US DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

OFFICE OF ACQUISITION, LOGISTICS, AND CONSTRUCTION

A Summary of Reviews in Fiscal Years 2022 and 2023 of Manufacturers' Noncompliance with Veterans Health Care Act Provisions on Pharmaceutical Pricing

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Executive Summary

The VA Office of Inspector General (OIG) conducts reviews of manufacturers' noncompliance with the Veterans Health Care Act of 1992 (referred to in this report as the public law), which helps ensure the government receives fair prices on pharmaceutical purchases.[1] Section 603 requires manufacturers of drugs subject to the public law to make them available under contract on the Federal Supply Schedule (FSS) and offer them to "Big 4" government customers—VA, the Department of Defense (DOD), the Public Health Service, and the Coast Guard—at a discount of at least 24 percent below the non-Federal Average Manufacturer Price (non-FAMP).[2] The public law places responsibility for compliance on manufacturers. The VA Office of Pharmacy Benefits Management Services provides those manufacturers with guidance on complying with the public law. The OIG, in turn, conducts reviews to identify noncompliance issues.

The reviews are prompted by concerns with manufacturers' disclosures, prior OIG reviews where noncompliance issues were identified but not resolved, and noncompliance issues identified by the VA Office of Pharmacy Benefits Management Services or VA's National Acquisition Center. The reviews are not published because they contain sensitive commercial information protected from release under the Trade Secrets Act.[3]

To promote transparency, this report summarizes the 15 reviews completed by the OIG in fiscal years (FYs) 2022 and 2023 to identify any instances of noncompliance with the public law.[4] Cumulatively, the OIG identified approximately $61.2 million in overcharges that manufacturers owed to the government. This amount includes approximately $27 million resulting from manufacturers' noncompliance with the public law and about $34.1 million resulting from manufacturers' violations of the price reduction clause in the FSS contract that were unrelated to the public law.[5]

This report presents an overview of the four actions the OIG took with respect to the reviews:[6]

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[1] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603.

[2] Veterans Health Care Act of 1992, § 603.

[3] 18 U.S.C. § 1905; Trade Secrets Act, 41 U.S.C. § 423(a); 38 C.F.R. § 1.558(c). The OIG's contract review reports are marked "For Official Use Only" and are not disclosed outside the government, except through procedures established in the Freedom of Information Act. Exemption 4 of the act exempts company trade secrets and confidential commercial or financial information from mandatory disclosure to the public. The OIG team used numbers to refer to manufacturers in lieu of names throughout this report.

[4] Appendix A provides more information on the monetary impact of the 15 reviews.

[5] Numbers are rounded. Public law overcharges were $27,005,092.40, and price reduction clause overcharges were $34,148,423.87. When combined, the total rounds to $61.2 million ($27,005,092.40 + $34,148,423.87 = $61,153,516.27).

[6] For more information on the teams' scope and methodology, see appendix B.

1. **Evaluating manufacturers' calculations of the non-FAMPs** used to determine the federal ceiling prices for covered drugs.[7] The public law requires manufacturers to submit non-FAMP data to VA annually for each covered drug that they sell under contract to "Big 4" government customers. Pharmacy Benefits Management Services uses the data to calculate the drugs' annual ceiling prices. The OIG's reviews involved disclosures of non-FAMP calculation errors for four manufacturers. Collectively, the errors affected 306 National Drug Codes.[8] The OIG determined the errors resulted in approximately $16.9 million in overcharges to the government.
2. **Determining if manufacturers made all covered drugs available under Federal Supply Schedule (FSS) contracts** in accordance with the public law and VA guidelines. Manufacturers must make covered drugs available on the FSS. When these drugs are not available on FSS contracts, manufacturers are not in compliance with the public law, and the government is at risk of purchasing the drugs on the open market at pricing higher than the statutory ceiling prices. The OIG's reviews involved 10 manufacturers' disclosures of noncompliance related to the late addition of covered drugs to their FSS contracts.[9] Specifically, the manufacturers mishandled changes to National Drug Code numbers and package sizes or misclassified drugs as noncovered. Collectively, the late additions affected 155 National Drug Codes. OIG determined that the late additions resulted in approximately $6 million in overcharges to the government.
3. **Determining if manufacturers had any General Services Administration price reduction clause violations** affecting the ceiling prices for covered drugs. The clause requires the government and the manufacturer to agree on a customer or category of customers to which the government's price or discount can be linked for the purposes of possible price reductions. The clause mandates lowering the FSS contract price whenever the price charged to the negotiated tracking customers

[7] For this report, the term "covered drugs" refers only to drugs subject to the public law. Not all covered drugs are subject to the public law (for example, approved exemptions, drugs not commercially sold, and newly launched drugs that are not yet due on the FSS). VA identifies a covered drug as one that is commercially sold and approved by the US Food and Drug Administration under a new drug application (and is an innovator drug with at least one active ingredient on the Food and Drug Administration's reference list of original, licensed drugs) or under a biological licensing agreement. The latter applies to any biological product—any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of humans.

[8] Because the Food and Drug Administration assigns a unique code (National Drug Code) to all package sizes, drug strengths, and volumes of a drug, the code, rather than the individual drug, was the basis for the team's analysis.

[9] VA gives manufacturers 30 days to generate a temporary ceiling price and 45 additional days to submit the non-FAMP used to calculate the ceiling price in the FSS contract. When manufacturers take more than 75 days to comply, their items become late additions.

decreases.[10] The OIG's reviews involved disclosures of three manufacturers' possible violations; however, the OIG determined that one manufacturer had complied with the public law and had not violated the clause. The other two manufacturers, including one that also had late additions, violated the clause. The manufacturers' violations affected 535 National Drug Codes and resulted in approximately $38.2 million in overcharges to the government.[11]

4. **Calculating any overcharges to the government** for incorrectly calculated non-FAMPs and related ceiling prices, late additions, or price reduction clause violations. The OIG team used manufacturers' FSS sales data to determine any overcharges occurring while drugs were on FSS contracts. Additionally, the team used VA and DOD open-market sales data to determine overcharges resulting from covered drugs not being on the FSS contracts. Some manufacturers provided estimated overcharges in their disclosures, amounting to approximately $53.3 million. In contrast, the OIG recommended VA collect approximately $61.2 million. Overall, VA was able to collect approximately $59.3 million (about 97 percent) of the OIG's recommended amounts. VA does not expect to collect overcharges from one manufacturer, which filed for bankruptcy. Additionally, VA had not resolved overcharges with two manufacturers as of June 17, 2024.

This report summarizes recommendations the OIG previously made to VA to collect overcharges but does not propose any further VA action. The associate executive director of the National Acquisition Center concurred with the draft report and provided no comments. Appendix C provides the full text of the director's response.

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[10] General Services Administration, Acquisition Manual 552.238-81, "Price Reductions," May 2019. The manual requires the government and the manufacturer to agree on a customer or category of customers as the basis of the award. FSS pricing is tracked against this customer's (or category of customers') pricing for the duration of the contract. The objective of the price reduction clause is to maintain fair and reasonable pricing after the contract has been awarded.

[11] This amount included $4,027,279 in overcharges by one manufacturer that violated the price reduction clause and did not comply with the public law.

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Abbreviations

DOD	Department of Defense
FSS	Federal Supply Schedule
FY	fiscal year
non-FAMP	non-Federal Average Manufacturer Price
OIG	Office of Inspector General
OPAL	Office of Procurement, Acquisition and Logistics

Introduction

Congress passed the Veterans Health Care Act of 1992 (referred to in this report as the public law) to help ensure the government receives fair prices on pharmaceutical purchases.[12] Section 603 requires manufacturers of drugs subject to the public law to make them available under contract on the Federal Supply Schedule (FSS) and offer them to "Big 4" government customers—VA, the Department of Defense (DOD), the Public Health Service, and the Coast Guard—at a discount of at least 24 percent below the non-Federal Average Manufacturer Price (non-FAMP).[13] The public law places responsibility for compliance on manufacturers. The VA Office of Pharmacy Benefits Management Services provides manufacturers with guidance on complying with the public law, and the VA Office of Inspector General (OIG) conducts reviews to identify noncompliance issues.

The reviews are not published because they contain sensitive commercial information that is protected from release under the Trade Secrets Act.[14] However, to promote transparency, this report summarizes 15 reviews the OIG completed in fiscal years (FYs) 2022 and 2023 that identified approximately $61.2 million in overcharges manufacturers owed to the government. This amount includes about $27 million resulting from manufacturers' noncompliance with the public law and more than $34.1 million resulting from manufacturers' violations of the price reduction clause in the FSS contract.[15]

Purpose

The OIG conducts reviews to determine whether manufacturers made all their covered drugs available to the government through an FSS contract and correctly calculated and reported the

[12] Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603.

[13] Veterans Health Care Act of 1992, § 603.

[14] 18 U.S.C. § 1905; Trade Secrets Act, 41 U.S.C. § 423(a); 38 C.F.R. § 1.558(c). The OIG's contract review reports are marked "For Official Use Only" and are not disclosed outside the government except through procedures established in the Freedom of Information Act. Exemption 4 of the act exempts company trade secrets and confidential commercial or financial information from mandatory disclosure to the public. The OIG team used numbers to refer to manufacturers in lieu of names throughout this report.

[15] GSA Acquisition Manual 552.238-81, "Price Reductions," May 2019. The manual requires the government and the manufacturer to agree on a customer or category of customers as the basis of the award. FSS pricing is tracked against this customer's (or category of customers') pricing for the duration of the contract. The objective of the price reduction clause is to maintain fair and reasonable pricing after the contract has been awarded. Numbers are rounded. Public law overcharges were $27,005,092.40 and price reduction clause overcharges were $34,148,423.87. The total rounds to $61.2 million ($27,005,092.40 + $34,148,423.87 = $61,153,516.27).

drugs' non-FAMPs in compliance with the public law.[16] The non-FAMPs are used to establish Big 4 prices, also referred to as federal ceiling prices, in accordance with the public law and VA guidelines. The OIG undertakes reviews based on manufacturers' disclosures, prior OIG reviews where possible noncompliance issues were identified but not resolved, and Pharmacy Benefits Management Services or National Acquisition Center requests.

There are three primary errors by manufacturers that result in Big 4 customers being overcharged. Two are related to noncompliance with the public law, and the third involves a lack of adherence to the FSS contract's price reduction clause. Manufacturers fail to comply with the public law when they do not place covered drugs on an FSS contract and do not make them available to Big 4 customers at the statutory ceiling prices as required.[17] Manufacturers also violate the public law when they place covered drugs on an FSS contract but miscalculate the drugs' non-FAMPs, often leading to incorrect ceiling prices. Finally, when manufacturers lower prices for certain customers (known as negotiated tracking customers)—triggering the FSS contract's price reduction clause—but then fail to lower the government's price accordingly, this also leads to incorrect ceiling prices.

VA Federal Supply Schedule Program

The goal of VA's FSS program is to leverage the entire federal government's purchasing power to drive volume-based discounts that provide healthcare solutions at fair and reasonable prices to all authorized FSS users.[18] The FSS is a contracting program that provides commercial products to government buyers at fair and reasonable prices. The General Services Administration delegated authority to VA to award and administer nine FSS schedules to support its own healthcare acquisition needs and those of other government agency customers.[19] Federal agencies purchased about $17.8 billion and $18.9 billion in products and services through these nine schedules during FYs 2022 and 2023, respectively. In FY 2022, about 81 percent of government spending on Schedule 65 I B–Drugs, Pharmaceuticals, & Hematology Related Products was

[16] For this report, the term "covered drugs" refers only to those drugs subject to the public law. Not all covered drugs are subject to the public law (for example, approved exemptions, drugs not commercially sold, and newly launched drugs). VA identifies a covered drug as one that is commercially sold and approved by the Food and Drug Administration under a new drug application (and is an innovator drug with at least one active ingredient on the Food and Drug Administration's reference list of original, licensed drugs) or under a biological licensing agreement. The latter applies to any biological product—any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of humans.

[17] Common reasons for drugs not being on contract include drug classification errors, newly launched drugs, new package sizes, and mishandled drug transfers and National Drug Code number changes.

[18] FAR 38.101(a) (2021); FAR 8.402(a); FAR 8.404(d) (2021).

[19] FAR 8.402(a); "VA Schedule Programs" (web page), VA Office of Procurement, Acquisition and Logistics, last updated August 30, 2023, https://www.va.gov/opal/nac/fss/schedules.asp.

through VA's managed FSS program, demonstrating its importance for the health care of veterans, service members, and other Big 4 end users.[20]

When manufacturers want to obtain an FSS contract, the National Acquisition Center directs them to submit a completed proposal package. Manufacturers of covered drugs must also provide a signed master agreement and a pharmaceutical pricing agreement. The master agreement between VA (representing the government) and the manufacturer stipulates that covered drugs must be made available on the FSS. It also outlines the manufacturer's responsibilities and obligations under the public law—specifically, to submit a pharmaceutical pricing agreement with updated pricing and non-FAMP data to VA to establish ceiling prices annually.[21]

Under the public law, if a manufacturer of a covered drug does not enter into a master agreement or does not offer the drug on the FSS at or below the statutory ceiling price, the manufacturer may not receive any payment for those drugs from the Big 4 agencies, any entity that receives funds under the Public Health Service Act, or a state Medicaid plan.[22] The terms and conditions of the master agreement are nonnegotiable and are the same for all VA FSS contractors that manufacture and sell covered drugs. This agreement remains in effect unless terminated by either party with a 60-day notice.

VA Pharmacy Benefits Management Services

The public law requires manufacturers to submit non-FAMP data to VA annually for each covered drug.[23] Pharmacy Benefits Management Service uses the data to calculate the annual ceiling prices for covered drugs. VA also provides manufacturers with a process for making self-disclosures of any noncompliance with the public law or pricing errors that occurred during any period in which the manufacturers were subject to the public law. Manufacturers should state the noncompliance error, its cause, the drugs affected, the date ranges the errors occurred, estimated overcharges to the government, and remedial action proposed or taken.

[20] The 65 I B schedule covers items such as nonprescription medicated cosmetics, drugs (including generics and over-the-counter), IV delivery systems, nutritional supplements, and soaps and dispensing equipment. "Schedule 65 I B Drugs, Pharmaceuticals, & Hematology Related Products" (web page), VA Office of Procurement, Acquisition and Logistics (OPAL), accessed June 12, 2024, https://www.va.gov/opal/nac/fss/pharmaceuticals.asp.

[21] "Public Law 102-585, Veterans Health Care Act of 1992" (web page), VA Office of Procurement, Acquisition and Logistics, accessed July 28, 2022, https://www.va.gov/opal/nac/fss/publicLaw.asp.

[22] 38 U.S.C. § 8126 (a)(4).

[23] 38 U.S.C. § 8126 (d).

Summary Results for Reviews Completed in FYs 2022 and 2023

The OIG completed 15 reviews in FYs 2022 and 2023 to identify any instances of noncompliance with the public law. For 14 reviews, the OIG determined the impact to the government was approximately $61.2 million in overcharges. This amount included about $27 million resulting from manufacturers' noncompliance with the public law and more than $34.1 million resulting from manufacturers' violations of the price reduction clause in the FSS contract that were unrelated to the public law. For the other review, the OIG determined there were no overcharges because the manufacturer had complied with the public law and had not violated the price reduction clause. VA was able to recover approximately $59.3 million in overcharges resulting from OIG recommendations.[24]

What the OIG Did

The OIG team took four actions when reviewing noncompliance issues:

1. Evaluating a manufacturer's calculations of the non-FAMPs used to determine the ceiling price for a covered drug
2. Determining if manufacturers made all covered drugs available on the FSS in accordance with the public law and VA guidelines
3. Determining if manufacturers had any General Services Administration price reduction clause violations affecting the ceiling prices for covered drugs[25]
4. Calculating any overcharges to the government for incorrectly calculated non-FAMPs and related ceiling prices, late additions, or price reduction clause violations

To achieve these objectives, the OIG team evaluated non-FAMPs and related ceiling prices, late additions, and price reduction clause violations affecting the ceiling prices for covered drugs during any period in which the manufacturers were subject to the public law.

For each of the 15 reviews, the OIG sought to identify all issues affecting the ceiling prices for covered drugs along with the noncompliance issues that manufacturers disclosed. When the team determined a manufacturer needed to establish ceiling prices for new drugs or restate

[24] Appendix A provides more information on the monetary impact of the OIG's 15 reviews of public law noncompliance completed in FYs 2022 and 2023.

[25] GSA Acquisition Manual 552.238-81, "Price Reductions." The manual requires the government and the manufacturer to agree on a customer or category of customers as the basis of the award. FSS pricing is tracked against this customer's (or category of customers') pricing for the duration of the contract. The objective of the price reduction clause is to maintain fair and reasonable pricing after the contract has been awarded.

non-FAMPs for drugs already on contract, the team gave the manufacturer time to do so and then evaluated the manufacturer's non-FAMP methodology and calculations. The team also gave Pharmacy Benefits Management Services time to calculate the related ceiling prices and update VA's historical records. Additionally, the team gave contracting officers time to modify the manufacturer's contract. These steps were necessary because of the impact prior year prices could have on current prices.

The sections that follow summarize the OIG's findings for each of the four areas examined during the 15 reviews. Appendix B provides more information on the team's scope and methodology.

Evaluation of Non-FAMP Errors

The public law requires manufacturers to submit non-FAMP data to VA annually for each covered drug. Pharmacy Benefits Management Services uses the data to calculate the drugs' annual ceiling prices, which must be at least 24 percent lower than the non-FAMPs. Manufacturer errors in non-FAMP calculations put Big 4 customers at risk of purchasing drugs at higher prices.

Of the 15 reviews completed by the OIG, four involved disclosures of non-FAMP calculation errors affecting 306 covered drug codes.[26] The OIG determined the errors resulted in $16,899,092 in overcharges to the government.

Most of the errors identified were attributed to Manufacturer 1, which is the majority shareholder for Manufacturer 2.[27] Manufacturer 1 submitted disclosures for both companies. Together, the disclosures involved non-FAMP calculation errors resulting in higher ceiling prices for 207 of the 306 drug codes (about 68 percent). Of the 207 affected drug codes, 173 accounted for $16,800,528 (about 99 percent) of the total overcharges. The team worked with Manufacturer 1 to understand the disclosures and obtain information and documentation needed to complete both reviews. According to the manufacturer, the non-FAMP calculation errors for both companies occurred because of several errors in the manufacturer's government pricing system. The team expanded the scope of both reviews because it identified additional errors during the course of its work.

The action taken by Manufacturer 1 to prevent future errors included implementing routine monitoring of its system to ensure all relevant data are captured for the non-FAMP calculations. The manufacturer corrected the non-FAMPs for all 207 drug codes. The OIG accepted the restated non-FAMPs and verified that the Pharmacy Benefits Management Service updated its

[26] Because the Food and Drug Administration assigns a unique code (National Drug Code) to all package sizes, drug strengths, and volumes of a drug, the code, rather than the individual drug, was the basis for the team's analysis.

[27] The OIG team used numbers to refer to specific manufacturers in lieu of names. The numbers assigned are based on order of mention in the report. Once assigned, the number remains with the manufacturer.

records to reflect the correct non-FAMPs and related ceiling prices for the affected periods. The remaining non-FAMP errors were attributed to Manufacturers 3 and 4.

Evaluation of Late Additions

Late additions to FSS contracts put the government at risk of paying higher prices for covered drugs on the open market and potentially while on contract if the federal ceiling prices are incorrectly calculated.[28] The OIG team identified open-market purchases through VA and DOD open-market sales reports.

Of the 15 reviews, 10 involved possible late additions of 174 National Drug Codes. Of the 174 drug codes, the OIG excluded 19 from its review: the OIG had already identified 14 in reviews completed prior to FY 2022; four were not actively marketed, exempting them from FSS inclusion; and one was not subject to the public law. The OIG team analyzed the remaining 155 codes and determined the late additions resulted in $6,078,721 in overcharges to the government ($4,685,611 for open-market purchases and $1,393,110 while on contract). Ten of the 155 were not added to manufacturers' FSS contracts because they were discontinued, replaced, or unallowed—due to violations identified by the Food and Drug Administration at a drug manufacturing facility—after the time they were supposed to be added.[29] Table 1 summarizes the reasons the 10 manufacturers gave for not adding the drugs to the FSS in a timely manner. The reasons are explained in detail following the table.

[28] VA gives manufacturers 30 days to generate a temporary ceiling price and 45 additional days to submit the non-FAMP used to calculate the ceiling price in the FSS contract. When manufacturers take more than 75 days to comply, their items become late additions.

[29] The 10 codes should have been added to FSS contracts when required. For example, Manufacturer 5 should have added 71 transferred drug codes to its FSS contract at the time of transfer. The manufacturer subsequently only added 67 because four were discontinued after the transfer occurred and before they could be added.

Table 1. Drug Codes Not Added on Time to the FSS, by Reason and by Manufacturer Number

Reason	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	Total
Transferred drugs	—	71	—	—	1	—	4	—	—	—	76
New covered drugs	1	9	12	9	7	2	2	4	2	2	50
National Drug Code number change	—	13	3	—	—	—	—	—	—	—	16
New package sizes	—	6	1	—	—	—	—	—	—	—	7
Misclassified drugs	—	—	—	—	—	6	—	—	—	—	6
Total	**1**	**99**	**16**	**9**	**8**	**8**	**6**	**4**	**2**	**2**	**155**

Source: OIG analysis of reviews of public law noncompliance completed in FYs 2022 and 2023.

Transferred Drugs

Of 155 drug codes determined to be late additions, 76 (about 49 percent) were transferred from one manufacturer (the "transferor") to another (the "transferee"). When a covered drug is transferred, the transferee is required to add the drug to its FSS contract at the transferor's ceiling price at the time of transfer.

As shown in table 1, Manufacturer 5 added 71 transferred drug codes to the FSS late. Four were discontinued and not added; the remaining 67 were added in succession: 64 appeared one year after transfer, and three appeared approximately 5.5 years later.

New Covered Drugs

The reason most frequently cited by manufacturers for adding drugs to the FSS late was that they had just entered the marketplace. Because the drugs were new, manufacturers lacked commercial pricing data for them. VA gives manufacturers 30 days to generate a temporary ceiling price and 45 additional days to submit the non-FAMP that Pharmacy Benefits Management Service uses to calculate the ceiling price recorded in the FSS contract. Of the 155 drug codes determined to be late additions, 50 (about 32 percent) were not made available on FSS contracts by the end of the 75-day data-gathering periods.

National Drug Code Number Changes

National Drug Code number changes are requested by manufacturers for a variety of reasons, including changes in a drug's manufacturer (drugs acquired through a transfer), name, active pharmaceutical ingredient, strength of any active pharmaceutical ingredient, dosage form, or distinguishing characteristics.[30] If a drug's code number changes, the new number must be added to the manufacturer's FSS contract at the time of the first commercial sale and at the same ceiling price. Additionally, both the new and original code numbers must remain on the contract until the original code's last lot has expired or the drug is off the market and out of the supply chain, whichever comes first. Of the 155 drug codes reviewed, 16 (about 10 percent) were not added to FSS contracts on time.

New Package Sizes

Separate code numbers are required for a drug on contract sold in different package sizes with the same strength. When a manufacturer introduces a new package size of a covered drug to the market, the new code must be added to the manufacturer's contract. The initial ceiling price for the new size is prorated based on the ceiling price of the nearest size package that is already on contract at a permanent ceiling price. Of the 155 drug codes determined to be late additions, seven (about 5 percent) were for new package sizes.

Misclassified Drugs

Of the 155 drug codes determined to be late additions, six (about 4 percent) were misclassified as noncovered drugs and were on an FSS contract without ceiling prices. The OIG identified the misclassified drugs in 2010 and notified Pharmacy Benefits Management Services, which in turn notified the manufacturer the same year, but the OIG did not receive an update on whether the manufacturer became compliant with the public law. The OIG contacted the National Acquisition Center in 2011 but still got no update. In 2013, the OIG initiated a review and found the manufacturer was still noncompliant. The OIG discontinued the review in late 2015 because the manufacturer had made no progress in achieving compliance, but the OIG continued to follow up. In early 2017, the OIG determined the manufacturer's status was unchanged. VA's Office of General Counsel contacted the OIG in early 2020 to convey the manufacturer's position, which was that it was a repackager and therefore not subject to the public law. However, the public law's definition of a manufacturer includes repackagers.[31] The drugs were properly reclassified on the manufacturer's contract in late 2020. In FY 2022, the OIG reviewed the manufacturer's six drug codes, along with two other drug codes included in this report as new covered drugs, to determine the overcharges owed to the government for the late additions.

[30] 21 C.F.R. 207.35.

[31] 38 U.S.C. § 8126 (h)(4).

Evaluation of Price Reduction Clause Violations

When manufacturers lower the price charged to tracking customers, the price reduction clause requires that they also lower the FSS contract price. Tracking customers are agreed on during negotiations for each product at the time of the FSS contract award.[32] FSS contracts require manufacturers to report such price reductions during the period the contract is in effect.

Of the 15 reviews completed, three involved disclosures of possible clause violations affecting a total of 538 drug codes. The team substantiated that the prices for 535 of the 538 drug codes (about 99 percent) violated the clause, resulting in $38,175,703 in overcharges to the government. This amount included approximately $4,027,279 in overcharges by one manufacturer whose ceiling prices were affected. The remaining three drug codes belonged to Manufacturer 14, which the team determined had complied with the public law and not violated the clause.

Manufacturer 15 was responsible for most of the clause violations and accounted for approximately $37,060,123 of the total overcharges (about 97 percent), with 531 drug codes affected. Of the 531 drug codes, 140 (about 26 percent) were covered drugs. The other 391 drug codes (about 74 percent) were not covered drugs and were not subject to the public law. The manufacturer performed a self-audit and submitted a disclosure estimating covered drug overcharges to Big 4 customers to be about $4,027,279 as a result of lowered ceiling prices. The manufacturer also estimated covered drug overcharges to other government agency customers and noncovered drug overcharges to Big 4 and other government agency customers to be approximately $33,032,843. According to Manufacturer 15, which acquired the drugs in 2016, the transferor did not routinely monitor tracking customer prices, which decreased multiple times between July 1, 2010, and March 31, 2017. Subsequently, the price reductions were not passed along to the FSS. The OIG team did not find any issues outside of the manufacturer's disclosure and accepted the manufacturer's calculations of overcharges.

Lastly, Manufacturer 7 was responsible for clause violations, as well as its late additions, resulting in approximately $1,115,581 (about 3 percent) of the overcharges, with four of 535 drug codes affected. The manufacturer's parent company made four disclosures over approximately 15 months on behalf of the manufacturer. The OIG team determined that none of the disclosures were entirely accurate. Of the four drug codes, the manufacturer did not apply the correct tracking customer ratios to two.[33] Additionally, the manufacturer understated the date

[32] General Services Administration, Acquisition Manual 552.238-81, "Price Reductions.". The manual requires the government and the manufacturer to agree on a customer or category of customers as the basis of the award. FSS pricing is tracked against this customer's (or category of customers') pricing for the duration of the contract. The objective of the price reduction clause is to maintain fair and reasonable pricing after the contract has been awarded.

[33] The tracking customer ratio (government price divided by the tracking customer price) is the government's price or discount relationship to the identified customer or category of customers. The ratio is established when an FSS contract is awarded.

ranges of impact for three drug codes. Subsequently, prices for all four drug codes were affected and were not reduced in accordance with the price reduction clause for the periods reviewed.

Determination of Overcharges

The OIG used manufacturers' FSS sales data to determine overcharges resulting from non-FAMP errors, late additions, and price reduction clause violations while drugs were on FSS contracts. The team compared sales prices to the ceiling prices that should have been charged. If the prices found in the sales data were higher than the ceiling prices, the team multiplied the difference by the quantities sold to determine the overcharges. The team used VA and DOD open-market sales data to identify covered drugs that were purchased but not on contract to determine overcharges.

For 14 of the 15 reviews completed, the OIG calculated approximately $61.2 million in overcharges to the government (table 2). They consisted of non-FAMP errors (about $16.9 million), late additions (about $6.1 million), and price reduction clause violations (about $38.2 million). Of the $61.2 million, approximately $34.1 million resulted from price reduction clause violations attributable to Manufacturers 7 and 15 that did not affect compliance with the public law.

Table 2. Overcharges to the Government, by Manufacturer and Category ($ millions)

Manufacturer	Non-FAMP errors	Late additions	Price reduction clause violations	Total overcharges	Overcharges unrelated to compliance with the public law*
M1–M13†	16.9	6.1	1.1	24.1	1.1
M14	—	—	—	—	—
M15‡	—	—	37.1	37.1	33.0
Total	**16.9**	**6.1**	**38.2**	**61.2**	**34.1**

Source: OIG analysis of public law noncompliance reviews completed in FYs 2022 and 2023.

Note: The OIG learned of the overcharges by Manufacturer 15 (which did not conflict with the public law) during its review of the manufacturer's disclosure of public law noncompliance.

** Price reduction clause overcharges.*

† Two manufacturers had more than one noncompliance issue. Manufacturer 4 had non-FAMP errors and late additions, and Manufacturer 7 had late additions and price reduction clause violations.

‡ Manufacturer 15 overcharged other government agency customers for covered drugs. It also overcharged the government for noncovered drugs.

To recover the full $61.2 million, the OIG recommended contract specialists issue bills of collection to the respective manufacturers for their individual overcharges. One of the 15 reviews did not have a recommendation because the team determined Manufacturer 14 had complied with the public law and had not violated the price reduction clause.

For the remaining 14 reviews, 11 manufacturers concurred with the OIG's calculated overcharge amounts. As for the other three manufacturers, Manufacturer 9 did not agree with the OIG's calculated overcharges, Manufacturer 8 partially agreed, and Manufacturer 15 was not asked to provide concurrence because the OIG agreed with the estimated overcharges amount stated in the manufacturer's self-disclosure. VA has since collected approximately $59.3 million (about 97 percent) of the recommended amount from 11 of the 14 manufacturers. VA does not expect to collect Manufacturer 10's overcharges because the manufacturer filed for bankruptcy. Additionally, VA had not resolved overcharges with Manufacturers 4 and 9 as of June 17, 2024.

Collectively, the 15 manufacturers estimated only about $53.3 million in total overcharges compared to the OIG's calculated total overcharges amount of approximately $61.2 million. The difference of $7.9 million was the result of six manufacturers disclosing late additions without providing estimates of overcharges and one manufacturer providing an estimate when no price reduction clause violations occurred. Manufacturers are only asked by VA to estimate overcharges owed to the government, if known, because manufacturers do not have access to VA and DOD open-market sales data.

The OIG team expanded the scope of the reviews of disclosures by Manufacturers 1, 2, and 4. The team also expanded the scope of the reviews of Manufacturers 6 and 8 for possible noncompliance with the public law because of late additions identified while the reviews were ongoing. Lastly, estimates by Manufacturers 6, 7, 11, and 13 of overcharges for late additions were rough calculations because the manufacturers did not have access to actual data. Manufacturer 7 also did not calculate overcharges for price reduction clause violations correctly (by using incorrect tracking customer ratios and periods and failing to take into account an administrative fee).[34]

Appendix A provides more information on the monetary impact of the OIG's 15 reviews of public law noncompliance completed in FYs 2022 and 2023.

Conclusion

The federal government spends billions of dollars annually on pharmaceuticals through VA's FSS program. The OIG's findings and recommendations helped VA contracting officers collect approximately $59.3 million in overcharges to the government. As of June 17, 2024, VA had not resolved approximately $1.2 million in overcharges with two manufacturers.

This report provides summary information about prior recommendations made to VA; it does not make additional recommendations that require VA response or action.

[34] The Industrial Funding Fee is an administrative fee built into the pricing of all products and services offered under VA's FSS program.

VA Management Comments

The associate executive director of the National Acquisition Center concurred with the draft report and provided no comments. Appendix C provides the full text of the director's response.

Appendix A: Estimated and Collected Overcharges Resulting from OIG Reviews of Public Law Noncompliance during Fiscal Years 2022 and 2023

The VA Office of Inspector General (OIG) recommended VA collect overcharges owed to the government in the amount of approximately $61.2 million for the public law noncompliance reviews completed in fiscal years (FYs) 2022 and 2023. In contrast, the manufacturers' estimates of overcharges totaled only approximately $53.3 million. Overall, VA was able to collect approximately $59.3 million (about 97 percent) of the OIG's recommended amount. This amount includes interest paid by Manufacturers 6 and 11. VA does not expect to collect overcharges from Manufacturer 10 because the manufacturer filed for bankruptcy. Additionally, VA had not resolved overcharges with Manufacturers 4 and 9 as of June 17, 2024. Table A.1 shows the manufacturers' estimated overcharges, OIG calculated overcharges, and the overcharges VA collected.

Table A.1. Overcharges Data by Manufacturer for Disclosures Reviewed

Manufacturer number*	Report issuance date	Manufacturer's estimated overcharges ($)	OIG's calculated overcharges ($)	Overcharges VA collected ($)	Date collected
1	11/17/2022	4,359,123	6,477,028	6,477,028	5/25/2023
2	11/17/2022	10,119,559	10,323,500	10,323,500	8/21/2023
3	3/15/2022	147,683	98,564	98,564	4/2/2022
4	11/18/2021	—	230,317	—	—
5	9/28/2023	—	1,251,901	1,251,901	10/11/2023
6	2/15/2022	44,455	1,930,696	1,935,528	9/19/2022
7	2/23/2023	1,440,763	1,833,889	1,833,889	9/11/2023
8	2/23/2022	—	91,623	91,623	6/7/2022
9	9/12/2022	—	979,553	—	—
10	2/8/2023	—	639,032	—	—
11	3/21/2022	677	502	504	7/10/2023
12	11/10/2021	—	37,351	37,351	2/9/2022
13	8/2/2022	109,977	199,437	$199,437	9/23/2022

Manufacturer number*	Report issuance date	Manufacturer's estimated overcharges ($)	OIG's calculated overcharges ($)	Overcharges VA collected ($)	Date collected
14	8/18/2023	7,123	—	—	—
15	2/2/2022	37,060,123	37,060,123	37,060,123	4/4/2022
Total		**53,289,482**	**61,153,516**	**59,309,448**	

Source: OIG reports and bill of collection updates from VA offices.

Note: Numbers in table may not sum due to rounding. A dash indicates the OIG did not make a recommendation or VA does not expect to collect OIG's calculated overcharges.
**The OIG did not use manufacturer names. Instead, the team assigned numbers to the manufacturers in the order they were presented in this report.*

Appendix B: Scope and Methodology

Scope

The review team conducted its work from January 2024 through July 2024 and focused on summarizing the information in prior OIG public law noncompliance review reports and presenting overcharges subsequently collected. The team assessed relevant sources of information, including the review reports and bills of collection updates from VA's contracting offices (Pharmacy Benefits Management Services and the National Acquisition Center).

Methodology

The OIG team summarized 15 public law noncompliance review reports issued in FYs 2022 and 2023. The team also worked closely with VA's contracting offices to determine any overcharges collected.

Fraud Assessment

The review team assessed the risk of fraud and noncompliance with provisions of laws, regulations, and contracts significant to the individual objectives for the 15 public law noncompliance reviews completed in FYs 2022 and 2023. However, this project is a summary of prior OIG reports and did not involve collecting any new data or information from manufacturers, VA, or DOD except for bills of collection information obtained from VA. The team exercised due diligence in staying alert to fraud indicators. The OIG did not identify instances of fraud or potential fraud during this review.

Data Reliability

The team relied on computer-processed data to determine the amount of overcharges to the government collected by VA to date. VA provided the data from VA's Integrated Financial and Acquisition Management System, and the team conducted limited testing on the data, including a reasonableness test comparing the amount collected with the recommended overcharges per report. The team also met with an official from the Office of Revolving Funds to ensure understanding of the quarterly collection reporting process. As a result of the testing and understanding of the reporting process, the team determined that the data was sufficiently reliable for the purpose of this review.

Government 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.*

Appendix C: VA Management Comments

Department of Veterans Affairs **Memorandum**

Date: August 6, 2024

From: Associate Executive Director (National Acquisition Center (NAC/FSS)

Subj: Office of Inspector General Draft Report: A Summary of Reviews in Fiscal Years 2022 and 2023 of Manufacturers' Noncompliance with Veterans Healthcare Act Provisions on Pharmaceutical Pricing, 2024-01035-AE-0038

To: Audit Operations Division (52D02)

1. The Office of Procurement, Acquisition and Logistics (OPAL) completed its review of the subject Draft Report and concur without comments.

The OIG removed point of contact information prior to publication.

(Original signed by)

Christopher Parker

For accessibility, the original format of this appendix has been modified to comply with Section 508 of the Rehabilitation Act of 1973, as amended.

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