Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

UPDATE: EXCESSIVE MEDICARE REIMBURSEMENT FOR IPRATROPIUM BROMIDE

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EXECUTIVE SUMMARY

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for ipratropium bromide to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Ipratropium bromide is an inhalation drug commonly used with a nebulizer to treat patients suffering from chronic bronchitis or emphysema. Prior to 2004, Medicare's reimbursement methodology for ipratropium bromide and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, reimbursement for a covered drug was set at 95 percent of the drug's average wholesale price (AWP). Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 lowered reimbursement for many Part B drugs, including ipratropium bromide. In 2004, Medicare reimbursement for ipratropium bromide will be 80 percent of AWP.

Medicare beneficiaries are responsible for paying a 20 percent coinsurance payment for covered drugs. In calendar year (CY) 2002, Medicare and its beneficiaries paid $594 million for ipratropium bromide, up from $348 million in CY 2000.

Ipratropium bromide is usually provided to Medicare beneficiaries by pharmacies, which then submit claims for reimbursement to Medicare. Medicaid beneficiaries also obtain ipratropium bromide through pharmacies. Pharmacies can purchase drug products through group purchasing organizations (GPOs), wholesalers, and directly from manufacturers. Unlike Medicare and Medicaid, VA provides veterans with drugs purchased directly from manufacturers or wholesalers. There are several purchase options available to VA, including the Federal Supply Schedule, blanket purchase agreements, and VA national contracts.

We obtained Medicare's CY 2003 reimbursement amount for ipratropium bromide. For comparison, we: (1) obtained Medicaid's 2003 reimbursement amount for ipratropium

bromide by reviewing the Federal Upper Limit list, (2) estimated 2003 pharmacy acquisition costs for ipratropium bromide by obtaining pricing information from a national wholesaler/distributor and a GPO, and (3) determined the VA's 2003 payment amount for ipratropium bromide by accessing pricing data available on its website. We also obtained manufacturer-reported wholesale acquisition costs (WACs) from the January 2003 edition of the *Drug Topics Red Book*. We calculated potential savings by multiplying Medicare's 2002 total payments for ipratropium bromide by the percentage difference between the Medicare reimbursement amount and the Medicaid reimbursement amount.

The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for ipratropium bromide was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit Amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse ipratropium bromide at the Federal Upper Limit amount.

FINDINGS

Medicare continues to pay more for ipratropium bromide than other payors, costing the program and its beneficiaries millions of dollars a year. In 2003, the Centers for Medicare & Medicaid Services (CMS) set the Medicaid Federal Upper Limit amount for ipratropium bromide at $1.17 per milligram (mg), 65 percent less than the $3.34 that Medicare pays for the same amount of the drug. If Medicare could reimburse for ipratropium bromide at the Medicaid Federal Upper Limit Amount, Medicare and its beneficiaries would have saved $386 million in 2002. Approximately $77 million of the savings would have resulted from reduced coinsurance payments.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase ipratropium bromide for substantially less than the Medicare reimbursement amount. In spring 2003, the median price of ipratropium bromide at the wholesaler/distributor was $0.57 per mg, while it was $0.05 higher ($0.62 per mg) at the GPO. Medicare's

reimbursement amount of $3.34 per mg was over five times more for the same amount of the drug. We did not collect data from pharmacies regarding any additional costs related to providing ipratropium bromide to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase ipratropium bromide for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $1.01 per mg.

If Medicare were able to use prices available to the supplier community as a basis for ipratropium bromide reimbursement, the program and its beneficiaries would save millions of dollars a year.

Since our 2002 report, which was based on 2001 data, the price at which ipratropium bromide was available to the supplier community had decreased, while the Medicare reimbursement amount had remained the same. In 2001, we calculated that the median price of ipratropium bromide through wholesaler/distributors and GPOs was $0.82 per mg, substantially higher than 2003 prices. In addition, manufacturer-reported WACs also decreased, from a median of $1.20 per mg in 2001 to $1.01 in 2003.

The median Federal Supply Schedule price available to VA for ipratropium bromide was $0.39 per mg. In comparison, Medicare reimbursed 8 times more ($0.47 per mg) for the same amount of the drug in 2003. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

The VA price for ipratropium bromide has decreased substantially since our previous report, while Medicare's price has remained constant. The VA price has fallen from $0.66 per mg in 2001 to $0.39 per mg in 2003 (in 1998, the VA price was even higher at $1.29 per mg).

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high

premium for ipratropium bromide. This report is part of a series of reports on ipratropium bromide that have consistently found that the published average wholesale prices, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published average wholesale prices, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for ipratropium bromide than they did several years ago. In addition, Medicare's total reimbursement for ipratropium bromide continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, ipratropium bromide is usually provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for ipratropium bromide and the price at which suppliers are able to purchase the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-eighth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including ipratropium bromide. Based on the new Act, Medicare will reimburse ipratropium bromide at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

TABLE OF CONTENTS

INTRODUCTION

OBJECTIVE

To update data provided in a 2002 report comparing Medicare reimbursement for ipratropium bromide to prices available to Medicaid, the supplier community, and the Department of Veterans Affairs (VA).

BACKGROUND

Medicare Coverage of Ipratropium Bromide

Currently, Medicare does not pay for over-the-counter or most outpatient prescription drugs. However, Medicare Part B will cover drugs that are necessary for the effective use of durable medical equipment. One such product, ipratropium bromide, is an inhalation solution commonly used with a nebulizer to treat patients suffering from chronic bronchitis or emphysema. Ipratropium bromide is typically provided to Medicare beneficiaries by pharmacies.

Medicare Reimbursement of Ipratropium Bromide

The Centers for Medicare & Medicaid Services (CMS) contracts with four companies, known as durable medical equipment regional carriers (DMERCs), to process and reimburse medical equipment and supply claims, including ipratropium bromide. Each DMERC is responsible for determining the reimbursement amount for ipratropium bromide in their respective region, based on Medicare's reimbursement methodology.

Prior to 2004, Medicare's reimbursement methodology for ipratropium bromide and other prescription drugs was set forth in section 1842(o) of the Social Security Act, as amended by section 4556 of the Balanced Budget Act of 1997. At the time, the Social Security Act stated that reimbursement for a covered drug was to be set at 95 percent of the drug's average wholesale price (AWP). CMS directed carriers to obtain average wholesale price data from the *Drug Topics Red Book* or similar pricing publications used by the pharmaceutical industry. In 2003, each DMERC reimbursed $3.34 per milligram (mg) for ipratropium bromide.

Recently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act) lowered payments for many

Part B drugs in 2004 and beyond by revising Section 1842(o) of the Social Security Act. According to the new Act, the payment for a drug contained in the table, "Medicare Part B Drugs in Most Recent GAO and OIG Studies" published in the Federal Register (68 FR 50445) will be the percentage of the AWP indicated in the table. If the percentage in the table is less than 80 percent, then the percentage applied to reimbursement will be 80 percent. Based on the data presented in this table, in 2004, Medicare reimbursement for ipratropium bromide will be 80 percent of AWP.

Medicare paid $594 million for ipratropium bromide in calendar year (CY) 2002, up from $348 million in 2000. This total represents 7 percent of the $8.2 billion Medicare paid for all prescription drugs in 2002. Medicare payments include both the 80 percent that Medicare reimburses, and the 20 percent coinsurance payment for which beneficiaries are responsible.

CMS Use of Office of Inspector General (OIG) Data

In a proposed rule published in the Federal Register on August 20, 2003 CMS states, "If the OIG performs a new market analysis, we expect to incorporate this information into the Medicare payment limits…Initially, we would use the market analyses available to us from GAO and OIG studies to transition widely available market prices into the Medicare payments." Because of the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the proposed rule did not take effect. However, according to the Act, new pricing data may be useful for setting Medicare reimbursement amounts in the future.

Recent Attempts to Lower Medicare Reimbursment

Inherent Reasonableness. Section 4316 of the Balanced Budget Act of 1997 allows CMS to diverge from Medicare=s statutorily-defined payment method if the method results in payment amounts that are not inherently reasonable. In late 1998, CMS attempted to use this authority to lower what it considered excessive reimbursement for several items. One of these items was albuterol, an inhalation drug similar to ipratropium bromide, which was targeted for an 11 percent fee reduction. However, the lower prices were never implemented, as Congress suspended the use of CMS's inherent reasonableness authority through a provision of the Medicare, Medicaid, and SCHIP

Balanced Budget Refinement Act of 1999. This provision required the General Accounting Office (GAO) to complete a study on the potential effects of using inherent reasonableness measures before CMS could invoke the authority. The GAO report, issued in July 2000, found that inherent reasonableness reductions for some items were justified. However, GAO questioned the methodology that the carriers used in their collection of pricing data for albuterol.

On February 11, 2003, a new interim final rule for the application of inherent reasonableness went into effect. According to the regulation, payment amounts may be considered unreasonable based on a number of criteria, including: (1) payment amounts are grossly excessive when compared to other purchasers in the same locality, or (2) payment amounts are grossly excessive when compared to acquisition costs. According to the regulation, a payment amount is considered grossly excessive if a reduction of at least 15 percent is required to produce a realistic and equitable reimbursement amount.

Competitive Bidding. CMS included ipratropium bromide and several other inhalation drugs in a competitive bidding project in the San Antonio, Texas area that sought to use market forces to set accurate prices for durable medical equipment and related supplies. In November 2000, CMS announced the selection of durable medical equipment suppliers who had submitted competitive bids for the included items. New prices for these items went into effect in the bidding area on February 1, 2001. The new reimbursement amount for ipratropium bromide set by the competitive bidding process was $2.55 per mg, approximately 24 percent below the usual Medicare amount. CMS hopes to use the results from these demonstrations more generally in the Medicare program.

Medicaid Reimbursement of Ipratropium Bromide

As with Medicare, Medicaid beneficiaries typically receive ipratropium bromide from pharmacies. Pharmacies are then reimbursed by the Medicaid program.

Federal regulations require that each State Medicaid agency's reimbursement for a drug not exceed the lower of its estimated acquisition cost plus a reasonable dispensing fee, or the provider's usual and customary charge to the public for the

drug. CMS allows States flexibility in defining estimated acquisition cost. Like Medicare, most States base their calculation of estimated acquisition cost on a drug's AWP discounted by a certain percentage. This discount ranged from 5 percent to 15 percent in the year 2001. A few States use published wholesale acquisition costs (WACs) plus a percentage markup rather than average wholesale prices when calculating estimated acquisition cost.

For certain drugs, States also use the Federal Upper Limit and State Maximum Allowable Cost programs in determining reimbursement amounts. According to CMS, the purpose of Federal Upper Limits is to ensure that the Federal Government acts as a prudent purchaser by taking advantage of current market prices for multiple-source products. CMS has established Federal Upper Limit amounts for over 400 drugs. In addition, more than half of the States have implemented a Maximum Allowable Cost program in order to reduce reimbursement amounts for certain drugs. Individual States determine the types of drugs that are included in their Maximum Allowable Cost program, and the method by which the Maximum Allowable Cost for a drug is calculated.

Acquisition Sources of Ipratropium Bromide for Pharmacies

Pharmacies can purchase drug products through several sources, including group purchasing organizations (GPOs), wholesalers/distributors, and directly from manufacturers. GPOs provide their members with lower cost products by negotiating prices for specific drugs from manufacturers. The member can then purchase drugs at the negotiated price either directly from the manufacturer or from a wholesaler/distributor who accepts GPO's price. Wholesalers/distributors purchase large volumes of drugs from manufacturers and sell them directly to physicians, suppliers, and pharmacies.

VA Payments for Ipratropium Bromide

Unlike Medicare and Medicaid, VA purchases drugs for its health care system directly from manufacturers or wholesalers. There are several options available to VA when purchasing drugs, with the most common being the Federal Supply Schedule. The Federal Supply Schedule provides agencies like VA with a simple process for purchasing commonly-used products in any quantity while still obtaining the discounts

associated with volume buying. Using competitive procedures, contracts are awarded to companies to provide supplies over a given period of time at the Federal Supply Schedule price. However, VA is sometimes able to negotiate prices lower than Federal Supply Schedule amounts through other avenues, such as blanket purchase agreements and VA national contracts.

Related Work on Ipratropium Bromide

OIG has previously found that Medicare's usual reimbursement amount for ipratropium bromide (based on AWP) is excessive. In our report *Excessive Medicare Reimbursement for Ipratropium Bromide* (March 2002), we calculated that the Medicare reimbursement amount for ipratropium bromide in 2000 was more than 5 times higher than the VA purchase price and over 4 times the actual acquisition cost to pharmacies. According to our findings, excessive reimbursement for ipratropium bromide alone was costing Medicare and its beneficiaries up to $279 million per year.

In addition to OIG, GAO has also found that Medicare reimbursement for ipratropium bromide is excessive. In its September 2001 report, *Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs* (GAO-01-1118), GAO found that the average widely available price to pharmacies for ipratropium bromide was 78 percent below the published average wholesale price of the drug.

METHODOLOGY

We reviewed laws and regulations concerning Medicare drug reimbursement. We accessed CMS's Part B Extract Summary System to determine Medicare's total payments for ipratropium bromide in CY 2002. We obtained Medicare's CY 2003 reimbursement amounts for ipratropium bromide from all 4 DMERCs.

To determine Medicaid's 2003 reimbursement amount for ipratropium bromide, we obtained pricing information for the drug from the Medicaid Federal Upper Limit list.

To estimate pharmacy acquisition costs for ipratropium bromide, we obtained spring 2003 pricing information for the drug from a national wholesaler/distributor and from a GPO. As an additional estimate of pharmacy acquisition costs, we also

obtained manufacturer-reported WACs from the January 2003 edition of the *Red Book*. The *Red Book* defines WACs as manufacturer-quoted list prices to wholesale distributors. These prices are not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

To determine the VA's 2003 payment amounts for ipratropium bromide, we accessed a file on their website that lists prices available to the agency through the Federal Supply Schedule.

To calculate potential Medicare savings based on Medicaid, we compared Medicare's reimbursement amount for 1 mg of ipratropium bromide to the Medicaid Federal Upper Limit amount. We determined the percentage difference in price by subtracting Medicaid's price from Medicare's price and then dividing the result by the Medicare price. This percentage indicates how much Medicare would save if the program could base reimbursement on the Medicaid Federal Upper Limit amount. We then multiplied the percentage difference by the total amount Medicare paid for ipratropium bromide in 2002 to calculate dollar savings.

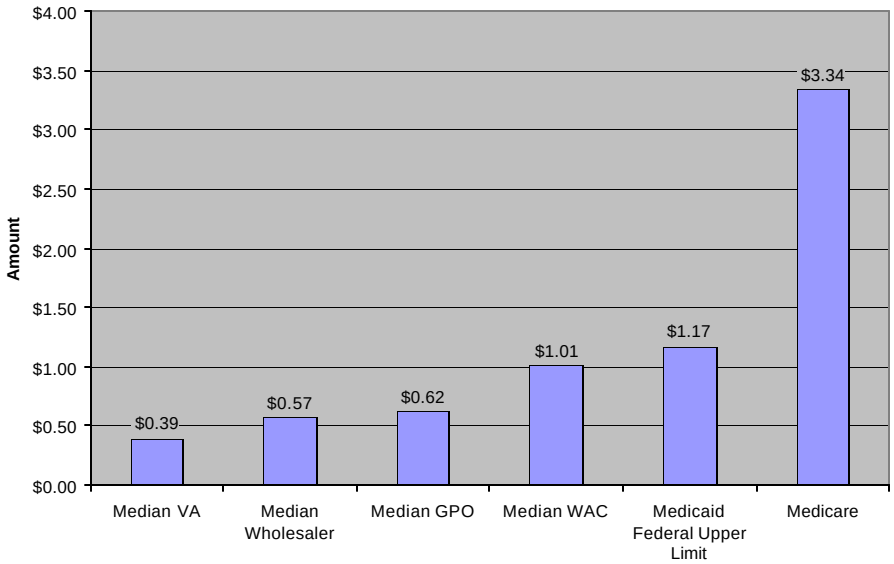
The exact savings estimates presented in this report are for 2002. Because the 2004 reimbursement amount for ipratropium bromide was lowered to 80 percent of AWP from 95 percent of AWP, the savings that Medicare would achieve by paying the Medicaid Federal Upper Limit amount would now be lower. However, the difference in price between Medicare and Medicaid would still be large, and significant savings would still result if Medicare were able to reimburse ipratropium bromide at the Federal Upper Limit amount.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President=s Council on Integrity and Efficiency.

In 2003, Medicare reimbursed $3.34 per mg for ipratropium bromide, an amount that was considerably higher than the reimbursement amounts of other Government payors and the prices available to the supplier community. If Medicare were able to base its reimbursement amount for ipratropium bromide on prices available to these sources, the program and its beneficiaries could have saved millions of dollars in 2002. Chart 1 below compares the Medicare reimbursement amount to prices available to Medicaid, the supplier community, and VA.

Medicare continues to pay more for ipratropium bromide than other payors, costing the program and its beneficiaries millions of dollars a year.

Chart 1: Comparison of Ipratropium Bromide Prices



Source: VA website, OIG survey of pharmacy prices, 2003 *Red Book*, Medicaid Federal Upper Limit list, and DMERC pricing publications.

Medicare and its beneficiaries would have saved $386 million in 2002 if the program were able to reimburse ipratropium bromide at the Medicaid Federal Upper Limit amount.

CMS sets the Medicaid Federal Upper Limit amount for ipratropium bromide at $1.17 per mg, 65 percent less than Medicare ($3.34 per mg) for the same amount of the drug. If Medicare were able to reimburse for ipratropium bromide at the

Medicaid Federal Upper Limit amount, the program would have saved $386 million in 2002. Approximately $77 million of the savings would have had a direct impact on Medicare beneficiaries through reduced coinsurance payments.

The Medicare reimbursement amount for ipratropium bromide was five times higher than the median price available to the supplier community.

Data collected from a drug wholesaler/distributor and a GPO showed that pharmacies were able to purchase ipratropium bromide for substantially less than the Medicare reimbursement amount. In spring 2003, generic versions of ipratropium bromide were available from these sources at prices ranging from a low of $0.40 per mg to a high of $0.79 per mg. The median price of ipratropium bromide at the wholesaler/distributor was $0.57 per mg, while it was $0.05 higher ($0.62 per mg) at GPO. Medicare's reimbursement amount of $3.34 per mg was over five times more for the same amount of the drug.

Pharmacies were able to acquire ipratropium bromide for less than a Medicare beneficiary would pay in coinsurance alone ($0.67 per mg). For example, a beneficiary, using a typical monthly supply of ipratropium bromide (50 mg), would pay $33.40 in Medicare coinsurance. Through the sources we identified, pharmacies, on average, would pay between $28.50 and $31.00 for the same supply. We did not collect data from pharmacies regarding any additional costs related to providing ipratropium bromide to Medicare beneficiaries.

Furthermore, manufacturer-reported WACs published in the *Red Book* also showed that pharmacies were able to purchase ipratropium bromide for prices substantially below the Medicare reimbursement amount. In January 2003, the median WAC reported in the *Red Book* was $1.01 per mg. The *Red Book* defines WAC as manufacturer-quoted list prices to wholesale distributors, not reflective of bids, rebates, volume purchase agreements, or other types of exclusive contracts.

Since our last report, the price at which ipratropium bromide was available to the supplier community decreased, while the Medicare reimbursement amount remained the same. In 2001, we calculated that the median price of ipratropium bromide through wholesaler/distributors and GPOs was $0.82 per mg,

substantially higher than 2003 prices. In addition, manufacturer-reported WACs had also decreased from a median of $1.20 per mg in 2001 to $1.01 in 2003.

If Medicare were able to use prices available to the supplier community as a basis for ipratropium bromide reimbursement, the program and its beneficiaries would save millions of dollars a year.

The Medicare reimbursement amount for ipratropium bromide was eight times higher than the median price available to the VA. In 2003, the median Federal Supply Schedule price available to VA for ipratropium bromide was $0.39 per mg. In comparison, Medicare reimbursed eight times more ($3.34 per mg) for the same amount of the drug. However, it should be noted that, unlike Medicare, VA purchases drugs for its health care system directly from manufacturers or wholesalers, rather than reimbursing pharmacies for the drug.

The VA price for ipratropium bromide decreased substantially since our previous report, while Medicare's price has remained constant. The VA price has fallen from $0.66 per mg in 2001 to the 2003 price of $0.39 per mg (in 1998, the VA price was even higher at $1.29 per mg).

CONCLUSION

Despite numerous attempts by CMS to lower reimbursement amounts for prescription drugs, Medicare still pays a high premium for ipratropium bromide. This report is part of a series of reports on ipratropium bromide that have consistently found that the published AWPs, which, as prescribed by Federal law, form the basis of Medicare drug reimbursement, bear little or no resemblance to actual wholesale prices that are available to pharmacies and large Government purchasers.

Because of Medicare's reliance on published AWPs, the program's reimbursement remains constant, despite the fact that other purchasers pay significantly less for ipratropium bromide than they did several years ago. In addition, Medicare's total reimbursement for ipratropium bromide continues to increase substantially each year. Consequently, the Medicare program loses progressively more money every year.

We understand that, unlike most drugs covered by Medicare, ipratropium bromide is provided by pharmacies rather than administered by physicians. These pharmacies obviously need to make a profit from the products they supply, yet the spread between what Medicare reimburses for ipratropium bromide and the price that suppliers pay for the drug is significant.

Furthermore, we recognize that the VA acts as a purchaser of drugs while Medicare reimburses pharmacies for the product. However, the fact that one Government agency is able to purchase a drug for one-eighth of Medicare's reimbursement amount is disconcerting.

Congress has recently passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Act). This Act provides for numerous changes in Medicare's reimbursement methodology for drugs covered under Part B, including ipratropium bromide. Based on the new Act, Medicare will reimburse ipratropium bromide at 80 percent of AWP in 2004. We hope that the data presented in this report is helpful to CMS in determining an appropriate payment amount for the drug beyond 2004.

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This report was prepared under the direction of Robert A Vito, Regional Inspector General for Evaluation and Inspections in the Philadelphia Regional Office, and Linda M. Ragone, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

David Tawes, *Team Leader*

Cynthia Hansford, *Program Assistant*

Linda Frisch, Program Specialist