (incomplete) data on all non-prime vendor purchases and data on all purchases made through institutions' prime vendor open market accounts from FY 2016 through FY 2018. We also compared open market prices paid to Federal Supply Schedule (FSS) and Big 4 prices to determine how much the BOP could have saved if it had purchased at the latter prices. Lastly, we analyzed data on the BOP's drug cost savings in FY 2016 and FY 2017 that resulted from its

⁷⁸ The BOP provided the first version on December 11, 2017, and the second on December 13, 2017. On May 2, 2018, the BOP provided a third version because we requested a dataset that included credits. Each version varied in total funds spent.

⁷⁹ We used September 2017 FSS prices that the U.S. Department of Veterans Affairs provided. The BOP started collecting data on non-prime vendor purchases in FY 2016. Therefore, we were able to analyze non-prime vendor purchase data for only FY 2016 and FY 2017.

Temporary Price Reduction agreements. We also analyzed data on Hepatitis C spending and treatment approvals from FY 2012 through FY 2018.

Interviews

We conducted more than 40 interviews during the course of our review. At the Department level, we interviewed officials including a Counselor to the Attorney General, an Associate Deputy Attorney General, and a Counsel to the Deputy Attorney General.

We interviewed officials from five divisions at the BOP's Central Office, including the Chief of Staff of the Office of the Director, the Chief of Legislative Affairs, the Assistant Director to the General Counsel, and the Assistant General Counsel. From the Health Services Division, we interviewed the Assistant Director and the Senior Deputy Assistant Director. From Pharmacy Services, we interviewed the Chief Pharmacist and the Chief of Pharmacy Logistics Support. We also interviewed the Chief Financial Management Lead, the Chief and Deputy Chief of Budget Execution, the Core Section Chief of the Program Review Division, and the Senior Deputy Assistant Director of Administration of the Financial Management Division. Further, we spoke with the Chief of the Field Acquisition Office.

To learn about institution drug procurement practices, we interviewed 12 staff from 6 BOP-managed institutions, specifically 6 Health Services Administrators, 4 Chief Pharmacists, 1 Deputy Chief Pharmacist, and 1 Regional Pharmacist. The institution staff we interviewed were from (1) Federal Correctional Institution Aliceville, (2) Federal Correctional Complex Beaumont, (3) Federal Medical Center Butner, (4) Federal Correctional Institution Fort Dix, (5) Federal Medical Center Lexington, and (6) Federal Correctional Complex Pollock. We selected these institutions due to varying characteristics, including use of the Pharmacy Inventory Management System (PIMS), use of Central Processing Pharmacy Services, geographic location, care level, facility type, and annual drug spending per inmate. We also interviewed the BOP's National Program Coordinator for the Regional Hepatitis Clinical Pharmacist Consultant Program and three BOP Physicians regarding the BOP's management of Hepatitis C at the institution level.

We interviewed officials from the U.S. Department of Veterans Affairs (VA) to gain additional perspectives on the BOP's prime vendor contract. We interviewed two VA officials and an Audit Manager at the VA Office of Inspector General. To learn more about the FSS, Big 4 pricing, and the PPV Program, we interviewed a Contract Specialist and a Contracting Officer from the VA Office of Acquisition and Logistics.

As part of our follow-up research on Hepatitis C testing and treatment at the state level, we interviewed officials from five state departments of corrections: California, Georgia, New York, Pennsylvania, and Texas. We selected these 5 states because they are among the 10 states that have the largest inmate populations.

Policy and Document Review

We reviewed policies, procedures, and guidance related to the BOP's pharmacy program. To understand current practice and ongoing operations, we reviewed BOP policies and guidance, including the Pharmacy Services Program Statement, Health Services Program Review Guidelines, Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection (Hepatitis C Clinical Guidance), BOP Central Processing Pharmacy Services Procedures, and the prime vendor contract. We also reviewed BOP Central Office memoranda related to pharmaceutical procurement and drug costs, although they are not considered actual BOP policy.

Additionally, we reviewed BOP documents, including the National Pharmacy and Therapeutics Committee Meeting minutes from FY 2012 through FY 2017, Health Services Program Review Reports for select BOP-managed institutions from FY 2012 through FY 2017, training slides on drug procurement, and the training manual for PIMS. Further, we reviewed case summaries of civil litigation regarding Hepatitis C treatment from FY 2012 through FY 2017 in which the BOP or its employees were named as defendants.

Finally, we reviewed proposed policy and legislation, including updates to the BOP's Pharmacy Services Program Statement, updates to its Over-the-Counter Drug Policy, and a draft legislative amendment attempting to make the BOP eligible for Big 4 pricing.

DRUG TYPES AND DESCRIPTIONS

Relative BOP Cost	Drug Type	Description
Less Expensive	U.S. Department of Veterans Affairs (VA) National Contract	A drug, on a VA mandatory contract, which the BOP must purchase first through the Pharmaceutical Prime Vendor (PPV) Program. Its pricing consists of manufacturer discounts in exchange for a commitment to purchase specific drugs.
	Temporary Price Reduction/ Federal Supply Schedule (FSS) Restricted	An FSS-listed drug whose price has been temporarily reduced due to a nonbinding agreement between a drug manufacturer and one or more government agencies
	Big 4 Price*	An FSS-listed drug whose price represents the highest price that manufacturers can charge the Big 4 federal agencies. The price is calculated annually and cannot exceed the previous year's FSS price.
	FSS	A drug that all federal agencies can purchase from the VA-negotiated FSS. Its price is based on the prices that manufacturers charge their Most Favored Commercial Customer. The FSS may not increase faster than inflation from year to year.
	Blanket Purchase Agreement	A drug for which the VA or another agency participating in the PPV Program negotiates a commitment-based agreement, often based on purchase volume and performance. Its pricing is either a discount off the FSS price or varies depending on the volume purchased.
More Expensive	Wholesale Acquisition Cost Based Priced Generic	A generic drug available through the PPV Program. Its price is determined using the listed Wholesale Acquisition Cost.

^{*} The Big 4 price was not available to the BOP when we issued our report.

Sources: PPV Program contract, the BOP, VA, and Congressional Budget Office

THE DEPARTMENT AND BOP'S RESPONSE TO THE DRAFT **RFPORT**



U.S. Department of Justice

Federal Bureau of Prisons

Office of the Director

Washington, D.C. 20534

January 8, 2020

MEMORANDUM FOR NINA S. PELLETIER

ASSISTANT INSPECTOR GENERAL OFFICE OF INSPECTOR GENERAL

EVALUATIONS AND INSPECTIONS DIVISION

FROM:

Bradley Weinsheimer G. Bradley Weinsheimer Associate Deputy Attorney General

Thomas R. Kane

Deputy Director

SUBJECT:

Response to the Office of Inspector General's (OIG) FORMAL DRAFT REPORT: Review of the Federal Bureau of Prisons' Pharmaceutical Drug Costs and Procurement,

Assignment Number A-2017-004

The Department of Justice (Department) and Bureau of Prisons (BOP) appreciate the opportunity to provide a response to the Office of the Inspector General's above-referenced report. Therefore, please find the Department's and BOP's responses to the recommendations below:

Recommendations:

To help the BOP control drug costs, we recommend that the Department:

Recommendation 1: In consultation with the appropriate Department components and other federal stakeholders: formally assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate, for the Department and all of its components, and, if warranted by the assessments, develop a plan to obtain such pricing and/or authority, including timeframes and assignments of responsibility for pursuing the plan.

Initial Response: The Department concurs with this recommendation. The Department, in consultation with the appropriate Department components and other federal stakeholders, will assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate. If warranted by its assessment, the Department will develop a plan to obtain such pricing and authority.

To help the BOP ensure that institutions follow cost-efficient procurement practices and seek the lowest price when purchasing drugs, to improve data collection and analysis, and to maximize its efforts to control drug costs, we recommend that the BOP:

Recommendation 2: Establish and issue to institutions purchasing guidelines to help identify the lowest-priced drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable, and consider including the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services.

Initial Response: The BOP agrees with this recommendation. The BOP will establish and issue to institutions purchasing guidelines to help identify the lowest-priced drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable, and will include the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services.

Recommendation 3: Ensure that institutions follow federal procurement regulations to compete all drug purchases equal to or greater than the micro-purchase threshold.

Initial Response: The BOP agrees with this recommendation. The BOP will ensure that institutions follow federal procurement

regulations to compete all drug purchases equal to or greater than the micro-purchase threshold.

Recommendation 4: Ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review.

Initial Response: The BOP agrees with this recommendation. The BOP will ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review.

Recommendation 5: Ensure that institutions track and report to the Central Office all of their drug purchases, particularly those from non-prime vendor sources, and capture details such as source, purchase date, quantity, and price.

Initial Response: The BOP agrees with this recommendation. The BOP will ensure that institutions track and report to the Central Office all of their drug purchases, particularly those from non-prime vendor sources, and capture details such as source, purchase date, quantity, and price.

Recommendation 6: Require that institutions place orders for out-of-stock drugs through the prime vendor, or otherwise implement a method for notifying the prime vendor when needed drugs are unavailable that also ensures that the BOP is receiving all credits to which it is contractually entitled.

Initial Response: The BOP agrees with this recommendation. The BOP will require that institutions place orders for out-of-stock drugs through the prime vendor, or implement a method for notifying the prime vendor when needed drugs are unavailable that also ensures that the BOP is receiving all credits to which it is contractually entitled.

Recommendation 7: Assess the costs and benefits of the programs that are on hold or limited due to resources, including pharmacy clinics, Central Fill and Distribution, and the BOP Mail Order Pharmacy, and determine whether expansion or initiation of these programs would be helpful to control long-term costs.

Initial Response: The BOP agrees with this recommendation. The BOP will assess the costs and benefits of the programs that are on hold or limited due to resources, including pharmacy clinics, Central Fill and Distribution, and the BOP Mail Order Pharmacy, and determine whether expansion or initiation of these programs would be helpful to control long-term costs.

Recommendation 8: Complete and implement the Hepatitis C dashboard that will allow the BOP to accurately track and report Hepatitis C testing, diagnoses, priority levels, and treatment, and require institutions to maintain it.

Initial Response: The BOP agrees with this recommendation. The BOP will complete and implement the Hepatitis C dashboard that will allow the BOP to accurately track and report Hepatitis C testing, diagnoses, priority levels, and treatment, and require institutions to maintain it.

Recommendation 9: Assess the costs and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing, and determine whether implementing this policy would be appropriate.

Initial Response: The BOP agrees with this recommendation. The BOP will assess the costs and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing, and determine whether implementing this policy would be appropriate.

OIG ANALYSIS OF THE DEPARTMENT AND BOP'S RESPONSE

The Office of the Inspector General provided a draft of this report to the Department and the BOP for their comment. The joint response from the Office of the Deputy Attorney General (ODAG) and the BOP is included in Appendix 3 to this report. The OIG's analysis of the Department and BOP's response and the actions necessary to close the recommendations are discussed below.

Recommendation to the Department

Recommendation 1: In consultation with the appropriate Department components and other federal stakeholders: formally assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate, for the Department and all of its components, and, if warranted by the assessments, develop a plan to obtain such pricing and/or authority, including timeframes and assignments of responsibility for pursuing the plan.

Status: Resolved.

ODAG Response: The Department concurred with the recommendation and stated that it would, in consultation with the appropriate DOJ components and other federal stakeholders, assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate. If warranted by its assessment, the Department will develop a plan to obtain such pricing and authority.

OIG Analysis: The Department's planned actions are responsive to our recommendation. By April 27, 2020, please describe the actions the Department has taken or plans to take to formally assess the risks and benefits of seeking to obtain Big 4 pricing for pharmaceutical purchases, as well as the authority to cap reimbursement for outside medical care at the Medicare rate, for the Department and all of its components, or a status update on your progress.

Recommendations to the BOP

<u>Recommendation 2</u>: Establish and issue to institutions purchasing guidelines to help identify the lowest price drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable, and consider including the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will establish and issue to institutions purchasing guidelines to help identify the lowest price drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable and that it will consider including the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please provide a copy of the purchasing guidelines issued to institutions to help identify the lowest price drugs when Pharmaceutical Prime Vendor Program drugs are out of stock or unavailable, or a status update on your progress. Also, please provide an update on the steps the BOP has taken or plans to take to consider including the drug purchasing hierarchy in the Health Services Program Review Guidelines for Pharmacy Services, or a status update on your progress.

Recommendation 3: Ensure that institutions follow federal procurement regulations to compete all drug purchases equal to or greater than the micropurchase threshold.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will ensure that institutions follow federal procurement regulations to compete all drug purchases equal to or greater than the micro-purchase threshold.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please describe the steps that the BOP has taken or plans to take to ensure that institutions follow federal procurement regulations to compete all drug purchases equal to or greater than the micropurchase threshold, or a status update on your progress.

Recommendation 4: Ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please describe the steps the BOP has taken or plans to take to ensure that institutions' compliance with cost-efficient drug procurement practices is monitored through program review, or a status update on your progress.

Recommendation 5: Ensure that institutions track and report to the Central Office all of their drug purchases, particularly those from non-prime vendor sources, and capture details such as source, purchase date, quantity, and price.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will ensure that institutions track and report to the Central Office all of their drug purchases, particularly those from non-prime vendor sources, and capture details such as source, purchase date, quantity, and price.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please provide documentation demonstrating that institutions are tracking and reporting all of their drug purchases to the Central Office, including details such as source, purchase date, quantity, and price, or a status update on your progress.

Recommendation 6: Require that institutions place orders for out-of-stock drugs through the prime vendor, or otherwise implement a method for notifying the prime vendor when needed drugs are unavailable that also ensures that the BOP is receiving all credits to which it is contractually entitled.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will require that institutions place orders for out-of-stock drugs through the prime vendor or that it will implement a method for notifying the prime vendor when needed drugs are unavailable that also ensures that the BOP is receiving all credits to which it is contractually entitled.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please provide documentation demonstrating that institutions are required to place orders for out-of-stock drugs through the prime vendor. If the BOP selects another method for notifying the prime vendor when needed drugs are unavailable, please provide documentation describing that method and the means by which the BOP will receive all credits to which it is contractually entitled, or a status update on your progress.

Recommendation 7: Assess the costs and benefits of the programs that are on hold or limited due to resources, including pharmacy clinics, Central Fill and Distribution, and the BOP Mail Order Pharmacy, and determine whether expansion or initiation of these programs would be helpful to control long-term costs.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will assess the costs and benefits of the programs that are on hold or limited due to resources, including pharmacy clinics, Central Fill and Distribution, and the BOP Mail Order Pharmacy, and that it will determine whether expansion or initiation of these programs would be helpful to control long-term costs.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please describe the steps the BOP has taken or plans to take to determine whether expansion or initiation of pharmacy clinics, Central Fill and Distribution, and the BOP Mail Order Pharmacy would be helpful to control long-term costs, or a status update on your progress.

Recommendation 8: Complete and implement the Hepatitis C dashboard that will allow the BOP to accurately track and report Hepatitis C testing, diagnoses, priority levels, and treatment, and require institutions to maintain it.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will complete and implement the Hepatitis C dashboard that will allow the BOP to accurately track and report Hepatitis C testing, diagnoses, priority levels, and treatment and that it will require institutions to maintain it.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please provide documentation showing that the BOP has completed and implemented the Hepatitis C dashboard, or a status update on your progress.

Recommendation 9: Assess the costs and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing, and determine whether implementing this policy would be appropriate.

Status: Resolved.

BOP Response: The BOP concurred with the recommendation and stated that it will assess the costs and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing and that it will determine whether implementing this policy would be appropriate.

OIG Analysis: The BOP's planned actions are responsive to our recommendation. By April 27, 2020, please describe how the BOP will assess the cost and benefits of requiring institutions to implement universal, voluntary opt-out Hepatitis C testing and determine whether implementing this policy would be appropriate, or a status update on your progress.



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