



# US DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Audits and Evaluations

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## VETERANS HEALTH ADMINISTRATION

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### **Manufacturers Failed to Make Some Drugs Available to Government Agencies at a Discount as Required**

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## Executive Summary

To help ensure that the federal government receives fair prices on pharmaceuticals, Congress passed the Veterans Health Care Act of 1992 (referred to in this report as the public law). It requires the manufacturers of covered drugs to make them available 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 off the market price.<sup>1</sup> The public law uses the technical definition of a covered drug as it appeared in the Social Security Act in November 1992.<sup>2</sup> Because the technical definition made it difficult to quickly identify which drugs were covered, VA established a simpler definition: a covered drug must be commercially marketed, sold, and approved by the Food and Drug Administration (FDA) under a new drug application (if at least one active ingredient is on the FDA’s reference list of original, licensed drugs) or under a biological licensing agreement.<sup>3</sup> The VA Office of Inspector General (OIG) used VA’s definition and determinations when examining the items in this review. The public law also requires manufacturers to sign a master agreement and a pharmaceutical pricing agreement.<sup>4</sup>

Drug manufacturers that comply with the public law not only gain the business of the entire federal government, but also become eligible to participate in federal government-funded programs including Medicare and Medicaid.<sup>5</sup> During fiscal year 2021, the federal government spent about \$13.2 billion on pharmaceuticals offered on FSS contracts managed by VA.<sup>6</sup>

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<sup>1</sup> Veterans Health Care Act of 1992, Pub. L. No. 102–585, § 603 (1992).

<sup>2</sup> Social Security Act § 1927(k)(7)(A)(ii) and (iv). The act states that a covered drug is either a single source (only one drug produced under a new drug application, also known as a brand-name drug) or innovator multiple source drug (two or more drugs that are pharmaceutically equivalent and produced under a new drug application).

<sup>3</sup> 38 U.S.C. § 8126 (h)(2) and defined in the Social Security Act § 1927; 21 C.F.R. § 600.3(h). A biological licensing agreement applies to any biological product—i.e., any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of humans. The public law only applies to covered drugs, which are brand-name drugs and authorized generics (copies of brand-name drugs with minor differences and without the brand name on their label).

<sup>4</sup> The master agreement outlines the manufacturer’s responsibilities and obligations associated with the public law and instructs each manufacturer of a covered drug to enter into a pharmaceutical pricing agreement. The pharmaceutical pricing agreement documents that the manufacturer agrees that the annual ceiling price for each covered drug will be the maximum price the government pays.

<sup>5</sup> 38 U.S.C. § 8126 (a)(4).

<sup>6</sup> The General Services Administration (GSA) directs and manages the FSS, which provides federal agencies and other authorized users with a simplified process of acquiring commercial supplies and services at established fair and reasonable prices from responsible vendors. In January 1981, GSA delegated to VA contracting responsibility for medical items. This delegation continued with the creation of FSS contracts for medical equipment, medical supply, pharmaceutical, and medical service-related schedule programs for VA. On February 8, 2022, GSA completed an official Assignment of Function to the Secretary of VA for managing the medical and healthcare multiple-award schedules.

Nonetheless, some manufacturers do not comply with the public law and may cause Big 4 government customers to pay higher prices for these covered drugs. Contributing to the noncompliance is the fact that VA is not required to perform any checks to ensure that covered drugs are offered as required since the law places responsibility on manufacturers to ensure compliance. Manufacturers must self-report noncompliance to VA, and VA typically requests that the manufacturer perform a self-audit. If noncompliance is not reported, however, manufacturers may continue to charge the Big 4 higher prices and benefit from government-funded programs when they should not.

The OIG conducts individual audits of manufacturers that have self-disclosed a potential noncompliance issue with the public law. However, this review was conducted to proactively determine the number of covered drugs that manufacturers did not make available on the FSS as required by the public law, and the possible reasons manufacturers did not comply.

## What the Review Found

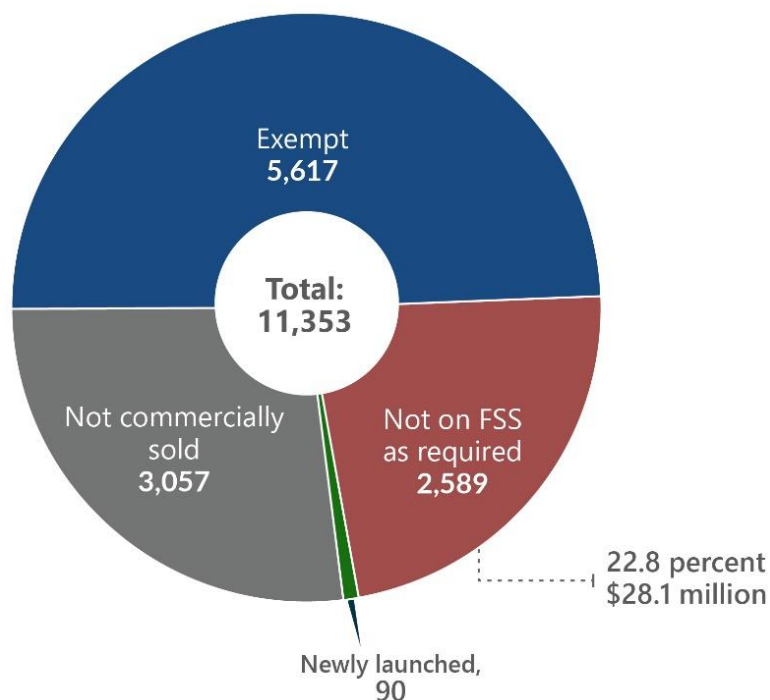
The OIG team identified 17,873 national drug codes that fit the definition of a covered drug under the public law as of March 31, 2022. Of these, 6,520 drugs were properly made available on FSS. The OIG found the remaining 11,353 covered drugs were not on an FSS contract and, by applying VA's determinations on the public law, ascertained the makeup of this group (shown in summary figure 1 on the next page). Of the 11,353 covered drugs not on the FSS, there were 8,764 not required to be because 5,617 drugs received exemptions from VA's Public Law Policy Group, another 3,057 drugs were not commercially sold, and 90 were newly launched.<sup>7</sup> The remaining 2,589 drugs (22.8 percent) should have been made available on the FSS as required by the public law.<sup>8</sup> As a result, the team found that VA and the DOD potentially overpaid approximately \$28.1 million (\$6.8 million for VA and \$21.3 million for DOD) on 375 covered drugs from May 17, 2016, to March 31, 2022.<sup>9</sup>

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<sup>7</sup> The VA Public Law Policy Group provides general guidance to manufacturers on the public law and, upon request from a specific manufacturer, provides a determination on the public law's applicability to the manufacturer's drugs. If the public law is found not to apply to a particular drug or drug line, the group agrees that the manufacturer has received an exemption from having to make the drug available on the FSS. Any references to exemptions in this report represent the group's application of the public law, which the OIG team also used when evaluating items in this review. "2022 FCP Guidance for New Covered Drugs" (web page), VA Pharmacy Benefits Management Services, accessed July 31, 2022, [www.va.gov/opal/docs/nac/fss/pl102585-2022pbmFcpGuidanceForNewCoveredDrugs.pdf](http://www.va.gov/opal/docs/nac/fss/pl102585-2022pbmFcpGuidanceForNewCoveredDrugs.pdf). VA gives 30 days after the drug's first commercial sale for manufacturers to generate more sales, plus an additional 45 days for them to submit pricing data and calculations and request to be added to the FSS. (As of March 21, 2023, this document had been replaced with 2023 guidance.)

<sup>8</sup> The 22.8 percent is based on 2,589 of 11,353 covered drugs not made available on the FSS.

<sup>9</sup> While the team identified noncompliant manufacturers with 2,589 covered drugs not available on the FSS, only 375 of these drugs were purchased in the open market by VA or DOD.



**Summary figure 1.** Breakdown of the 11,353 covered drugs not on FSS.

Source: VA OIG analysis of drugs not on the FSS.

Manufacturers' noncompliance with the public law exposes the government to paying higher drug prices for medicines that are essential for veterans' health care. Manufacturers gave several reasons for not having their covered drugs available on the FSS, primarily that the drugs were not subject to the public law or were otherwise exempt. However, the OIG determined that these reasons were inconsistent with VA's application of the public law. The review team also found some manufacturers were not aware of or overlooked the requirements, while others did not provide additional information as to the reason for their noncompliance.

Furthermore, the review team found that VA has not formalized its process for granting exemptions and lacks an established mechanism to communicate to manufacturers how to request exemptions. VA also does not have a standard procedure for publicizing decisions it made that might affect entire groups of manufacturers. For example, allergen products represented a considerable portion of the exemptions, yet the review team found no evidence VA had communicated to makers of allergen products the VA Public Law Policy Group's decision that those products were not subject to the public law.

Given the significant number of noncompliant manufacturers and corresponding covered drugs that should have been on the FSS, the OIG has identified additional steps that VA could take that would mitigate the identified causes.

## What the OIG Recommended

To reduce noncompliance and keep drugs for veterans more affordable, the OIG made eight recommendations that include communicating the exemption given to allergens, as well as conveying the process for requesting exemptions, and formalizing the internal process for granting exemptions. VA should also follow up with makers of the covered drugs identified in the report as not commercially sold (in case they have become available) or newly launched (to ensure they have an established annual ceiling price and are available on the FSS at the end of the 75-day grace period). VA should also request self-audits by noncompliant manufacturers identified by the OIG and submit their findings for remediation. The OIG made recommendations for intervening in key steps in the covered drug process as well: VA should engage with the FDA on making certain that drug manufacturers are made aware of the public law requirements when manufacturers request new national drug codes. In addition, when a manufacturer submits an FSS proposal, VA should require its contracting staff to check all of the manufacturer's drugs to see if any others are covered.

## VA Comments and OIG Response

The principal executive director and chief acquisition officer at the Office of Acquisition, Logistics and Construction (OALC), in conjunction with the Veterans Health Administration (VHA), concurred in principle with the findings identified; concurred with recommendations 1, 2, 3, 6, and 8; and did not concur with recommendations 4, 5, and 7. OALC concurred with recommendation 6 if clarified to distinguish manufacturers who have signed a master agreement with VA. The intent of the recommendation is also to focus on engagement and education for noncompliant manufacturers identified in this report that have no master agreement with VA, to make them aware of their responsibility under the public law.

For recommendations 4 and 5, OALC believes it is not responsible for enforcement of the law or policing the supply chain of all covered drugs. The OIG is not asking OALC's National Acquisition Center (NAC) to police or monitor the supply chain of all covered drugs that are not under a master agreement or an existing FSS contract. The OIG is recommending the NAC specifically monitor the 3,057 covered drugs that were found to be not commercially sold and the 90 newly launched drugs referred to in this report—not all covered drugs that exist. The 90 newly launched drugs are manufactured by FSS contractors with existing master agreements, and these drugs should be added to their FSS contracts. For the 3,057 drugs identified as not commercially sold, only 553 drugs belong to manufacturers with no master agreement.

For recommendation 7, the principal executive director and chief acquisition officer disagreed with OIG and VHA asked to delete this recommendation, which focuses on efforts to communicate with the FDA (notwithstanding the roles played by the Office of Federal Procurement Policy, federal comptrollers, and acquisition officials). However, the recommendation does not require VA to monitor or track manufacturers, nor does it mandate that

the FDA provide information to manufacturers. The goal of the recommendation is to initiate collaboration between government agencies so that manufacturers are more aware of the public law requirements.

VA comments are presented in full in appendix C. The corrective action plans for recommendations 1, 2, 3, and 8 are responsive to the intent of the recommendations. The OIG will monitor the implementation of the recommendations until all actions are documented as completed.



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## Abbreviations

DOD	Department of Defense
FDA	Food and Drug Administration
FSS	Federal Supply Schedule
FY	fiscal year
GSA	General Services Administration
NAC	National Acquisition Center
OALC	Office of Acquisition, Logistics and Construction
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management Services
VHA	Veterans Health Administration



## Introduction

During fiscal year (FY) 2021, the federal government spent approximately \$13.2 billion on pharmaceuticals offered on Federal Supply Schedule (FSS) contracts managed by VA.<sup>10</sup> The contracts are nine healthcare-related multiple-award schedules that any eligible federal government agency or other authorized entity can use to purchase supplies and services at a lower cost.<sup>11</sup> The pharmaceutical schedule made 14,136 drugs available to service members, veterans, and others as of March 31, 2022.<sup>12</sup>

Congress passed the Veterans Health Care Act of 1992 (referred to in this report as the public law) to help control the cost of pharmaceuticals purchased by the federal government. It mandates that manufacturers give VA and the other “Big 4” government customers—the Department of Defense (DOD), Public Health Service (including Indian Health Service), and Coast Guard—a discount on drugs.<sup>13</sup> The public law requires the manufacturers of covered drugs approved by the Food and Drug Administration (FDA) to list them on the FSS and offer them to the government and veterans at a discount of at least 24 percent off market price.<sup>14</sup> Although drug manufacturers must provide a discount, they also benefit from complying with the public law. They gain the business of supplying the largest government agencies with needed drugs. They are also eligible to participate in and receive funds from federal government-funded programs including Medicare and Medicaid.<sup>15</sup>

The public law places responsibility for compliance on manufacturers. Although VA is not responsible, it does conduct some compliance checks related to the public law. The result, however, is that VA and the other three federal agencies in the Big 4 may be charged higher

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<sup>10</sup> In January 1981, the General Services Administration (GSA) delegated its authority to VA for managing these multiple-award schedules, which consist of long-term government-wide contracts with commercial firms providing government buyers access to commercial products and services at volume discount pricing. The FSS provides federal agencies and other authorized users with a simplified process of acquiring commercial supplies and services at established fair and reasonable prices from responsible vendors. FAR 38.101. On February 8, 2022, GSA completed an official Assignment of Function to the Secretary of VA for managing the medical and healthcare multiple-award schedules.

<sup>11</sup> FAR 38.101 and 8.404(d).

<sup>12</sup> VA’s Federal Supply Code 65, part I, section B, includes drugs, pharmaceuticals, and hematology-related products. This includes 7,065 covered drugs and 7,071 generic drugs. A generic drug is a copy of a brand-name drug with minor differences that is not a covered drug under the public law.

<sup>13</sup> Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 603 (1992).

<sup>14</sup> Veterans Health Care Act of 1992, § 603. A covered drug is one that is commercially marketed, sold, and approved by the FDA under a new drug application (if at least one active ingredient is on the FDA’s reference list of original, licensed drugs) or a biological licensing agreement. The latter applies to any biological product—i.e., any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of humans. Drugs may be offered in different configurations; each is issued a unique three-part number called a national drug code, which the FDA uses for tracking purposes.

<sup>15</sup> 38 U.S.C. § 8126 (a)(4).

prices if noncompliance is not reported by the manufacturer or if VA does not happen to detect an error. Noncompliant manufacturers may also improperly participate in Medicare and state Medicaid plans without penalty.<sup>16</sup>

On March 31, 2022, 17,873 drugs fit the definition of a covered drug under the public law. Of these, 6,520 drugs were available on FSS contracts consistent with the law, so they were not evaluated further. The VA Office of Inspector General (OIG) examined the remaining 11,353 covered drugs to determine whether manufacturers should have made those covered drugs available on the FSS as required by the public law, and the possible reasons for any noncompliance.<sup>17</sup>

The following sections provide relevant background information.

### **Veterans Health Care Act of 1992 (Public Law 102–585)**

On November 4, 1992, Congress enacted the public law, with section 603 limiting the prices of covered drugs procured by the Big 4.<sup>18</sup> Section 603 was codified in the United States Code.<sup>19</sup> The public law uses the definition of a covered drug that appears in the Social Security Act, but as it was written in November 1992.<sup>20</sup> This technical definition does not provide a way to quickly identify drugs classified as covered.<sup>21</sup> As a result, VA has provided a simple way of identifying a covered drug: it must be commercially sold and approved by the FDA under a new drug application (and is an innovator drug where at least one active ingredient is on the FDA’s reference list of original, licensed drugs) or under a biological licensing agreement. The latter applies to any biological product—i.e., any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment, or cure of diseases or injuries of humans.<sup>22</sup> The OIG has used VA’s own simplified definition and its determinations when examining the items in this review.

If a manufacturer has a covered drug that is commercially sold, whether or not the manufacturer receives government funds or had prior government sales, the manufacturer is still subject to the public law and must make the drug available on the FSS.<sup>23</sup> If a manufacturer does not comply

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<sup>16</sup> 38 U.S.C. § 8126 (a).

<sup>17</sup> Any reference to availability on the FSS in this report indicates there is also a signed master agreement. A manufacturer may have an FSS contract with only generic drugs, which does not require a master agreement.

<sup>18</sup> Veterans Health Care Act of 1992, § 603.

<sup>19</sup> Title 38 U.S.C. § 8126. Veterans Health Care Act of 1992, § 603 (Public Law 102-585 Sec. 603), and Title 38 U.S.C. § 8126 are used interchangeably in this report.

<sup>20</sup> 38 U.S.C. § 8126 (h)(2) and § 8126 (g)(1).

<sup>21</sup> For the technical definition of covered drug, the public law points to the terms “single source” and “innovator multiple source” drugs defined in the Social Security Act § 1927 (k)(7)(A)(ii) and (iv).

<sup>22</sup> 38 U.S.C. § 8126 (h)(2); Social Security Act § 1927.

<sup>23</sup> 38 U.S.C. § 8126 (a).

with these requirements, it should not receive funds from the Big 4 or other government-funded agencies or from programs such as Medicare and Medicaid.<sup>24</sup>

To comply with the public law, manufacturers of covered drugs must meet four interrelated requirements, illustrated in figure 1.



**Figure 1.** Requirements of the public law.

Source: VA OIG analysis of public law requirements.

\* The manufacturer provides the average commercial pricing data, also known as the nonfederal average manufacturer price, to calculate the annual ceiling price.

## Prices for Covered Drugs

The law requires manufacturers to submit average commercial pricing data to VA every year for each covered drug.<sup>25</sup> VA Pharmacy Benefits Management Services (PBM) collects these data, which include the manufacturer's sales to wholesalers only, less adjustments.<sup>26</sup> VA uses the data to calculate the annual ceiling price for each covered drug, which is at least a 24 percent discount from the average manufacturer price. The annual ceiling price limits the amount the manufacturer may charge the Big 4 for a covered drug.

<sup>24</sup> 38 U.S.C. § 8126 (a).

<sup>25</sup> 38 U.S.C. § 8126 (d).

<sup>26</sup> Adjustments may include removing sales to the federal government. 38 U.S.C. § 8126 (h)(5).

If a manufacturer does not have commercial pricing data (i.e., it does not sell a covered drug commercially), the drug is not subject to the law.

## **Master and Pharmaceutical Pricing Agreements**

The master agreement between VA (representing the government) and the manufacturer stipulates that covered drugs must be made available on the FSS and outlines the manufacturer's responsibilities and obligations under the public law. Specifically, the master agreement instructs manufacturers to enter into a pharmaceutical pricing agreement and requires them to submit average manufacturer price data to VA to establish federal ceiling prices.<sup>27</sup> The terms and conditions of this agreement are nonnegotiable and are the same for all VA FSS contractors. This agreement is between the manufacturer and VA and does not expire unless terminated by either party with a 60-day notice.

When manufacturers want to obtain an FSS contract, the VA National Acquisition Center (NAC) directs them to submit a completed proposal, which includes a signed master agreement and a pharmaceutical pricing agreement, to begin the process.

Through the pharmaceutical pricing agreement, manufacturers acknowledge that the annual ceiling price for each covered drug constitutes the maximum price that the government may be charged. Through addendum A to the agreement, manufacturers provide a complete list of their available covered drugs. This list includes the product names, all applicable national drug codes, and the current ceiling price for each drug.<sup>28</sup>

## **Process for Adding Covered Drugs to the FSS**

The public law also requires manufacturers to make their covered drugs available on the FSS. In order to do so, manufacturers typically follow the process depicted in figure 2.

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<sup>27</sup> "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>.

<sup>28</sup> Pharmaceutical Pricing Agreement Between The Secretary of Veterans Affairs And The Manufacturer.



**Figure 2.** Process overview of adding covered drugs to FSS.

Source: VA OIG analysis of adding a covered drug to the FSS.

\*When a manufacturer responds to the solicitation, a master agreement and pharmaceutical pricing agreement are signed, and an interim agreement is put in place while the FSS contract is being processed. An interim agreement bridges the gap while a manufacturer and the NAC negotiate an FSS contract, so that the manufacturer can immediately meet the requirements of the public law.

## Roles and Responsibilities of VA Entities That Oversee Compliance with the Public Law

Two main VA offices oversee aspects of compliance with the public law—the NAC and PBM. Both offices have members that are part of the VA Public Law Policy Group, described on the following page.

## National Acquisition Center's FSS Service

The VA FSS Service at the NAC awards and administers nine FSS schedules to support the healthcare acquisition needs of the Big 4 and other authorized users.<sup>29</sup> The goal of the FSS Service is to leverage the entire federal government's purchasing power to obtain volume-based discounts.<sup>30</sup>

FSS contracting staff enter into and administer all master and pharmaceutical pricing agreements with manufacturers. This includes managing interim agreements with manufacturers that do not yet have an FSS contract.<sup>31</sup> Contracting staff also enter into negotiations for the federal government by determining fair and reasonable pricing and ensuring that prices for covered drugs are equal to or below the ceiling price—a minimum equal to or greater than a 24 percent discount from the market price, calculated annually for each form of each drug.<sup>32</sup> As part of the proposal review and contract award, contracting staff conduct limited compliance checks related to the public law.<sup>33</sup>

## Pharmacy Benefits Management Services

The Veterans Health Administration's PBM is responsible for maintaining the ceiling prices for covered drugs through the public law annual reporting process.<sup>34</sup> PBM staff obtain pricing data from manufacturers, store the data, use them to calculate ceiling prices, and report those prices to FSS contracting staff.

## Public Law Policy Group

The VA Public Law Policy Group (the group) is made up of VA representatives from the NAC, PBM, and Office of General Counsel. In an independent capacity, at least one OIG staff person was a member of the group in an advisory role.<sup>35</sup> The group was formed approximately one year after the Veterans Health Care Act of 1992 was enacted. At that time, a team of representatives from VA's Office of General Counsel and the NAC and an OIG designee met to discuss

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<sup>29</sup> FAR 8.402.

<sup>30</sup> General Services Administration, *Multiple Award Schedules Desk Reference*, Spring 2019; FAR 8.402 (a).

<sup>31</sup> "Public Law 102-585, Veterans Health Care Act of 1992" (web page), VA Office of Procurement, Acquisition and Logistics.

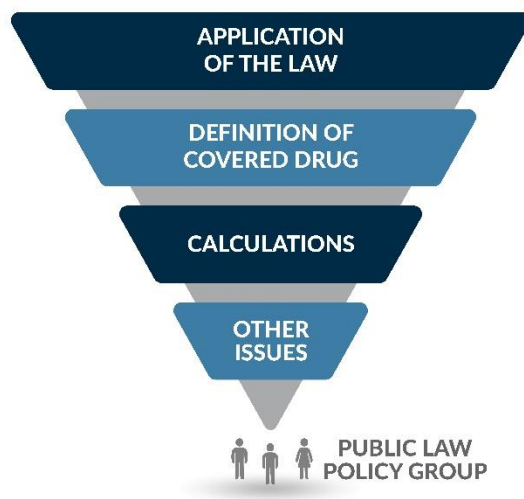
<sup>32</sup> The computation is 24 percent off the average manufacturer price, less any additional discount. Annual commercial average prices are calculated and submitted to VA in November to calculate the ceiling price for the following calendar year.

<sup>33</sup> NAC, *Offer Summary, Compliance Checks, Performance, and Responsibility Determination*, revised October 2016.

<sup>34</sup> PBM, *Dear Manufacturer Letter Annual Guidance*, October 2021.

<sup>35</sup> As of November 2022, the OIG is no longer a member of the VA Public Law Policy Group. The OIG used the decisions made by the group regarding prior exemptions when evaluating items in this review.

implementation of the public law and agreed to meet at least annually to resolve issues.<sup>36</sup> While the group created a draft charter assigning specific responsibilities to each member and outlining the evaluation process, in practice the group makes decisions through collaboration and consensus, drawing on the expertise of each member and adviser.<sup>37</sup> Between October 1, 2018, and March 31, 2022, the group addressed 563 issues, categorized as shown in figure 3.



**Figure 3.** Responsibilities of the Public Law Policy Group.

*Source: VA OIG summary of roles and responsibilities of the group drawn from a draft charter document, as the group was not found in VA organizational charts and handbooks.*

As a result of manufacturers’ inquiries, the group develops interpretive guidance through “Dear Manufacturer Letters,” which clarify existing obligations of manufacturers under the public law, including proper pricing calculations.<sup>38</sup> VA sends these letters to manufacturers to also provide demonstrated practices for compliance with the public law, which it then makes publicly available on the NAC’s website.<sup>39</sup> VA may publish a letter when specific issues arise repeatedly, but also sends a letter each October to FSS contractors to remind them of the annual reporting

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<sup>36</sup> Deputy assistant secretary, Office of Acquisition and Materiel Management, “Updated Veterans Health Care Act of 1992, Public Law 102-585, Section 603, Policy Group Charter,” draft memorandum to associate deputy assistant secretary for national healthcare acquisitions, National Acquisition Center, January 25, 2017.

<sup>37</sup> Based on interviews with Public Law Policy Group members on June 30, July 5, and July 7, 2022.

<sup>38</sup> In its independent role providing information to the Public Law Policy Group, the OIG does not make decisions or develop guidance. For the purposes of this review, the OIG team also did not evaluate VA’s application of the public law, but rather used its simplified definition and other guidance to determine whether manufacturers were compliant.

<sup>39</sup> “Public Law 102-585, Veterans Health Care Act of 1992” (web page), VA Office of Procurement, Acquisition and Logistics.



requirements under the public law, which include submitting their annual pricing data. From November 1992 through September 2022, VA issued 68 formal letters to manufacturers covering a variety of public law topics, such as how to handle private labels, influenza vaccines, and new covered drugs.<sup>40</sup>

## **VA Office of Inspector General**

The VA OIG has had a long-standing role of auditing manufacturers' compliance with the Veterans Health Care Act of 1992.<sup>41</sup> The act authorizes the VA Secretary to "audit the relevant records of the manufacturer or of any wholesaler that distributes the drug."<sup>42</sup> Since 1993, the OIG has performed these audits at the request of the VA Secretary to help ensure covered drug manufacturers comply with the requirements of the statute. The OIG conducts postaward audits based on a manufacturer self-disclosing a noncompliance issue to the Public Law Policy Group and providing the self-audit. The OIG also may initiate an audit of a contractor as part of its general oversight duties. The OIG has conducted significant postaward work related to public law compliance. For example, the team issued 110 nonpublic reports from FY 2016 through FY 2021 that led to almost \$70 million in recommended recoveries.<sup>43</sup>

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<sup>40</sup> "Archive" (web page), VA Office of Procurement, Acquisition and Logistics, accessed September 30, 2022, <https://www.va.gov/opal/docs/nac/fss/pl102585-annualGuidanceDmls.zip>.

<sup>41</sup> Veterans Health Care Act of 1992, § 603.

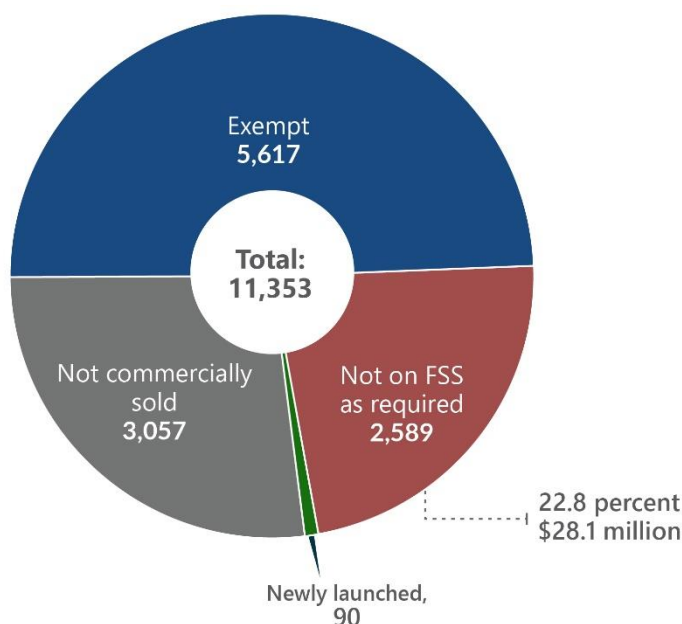
<sup>42</sup> Veterans Health Care Act of 1992, § 603 (a) (1)(e)(3).

<sup>43</sup> 18 U.S.C. § 1905, Trade Secrets Act, 41 U.S.C. § 423(a), Restrictions on Disclosing Source Selection Information, and the implementing regulation at 38 C.F.R. § 1.558(c), prohibit the OIG from publishing these reports because they contain confidential business information. This review involves drugs that were not available on the FSS and were not previously identified in the 110 reports.

## Results and Recommendations

### Finding: VA and DOD Potentially Overpaid \$28.1 Million Because Manufacturers Did Not Make All Required Covered Drugs Available on the Federal Supply Schedule

The OIG found 11,353 of 17,873 covered drugs were not on an FSS contract on March 31, 2022. As figure 4 illustrates, of the 11,353 covered drugs not on the FSS, 8,764 were not required to be available. This was because 5,617 drugs received exemptions from the Public Law Policy Group, another 3,057 drugs were not commercially sold, and 90 were newly launched.<sup>44</sup> The OIG found manufacturers did not make the remaining 2,589 covered drugs (22.8 percent) available on the FSS as required by the public law.<sup>45</sup>



**Figure 4.** Breakdown of covered drugs.

Source: VA OIG analysis of drugs not on the FSS.

To determine why manufacturers did not comply with the public law, the review team requested and received information from manufacturers whose covered drugs were not available on the FSS. Manufacturers provided several reasons, primarily related to their understanding of what constitutes a covered drug or how the law should apply. Other manufacturers were not aware of or overlooked the requirements, while still others did not or could not provide information on

<sup>44</sup> If the public law is found not to apply to a particular drug or drug line, the group agrees that the manufacturer has received an exemption from having to make the drug available on the FSS. Any references to exemptions in this report represent the group applying the public law to situations presented to them.

<sup>45</sup> The 22.8 percent is based on 2,589 of 11,353 covered drugs not made available on the FSS.

why they did not comply. As a result of the noncompliance, the OIG team estimated that VA and DOD potentially overpaid \$28.1 million (\$6.8 million for VA and \$21.3 million for DOD) on 375 covered drugs between May 2016 and March 2022.<sup>46</sup> Manufacturers' noncompliance with the public law jeopardizes access to reasonably priced drugs that are essential for veterans and other recipients of drugs from authorized FSS users.

VA could take steps to help minimize waste and ensure funds are used effectively to provide affordable health care to veterans and other FSS users. They include working with the FDA to increase awareness of the public law, formalizing public law compliance checks, and enhancing related guidance. Beyond that, VA could follow up with manufacturers the OIG identified as noncompliant to have them conduct self-audits. The OIG believes the NAC also could consider additional monitoring given the large number of noncompliant manufacturers and corresponding covered drugs identified in this review.

## What the OIG Did

The review team examined the Veterans Health Care Act of 1992; the Federal Acquisition Regulation; and other guidance, such as Dear Manufacturer Letters and the master agreement. Using FDA databases, the team identified 17,873 drugs that fit the definition of "covered." Of these, the team found that 6,520 were offered on the FSS and did not evaluate them further. The team used VA's simplified definition and other determinations related to the public law in assessing the remaining 11,353 drugs that were not on the FSS. This included relying on VA's written decisions to manufacturers regarding exemptions and other matters, as well as documented discussions of the Public Law Policy Group. Although the team had information on some of the 11,353 drugs, such as emails from manufacturers or entries in the PBM average commercial pricing database, the team sent inquiry letters to manufacturers for additional information. The team obtained explanations from these manufacturers, including their possible reasons for noncompliance with the public law. Based on their responses, the team categorized the manufacturers' covered drugs into those subject to and not subject to the public law. The review team then calculated how much VA and DOD paid on the open market for covered drugs subject to the law but not currently available on the FSS. Appendix A provides additional details on the scope and methodology.

The OIG finding is based on the following determinations:

- Not all manufacturers' covered drugs are subject to the public law.
- Some manufacturers did not comply with the public law.

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<sup>46</sup> While the team identified noncompliant manufacturers with 2,589 covered drugs not available on FSS, only 375 of these drugs were purchased in the open market by VA or DOD.

- Manufacturers’ noncompliance resulted in VA and DOD potentially overpaying an estimated \$28.1 million.<sup>47</sup>

## Not All Manufacturers’ Covered Drugs Are Subject to the Public Law

The 8,764 drugs that fit the definition of a covered drug but were not required to be available on the FSS received exemptions from the Public Law Policy Group, were not commercially sold, or were newly launched (table 1).

**Table 1. Covered Drugs Not Required to Be on the FSS**

Reason drugs are not subject to the law	Number of drugs
Approved exemptions	5,617
Not commercially sold	3,057
Newly launched	90
<b>Total</b>	<b>8,764</b>

*Source: VA OIG summary of drugs not subject to the law.*

## Approved Exemptions and How VA Handles Them

Exemptions approved by VA accounted for 5,617 of the 8,764 drugs (64 percent) the team identified as not subject to the law, so these covered drugs did not have to be made available on the FSS. The Public Law Policy Group has given exemptions on specific items or on a class of items that are considered covered drugs, which the OIG team excluded from further consideration (as the team did not validate the group’s rationale for any exemptions) from its review of covered drugs. Allergen and parenteral products represented a large portion of the exemptions.<sup>48</sup>

- **Allergen products.** Allergen extracts and allergen dilutions usually require biologic licenses from the FDA, so they are considered covered drugs.<sup>49</sup> In 1992 the VA Office of General Counsel, in conjunction with the Public Law Policy Group, concluded that these allergen products were not subject to the public law.<sup>50</sup> However, the OIG review team found no evidence that the group communicated this to manufacturers.

<sup>47</sup> Appendix B presents this amount as the estimated potential savings from adding covered drugs to the FSS.

<sup>48</sup> There were other drugs with approved exemptions in addition to allergens and parenteral products. Parenteral products are those that are introduced and administered via injection, infusion, or implantation.

<sup>49</sup> 38 U.S.C. § 8126 (h)(2)(C).

<sup>50</sup> Public Law Policy Group Meeting Minutes, September 28, 2011; discussions with the VA Office of General Counsel on April 1 and July 5, 2022.

Recommendation 1 points to the need for VA to make sure all manufacturers are aware that allergens are exempt from the public law and how the determination was reached.

- **Parenteral products.** Parenteral products and intravenous dilutants originally did not require new drug applications. The FDA then required makers of some of these parenteral products to obtain new drug applications, causing them to fall under the definition of a covered drug.<sup>51</sup> However, VA determined these were exempt from the public law because they were not originally under a new drug application but were required to obtain one.<sup>52</sup>

The Public Law Policy Group has applied the public law to situations described in questions from manufacturers and concluded that some drugs are not covered by the law. However, VA has provided no written guidance easily accessible to manufacturers explaining the process for requesting advice as to the public law's applicability or exemptions. Instead, the Public Law Policy Group has responded to questions from manufacturers and provided case-by-case determinations.<sup>53</sup>

The NAC website provides guidance (1) for manufacturers on how to enter into interim agreements; (2) for existing FSS contractors, such as an archive of Dear Manufacturer Letters; and (3) on the annual public law pricing update.<sup>54</sup> However, the guidance provided on the website does not specifically discuss the group's process of reviewing and granting exemptions, nor does the group have an internal written document that does so.

If manufacturers have questions about whether their drugs are subject to the public law but do not know how to seek guidance from VA, they might not offer their drugs as required by the law, and the government will not be able to purchase much-needed drugs at lower prices. A formal, written process for requesting exemptions that is clearly communicated to manufacturers would decrease the likelihood of manufacturers' misinterpretation and clarify the responsibilities of both VA and the manufacturer.

Recommendations 2 and 3 are for VA to formalize and communicate the internal and external processes related to manufacturers' requests for exemptions.

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<sup>51</sup> VA Office of General Counsel, "Dear Member of the I.V. Solutions Industry," April 22, 1993.

<sup>52</sup> VA Office of General Counsel, "Dear Member of the I.V. Solutions Industry."

<sup>53</sup> The disclosures made by manufacturers may relate not only to covered drug status or the availability of drugs on the FSS, but also to calculation or methodology issues.

<sup>54</sup> "Public Law 102-585, Veterans Health Care Act of 1992" (web page), VA Office of Procurement, Acquisition and Logistics. In a letter dated May 4, 2021, the NAC and PBM documented VA's definition of a covered drug and provided an email for questions; however, this letter does not appear in the archive of Dear Manufacturer Letters so new manufacturers are not aware some guidance exists. The review team obtained this letter from another OIG audit group that conducts postaward reviews.

## Drugs Not Commercially Sold

Not all covered drugs are sold commercially—for example, samples, inner packs (a drug that is inside a packaged product), discontinued and divested items, products that were never marketed or sold commercially, and custom or private-label substances.<sup>55</sup> If a covered drug is not sold commercially, it is not required to be made available on the FSS as it is not available for purchase.<sup>56</sup> Similarly, manufacturers lack pricing data for drugs not sold commercially and so cannot submit information for VA to calculate a ceiling price.

The team identified 3,057 drugs that fit this category and therefore were not subject to the law. For example, inner packs are assigned a drug code but are only sold in conjunction with an outer package product. Only the packaged, commercially sold product needs to be offered on the FSS. When a drug is discontinued or divested, it is no longer sold commercially by that manufacturer but in most cases must remain available on the FSS until all stock is depleted. Additionally, some drugs are never marketed or sold commercially. These include items that manufacturers had requested national drug codes for, such as different package sizes, and new drugs not launched into the market yet or that will never be launched. These also include items from companies that do not sell them but merely assist the manufacturer by physically rebottling, repackaging, or relabeling and, in some cases, shipping them.<sup>57</sup> Custom or private-label drugs are packaged specifically for one customer and are not commercially sold; the Public Law Policy Group has determined that manufacturers do not need to offer these on the FSS.<sup>58</sup>

If they do enter the commercial market, manufacturers will need to ensure these drugs comply with the public law.<sup>59</sup> Recommendation 4 is for VA to continue to monitor any covered drugs identified in this review that are not commercially sold.

## Newly Launched Drugs

When a covered drug is introduced into the market, VA gives manufacturers time to establish the drug's average market price. VA provides 30 days after the drug's first commercial sale for manufacturers to generate more sales, plus an additional 45 days for them to submit pricing data and calculations and request to be added to the FSS.<sup>60</sup>

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<sup>55</sup> 21 C.F.R. 203.3(aa); 21 C.F.R. 201.62(e)(2); PBM, *Dear Manufacturer Letter Annual Guidance*, October 15, 1997. Drugs labeled as samples are not for sale. Divested drugs are sold to other manufacturers.

<sup>56</sup> 38 U.S.C. § 8126 (h)(6) (for only covered drugs that are priced and sold); Master Agreement Between The Secretary of Veterans Affairs And The Manufacturer.

<sup>57</sup> 21 C.F.R. § 207.5.

<sup>58</sup> VA Office of General Counsel's Letter to Pharmacia & Upjohn, November 21, 1997.

<sup>59</sup> If the government can buy a drug in the open market, the drug is available and being sold commercially.

<sup>60</sup> "2022 FCP Guidance for New Covered Drugs" (web page), PBM, accessed July 31, 2022, <https://www.va.gov/opal/docs/nac/fss/pl102585-2022pbmFcpGuidanceForNewCoveredDrugs.pdf>. (As of March 21, 2023, this document had been replaced with 2023 guidance.)

The team identified 90 covered drugs that were not made available on FSS; however, they were newly launched and still within the data-gathering period.<sup>61</sup> While these drugs were not subject to the public law during the review period, VA should ensure they are made available on the FSS when required.

Recommendation 5 is that VA monitor newly launched covered drugs identified in this review and ensure they have an established ceiling price and are made available on the FSS at the end of the 75-day period.

## **Some Manufacturers Did Not Comply with the Public Law**

The OIG identified 2,589 drugs that were subject to the public law but were not available on the FSS. This represented approximately 22.8 percent of covered drugs required to be available on the FSS.<sup>62</sup> The 2,589 drugs not available on the FSS include 1,962 drugs from manufacturers that responded to a query from the review team about why they did not appear to be in compliance with the public law. The OIG review team then confirmed based on the responses that those manufacturers were not complying with the public law for those drugs. There were 85 manufacturers that did not provide additional information on 627 drugs, and there was no evidence of an exemption.

Although the VA Secretary or a delegate may audit a manufacturer's records to determine the accuracy of a drug price, the public law places responsibility for compliance on manufacturers.<sup>63</sup> Manufacturers, even those with an FSS contract and a master agreement, vary in fulfilling that responsibility. Table 2 breaks down the noncompliant manufacturers into those that have an FSS contract with a master agreement and those that do not.<sup>64</sup> Those with a master agreement did not make all of their covered drugs available despite having prior knowledge of the public law's requirements.

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<sup>61</sup> As of March 31, 2022, these drugs were still within the 75-day period, so compliance was not yet required.

<sup>62</sup> The 22.8 percent is based on 2,589 of 11,353 covered drugs not made available on the FSS.

<sup>63</sup> Veterans Health Care Act of 1992, § 603(a). The Secretary may only delegate to VA, DOD, the Public Health Service, or the Coast Guard.

<sup>64</sup> The public law requires manufacturers to sign the master agreement, which reiterates that covered drugs must be made available on the FSS and outlines the manufacturer's responsibilities and obligations associated with the public law.

**Table 2. Noncompliant Manufacturers and Drugs**

Does the manufacturer have an FSS contract with a master agreement?	Number of manufacturers	Number of drugs
Yes*	103	567
No	133	2,022
<b>Total</b>	<b>236</b>	<b>2,589</b>

Source: VA OIG summary of noncompliant manufacturers and drugs.

\* These 103 manufacturers may already have some of their covered drugs on their FSS contracts, but the OIG team identified 567 additional drugs not included on their FSS contracts.

VA has an established relationship with the 103 noncompliant manufacturers that currently have an FSS contract, since both the NAC and PBM have at least annual communication with them. VA could institute a more consistent and comprehensive covered drug check for all of a manufacturer’s drugs whenever a new proposal or product addition modification is submitted.

To determine why manufacturers did not comply with the public law, the review team requested and received information from manufacturers whose covered drugs were not available on the FSS. As mentioned earlier, manufacturers provided several reasons for not having the items available on the FSS, primarily related to their understanding of what constitutes a covered drug or how the law should apply. Other manufacturers were not aware of or overlooked the requirements, while still others did not or could not provide information on why they did not comply.

### **Manufacturers Incorrectly Interpreted the Law**

The review team found that at least 1,561 of 1,962 drugs were not available on the FSS because manufacturers incorrectly interpreted the public law and its applicability to their drugs. Because monitoring compliance with the public law relies on manufacturers’ self-disclosures, manufacturers must be able to determine whether the law applies to the drugs they manufacture. Some manufacturers seek advice or guidance from VA and specifically the Public Law Policy Group to verify their obligations under the public law. Yet some manufacturers the team reviewed incorrectly determined for themselves the drugs at issue were not subject to the law. The team determined these manufacturers were noncompliant. The following are examples of the assertions manufacturers made to the OIG that the review team determined were contrary to the public law or otherwise inaccurate.

- **Relabelers and repackagers are manufacturers under the public law.** Relabelers and repackagers are entities that buy finished drugs for resale after repackaging or relabeling them into new containers.<sup>65</sup> Even though they do not make the drugs, under the public

<sup>65</sup> 21 C.F.R. § 207.1.



law relabelers and repackagers are considered manufacturers.<sup>66</sup> The review team found that eight relabelers and repackagers with 692 covered drugs believed the public law did not apply to them because they do not manufacture the drug. However, the public law is clear that “manufacturer” includes relabelers and repackagers.<sup>67</sup>

The team noted that four relabelers and repackagers with 29 covered drugs have been unable to obtain a letter of supply (also referred to as a letter of commitment), which VA requires prior to awarding an FSS contract for companies that are not manufacturers.<sup>68</sup> A letter of supply is usually provided by the manufacturer to a wholesaler, distributor, relabeler or repackager; these parties must then provide it to the NAC to demonstrate their ability to deliver an uninterrupted supply of the drug.<sup>69</sup> The NAC will not allow items on the FSS if a letter of supply is not provided.<sup>70</sup> The manufacturers of the 29 covered drugs determined they would be unqualified to be an FSS contractor for those drugs as they had not yet been able to obtain a letter of supply. The review team still classified these four relabelers and repackagers as noncompliant for not making their 29 drugs available on the FSS as required by the law.

- **Compliance is not contingent on manufacturers’ receipt of government funds.** 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 ceiling price, it may not receive any payment for drugs from the Big 4 agencies, any entity that receives funds under the Public Health Service Act, or a state Medicaid plan.<sup>71</sup> The public law places the responsibility on manufacturers to identify which of their products are covered drugs and to proactively ensure compliance with requirements. The public law does not waive the need for compliance based on whether a manufacturer receives government funds for just some or all its drugs. However, 22 manufacturers stated they do not have to make their 637 drugs available on the FSS because they do not participate in any government-funded programs or have any sales to government entities. Regardless of the receipt of government funds, a manufacturer with a covered drug must make it available on the FSS.<sup>72</sup> The law explicitly states,

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<sup>66</sup> 38 U.S.C. § 8126 (h)(4)(B).

<sup>67</sup> 38 U.S.C. § 8126 (h)(4)(B).

<sup>68</sup> Solicitation Number M5-Q50A-03-R8, *02 Vendor Response Document*, “I-FSS-644 Dealers and Suppliers,” October 1988 (the clause addressing letters of supply is included in this solicitation).

<sup>69</sup> Solicitation Number M5-Q50A-03-R8, *02 Vendor Response Document*, “I-FSS-644 Dealers and Suppliers,” October 1988 (contains the requirement for a letter of supply); “Other Contract Policies and Obligations” (web page), NAC, accessed February 27, 2023, <https://www.va.gov/opal/nac/fss/ocpo.asp>.

<sup>70</sup> NAC, *Offer Summary, Compliance Checks, Performance, and Responsibility Determination*, version dated October 2016.

<sup>71</sup> 38 U.S.C. § 8126 (a)(4).

<sup>72</sup> 38 U.S.C. § 8126 (a)(4).

[U]nless the manufacturer meets the requirements ... the manufacturer may not receive payment for the purchase of drugs or biologicals from (A) a State plan under title XIX of the Social Security Act, except as authorized under section 1927(a)(3) of such Act, (B) any Federal agency described in subsection (b), or (C) any entity that receives funds under the Public Health Service Act.<sup>73</sup>

If a manufacturer does not comply with the public law for even a single covered drug, it cannot receive any government funds for any drugs it sells.<sup>74</sup>

- **Items that manufacturers said were not sold commercially actually were, making them subject to the public law.** The review team identified 136 drugs that 57 manufacturers stated were not commercially sold and consequently were not subject to the public law. However, the team asked VA and DOD to provide a list of open-market purchases of these drugs and noted approximately \$19 million in sales to the government during the review period. The team classified the manufacturers of these drugs as noncompliant. If the items were commercially sold in the open market and not otherwise exempt, they should have been on the FSS. VA should follow up with manufacturers to determine why they stated particular drugs were not commercially sold, despite the sales the team identified (see recommendation 4).
- **The public law applies regardless of exemptions received from another agency under different laws.** The review team found that seven manufacturers were noncompliant because they believed that having acquired an exemption or special designation from another agency under other laws exempted their 48 drugs from the public law. The provisions of the public law do not support this belief.

For example, some manufacturers told the review team that the Centers for Medicare & Medicaid Services granted their drugs exceptions, which the team learned were under the Medicaid Services Investment and Accountability Act of 2019. The 2019 act adopted a revised version of the Social Security Act's definition of a covered drug.<sup>75</sup> However, the revised definition did not supersede the public law's reference to the original covered drug definition in the Social Security Act.<sup>76</sup> The public law states that any reference to the Social Security Act will be as it was written on November 4, 1992. The

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<sup>73</sup> 38 U.S.C. § 8126 (a)(4).

<sup>74</sup> 38 U.S.C. § 8126 (a)(4).

<sup>75</sup> Medicaid Services Investment and Accountability Act § 6(c), Public Law No.116-16 § 6(c).

<sup>76</sup> 38 U.S.C. § 8126 (g).

manufacturers' reliance on the 2019 act's definition of a covered drug and related exemptions were therefore improper.<sup>77</sup>

Other manufacturers believed their drugs were not subject to the public law because the FDA granted an orphan drug designation.<sup>78</sup> The team did not find any reference to exemptions in the public law for orphan drugs.<sup>79</sup> Manufacturers still had drugs that fit the definition of a covered drug; therefore, the FDA's designation does not affect a manufacturer's responsibilities under the public law.<sup>80</sup>

- **There are provisions of the public law that apply even to drugs that do not qualify for inclusion on the FSS.** For example, when a manufacturer's factory is not FDA-approved, its drugs may not qualify for inclusion on the FSS at that time.<sup>81</sup> However, the public law requires a manufacturer to offer a covered drug to the government and does not provide an exemption from other public law requirements (such as providing pricing data and ceiling prices) for drugs that may not meet FSS requirements. VA PBM confirmed for the OIG team that the Public Law Policy Group may ultimately determine that the public law is not applicable to a drug produced in a factory that is not FDA-approved. PBM also verified that VA may still require the manufacturer to submit pricing data annually so that ceiling prices can be calculated in accordance with the public law.<sup>82</sup> PBM has historically asked manufacturers to submit pricing data and establish ceiling prices so that if the government purchases the drug in the commercial market, or when the factory does gain approval, the drug can be added to the FSS.<sup>83</sup> The team identified four manufacturers with 29 drugs in this category.
- **All covered drugs must be made available on the FSS whether or not similar products are already listed.** Three manufacturers argued that, because similar or identical items are already offered on the FSS, their 19 drugs do not need to be on an FSS

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<sup>77</sup> 38 U.S.C. § 8126 (g).

<sup>78</sup> "Designating an Orphan Product: Drugs and Biological Products" (web page), FDA, accessed on July 28, 2022, <https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions/designating-orphan-product-drugs-and-biological-products>. An orphan drug is one intended for use in a rare disease or condition; it may be sold commercially in very limited quantities or stockpiled only by the government. The FDA has authority to grant orphan drug designation.

<sup>79</sup> 38 U.S.C. § 8126.

<sup>80</sup> 38 U.S.C. § 8126 (h)(2).

<sup>81</sup> FDA ensures the quality of drug products by monitoring manufacturers' compliance with its regulations, which contain minimum requirements for the methods, facilities, and controls used in the manufacturing, processing, and packing of a drug. "Current Good Manufacturing Practice (CGMP) Regulations" (web page), FDA, accessed December 6, 2022, <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>.

<sup>82</sup> Interview with PBM officials, July 7, 2022; 38 U.S.C. § 8126 (e)(1).

<sup>83</sup> Solicitation Number M5-Q50A-03-R8, *02 Vendor Response Document*, "AS8005 Manufacturing Facilities/Place of Performance," September 2010.

contract. An example of this is a covered drug with two or more intended uses—cosmetic and pharmaceutical—each with a unique drug code. Manufacturers must make them available on the FSS regardless of their use because the public law makes no such exception.<sup>84</sup> The team identified at least two manufacturers that offered one covered drug on the FSS but believed they were not required to offer other versions.

- **Authorized generics are covered drugs.** The term “authorized generic” is used to describe a covered drug that is the exact same drug sold in the commercial marketplace without the brand name on its label, as if it were a generic product.<sup>85</sup> While a generic product is not a covered drug under the law, an authorized generic is a covered drug because it is produced under a new drug application and is a reference-listed drug.<sup>86</sup> The review team noted some manufacturers incorrectly believed their authorized generics are not subject to the public law and did not make them available on the FSS.

As discussed above, much of the noncompliance the OIG identified resulted from manufacturers’ misinterpretation of the public law. If manufacturers remain noncompliant, the federal government may continue to unnecessarily pay higher prices.

Recommendation 6 is that VA ask noncompliant manufacturers identified by the OIG team to conduct a self-audit and report their findings for remediation.

## Manufacturers Lacked Oversight and Awareness

The manufacturers of the remaining 401 of 1,962 drugs did not comply because they overlooked that their drugs were not on their contract or were unaware they had covered drugs. For example, some manufacturers did not know their covered drugs were not on their FSS contract, or said that their drugs launched years ago, and they had been noncompliant for that entire time because they were uninformed of the public law requirements.

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<sup>84</sup> 38 U.S.C. § 8126 (a)(1).

<sup>85</sup> A generic drug is a copy of a brand-name drug with minor differences. “FDA List of Authorized Generic Drugs” (web page), FDA, accessed September 8, 2022, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>.

<sup>86</sup> 38 U.S.C. § 8126 (h)(2) and defined in the Social Security Act § 1927; 21 C.F.R. § 600.3(h). According to the FDA, a reference-listed drug is an approved drug product to which new generic versions are compared to show that they are bioequivalent. “Drugs@FDA Glossary of Terms” (web page), FDA, accessed on March 2, 2023, <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#RLD>. “2022 FCP Guidance for New Covered Drugs” (web page), PBM, accessed July 31, 2022, <https://www.va.gov/opal/docs/nac/fss/pl102585-2022pbmFcpGuidanceForNewCoveredDrugs.pdf>. (As of March 21, 2023, this document had been replaced with 2023 guidance.)

Manufacturers of any new drug must go to the FDA for approval and assignment of a national drug code.<sup>87</sup> At that time, manufacturers could be informed of any requirements related to a covered drug. This early stage in the process is an opportunity for VA to collaborate with the Department of Health and Human Services to ensure the FDA makes covered drug manufacturers aware of the public law requirements.

Recommendation 7 calls on VA to work with the FDA to ensure that when manufacturers request new national drug codes, the manufacturers are made aware of the public law requirements.

### **Some Manufacturers Did Not Provide Information**

The review team did not or could not obtain additional information from 85 manufacturers as to why they have not met the public law requirements. The OIG considers these manufacturers noncompliant because they have 627 covered drugs that are not made available on the FSS and no exemptions were identified. For example, the OIG sent a manufacturer of 137 covered drugs an email letter inquiring why the manufacturer was noncompliant with the public law. The manufacturer confirmed receipt but never provided the requested information even after the team sent a follow-up email. Another manufacturer was no longer in business. As a result, the team did not find evidence that the 627 covered drugs are not subject to the law. The OIG has advised VA of these manufacturers so appropriate action can be considered.

### **Manufacturers' Noncompliance Resulted in VA and DOD Potentially Overpaying an Estimated \$28.1 Million**

To determine the estimated monetary impact of 2,589 covered drugs that were not made available on the FSS, the review team obtained open-market sales to VA and DOD from May 17, 2016, to March 31, 2022. The team calculated the difference between the price paid and the estimated annual ceiling price multiplied by the quantity purchased.<sup>88</sup> As a result of manufacturers' noncompliance, VA potentially overpaid approximately \$6.8 million, and DOD potentially overpaid approximately \$21.3 million on 375 covered drugs.<sup>89</sup> Table 3 summarizes

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<sup>87</sup> "Electronic Drug Registration and Listing Instructions" (website), Electronic Drug Registration and Listing System, accessed July 28, 2022, <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrpls/electronic-drug-registration-and-listing-instructions>.

<sup>88</sup> The potential overcharges are only estimates based on the price paid in the open market (not the actual commercial average price) less the 24 percent statutory discount. This price may not reflect the actual ceiling price. To determine the actual overcharges, each identified manufacturer would need to conduct a self-audit to confirm noncompliance and report its findings to the NAC and PBM, including calculating ceiling prices. The review team only examined VA- and DOD-provided sales data.

<sup>89</sup> While the OIG review team identified noncompliant manufacturers with 2,589 covered drugs not available on the FSS, only 375 of these drugs were purchased in the open market by VA or DOD. The dollar amounts do not include the four relabelers and repackagers the team identified as unable to obtain letters of supply.

the top 10 noncompliant manufacturers responsible for approximately 84 percent of the estimated overcharges.<sup>90</sup>

**Table 3. Top 10 Noncompliant Manufacturers by Amount of Potential Overcharges**

Manufacturer*	Number of drugs	Estimated overcharges (\$)
Manufacturer 1	28	4,987,935
Manufacturer 2	3	3,553,429
Manufacturer 3	11	3,378,149
Manufacturer 4	37	2,471,851
Manufacturer 5	2	2,200,006
Manufacturer 6	6	2,177,608
Manufacturer 7	7	1,390,546
Manufacturer 8	4	1,365,351
Manufacturer 9	3	1,254,302
Manufacturer 10	8	758,724

Source: VA OIG analysis.

\* The review team did not use manufacturer names because the overcharges are not final numbers and the information is proprietary and not publicly available, per the Procurement Integrity Act, or it is business sensitive information submitted to the agency and protected under the Trade Secrets Act. They are estimates based on the price paid in the open market (not the actual commercial average price) less the 24 percent statutory discount.

A representative of the manufacturer with the largest overcharges (Manufacturer 1) stated the company did not believe the public law applied to its drugs because it had received an exemption from the Centers for Medicare & Medicaid Services. This manufacturer has a current FSS contract and should be aware that VA is available to clarify whether it could receive an exemption from the public law on any of its 28 drugs. Manufacturer 1 has been charging VA and DOD higher prices since at least 2006, when it removed some of its covered drugs from the FSS contract after unilaterally determining the drugs were no longer subject to the law.

Other results of the team’s analysis included the following:

- Manufacturer 2 had one drug that represents the largest number of potential overcharges based on VA and DOD open-market sales.
- Manufacturer 3 is a relabeler whose officials wrongly believed the public law did not apply to its products.

<sup>90</sup> Overcharges of the top 10 manufacturers divided by total overcharges (\$23,537,900 / \$28,118,539).

- Manufacturer 4 confirmed receiving but did not respond to the team’s inquiry; it is not compliant with the law due to the lack of a justification or a VA-approved exemption.

The remaining manufacturers listed in the table either incorrectly stated the drugs were discontinued or not commercially sold or believed they were relieved from complying with the public law because they had not been receiving government funds. The VA and DOD are at higher risk of paying higher prices for these drugs until manufacturers make them available on the FSS as required.

While the public law does not require VA to ensure that manufacturers comply with the public law regarding covered drugs, the findings of this review suggest VA could take some steps to monitor compliance with the public law. The FSS contracting officials at the NAC already conduct routine compliance checks when reviewing new offers or modifications to add new products to existing FSS contracts. Although the checks include compliance with FDA approval for manufacturing facilities and the Trade Agreements Act, no check exists for covered drugs not included in the offer or on the current FSS contract.<sup>91</sup> In practice, some FSS contracting officials conduct covered drug checks when reviewing FSS proposals; however, no formal process or policy exists to ensure consistency. By taking further actions, VA can lessen the potential overcharges Big 4 customers may pay.

Recommendation 8 is for the associate executive director of the NAC to require contracting staff to conduct a covered drug check for all of a manufacturer’s drugs when any pharmaceutical proposal or product addition modification is submitted.

## Conclusion

The government spends \$13.2 billion per year on pharmaceuticals through VA’s FSS program for the Big 4 federal agencies and other authorized users. When manufacturers comply with the public law, VA receives a discount on volume purchases. The team found that manufacturers of 375 drugs were not complying with the public law and not providing the required discount. This resulted in potential overpayments of an estimated \$28.1 million (\$6.8 million for VA and \$21.3 million for DOD). By formalizing guidance on public law compliance, working with the FDA to increase awareness of the public law, and following up with manufacturers the OIG identified as noncompliant, VA can help minimize waste and ensure funds are used effectively to provide VA and other FSS users with the drugs they need to serve veterans and other patients.

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<sup>91</sup> NAC, *Offer Summary, Compliance Checks, Performance, and Responsibility Determination*, version dated October 2016; 19 U.S.C. 13. The Trade Agreements Act of 1979 expanded US trade with approved countries.

## Recommendations 1–8

The OIG made seven recommendations to the associate executive director of the VA National Acquisition Center, in conjunction with the chief consultant at VA Pharmacy Benefits Management Services:

1. Issue guidance clarifying that allergens are exempt from the public law and include how the determination was reached.
2. Formalize and communicate the process for manufacturers to request exemptions.
3. Formalize the internal process for granting exemptions.
4. Establish a procedure for monitoring covered drugs identified in this report as not commercially sold.
5. Develop a procedure to monitor covered drugs identified in this report as newly launched to ensure they have an established ceiling price, and make certain they are made available on the Federal Supply Schedule at the end of the 75-day period.
6. Request that noncompliant manufacturers identified by the Office of Inspector General conduct a self-audit and submit their findings for remediation.
7. Engage with the Food and Drug Administration to ensure that when manufacturers request new national drug codes, they are made aware of the public law requirements.

The OIG made one recommendation to the associate executive director of the VA National Acquisition Center:

8. Require contracting staff at the National Acquisition Center to conduct a covered drug check for all of a manufacturer's drugs when any pharmaceutical Federal Supply Schedule proposal or product addition modification is submitted.

## VA Management Comments

The principal executive director and chief acquisition officer at the Office of Acquisition, Logistics and Construction (OALC), in conjunction with the Veterans Health Administration (VHA), concurred in principle with the findings identified; concurred with recommendations 1, 2, 3, 6, and 8; and nonconcurred with recommendations 4, 5, and 7. Both provided general and technical comments, which the OIG addressed below. Appendix C provides the full text of their comments.

In response to recommendations 1 and 3, the principal executive director and chief acquisition officer stated that OALC would request additional information from the OIG on the appropriate guidance to issue regarding allergen exemptions and on what would constitute a formalized process for granting exemptions.



For recommendation 2, the principal executive director and chief acquisition officer stated that the exemption process for manufacturers is already formalized to an extent and publicized, but that additional steps can be taken to effectively communicate it. NAC will review processes with VA OIG to assess current exemptions.

The principal executive director and chief acquisition officer disagreed with recommendations 4 and 5, stating that the NAC is not resourced to police the supply chain of all covered drugs or to perform federal oversight of newly launched covered drugs if the drugs are not under a master agreement and existing FSS contract. The principal executive director and chief acquisition officer noted the NAC does take steps to monitor existing FSS contractors.

For recommendation 6, the principal executive director and chief acquisition officer concurred with comments, stating the recommendation should be to another government entity that retains at least equivalent or greater authority to instruct noncompliant manufacturers who do not have master agreements with VA to perform a self-audit. The principal executive director and chief acquisition officer stated he would fully concur if the recommendation were clarified to mean manufacturers already under an FSS contract should perform a self-audit for any covered drugs not listed on their master agreement. By September 30, 2023, the NAC will communicate with the noncompliant manufacturers identified by the VA OIG who already hold a master agreement with NAC.

The principal executive director and chief acquisition officer also disagreed with recommendation 7, stating that while the FDA could be helpful in educating manufacturers, the Office of Federal Procurement Policy, federal comptrollers, and acquisition officials also should be included. In technical comments, VHA asked to strike this recommendation.

For recommendation 8, the principal executive director and chief acquisition officer stated NAC contract specialists already perform a covered drug check but agreed to issue written instructions emphasizing this step in the process.

## **OIG Response**

The corrective action plans for recommendations 1, 2, 3, and 8 are generally responsive to the intent of the recommendations. The OIG will monitor the implementation of the recommendations until all actions are documented as completed.

For recommendations 1 and 3, the principal executive director and chief acquisition officer stated that OALC would request additional information from the OIG on the appropriate guidance to issue regarding allergen exemptions and on what would constitute a formalized process for granting exemptions. The OIG asserts that it is inappropriate to provide direction regarding these recommendations because the burden to develop appropriate guidance and formalized processes falls on VA.

For recommendations 2 and 8, the principal executive director and chief acquisition officer concurred with the recommendations but stated that OALC already had processes in place to address both recommendations. However, the OIG did not find evidence of a formalized exemption process, nor did the OIG find any publicized communication to manufacturers regarding the detailed exemption process. In addition, the OIG did not find any requirement or established procedure for contract specialists to check for covered drugs. When the OIG requested support, NAC officials stated that covered drug checks are performed but to varying degrees based on the contract specialist performing them.

Regarding the intent of recommendations 4 and 5, the OIG is not asking the NAC to police or monitor the supply chain of all covered drugs that are not under a master agreement or an existing FSS contract. The OIG is recommending the NAC specifically monitor the 3,057 covered drugs that were found not to be commercially sold and the 90 newly launched drugs referred to in this report—not all covered drugs that exist. The 90 newly launched drugs are manufactured by FSS contractors with existing master agreements, and these drugs should be added to their FSS contracts. For the 3,057 drugs identified as not commercially sold, only 553 drugs belong to manufacturers with no master agreement. These drugs, whether the manufacturers have a master agreement or not, can all be identified through open market sales reports whenever VA purchases them.

The OIG acknowledges the principal executive director and chief acquisition officer's concerns about recommendation 6 regarding manufacturers with no master agreement. The intent of the recommendation is to focus on engagement and education for noncompliant manufacturers identified in this report that have no master agreement with VA. This is to make them aware of their responsibility under the requirements of the public law.

The principal executive director and chief acquisition officer disagreed with recommendation 7, and VHA asked to strike it. It focuses on efforts to communicate with the FDA (notwithstanding the roles played by the Office of Federal Procurement Policy, federal comptrollers, and acquisition officials). The recommendation does not require VA to monitor or track manufacturers, nor does it mandate that the FDA provide information to manufacturers. The goal of the recommendation is to initiate collaboration between government agencies so that manufacturers are more aware of the public law requirements.

In addition to their comments on the recommendations, the principal executive director and chief acquisition officer provided six technical comments and one general comment, and VHA provided two technical comments and two general comments.

The OIG incorporated changes to address OALC technical comments 1 and 2. For OALC technical comment 1, the OIG updated footnote 6 to reflect the most current delegation of authority from the General Services Administration to VA for managing the medical and healthcare multiple-award schedules. Regarding OALC technical comment 2, the OIG clarified

the heading on page 5 to “Roles and Responsibilities of VA Entities That Oversee Compliance with the Public Law” to reflect the focus on VA.

The remaining technical comments generally suggested responsible entities besides VA should be discussed in the report. The OIG did not make any changes based on these technical comments, for reasons discussed below.

Regarding OALC technical comment 3, the OIG believes recommendation 6 would mitigate OALC’s concern. The recommendation, as stated earlier, was that VA ask noncompliant manufacturers with no master agreement to conduct a self-audit and report their findings for remediation. If remediation occurs, federal agencies will not run the risk of purchasing drugs not on an FSS contract, which VA pointed out was prohibited.

OALC, in its technical comments 4 through 6, asserts that government entities other than VA—namely, the Department of Justice and the Office of Federal Procurement Policy—are responsible for enforcement of the public law and should both make sure manufacturers correctly interpret the law and enforce federal procurement policies. Specifically, OALC maintains that the report should address which government entities are responsible for enforcement of federal law, as the VA Public Law Policy Group is not. OALC further states that recommendations should address what government action should be taken because manufacturers are not aware of or are incorrectly interpreting the law. The principal executive director and chief acquisition officer suggested action by the Department of Justice regarding federal law and the Office of Federal Procurement Policy, which has responsibility for federal procurement. Finally, the principal executive director and chief acquisition officer stated the report does not address which government office has the primary responsibility to educate and enforce federal law and federal procurement policies that apply to all federal agencies.

The OIG made several recommendations to the NAC and PBM focusing on monitoring actions within their control and purview. As stated in the report, the public law places responsibility for compliance on manufacturers. The OIG does not believe VA is responsible for enforcement of the law or policing the supply chain of all covered drugs; however, VA has already taken steps to ensure compliance: both NAC and PBM actively monitor and facilitate issues involving the public law, such as issuing guidance through Dear Manufacturer Letters, approving exemptions, and calculating annual ceiling prices. Their involvement is not limited to manufacturers with master agreements under existing FSS contracts. If a manufacturer has a covered drug and wants to obtain an FSS contract, the NAC has an established procedure for getting the manufacturer into an interim agreement to ensure it complies with the public law. VA may also grant exemptions from the public law, which may affect a manufacturer without a master agreement or FSS contract. The OIG recognizes that other entities are involved in compliance with federal laws and procurement issues, but the recommendations specifically focus on what VA can continue to do in its role in monitoring the drugs not made available on FSS as required.

Regarding VHA technical comment 1, the OIG cannot make recommendations to the Public Law Policy Group, which has not been formalized or structured with clear responsibilities given to its members. Regarding VHA technical comment 2, in which VA recommended striking recommendation 7, the OIG reiterates that the recommendation does not require VA to monitor or track manufacturers, or mandate that the FDA provide information to manufacturers. The goal of the recommendation is to initiate collaboration between government agencies, so that manufacturers are more aware of the public law requirements. No change was made to the report based on either of VHA's technical comments.

In its general comment 1, VHA thanked the OIG for taking the time to analyze this particular issue, as it helped identify areas for improvement in the public law process. VHA general comment 2, noted that the information the OIG obtained from noncompliant manufacturers explaining why they were noncompliant will be helpful in determining areas for the Public Law Policy Group to improve communications with drug manufacturers. No change was made to the report based on either of VHA's general comments.

## Appendix A: Scope and Methodology

### Scope

The review team conducted its work from February 2022 through May 2023. The team identified all covered drugs not available on the FSS on March 31, 2022. The team did not review data after this period. The team also reviewed open-market pharmaceutical sales to VA and DOD from their prime vendors from May 17, 2016, to March 31, 2022, to determine the total government purchases of drugs not available on the FSS as required.<sup>92</sup>

### Methodology

To gain an understanding of the requirements of the public law, the team reviewed criteria including the following:

- Veterans Health Care Act of 1992, § 603
- Master agreement template
- Pharmaceutical pricing agreement template
- VA Dear Manufacturer Letters

To determine the number of manufacturers noncompliant with the public law and the related drug codes, the review team first identified the universe of drug codes from the FDA that would be classified as covered drugs, which totaled 17,873. The team compared the list to items already on FSS contracts on March 31, 2022, and found 11,353 national drug codes that were identified as covered drugs but were not on an FSS contract. The team requested and received 274 written responses from manufacturers explaining why their covered drugs were not available on the FSS.<sup>93</sup> The review team eliminated 8,764 of manufacturers' drugs as not subject to the law if they obtained exemptions, were not commercially sold, or were newly launched. For the remaining 2,589 drugs and 236 manufacturers, the team deemed the manufacturers noncompliant (table A.1).

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<sup>92</sup> General Services Administration, Standard Form 30, "Amendment of Solicitation/Modification of Contract, Schedule 65 I B Mass Modification 4," May 2016. The start of the review period is based on a mass modification that VA NAC issued in May 2016. It required all covered drugs manufactured in a non-Trade Agreements Act country to be made available on the FSS. Originally, or when the law was established, these covered drugs could not be offered on the FSS, as FSS customers were permitted to buy only US-made or designated-country end products.

<sup>93</sup> The team did not further examine manufacturers' responses related to items not sold commercially, such as discontinued or divested products. This did not affect the reliability of the OIG's findings and determinations. While interviews were not conducted, the team answered questions from manufacturers through phone calls and emails.

**Table A.1. Manufacturer Compliance Categories and Associated Number of Covered Drugs**

Category	Explanation	Number of national drug codes
Manufacturer’s drug was not subject to public law	<ul style="list-style-type: none"> <li>• Drug was granted an exemption</li> <li>• Drug was not commercially sold</li> <li>• Drug was newly launched*</li> </ul>	8,764
Manufacturer was noncompliant	<ul style="list-style-type: none"> <li>• Manufacturer interpreted the public law incorrectly</li> <li>• Manufacturer acknowledged noncompliance due to lack of awareness or effective oversight</li> <li>• Team was unable to obtain a reason for noncompliance†</li> </ul>	2,589
<b>Total</b>		<b>11,353</b>

Source: VA OIG categorized summary list.

\* VA gives 30 days after the drug’s first commercial sale for manufacturers to generate more sales, plus an additional 45 days for them to submit pricing data and calculations and request to be added to the FSS.

† The team could not determine 85 manufacturers’ reasons for noncompliance related to 627 drugs because OIG requests for additional information were unsuccessful.

The review team requested open-market pharmaceutical sales from VA and DOD prime vendors, totaling approximately \$117,160,569 (\$88,703,185 to DOD and \$28,457,384 to VA). The team calculated the estimated monetary impact of VA and DOD paying prices higher than the statutory 24 percent discount.<sup>94</sup>

The review team conducted a site visit to VA Pharmacy Benefits Management Services in Hines, Illinois. The team also conducted interviews with officials from the NAC, PBM, and Office of General Counsel.

## Internal Controls

The audit team assessed internal control components and principles associated with the audit objectives. The team identified recommendations 1–3 in finding 2 to assist in strengthening

<sup>94</sup> The team only calculated an estimate of the overcharges; an in-depth audit for each item would need to be completed to have an accurate actual overcharge amount.

operating procedures to lessen manufacturer noncompliance specifically for Component 5: Monitoring Activities, Principle 16—Perform Monitoring Activities.<sup>95</sup>

## **Fraud Assessment**

The review team assessed the risk that fraud and noncompliance with provisions of laws, regulations, policies, and contracts, significant in the context of the review objectives, could occur during this review. The team exercised due diligence by staying alert to any fraud indicators.

The OIG did not identify any instances of fraud or potential fraud during this review.

## **Data Reliability**

The team obtained electronic spreadsheets provided by VA Pharmacy Benefits Management Services and DOD. The data comprised VA and DOD open-market sales of covered drugs not available on the FSS, which were only used to calculate overcharge estimates. The team assessed and found that the electronic spreadsheets were sufficiently reliable because the data did not have personally identifiable information, and there were no concerns regarding data quality for the intended use. The team also obtained publicly available databases from the FDA and VA that the team deemed sufficient and reliable as they are widely accepted, generally recognized databases.

## **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*.

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<sup>95</sup> Government Accountability Office, *Standards for Internal Control in the Federal Government*, GAO-14-704G, September 2014.

## Appendix B: Monetary Benefits in Accordance with Inspector General Act Amendments

Recommendation	Explanation of Benefits	Better Use of Funds
6	Potential savings related to covered drugs that should be added to the FSS (\$6.8 million for VA purchases and \$21.3 million for DOD purchases). <sup>96</sup>	\$28.1 million
	<b>Total</b>	<b>\$28.1 million</b>

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<sup>96</sup> VA has historically collected any overcharges for VA and DOD in relation to public law compliance.



## Appendix C: VA Management Comments

### Department of Veteran Affairs Memorandum

Date: July 20, 2023

From: Principal Executive Director, Office of Acquisition, Logistics, and Construction (003) and Chief Acquisition Officer

Subj: Office of Inspector General (OIG) Draft Report: Manufacturers Failed to Make Some Drugs Available to Government Agencies at a Discount as Required (2022-01624-AE-0073) (VIEWS 10407560)

To: Assistant Inspector General for Audits and Evaluations (52)

1. The Office of Acquisition, Logistics, and Construction (OALC) and the Veterans Health Administration (VHA) responds to OIG's request to provide comments on the subject draft report. OALC and VHA concur in principle with the findings identified, concurred with recommendations 1, 2, 3, 6 and 8, and non-concurred with recommendations 4, 5, and 7. OALC and VHA will take the appropriate actions referenced in the implementation plan by the suggested target completion dates. Also, OALC and VHA provides technical and general comments as requested by OIG.

*The OIG removed point of contact information prior to publication.*

(Original signed by)

Michael D. Parrish

Attachments

**Attachment 1**

**Department of Veterans Affairs (VA) Comments to the  
Office of Inspector General (OIG) Draft Report**

**Manufacturers Failed to Make Some Drugs Available to Government Agencies  
at a Discount as Required - VA OIG Report 2022-01624-AE-0073**

**Background:**

The VA OIG submitted the draft report titled, “Manufacturers Failed to Make Some Drugs Available to Government Agencies at a Discount as Required (2022-01624-AE-0073)”, for the Office of Acquisition, Logistics, and Construction’s (OALC) review and comment. At the core of the covered drug program is the Federal Government-wide requirement, pursuant to Public Law 102-585 (PL), the Veterans Healthcare Act of 1995, that all covered drugs sold to the Federal Government must be provided under a Master Agreement with the VA National Acquisition Center’s (NAC) Federal Supply Schedule Service and that sales under its Federal Supply Schedule (FSS) Program to the “Big 4” customers, which are the U.S. Coast Guard, Department of Defense (DoD), Public Health Service, and VA, must include a pricing agreement discounted at least 24 percent below the non-Federal average manufacture price. OIG performed a review to determine what manufacturers do not appear to comply with the PL and to identify covered drugs not currently under a Master Agreement as required by the PL. OIG made eight recommendations.

**Findings:**

After filtering the covered drug item list using relevant parameters, 2,589 items were identified as the pool of covered drugs that should have been made available under the FSS Program as required by the PL. As a result, the team found that VA and the DoD potentially overpaid approximately \$28.1 million (\$6.8 million for VA and \$21.3 million for DoD) on 375 covered drugs from May 17, 2016, to March 31, 2022.

The NAC and Pharmacy Benefits Management Services concur in principle on the VA OIG methodology and the VA OIG alerting to potential overpayment for items that companies have not applied for a Master Agreement or have not been included in a Master Agreement. As a result, an ongoing evaluation of any impactful data will be necessary as each recommendation is addressed.

**Recommendations:**

**Recommendation 1:** Issue guidance clarifying that allergens are exempt from the public law and include how the determination was reached.

OALC Concur with Comments: OALC will request additional information from OIG with regard to what is considered to be appropriate guidance.

Target Implementation Date: September 30, 2023.

**Recommendation 2:** Formalize and communicate the process for manufacturers to request exemptions.

OALC Concur with Comments: This information is already formalized to an extent and publicized, but additional steps can be taken to ensure effective communication is provided to manufacturers. By September 30, 2023 FSS will review processes with VA OIG to assess current exemptions.

Target Implementation Date: September 30, 2023

**Recommendation 3:** Formalize the internal process for granting exemptions.

OALC Concur with Comments: The process is identified, but more information is needed from OIG on what standard they believe constitutes a formalized process. By September 30, 2023 FSS will review processes with VA OIG to assess internal process for granting exemptions.

Target Implementation Date: September 30, 2023

**Recommendation 4**: Establish a procedure for monitoring covered drugs identified in the report as not commercially sold.

OALC Non-concur: Agencies are specifically assigned to enforce law and compliance with Federal procurement policies. The NAC, and specifically FSS, does take steps to improve coverage with existing FSS contract holders and will continue to do so; however, it is outside of FSS mission set and resourcing to police the supply chain of all covered drugs, even those not procured by VA or any other FSS customer.

**Recommendation 5**: Develop a procedure to monitor covered drugs identified in the report as newly launched, and ensure they have an established ceiling price, and make certain they are made available on the federal supply schedule at the end of the 75-Day period.

OALC Non-concur: The NAC has not been resourced to perform Federal oversight to this degree for covered drugs not under a Master Agreement through an FSS contract.

**Recommendation 6**: Request that noncompliant manufacturers identified by the IG conduct a self-audit and submit their findings for remediation.

OALC Concur with Comments: This should be a recommendation to OIG or another Government entity which retains at least equivalent or greater authority to instruct non-compliant manufacturers who do not have contracts with VA to perform a self-audit. We concur if the recommendation is clarified to mean manufacturers already under a FSS contract should self-audit for any covered drugs not listed on their Master Agreement. By September 30, 2023, the FSS will communicate with the non-compliant manufacturers identified by VA OIG who already hold a Master Agreement with FSS.

Target Implementation Date: September 30, 2023

**Recommendation 7**: Engage with the Food and Drug Administration to ensure that when manufacturers request new national drug codes, they are made aware of the Public Law requirements.

OALC Non-concur: Compliance and impact on procurement should be overseen by the Office of Federal Procurement Policy (OFPP) as it pertains to other Federal Agencies. The OIG does not recognize the whole of Government impact on compliance, the role of the Department of Justice (DOJ), as well as Federal Comptrollers and Acquisition Officials, who are prohibited from procuring covered drugs not on a Master Agreement. The Food and Drug Administration (FDA) could be helpful in educating manufacturers, but that does not address the entire procurement community. It is appropriate to include OFPP to educate Federal Procurement Officials and Suppliers.

**Recommendation 8**: Require contracting staff at the NAC to conduct a covered drug check for all of the manufacturer's drugs when any pharmaceutical FSS proposal or project addition modification is submitted.

OALC Concur with Comments: This process is already performed by contract specialists when reviewing a proposal and when engaging with current FSS pharmaceutical contractors. By September 30, 2023, written instructions to FSS Contract Specialist will be issued to provide additional emphasis on this step of the process.

Target Implementation Date: September 30, 2023

**OALC's Technical Comments**

**VA OIG Draft Report**

**Manufacturers Failed to Make Some Drugs Available to Government Agencies  
at a Discount as Required - VA OIG Report 2022-01624-AE-0073**

**[OALC Technical Comment 1]**

**On Page 3:** Executive Summary – Footnote 6 - *General Services Administration (GSA) directs and manages the FSS, which provides federal agencies and other authorized users with the simplified process of acquiring commercial supplies and services and established fair and reasonable prices from responsible vendors. In January 1981, GSA delegated to the VA contracting responsibility for medical items. This delegation continued with the creation of emphasis contracts for medical equipment medical supply pharmaceutical in medical service-related schedule programs for VA.*

OALC Comment: Footnote 6 should be brought current to include that GSA completed an official Assignment of Function to the SECVA signed on February 8, 2022, for managing the medical and healthcare Multiple Award Schedules.

**[OALC Technical Comment 2]**

**On Page 13:** *Roles and Responsibilities of Entities That Oversee Compliance with the Public Law*

OALC Comment: The header as written proposes to identify all Federal Entities that Oversee U.S.C. 38; however, it goes on to leave out DOJ's U.S. Attorney General's office which has the primary function of overseeing compliance with Federal law and OFPP which oversees Government-wide procurement policy.

**[OALC Technical Comment 3]**

**On Page 20:** *If manufacturers have questions about whether their drugs are subject to the public law but do not know how to seek guidance from VA, they may not offer their drugs as required by the law, and the government will not be able to purchase much-needed drugs at lower prices.*

OALC Comment: The sentence only describes part of the impact of covered drugs not having a Master Agreement. The true impact is that the law prohibits the Federal Government from purchasing any covered drugs which are not under a Master Agreement. The impact is not just that VA drugs could be obtained at lower prices. Another action of this audit for consideration is that Federal Agencies will need to be notified that purchases of the 2,589 covered drugs determined by OIG to not be on Master Agreements are prohibited.

**[OALC Technical Comment 4]**

**On Page 22:** Footnote 63 – *Although the VA Secretary or a delegate may audit a manufacturer's records to determine the accuracy of a drug price, the public law places responsibility for compliance on manufacturers.*

OAL Comment: The draft report establishes that the law places responsibility for compliance on private entities. The report should address what Government entities are responsible for enforcement of Federal law, which is not the VA Public Law Policy Group.

**[OALC Technical Comment 5]**

**On Page 23:** *Other manufacturers were not aware of or overlooked the requirements, while still others did not or could not provide information on why they did not comply.*

OALC Comment: It should be addressed in recommendations what action by Government should be taken because manufacturers are not aware of or are incorrectly interpreting the law. Recommend this would be DOJ regarding Federal law and OFPP, which has responsibility for Federal procurement across the whole of Government.

**[OALC Technical Comment 6]**

**On Page 25:** *Footnote 74 - If a manufacturer does not comply with the public law for even a single covered drug, it cannot receive government funds for any drugs it sells.*

OALC Comment: The report leaves a large hole with no recommendation on what Government office has the primary responsibility to educate and enforce Federal law and Federal procurement policies that apply to all Federal Agencies.

**OALC's General Comment**

**VA OIG Draft Report**

**Manufacturers Failed to Make Some Drugs Available to Government Agencies**

**at a Discount as Required - VA OIG Report 2022-01624-AE-0073**

**OALC Comment:** Any suspected or confirmed non-compliance is to be reported to DOJ and to OFPP through the VA OIG.

**Veterans Health Administration's (VHA) Technical Comments**

**VA OIG Draft Report**

**Manufacturers Failed to Make Some Drugs Available to Government Agencies  
at a Discount as Required - VA OIG Report 2022-01624-AE-0073**

**[VHA Technical Comment 1]**

**VHA Comment:** Suggest revision on page 31 under "recommendations 1-8".

Current Language: "The OIG made seven recommendations to the Associate Executive Director of the VA National Acquisition Center, in conjunction with the Chief Consultant at Pharmacy Benefits Management Services."

Suggested Revision: "The OIG made seven recommendations to the Associate Executive Director of the VA National Acquisition Center, in conjunction with the Public Law Policy Group."

Comment and Justification: Recommend that OIG considers altering the responsible individuals for implementing the recommendations. All of the recommendations are actions that must be implemented by the Public Law Policy Group based on the delegation of authority to that group for decision making.

**[VHA Technical Comment 2]**

**VHA Comment:** Regarding OIG's recommendation 7, (Engage with the Food and Drug Administration to ensure that when manufacturers request new national drug codes, they are made aware of the public law requirements), VA would like for OIG to consider that the FDA is the regulatory body responsible for approval of new medications and the assurance of quality in the manufacturing of pharmaceuticals. Public Law process is a contracting related activity. FDA is not involved in contracting related activities for the Government, and it may pose a conflict of interest or perception of bias if contracting related discussions are linked to the clinical process of drug approval. The FDA would also not be able to answer any specific questions pertaining to Public Law, should questions be posed by a manufacturer. VA would have no way to monitor and track whether FDA is providing this information to manufacturers, even if the agency is agreeable to collaborating. Recommend striking this recommendation.

**VHA's General Comments**

**VA OIG Draft Report**

**Manufacturers Failed to Make Some Drugs Available to Government Agencies  
at a Discount as Required - VA OIG Report 2022-01624-AE-0073**

**[VHA General Comment 1]**

**VHA Comment:** VHA is thankful that OIG took the time to analyze this particular issue, as it helped to identify areas for improvement in the Public Law process.

**[VHA General Comment 2]**

**VHA Comment:** VHA finds the information that OIG obtained from non-compliant manufacturers, as to why they were non-compliant, to be helpful in determining areas for the Public Law Policy group to improve communications with drug manufacturers.

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



## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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## Report Distribution

### VA Distribution

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