

Department of Veterans Affairs Office of Inspector General

# Review of a Covered Drug Manufacturer's Interim Agreement under Letter Contract with VA's National Acquisition Center

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VA Office of Inspector General Washington, DC 20420 September 30, 2015

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# **Executive Summary**

## Introduction

The Office of Inspector General (OIG) Office of Contract Review (OCR) performed a review of Interim Agreement (IA) FSS-IA-08-16 awarded to GE Healthcare Inc. (GE) under Letter Contract V797P-5031E. The VA National Acquisition Center (NAC) awarded this IA effective October 1, 2008. This IA has been extended multiple times and is currently set to expire September 30, 2015. All IAs awarded by the NAC are letter contracts established for purposes of compliance with Section 603 of the Veterans Health Care Act of 1992, Public Law 102-585 (P.L.). The P.L. requires manufacturers to offer drugs covered by the P.L. to the Federal Supply Schedule (FSS), and calculate a Federal Ceiling Price (FCP) for each covered drug. This review determined whether it was appropriate for GE's IA to be in place since October 1, 2008, whether GE was able to correctly calculate the FCPs under its IA, and if there were other long-term IAs in place similar to GE's.

## Results

The IA with GE is not in compliance with the Federal Acquisition Regulation (FAR) or VA policy. FAR Section 16.603, Letter Contracts, states that the definitization of an actual contract should occur within 180 days of implementing a letter contract with a vendor. The NAC has adopted a standard of 120 days to award a permanent FSS contract. Yet, as of July 31, 2015, GE's IA has been in place 2,494 days, or nearly seven years. FAR clause 52.216-25, which was included in GE's IA, stipulates that a schedule for definitizing the contract shall be inserted into the contract that will include target dates and milestones such as a date for a proposal, a date for any required data submission, and a date for beginning of negotiations. However, the NAC did not include a schedule, dates, or milestones in GE's IA. The repeated extensions and delays were the result of lack of action by both GE and the NAC. Finally, the P.L. includes financial penalties for companies that do not comply with its requirements, but the NAC has not used this leverage to compel GE to negotiate a permanent FSS contract in a timely manner.

GE's FCPs for 2015 were not calculated in accordance with the P.L. because the dual calculation mandated by the P.L. was not performed. The dual calculation is based on the permanent FSS price on September 30 for the second and subsequent years of a multi-year contract. Any increase in the FCP is limited by the FSS price on September 30 plus the change in the Consumers Price Index-Urban. VA has stated that an IA price does not meet the definition of a permanent FSS price; therefore, GE and other IA holders cannot perform the dual calculation as required by the P.L. in the determination

of FCPs for covered drugs. This removes an important limiter contained in the P.L. which limits how much FCPs can increase each year.

In the last ten years we found that the NAC has awarded 165 IAs to manufacturers of covered drugs. FSS sales under these 165 IAs have totaled more than \$490 million through the 10 years ending in the second quarter of FY 2015. We determined that 153 of the 165 IAs have exceeded the 120 day maximum stipulated by VA in FAR clause 52.216-25. As of July 1, 2015, there were 43 active IAs in place with manufacturers of covered drugs. FSS sales through these IAs have totaled more than \$92 million from their effective dates through the end of the second quarter of FY 2015. We found that 35 of the active IAs have been in place for over the 120 days and 16 of these have been in place for over a year.

## Recommendations

We recommend that the Principal Executive Director for the Office of Acquisition, Logistics, and Construction:

- 1. Develop a plan of action with established milestones to establish a long-term FSS contract with GE.
- 2. Develop a plan of action with established milestones to establish a long-term FSS contract with all 43 manufacturers with IAs.
- 3. Establish policies to ensure all future IAs are limited to new manufacturers of covered drugs and do not exceed the prescribed 120 day limit currently used by the NAC, or establish policy allowing 180 days as permitted by FAR. Policy should ensure Contracting Officers are held accountable for non-compliance.
- 4. Direct the P.L. Policy Group to review and justify the appropriateness of VA's policy that prices under an IA cannot be used in performing the dual calculation.

## Management Comments and OIG Response

We received comments from the Principal Executive Director, Office of Acquisition, Logistics, and Construction on September 24, 2015. The Principal Executive Director concurred with our findings and recommendations. Management included an acceptable action plan and we will follow up on the planned actions until they are complete.

Mauren Regan

MAUREEN T. REGAN Counselor to the Inspector General

# Introduction

## Purpose

The Office of Inspector General (OIG) Office of Contract Review (OCR) initiated a review of Interim Agreement (IA) FSS-IA-08-16 awarded to GE Healthcare Inc. (GE) under Letter Contract V797P-5031E, which was effective on October 1, 2008, and has been extended multiple times. The IA, which includes covered drugs defined by Section 603 of the Veterans Health Care Act of 1992, Public Law 102-585 (P.L.), is currently set to expire on September 30, 2015. Our purpose in conducting the review was to determine if GE and other manufacturers with IAs longer than 120 days were able to comply with the requirements set forth in the P.L.

## Background

P.L. Requirements. On November 4, 1992, Congress enacted the P.L., which was codified in Title 38 of the United States Code, Section 8126. Section 603 of the P.L. contains limitations on prices of covered drugs procured by VA, Department of Defense, Public Health Service, and the Coast Guard (collectively, the Big 4).<sup>1</sup> Section 603 of the P.L. requires manufacturers of covered drugs to:

- 1. make their products available to the Federal Supply Schedule (FSS);
- 2. sign a Master Agreement and Pharmaceutical Pricing Agreement;
- 3. collect and submit non-Federal Average Manufacturer Price (NFAMP) data to VA on a quarterly and annual basis, so that a Federal Ceiling Price (FCP) for each covered drug can be calculated; and
- 4. sell their covered drugs on the FSS to Big 4 customers at prices no higher than the calculated FCPs.

An FCP is computed for each unique National Drug Code (NDC) of a covered drug. The prescribed formula in the P.L. for the FCP is 76 percent of the NFAMP, less any additional discount.<sup>2</sup> The NFAMP is the weighted average price of a single package NDC of a drug sold to wholesalers. Annual NFAMPs are calculated and submitted to VA in November of each year in order to calculate the FCP for the following calendar year.

The P.L. also requires a second or *dual* calculation in the second and subsequent years of a multi-year FSS contract. Under the dual calculation, an FSS Max Cap is established, which is the permanent price on the manufacturer's FSS contract on September 30 of the

<sup>&</sup>lt;sup>1</sup> In general, a "covered drug" is a drug approved by the U.S. Food and Drug Administration under a New Drug Application or a Biological Licensing Agreement, and is available in the commercial marketplace. <sup>2</sup> The additional discount is calculated based on changes to a drug's 3<sup>rd</sup> quarter NFAMP values. The details of the

calculation are spelled out in the P.L., but for brevity are not provided here.

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current year, increased by the percentage change in the Consumer Price Index-Urban (CPI-U) for the preceding year. The FCP is then the *lower* of the calculated FCP (76 percent of the annual NFAMP, less any additional discount) or the FSS Max Cap (permanent FSS price on September 30 plus the CPI-U) established by the dual calculation. The illustration below shows an example where the FCP based on NFAMP is \$130. However, the dual calculation results in a price of \$102. Therefore the FCP is \$102, the lower of the two.

	ANNUAL (NFAMP	X	0.76)	-	Any Additional Discount	=	NFAMP Calculated FCP	I	FCP
NFAMP									
Calculation:	(\$200	Х	0.76)	-	\$22	=	\$130	the LOWER =	\$102
	Septembe	r 30						of	
	Permanent	FSS			CPI-U		FSS		
	Price		Х	(1 +	Increase)	=	Max Cap FO	CP /	
Dual									
Calculation:	\$100		Х	(1 +	0.02)	=	\$102	K	

Illustration of FCP Calculation

Interim Agreements. In order to make it feasible for new manufacturers of covered drugs without an FSS contract to quickly comply with the P.L. while the manufacturer establishes a permanent FSS contract, the VA National Acquisition Center (NAC) instituted a policy of awarding IAs. The NAC cited the authority provided by Federal Acquisition Regulation (FAR) Section 16.603, Letter contracts, to award IAs. Per FAR, a letter contract is a written preliminary contractual instrument that authorizes the contracts are used when the Government's interests demand that a contractor be given a binding commitment to start work immediately, and negotiating a definitive contract is not possible in sufficient time to meet the requirement. The NAC assigns IAs a tracking number separate from the letter contract number—in GE's case, the IA number was FSS-IA-08-16 and the letter contract number was V797P-5031E. However, an IA can only exist under a letter contract, and the IA remains effective for as long as the letter contract remains effective. All IAs awarded by the NAC are letter contracts, as defined by FAR, that have been established for purposes of P.L. compliance.

The IA gives both the FSS Service and the manufacturer the time needed to move through the new offer review process, negotiations, and award of a new contract, while allowing the manufacturer to immediately comply with the requirements of the P.L. FAR Subsection 16.603-2 states that the definitization of a contract should occur within 180 days after the date of the letter contract. Clause 52.216-25 (Contract Definitization)

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used by the NAC in its IAs states that the time to definitization shall be within 90 to 120 days from the date of the letter contract.

### Scope and Methodology

The objectives of our review were to determine if the:

- repeated extensions of the GE IA were in accordance with the FAR and VA policy;
- FCPs for GE's covered drugs have been calculated in accordance with the P.L.; and
- NAC has awarded other long-term IAs.

To address these objectives we reviewed:

- the P.L., FAR, and other relevant guidance;
- transactional sales data from GE for the period October 1, 2011, to September 30, 2013;
- explanations from GE concerning the reason for the IA, and the length of the IA;
- the contract file for GE's IA;
- GE's original NFAMP filings for the calculations of FCPs from 2009 through 2015, obtained from VA's Pharmacy Benefits Management (PBM) Services; and
- NAC data on IAs awarded to manufacturers of covered drugs during the past ten years.

# **Results and Conclusions**

### I. The Interim Agreement is Not Compliant with FAR Requirements Regarding Letter Contracts

As of July 31, 2015, GE's IA has been in place for 2,494 days, or nearly seven years. This IA is not compliant with the FAR because of its length and the lack of a schedule for definitizing the contract. The NAC has stated the authority to enter into an IA under the FSS Program is FAR Section 16.603, Letter contracts, which states that the definitization of an actual contract should occur within 180 days. The NAC has adopted a 120 day standard to award a permanent FSS contract after implementing an IA with a vendor. FAR 16.603 prescribes FAR clause 52.216-25 be inserted into an IA. FAR clause 52.216-25 stipulates that a schedule for definitizing the contract shall be inserted and will include target dates and milestones such as a date for a proposal, a date for any required data submission, and a date for beginning of negotiations. Although the NAC included FAR clause 52.216-25 in GE's IA, the NAC did not include a schedule, dates, or milestones of any kind. The IA simply stated that a permanent FSS contract would be awarded in 90 to 120 days without any defined schedule.

Our review of the documentation found that the NAC officials did not actively seek a proposal from GE until almost three years had passed under the IA. We concluded that GE's IA was not compliant with FAR as it was not appropriately administered as a temporary letter contracts stipulated in FAR Section 16.603. Furthermore, the documentation does not provide a valid reason as to why an established manufacturer of covered drugs, who had an FSS contract in place for ten years, was awarded an IA, as there was plenty of time for GE to submit an offer and negotiate an FSS contract.

GE's IA was awarded and effective on October 1, 2008. GE was not a new manufacturer of covered drugs and had a prior FSS contract, FSS Contract V797P-5317x, which had been effective for ten years. Because GE was not a new pharmaceutical FSS contractor and had a long-term FSS contract, VA should not have entered into an IA to negotiate a new FSS contract. The NAC intended IA's to be used with new manufacturers seeking a new FSS contract under the P.L., not with manufacturers with existing FSS contracts that simply had run out of time to negotiate and award a follow-on FSS contract.

Before contract V797P-5317x expired, GE submitted a proposal under solicitation number M5-Q50A-03-R1 on September 27, 2007. The proposal was submitted to OIG's OCR in January 2008 for a pre-award review; however, the review was cancelled because GE's Commercial Sales Practices (CSP) data was not up-to-date and the proposal did not reflect new 2008 FCPs. In June 2008, the NAC returned GE's proposal to GE and requested GE to submit a new proposal under solicitation number M5-Q50A-03-R2 with up-to-date CSP data. There is no evidence that GE submitted a proposal in response to

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the NAC's request. V797P-5317x was allowed to expire because it had reached its 10-year maximum limit on September 30, 2008.

Between October 1, 2008, and March 1, 2011, there were ten separate modifications to the IA that ultimately extended it through June 30, 2011 (see Exhibit A for timeline of events). These ten modifications did not include any documentation that shows that VA NAC officials requested a proposal or threatened administrative action such as the penalties contained in the P.L. The P.L. stipulates that non-compliant manufacturers of covered drugs can be prohibited from receiving payment for the purchase of drugs or biologicals from: (a) a state plan under title XIX of the Social Security Act, (b) any of the Big 4 Federal Agencies, or (c) any entity that receives funds under the Public Health Service Act. There is no evidence that NAC officials attempted to use its leverage under the P.L. to ensure GE was making a good faith effort to put a permanent FSS contract in place. It was not until June 23, 2011 that the NAC instructed GE that a proposal must be submitted no later than August 31, 2011 as a condition to extend the IA beyond June 2011.

GE agreed and submitted a proposal under solicitation number M5-Q50A-03-R4 on August 31, 2011. The offer was assigned to a Contracting Officer (CO) in September, 2011, but the offer was misplaced and determined to be missing by the NAC in November 2012, more than a year later. However, the NAC did not notify GE or ask for a new proposal at that time. In February 2013, GE formally withdrew its offer. There is no evidence that a new proposal was submitted at that time. During the period of July 1, 2011, and April 1, 2013, there were six additional modifications that extended the IA through March 31, 2014; the last modification was for a full year.

On April 1, 2014, the NAC extended GE's IA for another year through March 31, 2015, contingent upon GE submitting a new proposal by August 31, 2014. GE agreed and submitted a proposal under solicitation number M5-Q50A-03-R7 on August 31, 2014. The NAC took no action on the proposal for more than 4 months even though GE's IA had been in place now for over 5 years. The CO sent correspondence requesting clarifications to GE on January 16 and March 13, 2015, and GE requested the opportunity to update the CSP and proposed pricing on April 15, 2015. On April 1, 2015, the IA was extended through September 30, 2015. The CO submitted GE's proposal to the OIG Liaison at the NAC on May 8, 2015 for the OIG preliminary review to determine if the proposal was adequate for review. On May 18, 2015, the OIG Liaison determined that GE's proposal was complete and that the CO could now request the OIG to perform a pre-award review. However, no pre-award request was made to the OIG until the OIG asked the CO about the GE proposal in July 2015. At that time, the CO stated that an OIG pre-award audit was needed and requested that the OIG initiate the pre-award review.

The NAC has implemented the use of IAs so that manufacturers of covered drugs could comply with the P.L. The NAC has primary responsibility to ensure a contractor complies with the P.L. The P.L. stipulates that non-compliant manufacturers of covered drugs could be prohibited from receiving payment for the purchase of drugs, but NAC officials did not use its leverage under the P.L. to ensure GE made a good faith effort to submit a proposal in a timely fashion, nor did NAC officials react in a manner that indicated it was a priority to end GE's IA by taking timely action to negotiate a long-term FSS contract with GE.

The effect of GE's long-term IA is that GE's FCPs are not properly calculated per the requirements of the P.L. The P.L. requires that FSS contract prices be used as part of the FCP calculation for most years. Under current VA policy, an IA is not considered a permanent FSS contract; therefore, an IA holder's FCPs cannot be computed correctly as stipulated in the P.L. The miscalculated FCPs result in potentially higher prices to the Government. This also provides manufacturers with an IA an unfair advantage over holders of permanent FSS contracts, who must calculate FCPs according to statute.

### II. The Manufacturer's Federal Ceiling Prices under P.L. 102-585 are not Correctly Calculated

Currently, GE's FCP's are not correctly calculated because VA has determined that the dual calculation, as stipulated in the P.L., cannot be used in determining FCPs for items on IAs. We found that this policy was inconsistent with the P.L. and was harming the Government by increasing costs.

As discussed in the Background section of this report, the NAC implemented IAs with new manufacturers of covered drugs so that new manufacturers without a prior FSS contract could comply with the P.L. requirement to offer their covered drugs to the FSS. As IAs lasting more than a year became more prevalent, manufacturers holding such IAs began raising questions as to how their FCPs should be calculated. Ultimately, the VA P.L. Policy Group determined that prices under an IA would *not* be considered permanent prices for purposes of the dual calculation. Thus, FCPs would be determined based on the manufacturer's NFAMP submissions only and the dual calculation limitation would not apply.

This policy was never published, and implementation actions were inconsistently applied across manufacturers prior to 2014. The policy was inconsistently applied because many manufacturers with IAs did not raise questions and accepted having their FCPs set using the dual calculation. Also, PBM did not have a process to ensure the dual calculation was not computed for manufacturers with an IA. However, in 2014, PBM instituted procedures so that dual calculations would not be performed under any IAs, thus negating the limit on increasing FCPs in the second and subsequent years of the multi-year contracts. These new procedures had no impact on the 2014 FCPs because 2014 was uniformly considered the first year of a multi-year contract for all covered drug manufacturers. The new procedures were fully in place at the time of the calculation of the 2015 FCPs. Thus, we consider the 2015 FCP year as the first year that the policy of no dual calculation for IAs was fully implemented by VA.

While IAs were instituted as a matter of enabling quick compliance with requirements in the P.L. that manufacturers of covered drugs make the drugs available on contract, changes in policy regarding IAs have made it impossible comply with the P.L.'s requirement to perform the dual calculation. Therefore, manufacturers under an IA are unable to compute a correct FCP that is compliant with the P.L., and have an unfair advantage over manufacturers who hold a permanent FSS contract, as the permanent FSS contract holders are subject to the dual calculation and the FSS Max Cap limiter.

To determine the potential impact of not performing the dual calculation, we reviewed GE's P.L. data maintained by PBM. We found that the dual calculation was applied to GE's covered drugs under its IA prior to 2014. Since the dual calculation was performed on GE's IA prior to 2014, we were able to review and determine how many times, if any, that the statutory FCP was actually determined by the FSS Max Cap set by the dual calculation, thus resulting in a lower FCP. We reviewed GE's FCPs for 2011, 2012, and 2013. We found that FCP was determined by the FSS Max Cap (the dual calculation) 65 times during these three years (Table 1) resulting in lower prices than if the FCP had been calculated using only the NFAMP data.

Table 1
<b>Covered Drugs Where FCP Set</b>
by FSS Max Cap

	Number of
Year	NDCs
2011	27
2012	16
2013	22
Total	65

We then reviewed the 65 covered drugs to determine the monetary impact if the FCP was determined without the dual calculation and the FSS Max Cap. We determined that because the dual calculation was performed and resulted in lower prices for these 65 items, the Government saved \$118,248.73, as shown in Table 2.

Table 2
Savings Due to Lower FCP Based
on the FSS Max Cap

Period	Savings
October 1 to December 31 2011	\$34,276.20
January 1 to December 31 2012	41,504.05
January 1 to September 30 2013	42,468.48
Total	\$118,248.73

Since 2014, VA has implemented policy and procedures so that the dual calculation and the FSS Max Cap are not used for covered drugs that are under an IA. Therefore, GE and other manufacturers with an IA cannot calculate a correct FCP as the dual calculation cannot be performed as stipulated in the P.L. We reviewed GE's P.L. data and IA prices to determine if the FSS Max Cap would have an impact on prices for the current calendar year (2015). We did not review 2014 because this was the first year of the multi-year

contract and the dual calculation is not required by the P.L. in the first year.<sup>3</sup> The data in Table 3 shows that the FCP would have been lower for 11 NDCs if the dual calculation had been performed. We determined the FSS Max Cap by using the IA price on September 30, 2014, increased by the CPI-U.

			FCP Under Dual	
		Actual	Calculation (FSS	
	NDC	2015 FCP	Max Cap)	Difference
1	00407-0690-10	\$164.31	\$136.99	\$27.32
2	00407-0690-15	208.16	207.02	1.14
3	00407-0690-22	310.84	309.15	1.69
4	00407-0691-63	320.94	302.26	18.68
5	00407-2222-52	174.54	157.34	17.20
6	00407-2222-53	380.87	363.88	16.99
7	00407-2223-16	185.53	172.40	13.13
8	00407-2223-21	577.00	560.31	16.69
9	00407-2223-54	185.53	172.40	13.13
10	00407-2223-57	577.00	560.31	16.69
11	00407-2707-03	443.15	394.08	49.07

Table 3Difference between Calculated FCP and Dual Calculation

Manufacturers with an IA cannot fully comply with the requirements of the P.L. as they cannot perform the dual calculation as required by the P.L. For GE, we determined that VA performed the dual calculation (even though it was VA's policy not to) on GE's covered drugs for calendar years 2009 through 2013. This resulted in a lower FCP for some items and savings of over \$118,000 based on sales data reviewed from October 1, 2011, through September 30, 2013. When PBM initiated procedures to ensure no dual calculation is performed for manufacturers with an IA, we determined that the FCPs were higher for 11 of GE's covered drugs for calendar year 2015, as shown in Table 3.

<sup>&</sup>lt;sup>3</sup> The NAC establishes the first year of a multi-year contract as a matter of policy for all FSS and IA contracts for the ease of administration.

### III. Interim Agreements Awarded by VA's National Acquisition Center Routinely Exceed 120 Days

After reviewing GE's IA in detail and determining that the statutory FCPs for manufacturers with an IA cannot be correctly computed under the P.L., we reviewed the NAC's contract database to determine the number of IAs awarded and in place by the NAC. We found that, in the last ten years, the NAC has awarded 165 IAs to manufacturers of covered drugs. FSS sales under these 165 IAs have totaled more than \$490 million through the second quarter of FY 2015. We determined that 153 of the 165 IAs have exceeded the 120 day maximum stipulated by clause 52.216-25. Exhibit B shows all IAs awarded in the last ten years.

Currently, as of July 1, 2015, there were 43 active IAs in place with manufacturers of covered drugs. FSS sales through these IAs have totaled more than \$92 million through the second quarter of FY 2015. We found that 35 of these IAs have been in place for over 120 days, while 16 of these IAs have been in place for over a year. Exhibit C lists IAs currently in place as of July 1, 2015. Because of the constant consolidation, creation of new companies or subsidiaries, and transfer of drugs in the pharmaceutical industry, it is difficult to determine how many of the IAs that have been improperly awarded to companies that are not new manufacturers of covered drugs such as the IA with GE.

### Conclusions

Our review of GE's IA found that the agreement has been in place since October 1, 2008. The agreement should not have been entered into because GE was not a new manufacturer. A new contract should have been awarded prior to the expiration of its existing contract. GE's IA has been inappropriately extended numerous times which far exceeded the 180 day maximum stipulated by FAR 16.603. The NAC did not develop or enforce a plan with milestones as stipulated by FAR Clause 52.216-25. The failure to timely award a permanent contract with GE was due to the NAC's poor administration and oversight, as demonstrated by its failure to: (a) actively pursue a contract with GE; (b) recognize that the proposal was lost or to request a new one when the issue was identified; and (c) take administrative action under the P.L. when GE did not provide a timely and complete offer when asked. The P.L. states that a manufacturer can be prohibited from receiving payment for the purchase of drugs or biologicals from: (a) a state plan under title XIX of the Social Security Act, (b) any of the Big 4 Federal Agencies, or (c) any entity that receives funds under the Public Health Service Act. If VA had not granted almost seven years of extensions to the IA, GE would be in violation of the P.L. and subject to penalties. In addition to inappropriately extending the contracts, VA did not provide a single warning to GE concerning potential penalties.

Because VA has taken the policy position that VA cannot impose the FSS Max Cap calculation on GE and other manufacturers holding IAs, manufacturers are not required to fully comply with the provisions in the P.L. in calculating the statutory FCPs. Our review of the NAC's contract database has found that the GE IA is not alone and that 43 additional covered drug manufacturers also have IAs and cannot comply with P.L. and calculate a correct FCP. This provides an unfair advantage to manufacturers with IAs over contractors who hold a permanent FSS contract as IA holders are not subject to the dual calculation and the FSS Max Cap limiter.

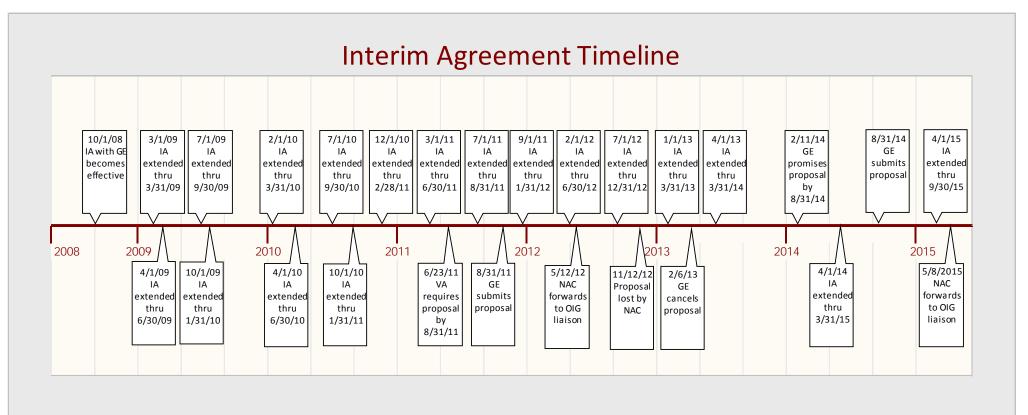
# Recommendations

We recommend that the Principal Executive Director for the Office of Acquisition, Logistics, and Construction:

- 1. Develop a plan of action with established milestones to establish a long-term FSS contract with GE.
- 2. Develop a plan of action with established milestones to establish a long-term FSS contract with all 43 manufacturers with IAs.
- 3. Establish policies to ensure all future IAs are limited to new manufacturers of covered drugs and do not exceed the prescribed 120 day limit currently used by the NAC, or establish policy allowing 180 days as permitted by FAR. Policy should ensure Contracting Officers are held accountable for non-compliance.
- 4. Direct the P.L. Policy Group to review and justify the appropriateness of VA's policy that prices under an IA cannot be used in performing the dual calculation.

# Acronyms

Big 4	VA, Department of Defense, Public Health Service/Indian Health Service, and Coast Guard
CO	Contracting Officer
CPI-U	Consumer Price Index-Urban
CSP	Commercial Sales Practices
FAR	Federal Acquisition Regulation
FCP	Federal Ceiling Price
FSS	Federal Supply Schedule
GE	GE Healthcare Inc.
IA	Interim Agreement
NAC	National Acquisition Center
NDC	National Drug Code
NFAMP	Non-Federal Average Manufacturer Price
OCR	Office of Contract Review
OIG	Office of Inspector General
PBM	Pharmacy Benefits Management
P.L.	Public Law 102-585 Section 603
VA	Department of Veterans Affairs



					Actual End	Active or	Total FSS Sales Through 2Q FY	No. of
Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
<b>1</b> V797P-5031E	GE Healthcare Inc.	9/26/2008	10/1/2008	9/30/2015		Active	\$82,487,077.70	2463
<b>2</b> V797P-5901X	Triax Pharmaceuticals LLC	4/11/2007	4/15/2007	11/30/2012		Expired	2,511,993.92	2056
<b>3</b> V797P-5244E	Almatica Inc.	6/6/2011	6/15/2011	12/31/2015		Active	1,852,765.00	1476
<b>4</b> V797P-5250E	Alvogen Inc.	6/24/2011	7/1/2011	12/31/2015		Active	639,805.00	1460
<b>5</b> V797P-5987X	Akrimax Pharmaceutical Inc.	2/28/2008	3/1/2008	7/31/2011		Expired	8,097,668.67	1247
<b>5</b> V797P-5126E	ViiV HealthCare Company	12/22/2009	1/1/2010	5/31/2013		Expired	158,792,077.80	1246
<b>7</b> V797P-2007E	Rouses Point Pharmaceuticals LLC	12/15/2011	1/1/2012	5/31/2015		Expired	595,140.00	1246
<b>B</b> V797P-5179E	Amedra Pharmaceuticals	2/3/2011	2/15/2011	4/30/2014		Expired	17,304,592.00	1170
<b>9</b> V797P-5170E	Prasco LLC	1/20/2011	2/1/2011	12/31/2013		Expired	44,168,972.60	1064
<b>0</b> V797P-5203E	ApoPharma USA Inc.	12/23/2010	1/1/2011	11/14/2013		Expired	4,171,920.00	1048
<b>1</b> V797P-5886X	Octapharma USA Inc.	5/7/2008	5/15/2008	2/28/2011		Expired	0.00	1019
<b>2</b> V797P-5976X	Cobalt Laboratories Inc.	1/24/2008	2/1/2008	11/1/2010		Expired	18,296.31	1004
<b>3</b> V797P-5129E	Leo Pharma Inc.	6/14/2010	7/1/2010	12/31/2012		Expired	38,667,914.48	914
<b>4</b> V797P-5870X	Septodont Inc.	1/1/2006	1/1/2006	6/1/2008		Expired	746,608.10	882
<b>5</b> V797P-5202E	Orphan-Europe, SARL	6/30/2011	7/15/2011	12/31/2013	11/30/2013	Expired	996.00	869
<b>5</b> V797P-5267E	Bio Products Laboratory Ltd.	8/25/2011	9/1/2011	12/31/2013		Expired	0.00	852
<b>7</b> V797P-5016E	Emmaus Medical Inc.	8/11/2008	8/15/2008	12/14/2010		Expired	1,295.35	851

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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						Active or	Total FSS Sales Through 2Q FY	No. of
Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
<b>18</b> V797P-5161E	Cangene bioPharma Inc.	6/14/2010	7/1/2010	9/14/2012		Expired	725,401.00	806
<b>19</b> V797P-5134E	Lupin Pharmaceuticals Inc.	1/6/2010	1/6/2010	6/30/2012	3/14/2012	Expired	1,929,188.09	798
<b>20</b> V797P-5219E	Avanir Pharmaceuticals	2/17/2011	3/1/2011	4/30/2013		Expired	919,755.00	791
<b>21</b> V797D-3005H	E Ariad Pharmaceuticals Inc.	3/8/2013	3/15/2013	6/30/2015	5/14/2015	Expired	2,328,881.00	790
<b>22</b> V797P-5218E	Cadence Pharmaceuticals Inc.	3/9/2011	3/15/2011	4/30/2013		Expired	1,390,155.00	777
<b>23</b> V797P-2004E	Wilshire Pharmaceuticals Inc.	1/23/2012	2/1/2012	3/31/2014	3/14/2014	Expired	3,652,423.00	772
<b>24</b> V797P-2002E	Iroko Pharmaceuticals LLC	10/28/2011	11/15/2011	11/14/2013		Expired	4,339.00	730
<b>25</b> V797D-3003H	E Rempex Pharmaceuticals Inc.	1/25/2013	2/1/2013	1/31/2015		Expired	4,587.78	729
<b>26</b> V797P-5254E	West-Ward Pharmaceuticals	8/25/2011	9/1/2011	8/14/2013		Expired	322,763.37	713
<b>27</b> V797P-5184E	BTG International Inc.	10/22/2010	11/1/2010	9/30/2012		Expired	2,670,494.00	699
28 V797D-3010F	E Exelixis Inc.	7/18/2013	8/1/2013	10/15/2015		Active	122,275.00	698
<b>29</b> V797P-5200E	New American Therapeutics Inc.	11/3/2010	11/15/2010	3/31/2013	10/5/2012	Expired	571,803.42	690
<b>30</b> V797P-5164E	County Line Pharmaceuticals LLC	12/2/2010	12/15/2010	1/31/2013	11/1/2012	Expired	1,406,086.00	687
<b>31</b> V797P-5066E	Rouses Point Pharmaceuticals LLC	7/9/2009	7/15/2009	5/31/2011		Expired	44,140.19	685
32 V797D-3008I	E NPS Pharmaceuticals Inc.	4/25/2013	5/15/2013	3/31/2015		Expired	781,889.00	685
<b>33</b> V797P-5191E	Arbor Pharmaceuticals Inc.	10/22/2010	11/1/2010	9/1/2012		Expired	3,736,757.90	670
<b>34</b> V797P-5162E	Pernix Therapeutics LLC	11/9/2010	11/15/2010	9/15/2012		Expired	6,897.00	670

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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								<b>Total FSS Sales</b>	
		_				Actual End	Active or	Through 2Q FY	<b>No. of</b>
	Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
35	V797D-3012E	Thrombogenics Inc.	8/21/2013	9/1/2013	7/31/2015		Active	388,054.00	667
36	V797D-3013E	Aegerion Pharmaceuticals Inc.	8/21/2013	9/1/2013	7/31/2015		Active	0.00	667
37	V797P-5245E	Pharmaxis Inc.	7/15/2011	8/1/2011	4/30/2013		Expired	56,064.00	638
38	V797P-2018E	Merus Labs International Inc.	6/29/2012	7/1/2012	3/31/2014		Expired	476.00	638
39	V797P-2019E	Vansen Pharma Inc.	6/29/2012	7/1/2012	3/31/2014		Expired	505.00	638
40	V797P-2020E	Pharma Romlev Inc.	6/29/2012	7/1/2012	3/31/2014		Expired	1,495.00	638
41	V797P-5199E	Human Genome Sciences Inc.	5/2/2011	5/15/2011	1/31/2013	2/1/2013	Expired	1,067,411.00	628
42	V797D-3018E	Concordia Pharmaceuticals Inc.	10/29/2013	11/1/2013	7/31/2015		Active	809,497.00	606
43	V797P-5072E	Guerbet LLC	6/1/2009	6/15/2009	1/31/2011		Expired	46,813.00	595
44	V797P-5169E	Nautilus Neurosciences Inc.	7/7/2010	7/15/2010	4/30/2012	2/15/2012	Expired	139,880.52	580
45	V797P-5039E	Biovitrum AB	12/15/2008	12/15/2008	7/31/2010	7/15/2010	Expired	3,182,769.05	577
46	V797P-5269E	GAVIS Pharmaceuticals LLC	9/23/2011	10/1/2011	4/30/2013		Expired	4,654.00	577
47	V797P-5253E	Cumberland Pharmaceuticals Inc.	7/19/2011	8/1/2011	3/31/2013	2/14/2013	Expired	1,115,945.00	563
48	V797P-5972X	ProEthic Pharmaceuticals	11/16/2007	12/1/2007	6/15/2009	6/15/2009	Expired	76,296.55	562
49	V797P-2003E	Wallace Pharmaceuticals	10/28/2011	11/15/2011	5/14/2013		Expired	159,343.00	546
50	V797P-5163E	Dendreon Corporation	5/4/2011	5/15/2011	10/31/2012		Expired	1,254,955.00	535
51	V797P-5107E	Affordable Pharmaceuticals LLC	8/6/2009	8/15/2009	1/31/2011		Expired	7,200.85	534

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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-	Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
52	V797P-2012E	COVIS Pharmaceuticals Inc.	4/2/2012	4/15/2012	4/14/2017	9/30/2013	Expired	7,806,597.00	533
53	V797P-2013E	Insys Therapeutics Inc.	4/13/2012	4/15/2012	9/30/2013		Expired	13,598.00	533
54	V797P-2008E	Incyte Corporation	1/20/2012	2/1/2012	9/30/2013	6/30/2013	Expired	5,095,869.00	515
55	V797P-5983X	Abraxis BioScience LLC	4/7/2008	4/15/2008	8/31/2009		Expired	574,711.60	503
56	V797P-5238E	Vertex Pharmaceuticals Inc.	5/25/2011	6/1/2011	10/31/2012	10/15/2012	Expired	40,075,451.00	502
57	V797D-3023E	Galena Biopharma Inc.	1/29/2014	2/15/2014	9/30/2015		Active	137,391.00	500
58	V797P-2014E	Kedrion BioPharma Inc.	4/2/2012	4/15/2012	8/14/2013		Expired	888,331.00	486
59	V797D-3001E	Macoven Pharmaceuticals LLC	11/1/2012	11/1/2012	6/30/2014	3/1/2014	Expired	307.00	485
60	V797P-5124E	Somerset Pharmaceuticals Inc.	10/5/2009	10/15/2009	1/31/2011		Expired	194,072.50	473
61	V797P-5002B	Adolor Corporation	8/11/2008	8/15/2008	11/30/2009		Expired	76,926.02	472
62	V797P-2005E	Seattle Genetics Inc.	12/6/2011	12/15/2011	3/31/2013		Expired	3,439,179.00	472
63	V797P-5185E	Actient Pharmaceuticals LLC	10/22/2010	11/1/2010	4/30/2012	2/15/2012	Expired	11,801,379.00	471
64	V797D-3019E	Marathon Pharmaceuticals LLC	11/18/2013	12/1/2013	3/14/2015		Expired	673,663.00	468
65	V797P-2011E	Halozyme Therapeutics Inc.	3/14/2012	3/15/2012	6/14/2013		Expired	42,510.00	456
66	V797P-2016E	Corcept Therapeutics	4/30/2012	5/1/2012	7/31/2013		Expired	0.00	456
67	V797D-3026E	Orexo US Inc.	3/10/2014	4/1/2014	12/31/2015		Active	10,542.00	455
68	V797D-3027E	Amerisource Health Services Corporation dba American Health Packaging	3/10/2014	4/1/2014	8/31/2015		Active	1,153.00	455

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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						Actual End		Total FSS Sales	No. of
	Contract	Vendor Name	Awarded	Effective	Expires	Actual End Date <sup>1</sup>	Active or Expired	Through 2Q FY 2015	No. of Days <sup>2</sup>
69	V797D-3029E	Discovery Laboratories Inc.	3/10/2014	4/1/2014	6/30/2015		Active	0.00	455
70	V797P-5123E	Allos Therapeutics Inc.	10/8/2009	10/15/2009	1/31/2011	1/1/2011	Expired	1,105,126.12	443
71	V797P-5041E	ZARS Pharma Inc.	1/26/2009	2/12/2009	4/30/2010		Expired	39,311.00	442
72	V797P-5187E	Aristos Pharmaceuticals	4/13/2011	4/15/2011	6/30/2012		Expired	368.00	442
73	V797D-3031E	Raptor Pharmaceutical Corp	3/18/2014	4/15/2014	10/31/2015		Active	0.00	441
74	V797D-3034E	Theravance Inc.	4/8/2014	4/15/2014	10/1/2015		Active	21,922.00	441
75	V797P-5178E	Labopharm Pharmaceuticals LLC	8/18/2010	9/1/2010	11/14/2011		Expired	18,627.00	439
76	V797P-2021E	Zydus Pharmaceuticals (USA) Inc.	9/21/2012	9/25/2012	11/30/2013		Expired	710,161.00	431
77	V797P-5213E	NextWave Pharmaceuticals Inc.	7/15/2011	8/1/2011	9/30/2012		Expired	1,616.00	426
78	V797P-5255E	Optimer Pharmaceuticals Inc.	7/13/2011	8/1/2011	9/30/2012		Expired	623,204.00	426
79	V797P-5973X	JHP Pharmaceuticals	10/29/2007	11/1/2007	12/31/2008	12/31/2008	Expired	1,631,594.95	426
80	V797D-3037E	Nextsource Biotechnologies LLC	4/14/2014	5/1/2014	6/30/2015		Active	23,404.00	425
81	V797D-3035E	BioCSL Inc.	5/12/2014	5/15/2014	9/30/2015		Active	0.00	411
82	V797P-2026E	Vivus Inc.	9/11/2012	9/15/2012	10/31/2013		Expired	203.00	411
83	V797P-5079E	Alkermes Inc.	6/1/2009	6/15/2009	7/31/2010		Expired	1,177,505.00	411
84	V797P-5111E	Eurand Pharmaceuticals Inc.	11/3/2009	11/15/2009	12/31/2010		Expired	4,028,610.95	411
85	V797D-3030E	Photocure	3/18/2014	4/15/2014	6/14/2015	5/21/2015	Expired	170,698.00	401

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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	Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
86	V797P-2017E	FSC Laboratories Inc.	9/14/2012	9/15/2012	10/31/2013	10/18/2013	Expired	4,590.00	398
87	V797D-3025E	Sucampo Pharmaceuticals Inc.	3/10/2014	4/1/2014	9/30/2015	5/1/2015	Expired	47,673.88	395
88	V797D-3038E	Tolmar Pharmaceuticals Inc.	5/27/2014	6/1/2014	12/31/2015		Active	436,908.00	394
89	V797P-2025E	Onyx Pharmaceuticals Inc.	9/20/2012	9/25/2012	10/14/2013		Expired	4,018,320.00	384
90	V797P-2010E	Horizon Pharma Inc.	1/24/2012	2/1/2012	1/31/2013		Expired	64,062.00	365
91	V797D-3024E	IGI Laboratories Inc.	3/10/2014	4/1/2014	3/31/2015		Expired	369,177.00	364
92	V797D-3039E	Arbor Pharmaceuticals Ireland Limited	6/17/2014	7/1/2014	12/31/2015		Active	1,045,037.00	364
93	V797D-3040E	Vanda Pharmaceuticals Inc.	6/17/2014	7/1/2014	12/31/2015		Active	0.00	364
94	V797D-3041E	Crealta Pharmaceuticals LLC	6/17/2014	7/1/2014	9/30/2015		Active	507,821.00	364
95	V797P-5988X	Cell Therapeutics Inc.	3/24/2008	4/1/2008	3/31/2009		Expired	142,469.78	364
96	V797D-3033E	Vansen Pharma Inc.	3/24/2014	4/1/2014	3/31/2015		Expired	283.40	364
97	V797D-3036E	Dara BioSciences Inc.	4/14/2014	5/1/2014	10/31/2015	4/30/2015	Expired	2,226.00	364
98	V797P-5143E	QLT Ophthalmics Inc.	1/15/2010	1/15/2010	1/31/2011	1/1/2011	Expired	104,410.00	351
99	V797P-2022E	Prestium Pharma Inc.	9/6/2012	9/15/2012	8/31/2013		Expired	429,747.00	350
100	V797D-3042E	Vertical Pharmaceuticals Inc.	7/1/2014	7/15/2014	10/31/2015		Active	49,575.00	350
101	V797D-3043E	Kaleo Inc.	7/1/2014	7/15/2014	7/14/2015		Active	147,823.00	350
102	V797P-5146E	Impax Laboratories Inc.	2/17/2010	3/1/2010	1/31/2011		Expired	29,694.86	336

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<b>104</b> V797P-5012E Sirion Therapeutics Inc. 12/15/2008 12/15/2008 10/31/2009 Expired 14,878.16	320
105         V797P-5101E         Paladin Labs (USA) Inc.         8/7/2009         8/15/2009         6/30/2010         Expired         0.00         2	319
<b>106</b> V797D-3028E Silvergate Pharmaceuticals Inc. 3/10/2014 4/1/2014 6/30/2015 2/14/2015 Expired 108,552.00	319
<b>107</b> V797D-3045E Zylera Pharmaceuticals LLC 7/28/2014 8/15/2014 8/15/2015 Active 2,630.00	319
108         V797D-3046E         Lineage Therapeutics Inc.         7/29/2014         8/15/2014         7/31/2015         Active         1,886,547.00         3	319
109         V797P-5266E         ANI Pharmaceuticals Inc.         9/12/2011         9/15/2011         7/15/2012         Expired         417,380.00         2	304
110         V797P-5273E         ParaPRO LLC         9/12/2011         9/15/2011         8/31/2012         7/15/2012         Expired         0.00         2	304
111         V797P-5112E         ONY Inc.         9/4/2009         10/1/2009         7/31/2010         Expired         120,575.36         2	303
<b>112</b> V797D-3047E Theratechnologies Inc. 8/4/2014 9/1/2014 12/31/2015 Active 21,578.00	302
113         V797P-5896X         PharmaDerm         12/12/2007         12/15/2007         9/30/2008         Expired         0.00         2	290
<b>114</b> V797P-5154E         NeurogesX Inc.         5/7/2010         5/15/2010         2/28/2011         Expired         24,233.00         2	289
115         V797D-3044E         Durata Therapeutics U.S. Limited         7/25/2014         8/15/2014         5/31/2015         Expired         0.00         2	289
<b>116</b> V797P-5216E Eyetech Inc.         9/23/2011         10/1/2011         6/30/2012         Expired         15,124.00         2	273
117         V797P-5190E         Somaxon Pharmaceuticals Inc.         10/22/2010         11/1/2010         7/31/2011         Expired         28,311.00         2	272
<b>118</b> V797P-2023E Vidara Therapeutics Inc.         9/6/2012         9/15/2012         6/14/2013         Expired         370,183.00         2	272
119         V797D-5001E         Retrophin Inc.         9/15/2014         10/1/2014         10/31/2015         Active         4,751.00         2	272

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	Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
120	V797D-5002E	Sebela Pharmaceuticals Inc.	9/15/2014	10/1/2014	9/30/2015		Active	206,824.00	272
121	V797P-5990X	ZymoGenetics Inc.	4/8/2008	4/15/2008	12/31/2008		Expired	703,077.42	260
122	V797P-5024E	Iroko Pharmaceuticals LLC	2/13/2009	2/15/2009	10/31/2009		Expired	8,320.39	258
123	V797D-3009E	Amarin Pharma Inc.	6/3/2013	6/15/2013	2/28/2014		Expired	352,617.00	258
124	V797D-3016E	WG Critical Care LLC	8/23/2013	10/15/2013	6/30/2014		Expired	7,488.00	258
125	V797P-5100E	AMAG Pharmaceuticals Inc.	7/27/2009	8/1/2009	4/15/2010		Expired	39,671.60	257
126	V797P-5214E	CNS Therapeutics Inc.	1/14/2011	2/1/2011	12/31/2011	10/15/2011	Expired	36,132.00	256
127	V797D-3020E	Recordati Rare Disease Inc.	11/18/2013	12/1/2013	8/14/2014		Expired	846,928.46	256
128	V797P-5165E	Rhodes Pharmaceuticals L.P.	6/14/2010	6/15/2010	2/14/2011		Expired	692.00	244
129	V797P-5033e	Biotest Pharmaceutical Corporation	10/30/2008	11/1/2008	6/30/2009		Expired	263,074.49	241
130	V797D-5004E	H2-Pharma LLC	9/30/2014	11/1/2014	4/30/2016		Active	7,552.00	241
131	V797P-5147E	Zogenix Inc.	3/9/2010	3/15/2010	10/31/2010		Expired	54,546.00	230
132	V797D-5005E	Afaxys Inc.	11/6/2014	11/15/2014	7/14/2015		Active	0.00	227
133	V797D-5006E	Duchesnay USA Inc.	11/6/2014	11/15/2014	7/14/2015		Active	75,653.20	227
134	V797P-5008E	Fontus Pharmaceuticals Inc.	6/24/2008	7/1/2008	1/31/2009		Expired	6,789.74	214
135	V797P-5032E	Baxter Healthcare Corporation	12/10/2008	12/15/2008	7/14/2009		Expired	2,750,009.32	211
136	V797D-3011E	Eclat Pharmaceuticals LLC	7/18/2013	8/1/2013	2/28/2014		Expired	89,619.00	211

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

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	Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
137	V797D-5007E	Intermune Inc.	11/24/2014	12/1/2014	8/31/2015		Active	1,447,980.00	211
138	V797D-5009E	Greer Laboratories Inc.	11/24/2014	12/1/2014	8/31/2015		Active	0.00	211
139	V797P-5091E	Fougera	6/23/2009	7/1/2009	3/31/2010	1/14/2010	Expired	0.00	197
140	V797P-5133E	Novalar Pharmaceuticals Inc.	3/18/2010	4/1/2010	9/30/2010		Expired	0.00	182
141	V797D-3021E	Galen US Incorporated	1/24/2014	2/1/2014	7/31/2014		Expired	21,616.00	180
142	V797P-5042E	Microbix Biosystems Inc.	1/1/2009	1/1/2009	6/30/2009		Expired	0.00	180
143	V797D-5008E	Medac Pharma Inc.	1/14/2015	1/15/2015	7/14/2015		Active	0.00	166
144	V797D-5003E	Becton Dickinson Rx Inc.	9/30/2014	11/1/2014	4/30/2015	4/14/2015	Expired	0.00	164
145	V797P-5054E	RIT Oncology LLC	3/19/2009	4/12/2009	10/31/2009	9/15/2009	Expired	23,092.86	156
146	V797P-2015E	Edgemont Pharmaceuticals LLC	4/2/2012	4/15/2012	9/15/2012		Expired	4,542.00	153
147	V797D-3017E	CorePharma LLC	10/1/2013	10/15/2013	4/14/2014	3/14/2014	Expired	1,409,245.00	150
148	V797D-3022E	Antares Pharma Inc.	1/29/2014	2/15/2014	8/14/2014	7/1/2014	Expired	29,443.00	136
149	V797D-5010E	BioCryst Pharmaceuticals Inc.	1/26/2015	2/15/2015	8/14/2015		Active	0.00	135
150	V797D-5011E	BioDelivery Sciences International Inc.	1/26/2015	2/15/2015	8/14/2015		Active	0.00	135
151	V797D-5012E	Meridian Medical Technologies Inc.	1/26/2015	2/15/2015	8/14/2015		Active	543.00	135
152	V797D-3032E	XenoPort Inc.	3/18/2014	4/15/2014	10/14/2014	8/15/2014	Expired	78,477.00	122
153	V797P-5025E	Spectrum Pharmaceuticals Inc.	9/25/2008	10/1/2008	1/31/2009		Expired	0.00	122

All IAs Awarded in the Last 10 Years - Sorted b	v Number of Days Active
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					Actual End	Active or	Total FSS Sales Through 2Q FY	No. of
Contract	Vendor Name	Awarded	Effective	Expires	Date <sup>1</sup>	Expired	2015	Days <sup>2</sup>
154 V797P-5142E	Dyax Corp.	3/9/2010	3/15/2010	6/30/2010		Expired	0.00	107
<b>155</b> V797D-5016E	Alcon Laboratories Inc.	3/12/2015	3/15/2015	9/14/2015	6/30/2015	Active	1,880,996.00	107
156 V797D-5013E	Alimera Sciences Inc.	3/27/2015	4/1/2015	9/30/2015		Active	0.00	90
157 V797D-5015E	Keryx BioPharmaceuticals Inc.	3/27/2015	4/1/2015	9/30/2015		Active	0.00	90
<b>158</b> V797P-5053E	ProStrakan Inc.	3/6/2009	3/15/2009	6/14/2009	5/31/2009	Expired	0.00	77
159 V797D-5014E	Pari Respiratory Equipment Inc.	4/21/2015	5/1/2015	10/31/2015		Active	0.00	60
160 V797D-3015E	Hyperion Therapeutics Inc.	10/1/2013	10/15/2013	11/30/2013		Expired	0.00	46
161 V797D-5018E	Glenmark Generics Inc., USA	5/6/2015	5/15/2015	11/14/2015		Active	0.00	46
162 V797D-5019E	Omeros Corporation	5/6/2015	5/15/2015	11/14/2015		Active	0.00	46
163 V797D-5020E	Digestive Care Inc.	5/6/2015	5/15/2015	11/14/2015		Active	0.00	46
<b>164</b> V797D-5021E	Libertas Pharma Inc. dba Mayne Pharma	5/8/2015	5/15/2015	11/14/2015		Active	0.00	46
165 V797D-5022E	Protein Sciences Corporation	5/8/2015	5/15/2015	11/14/2015		Active	0.00	46
Totals							\$490,697,370.26	

#### All IAs Awarded in the Last 10 Years - Sorted by Number of Days Active

**Note 1**: If there was an actual end date, the IA was cancelled prior to the expiration date.

# Exhibit C

A	ctive IAs as of July 1,	2015 - Sorted by M	Number of Days Active

	Contract	Vendor Name	Awarded	Effective	Expires	Total FSS Sales Through 2Q FY 2015	No. of Days <sup>1</sup>
1	V797P-5031E	GE Healthcare Inc.	9/26/2008	10/1/2008	9/30/2015	\$82,487,077.70	2463
2	V797P-5244E	Almatica Inc.	6/6/2011	6/15/2011	12/31/2015	1,852,765.00	1476
3	V797P-5250E	Alvogen Inc.	6/24/2011	7/1/2011	12/31/2015	639,805.00	1460
4	V797D-3010E	Exelixis Inc.	7/18/2013	8/1/2013	10/15/2015	122,275.00	698
5	V797D-3012E	Thrombogenics Inc.	8/21/2013	9/1/2013	7/31/2015	388,054.00	667
6	V797D-3013E	Aegerion Pharmaceuticals Inc.	8/21/2013	9/1/2013	7/31/2015	0.00	667
7	V797D-3018E	Concordia Pharmaceuticals Inc.	10/29/2013	11/1/2013	7/31/2015	809,497.00	606
8	V797D-3023E	Galena Biopharma Inc.	1/29/2014	2/15/2014	9/30/2015	137,391.00	500
9	V797D-3026E	Orexo US Inc.	3/10/2014	4/1/2014	12/31/2015	10,542.00	455
10	V797D-3027E	Amerisource Health Services Corporation dba American Health Packaging	3/10/2014	4/1/2014	8/31/2015	1,153.00	455
11	V797D-3029E	Discovery Laboratories Inc.	3/10/2014	4/1/2014	6/30/2015	0.00	455
12	V797D-3031E	Raptor Pharmaceutical Corp	3/18/2014	4/15/2014	10/31/2015	0.00	441
13	V797D-3034E	Theravance Inc.	4/8/2014	4/15/2014	10/1/2015	21,922.00	441
14	V797D-3037E	Nextsource Biotechnologies LLC	4/14/2014	5/1/2014	6/30/2015	23,404.00	425
15	V797D-3035E	BioCSL Inc.	5/12/2014	5/15/2014	9/30/2015	0.00	411
16	V797D-3038E	Tolmar Pharmaceuticals Inc.	5/27/2014	6/1/2014	12/31/2015	436,908.00	394
17	V797D-3039E	Arbor Pharmaceuticals Ireland Limited	6/17/2014	7/1/2014	12/31/2015	1,045,037.00	364
18	V797D-3040E	Vanda Pharmaceuticals Inc.	6/17/2014	7/1/2014	12/31/2015	0.00	364
19	V797D-3041E	Crealta Pharmaceuticals LLC	6/17/2014	7/1/2014	9/30/2015	507,821.00	364
20	V797D-3042E	Vertical Pharmaceuticals Inc.	7/1/2014	7/15/2014	10/31/2015	49,575.00	350
21	V797D-3043E	Kaleo Inc.	7/1/2014	7/15/2014	7/14/2015	147,823.00	350
22	V797D-3045E	Zylera Pharmaceuticals LLC	7/28/2014	8/15/2014	8/15/2015	2,630.00	319

**Note 1**: Number of days calculated from effective date through June 30, 2015

# Exhibit C

Active IAs as of July 1, 2015 - Sorted by Number of Days Active
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	Contract	Vendor Name	Awarded	Effective	Expires	Total FSS Sales Through 2Q FY 2015	No. of Days <sup>1</sup>
23	V797D-3046E	Lineage Therapeutics Inc.	7/29/2014	8/15/2014	7/31/2015	1,886,547.00	319
24	V797D-3047E	Theratechnologies Inc.	8/4/2014	9/1/2014	12/31/2015	21,578.00	302
25	V797D-5001E	Retrophin Inc.	9/15/2014	10/1/2014	10/31/2015	4,751.00	272
26	V797D-5002E	Sebela Pharmaceuticals Inc.	9/15/2014	10/1/2014	9/30/2015	206,824.00	272
27	V797D-5004E	H2-Pharma LLC	9/30/2014	11/1/2014	4/30/2016	7,552.00	241
28	V797D-5005E	Afaxys Inc.	11/6/2014	11/15/2014	7/14/2015	0.00	227
29	V797D-5006E	Duchesnay USA Inc.	11/6/2014	11/15/2014	7/14/2015	75,653.20	227
30	V797D-5007E	Intermune Inc.	11/24/2014	12/1/2014	8/31/2015	1,447,980.00	211
31	V797D-5009E	Greer Laboratories Inc.	11/24/2014	12/1/2014	8/31/2015	0.00	211
32	V797D-5008E	Medac Pharma Inc.	1/14/2015	1/15/2015	7/14/2015	0.00	166
33	V797D-5010E	BioCryst Pharmaceuticals Inc.	1/26/2015	2/15/2015	8/14/2015	0.00	135
34	V797D-5011E	BioDelivery Sciences International Inc.	1/26/2015	2/15/2015	8/14/2015	0.00	135
35	V797D-5012E	Meridian Medical Technologies Inc.	1/26/2015	2/15/2015	8/14/2015	543.00	135
36	V797D-5013E	Alimera Sciences Inc.	3/27/2015	4/1/2015	9/30/2015	0.00	90
37	V797D-5015E	Keryx BioPharmaceuticals Inc.	3/27/2015	4/1/2015	9/30/2015	0.00	90
38	V797D-5014E	Pari Respiratory Equipment Inc.	4/21/2015	5/1/2015	10/31/2015	0.00	60
39	V797D-5018E	Glenmark Generics Inc., USA	5/6/2015	5/15/2015	11/14/2015	0.00	46
40	V797D-5019E	Omeros Corporation	5/6/2015	5/15/2015	11/14/2015	0.00	46
41	V797D-5020E	Digestive Care Inc.	5/6/2015	5/15/2015	11/14/2015	0.00	46
42	V797D-5021E	Libertas Pharma Inc. dba Mayne Pharma	5/8/2015	5/15/2015	11/14/2015	0.00	46
43	V797D-5022E	Protein Sciences Corporation	5/8/2015	5/15/2015	11/14/2015	0.00	46
-	Totals					\$92,335,107.90	

Note 1: Number of days calculated from effective date through June 30, 2015

# Appendix A

# **Management Comments**

Department of Veterans Affairs	Memorandun
Date: SEP 2 4 2015	
	Acquisition, Logistics, and Construction (003)
subj: Office of Inspector General (OIG) Draft Agreement Under Letter Contract Num	Report: Review of GE Healthcare Inc.'s Interim ber V797P-5031E (VAIQ 7635725)
To: Director, Healthcare Resources Divisio	n, Office of Contract Review (55)
comments to the conclusions set forth Interim Agreement under Letter Contra with the recommendations in the draft r Department of Veterans Affairs (VA) Na established, administered, and extended (GE) and other manufacturers of cover	s Division, Office of Contract Review requested in the draft report, "Review of GE Healthcare Inc.'s ct Number V797P-5031E," along with concurrence report. The draft report addresses whether the ational Acquisition Center (NAC) improperly ad interim agreements (IAs) with GE Healthcare Inc. ed drugs under Federal Acquisition Regulation feterans Healthcare Act of 1992, Public Law
	and Construction (OALC) has completed its review three of the recommendations, does not concur provides the following comments.
	nmend that the Principal Executive Director, Office ruction develop a plan of action with established FSS contract with GE.
term Federal Supply Schedule (FSS Inspector General's pre-award repo solicitation number M5-Q50A-03-R7 the proposal are warranted. If upda the updates within a 14 day period. final review and analysis will be con contracting officer should be able to days from receipt of report or revise	agrees that VA must enter into a definitized, long- s) contract with GE. OALC is in receipt of the rt on GE's 2014 proposal submitted under and will review and ascertain whether updates to thes are warranted, GE will be requested to provide Upon receipt of any revised/updated information, a ducted prior to negotiations. It is anticipated the render an award decision within 30-60 calendar d/updated information, whichever is later. The IA award decision is rendered. <b>Estimated completion</b>
Acquisition, Logistics, and Construc	nmend the Principal Executive Director, Office of tion develop a plan of action with established FSS contract with all 43 manufacturers with IAs.

## Appendix A

#### Page 2.

Subject: Office of Inspector General (OIG) Draft Report: Review of GE Healthcare Inc.'s Interim Agreement Under Letter Contract Number V797P-5031E (VAIQ 7635725)

OALC Response: Concur. Although the draft report references 43 active IAs as of July 1, 2015, as of September 3, 2015, there are currently only 41 active IAs. (The other two IAs were cancelled between July 1, 2015, and September 3, 2015, once the covered drug manufacturers were awarded long-term FSS contracts.) For 31 of the 41 IAs, the covered drug manufacturers have submitted proposals to VA to obtain longterm FSS contracts. The remaining 10 covered drug manufacturers with IAs have not yet submitted a proposal. A detailed action plan for each of the 41 IA holders will be developed. These action plans also will include action for any IA holder's nonresponsiveness to our request for submission. Each IA will be amended to include a negotiated definitized schedule as required by FAR 16.603 and will include at a minimum: (1) planned submission date of proposal from covered drug manufacturer with interim agreement (if applicable); (2) planned completion date for submission of proposal clarification(s); (3) planned submission date of proposal to OIG for pre-award review (if applicable); (4) planned date of proposal negotiation completion; and (5) planned date to render awarded decision. Estimated completion date to establish all 41 action plans: November 30, 2015.

**c.** Recommendation 3: We recommend the Principal Executive Director, Office of Acquisition, Logistics, and Construction establish policies to ensure all future IAs are limited to new manufacturers of covered drugs and do not exceed the prescribed 120 day limit currently used by the NAC, or establish policy allowing 180 days as permitted by FAR. Policy should ensure Contracting Officers are held accountable for non-compliance.

**OALC Response:** Concur. OALC agrees that controls and processes do need to be put into place to ensure future IAs are limited to new manufacturers of covered drugs only. We also agree that many of the IAs were extended to the extreme, and that new processes and procedures should be established to keep future IAs within a reasonable period.

OALC will develop new processes and controls, which will encompass: (1) required research to ascertain if manufacturer has any other existing contract before contemplating entering into an IA; (2) a process for ensuring covered drug manufacturers are compliant with the P.L. requirements; (3) IA format and procedures to ensure IA is established timely, properly, and contain a realistic definitization schedule; (4) a report mechanism to monitor IA schedules and milestones; and (5) guidelines for implementing penalties against non-complying covered drug manufacturers. **Estimated completion date:** January 30, 2016.

# Appendix A

Page 3.

Subject: Office of Inspector General (OIG) Draft Report: Review of GE Healthcare Inc.'s Interim Agreement Under Letter Contract Number V797P-5031E (VAIQ 7635725)

d. **Recommendation 4**: We recommend the Principal Executive Director, Office of Acquisition, Logistics, and Construction direct the P.L. Policy Group to review and justify the appropriateness of VA's policy that prices under an IA cannot be used in performing the dual calculation.

**OALC Response:** Concur. The P.L. Policy Group Chairperson will bring the issue to all members of the group, which is comprised of NAC, OIG, Office of General Counsel, and VA's Pharmacy Benefit Management representatives, to review immediately. **Estimated completion date:** October 31, 2015.

3. Should you have any questions regarding this submission, please contact Melanie Griffin, at (202) 461-6626 or melanie.griffin@va.gov.

Gregory L. Giddens

# Appendix B

# **OIG Contact and Staff Acknowledgements**

OIG Contact	Maureen Regan
Acknowledgments	Mark Myers Gary Petrovich
	Michael Wazybok

# Appendix C

# **Report Distribution**

### **VA Distribution**

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## **Non-VA Distribution**

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National Veterans Service Organizations
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This report is available on our web site at <u>www.va.gov/oig</u>.