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AIDS HEALTHCARE FOUNDATION
7

8 UNITED STATES DISTRICT COURT
9 FOR THE CENTRAL DISTRICT OF CALIFORNIA
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12 AIDS HEALTHCARE FOUNDATION,
13 a California non-profit public-benefit
corporation,
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Plaintiff,
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v.
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17 APEXUS, LLC, a Delaware limited-
liability company,
18

Defendant.
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Case No.

COMPLAINT FOR DAMAGES

- 1. **Breach of Contract**
- 2. **Breach of the Implied Covenant of Good Faith and Fair Dealing**
- 3. **Unlawful, Unfair, or Fraudulent Business Practices**
- 4. **Declaratory Relief**

DEMAND FOR JURY TRIAL

20
21 Plaintiff AIDS Healthcare Foundation (“AHF”), by and through its counsel of
record, states the following for its Complaint against defendant Apexus, LLC
22 (“Apexus”) seeking damages and equitable relief.
23

NATURE OF THIS LAWSUIT

24 1. AHF is a not-for-profit safety-net medical care and services provider
25 focusing on people of limited economic means living with HIV/AIDS. AHF relies on
26 the Health Resources & Services Administration’s (“HRSA”) Section 340B Prime
27 Vendor Program—the management of which HRSA has contracted to Apexus—as a
28

1 lifeline to obtain sub-ceiling Section 340B HIV/AIDS prescription drug pricing. AHF
2 brings this civil action to recover the millions of dollars lost as a result of Apexus' failure
3 to act fairly, in good faith, and without discrimination, to negotiate sub-ceiling Section
4 340B discounts on HIV/AIDS prescription drugs, pursuant to its contractual obligations.
5 Moreover, AHF seeks specific performance, ordering Apexus to fulfill its contractual
6 obligations fairly, in good faith, and without discrimination going forward, and/or an
7 injunction preventing Apexus from committing unlawful, unfair, or fraudulent business
8 practices in the performance of its Section 340B Prime Vendor Program obligations.

9 **THE PARTIES**

10 2. Established in 1987, AHF is a California not-for-profit, public benefit, tax
11 exempt, 501(c)(3) corporation, domiciled and with its principal place of business in Los
12 Angeles, California. AHF is the world's largest non-government provider of health care
13 services to people living with HIV/AIDS and is the largest private-sector provider of
14 HIV/AIDS medical care to people in the United States. AHF's mission is to provide
15 cutting edge medical care to people living with HIV/AIDS regardless of their ability to
16 pay. AHF owns and operates specialty pharmacies and health care centers to accomplish
17 its mission. AHF provides care for free to people without means of paying for it, and to
18 people of limited means who rely on government programs such as Medicaid, Medicare,
19 and the Ryan White CARE Act to pay for care. AHF is an essential safety net provider
20 for disenfranchised, high-risk HIV/AIDS populations.

21 3. AHF is informed and believes and, based thereon, alleges as follows:
22 Apexus is a Delaware limited liability company, which is a wholly-owned subsidiary of
23 Vizient, Inc. (a Delaware corporation). Vizient, Inc., is a healthcare advisory business
24 with a contract portfolio that represents more than \$130 billion in annual purchasing
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1 volume,¹ and \$409.8 million in self-reported total provider and healthcare revenue in
2 2021.²

3 **SUBJECT-MATTER JURISDICTION**

4 4. This Court has subject matter jurisdiction over this civil action because the
5 amount of money in controversy exceeds \$75,000, exclusive of interest and costs, and
6 AHF and Apexus are citizens of different U.S. states. 28 U.S.C. § 1332.

7 **VENUE**

8 5. This judicial district is the proper venue for this civil action, because: (a)
9 Apexus conducts business within this judicial district; (b) Apexus is subject to personal
10 jurisdiction within this judicial district with respect to this civil action; and/or (c) a
11 substantial part of the events or omissions giving rise to the claim occurred within this
12 judicial district. 28 U.S.C. § 1391; Cal. Bus. & Prof. Code § 16750.

13 **STATEMENT OF FACTS**

14 6. Section 340B of the Public Health Services Act (42 U.S.C. 256b) sets
15 ceilings on prices drug manufacturers may charge for medications sold to specified non-
16 profit health-care facilities—known as covered member entities—which are dominantly
17 local providers of medical care for the indigent. The 340B Drug Pricing Program is
18 administered by HRSA, which is an agency of the Department of Health and Human
19 Services. Pharmaceutical manufacturers that wish to offer their products in the Medicaid
20 program are required to offer Section 340B prices on those drugs to covered member
21 entities, as a condition of participating in the Medicaid program.

22 7. A statutory formula determines the 340B ceiling price, which is the highest
23 price a manufacturer can charge to covered member entities enrolled in the 340B Drug
24 Pricing Program. Without the resources generated by the 340B Drug Pricing Program

25
26 ¹ Vizient Announces 21 New, Renewed or Expanded Members Agreements in Q2 (Sept.
27 26, 2022), <https://newsroom.vizientinc.com/vizient-announces-22-new-renewed-or-expanded-member-agreements-in-q2.htm?pressrelease> (last accessed November 8, 2022).

28 ² Management Consulting Firms Ranked by 2021 Total Healthcare Revenue, *Modern Healthcare*, August 15, 2022, p. 32.

1 discounts, many safety-net hospitals and clinics would have to reduce services for low-
2 income individuals—or, in some cases, close their doors and cease providing services.³

3 8. Additionally, HRSA awards a Prime Vendor Program (“PVP”) contract, to
4 an organization responsible for administering the 340B Drug Pricing Program, and for
5 negotiating additional sub-ceiling pricing discounts for covered member entities with
6 participating manufacturers.

7 9. As a not-for-profit safety-net provider, the 340B Drug Pricing Program is a
8 lifeline that allows AHF to obtain prescription drugs at below-retail prices. With Section
9 340B savings, AHF is able to stretch its grant funds, and offer a wider range of services
10 that improve the quality of care for uninsured and under-insured vulnerable populations
11 of people living with HIV/AIDS.

12 10. Importantly, negotiated sub-ceiling 340B pricing through the PVP is vital
13 to supporting not only AHF’s HIV/AIDS safety-net programs, but also other Ryan White
14 CARE Act HIV clinics and covered member entities. Accordingly, having a 340B Prime
15 Vendor that fulfills its contractual obligations with HRSA to negotiate sub-ceiling
16 pricing is crucial to AHF, as a covered member entity, and its mission of ridding the
17 world of AIDS.

18 11. Apexus has been awarded the PVP contract by HRSA, to be the sole 340B
19 Prime Vendor, since HRSA first implemented the PVP in 1999.

20 12. Upon information and belief, HRSA entered into its current PVP contract
21 with Apexus in or about the Fall of 2019, for a term of five years.⁴

22 13. Upon information and belief, HRSA’s prior PVP contract with Apexus had a
23 five-year performance period between September 30, 2014 to September 29, 2019.

24 14. In exchange for HRSA awarding Apexus the sole PVP contracts, Apexus
25 expressly promised, upon information and belief, to “directly provide price negotiating

26 ³ About 340B & PVP, <https://www.340bpvp.com/about-340b-and-pvp> (last accessed
27 November 11, 2022).

28 ⁴ AHF submitted a Freedom of Information Act request for the current PVP contract on
July 15, 2022, but has not yet received a copy of the contract in response despite diligent
follow-up on the Freedom of Information Act request. AHF intends to amend this
Complaint, as appropriate, upon obtaining a copy of the current PVP contract.

1 services in accordance with standard business practices with the purpose of providing
2 all member entities the most advantageous sub-ceiling prices.” HRSA 340B Prime
3 Vendor Agreement, HRSA-HSB-250-2014-PVA, § 1.2. A true and correct copy of the
4 HRSA 340B Prime Vendor Agreement from 2014, HRSA-HSB-250-2014-PVA, that
5 AHF obtained via a Freedom of Information Act request, is attached hereto as Exhibit
6 A.

7 15. Upon information and belief, Apexus also represented in its proposals—
8 which are incorporated into the PVP contracts—that it had the “capacity to conduct
9 timely and successful price negotiations with all types of drug manufacturers,” a “[p]lan
10 for conducting negotiations to lower prices for member entities below 340B statutory
11 ceilings for covered outpatient drugs,” and recognized that “[o]ne of the fundamental
12 requirements of the 340B PVP agreement is to negotiate sub-340B discounts on
13 outpatient covered drugs for all participating covered entities.”

14 16. Further, upon information and belief, the PVP contracts do more than
15 merely incorporate statutory obligations. Rather, Apexus is only bound to provide price
16 negotiating services for the 340B Drug Pricing Program because it has expressly agreed
17 to do so, among other things, in exchange for being designated HRSA’s sole 340B Prime
18 Vendor under the PVP contracts.

19 17. Unfortunately, Apexus has failed to directly provide price negotiating
20 services in accordance with standard business practices when it comes to HIV/AIDS
21 drugs, and has thus failed to provide all member entities advantageous sub-ceiling prices.
22 Apexus has demonstrated it lacks the capacity and/or the desire to conduct timely and
23 successful price negotiations with manufacturers of HIV/AIDS drugs, and upon
24 information and belief, has no good faith plan to competently negotiate sub-ceiling
25 pricing on HIV/AIDS drugs for covered member entities.

26 18. For example—and as AHF has raised with Apexus—Gilead Sciences,
27 Inc.’s recent price moves on pre-exposure prophylaxis (“PrEP”) medications like
28 Descovy and Truvada are sending big shockwaves through the safety-net provider

1 community. The Descovy moves are particularly problematic, because providers rely
2 on Descovy beyond PrEP (HIV/AIDS prevention), but also for treatment of HIV in
3 conjunction with other medications. In the two-year period between January 2020 and
4 January 2022, AHF's sub-ceiling price discount has virtually disappeared for Descovy.

5 19. Additionally, the current period of rapid inflation is only exacerbating the
6 financial squeeze, as the ceiling price of key medications is rising faster than the rate of
7 reimbursement. In other words, when 340B is needed the most to support safety-net
8 programs for the underserved, the biggest pharmaceutical companies are pocketing more
9 of the money, leaving significantly less money available for already undercompensated
10 and under-reimbursed care. Apexus should not be a mere observer, but should urgently
11 be using its market power and position as the sole PVP to negotiate sub-ceiling 340B
12 pricing to offset these growing harms.

13 20. Having Apexus negotiate better sub-ceiling discounts on HIV/AIDS
14 medications through a stronger understanding and more effective negotiation strategy is
15 not merely theoretical. AHF knows better pricing is possible, because outside of the
16 PVP, the National Alliance of State and Territorial AIDS Directors ("NASTAD")
17 successfully negotiated significant discounts on antiretroviral ("ARV") drug pricing on
18 behalf of its AIDS Drug Assistance Program ("ADAP") members, and the United States
19 Department of Veterans Affairs has negotiated even better pricing.

20 21. Apexus must provide price negotiation services for HIV/AIDS medications
21 in good faith. Good faith and fair dealing in this context mean timely, sincere, and
22 aggressive efforts to obtain real results—not perfunctory acts and dilatory excuses.⁵
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25 ⁵ In June 2019, in response to repeated urging for better pricing, Apexus created the
26 HIV 340B PVP Advisory Council to help develop an ARV negotiation strategy, and
27 agreed to conduct market analysis. Apexus was transparent in its lack of understanding
28 and study of the ARV market, but aside from lip service, has demonstrated little effort
to sufficiently learn the market. This has led to squandered opportunities, including
representatives of NASTAD members declining to join forces with other covered
entities, and Apexus' continued failure to make inroads with manufacturers like Gilead
Sciences, Inc. and ViiV Healthcare.

1 26. Upon information and belief, under the terms of the PVP contracts, Apexus
2 agreed among other promises, to directly provide price negotiating services in
3 accordance with standard business practices with the purpose of providing *all* member
4 entities the most advantageous sub-ceiling prices. Upon information and belief, it also
5 represented it had the capacity to conduct timely and successful price negotiations with
6 *all* types of drug manufacturers and a plan for conducting negotiations to lower prices
7 for member entities below Section 340B statutory ceilings for covered outpatient drugs.

8 27. A motivating purpose of the PVP contracts was to benefit covered member
9 entities, including AHF, who is an intended beneficiary.

10 28. Apexus has failed and refused, and continues to refuse, to tender its
11 performance as required by the PVP contracts, in that Apexus has failed to directly
12 provide price negotiating services in accordance with standard business practices when
13 it comes to HIV/AIDS drugs, and has thus failed to provide all member entities—
14 including Ryan White HIV/AIDS covered member entities like AHF—the most
15 advantageous sub-ceiling prices. Further, Apexus has demonstrated it lacks the capacity
16 and/or the desire to conduct timely and successful price negotiations for manufacturers
17 of HIV/AIDS drugs, and has demonstrated little effort to formulate a good faith plan to
18 competently negotiate sub-ceiling pricing on HIV/AIDS drugs for covered member
19 entities.

20 29. The failure and refusal of Apexus to perform its obligations under the
21 contracts fairly, in good faith, and without discrimination has cost AHF millions of
22 dollars in sub-ceiling Section 340B discounts on HIV/AIDS prescription drugs.
23 Moreover, AHF seeks specific performance, ordering Apexus to fulfill its contractual
24 obligations fairly, in good faith, and without discrimination going forward.

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SECOND CAUSE OF ACTION

BREACH OF THE IMPLIED COVENANT OF GOOD FAITH
AND FAIR DEALING

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4 30. AHF incorporates by this reference, as if set forth fully herein, all the
5 preceding allegations in the preceding paragraphs.

6 31. Implied in the PVP contracts are a covenant that Apexus would act in good
7 faith and deal fairly on behalf of the covered member entities, including AHF; would
8 not do anything to interfere with AHF's rights to receive the benefits due under the PVP
9 contracts; and that Apexus would give at least the same level of consideration to AHF's
10 interests as it gives to its own and its parent company's interests in price negotiating
11 services. Upon information and belief, all conditions required to make the PVP contracts
12 binding, and all conditions required for Apexus' performance had occurred.

13 32. Instead of complying with its duties, Apexus acted in bad faith and in
14 conscious disregard of AHF's rights by, among other things: failing to directly provide
15 price negotiating services in accordance with standard business practices when it comes
16 to HIV/AIDS drugs, so as to obtain for AHF the most advantageous sub-ceiling prices;
17 misrepresenting its capacity or failing to utilize its capacity to conduct timely and
18 successful price negotiations with manufacturers of HIV/AIDS drugs; failing to have or
19 act on a good faith plan to competently negotiate sub-ceiling pricing on HIV/AIDS
20 drugs; and failing and refusing to perform its obligations under the PVP contracts fairly,
21 in good faith, without discrimination, and without improper preference for the clientele
22 of its parent corporation.

23 33. In breach of the implied covenant of good faith and fair dealing, Apexus
24 did the things and committed the acts alleged above, upon information and belief, for the
25 purpose of consciously withholding from AHF (or with conscious disregard to) the rights
26 and benefits to which it is entitled as a covered member entity under the PVP contracts.
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1 34. As a direct and proximate cause of Apexus' breach of the implied covenant
2 of good faith and fair dealing, Apexus has caused AHF to lose millions of dollars in sub-
3 ceiling Section 340B discounts on HIV/AIDS prescription drugs.

4 THIRD CAUSE OF ACTION

5 UNLAWFUL, UNFAIR, OR FRAUDULENT BUSINESS PRACTICES

6 (CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.*)

7 35. AHF incorporates by this reference, as if set forth fully herein, all the
8 preceding allegations in the preceding paragraphs.

9 36. Section 17200 of the California Business and Professions Code provides
10 that unfair competition includes any unlawful, unfair or fraudulent business act or
11 practice. The remedies and penalties under Section 17200 are cumulative to those
12 imposed under the other laws.

13 37. Upon information and belief, Apexus' acts and/or omissions in unfairly
14 negotiating sub-ceiling pricing, have been undertaken to expressly benefit the clients of
15 its parent company, the healthcare management consulting firm Vizient, Inc., to the
16 detriment of covered member entities more generally, and in particular covered member
17 entities focused on the health of those living with HIV/AIDS. Upon information and
18 belief, Vizient, Inc. (and thus Apexus), has an interest in favoring its Section 340B
19 eligible hospital clients in negotiating sub-ceiling 340B pricing on the drugs most used
20 by those clients, rather than HIV/AIDS drugs. Apexus' discriminatory administration
21 of its contract in this regard, and any furtive attempts to obscure the financial preference
22 Apexus provides Vizient, Inc., constitutes unlawful, unfair, and/or deceptive business
23 practices that have and continue to harm AHF, HIV/AIDS patients, as well both Apexus
24 and Vizient, Inc.'s competitors.

25 38. Apexus' unlawful, unfair, and/or deceptive business practices have
26 deprived AHF of millions of dollars in sub-ceiling Section 340B discounts on HIV/AIDS
27 prescription drugs, while Apexus' negotiation efforts have instead been focused on drugs
28 that benefit Apexus' parent company's consulting clients. Accordingly, restitution is

1 warranted. Moreover, AHF seeks an injunction to prevent Apexus from committing
2 unlawful, unfair, or fraudulent business practices in the performance of its contractual
3 duty to attempt to negotiate advantageous sub-ceiling Section 340B discounts for all
4 covered member entities.

5 **FOURTH CAUSE OF ACTION**

6 **DECLARATORY RELIEF**

7 (CAL. CODE OF CIV. PROC. § 1060)

8 39. AHF incorporates by this reference, as if set forth fully herein, all the
9 preceding allegations in the preceding paragraphs.

10 40. Upon information and belief, an actual controversy has arisen and now
11 exists between AHF and Apexus, as to Apexus' obligations, performance, and ethics
12 concerning its contractual role as the sole PVP.

13 41. Resolution of AHF and Apexus' respective rights and duties under the
14 applicable PVP contracts by declaration of the Court will be necessary, if there exists no
15 adequate remedy at law.

16 **PRAYER FOR RELIEF**

17 Wherefore, AHF prays for relief as follows:

18 1. On the First Cause of Action for Breach of Contract:

- 19 a. Compensatory damages in an amount to be determined at trial;
20 b. For costs of suit, including if applicable reasonable attorneys' fees;
21 c. For interest on the sum of compensatory damages at the maximum
22 legal statutory rate;
23 d. For specific performance, ordering Apexus to fulfill its contractual
24 obligations fairly, in good faith, and without discrimination going forward.

25 2. On the Second Cause of Action for Breach of the Covenant of Good Faith
26 and Fair Dealing:

- 27 a. Compensatory damages in an amount to be determined at trial;
28 b. For costs of suit, including if applicable reasonable attorneys' fees;

1 c. For interest on the sum of compensatory damages at the maximum
2 legal statutory rate.

3 3. On the Third Cause of Action for Unlawful, Unfair, or Fraudulent
4 Business Practices:

5 a. For an injunction to prevent Apexus from committing unlawful,
6 unfair, or fraudulent business practices in the performance of its obligation to attempt to
7 negotiate sub-ceiling Section 340B discounts;

8 b. For restitution to AHF of the money that Apexus profited against
9 AHF by means of the unlawful, unfair, or fraudulent business practices;

10 c. For costs of suit, including if applicable reasonable attorneys' fees.

11 4. On the Fourth Cause of Action for Declaratory Relief:

12 a. For a declaration that Apexus has not fulfilled its contractual
13 obligations fairly, in good faith, and without discrimination, and/or that it has committed
14 unlawful, unfair, or fraudulent business practices concerning its administration of the
15 Prime Vendor Program.

16 For all causes of action, for other and further relief that the Court deems just and
17 proper.

18
19 **DEMAND FOR JURY TRIAL**

20 AHF demands a trial by jury of the first and second cause of action herein.

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22
23 DATED: November 18, 2022

24 By: /s/ David M. Gruen
25 Thomas A. Myers
26 Jonathan M. Eisenberg
27 David M. Gruen
28 Attorneys for Plaintiff
AIDS HEALTHCARE FOUNDATION

Exhibit A



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration
Office of Acquisition and Management
Division of Contract Services - 3
5600 Fishers Lane, Room 14W25C
Rockville, MD 20857

Date: September 26, 2014

Reference: HRSA 340B Prime Vendor Agreement
HRSA-HSB-250-2014-PVA

Apexus LLC
290 East John Carpenter Freeway
Irvine, Texas 75014

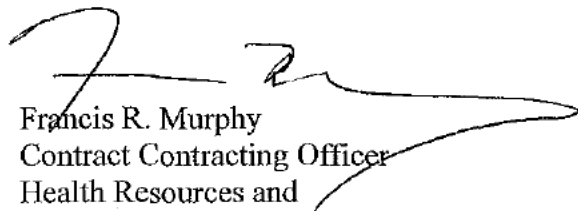
Attention: Christopher
President, Apexus

Dear Mr. Hatwig:

Enclosed is a fully executed copy of the referenced Agreement for your retention. Should you have any questions concerning the administration of this agreement, please contact me at (301) 443-5165 or write to:

Contracting Officer
Office of Acquisition Management and Policy
Health Resources and Services Administration
Parklawn Building, Room 14W31
5600 Fisher Lane
Rockville, Maryland 20857

Sincerely,


Francis R. Murphy
Contract Contracting Officer
Health Resources and
Services Administration

Enclosure (1)



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration
Office of Acquisitions Management & Policy

Parklawn Building, Room 14W31
5600 Fishers Lane
Rockville, MD 20857-5600

HRSA 340B PRIME VENDOR AGREEMENT
HRSA-HSB-250-2014-PVA

THIS HRSA 340B PRIME VENDOR AGREEMENT (the "Agreement") is entered into by and between the Health Resources and Services Administration ("HRSA"), an agency of the U.S. Department of Health and Human Services ("HHS"), and Apexus, LLC. ("Apexus"), with primary mailing address 290 East John Carter Freeway, Irving, Texas 76082.

WHEREAS, HRSA, Office of Pharmacy ("OPA"), administers the Drug Pricing Program established by Section 340B of the Public Health Service Act, as amended (42 U.S.C. 256b) ("340B Program");

WHEREAS, HRSA is the HHS agency with the delegated authority to sign the Pharmaceutical Pricing Agreement ("PPA") between participating drug manufacturers and HHS, as specified by Section 340B in order for manufacturers to provide covered outpatient drugs at or below the ceiling price established by Section 340B;

WHEREAS, HRSA is responsible for the establishment of a prime vendor program as mandated by subparagraph (a)(8) of Section 340B ("340B Prime Vendor Program"), under which the prime vendor (the "340B Prime Vendor") will develop, maintain and coordinate a program capable of distribution facilitation and other activities in support of the 340B Program;

WHEREAS, HRSA wishes to establish the 340B Prime Vendor Program via this agreement;

NOW THEREFORE, in consideration of the mutual promises contained in this Agreement, HRSA and Apexus agree as follows:

Section 1. 340B Prime Vendor Status and Responsibilities. Independently and not as an agent of the Federal Government, Apexus will perform the 340B Prime Vendor services set forth below in this Section, and adhere to the other provisions set forth in this Agreement, in exchange for being designated by HRSA as the 340B Prime Vendor for the duration of this Agreement. Apexus shall, in meeting the requirements of this Agreement, perform work in accordance with its proposal dated July 23, 2014, as amended on August 28, 2014, which is hereby incorporated into this Agreement as Attachment 1. If there is any conflict between the provisions of the proposal and the provisions of this Agreement, the provisions of this Agreement shall control.

The 340B Prime Vendor services are as follows:

1.1 Distribution Services: for all covered outpatient drugs shall be provided to member entities. In addition, other value-added catalog items may be offered to member entities. HRSA, in cooperation with other HHS components, will maintain a list of covered entities and their sites authorized to purchase covered outpatient drugs at or below 340B prices, as defined in Section 340B. This list will be made available to the 340B Prime Vendor as a searchable database. For purposes of the 340B Program, covered entities are organizations that participate in the 340B Program and are listed on HRSA's public database; whereas member entities are those covered entities that participate in the 340B Prime Vendor Program.

- 1.1.1 Supply of covered outpatient drugs sufficient to their needs shall be available to meet the orders of member entities.
- 1.1.2 Internet-based, ordering systems shall be provided by wholesaler-distributor sub-contractors, consistent with normal business practices, to each member entity, at no cost to the member entity, and appropriate for electronic order entry and inventory control. Maintenance of such systems and appropriate training in its use shall be provided. A contact person with all related contact information must be provided in the event that additional instruction is necessary.
- 1.1.3 **Fill Rate**: Wholesaler-distributor sub-contractors shall provide next-day delivery for items ordered consistent with standard business practices, with the understanding that items ordered on a Friday shall be delivered on the succeeding Monday, with a fill rate that meets or exceeds current commercial standards in the drug distribution industry. The fill rate shall be individually calculated on a monthly basis for each member entity and a fill rate report will be provided to a member entity upon request.
- 1.1.4 Delivery is required daily, Monday through Friday, or at other mutually agreed upon delivery intervals, to the delivery point established by the member entity facility's representative. Multiple delivery sites may be needed by member entities. Delivery shall be between the hours of 8:00 AM and 4:00 PM local time.
- 1.1.5 **Emergency Delivery Service** shall be provided by national, full-service wholesaler-distributor sub-contractors, twenty-four (24) hours per day, seven (7) days per week. Delivery shall occur within six (6) hours of receipt of emergency order by the wholesale-distributor sub-contractor or be deemed a failure. Such failures will be included in fill rate calculations. Emergency delivery of covered drugs required in less than six hours in life threatening situations may be procured from other than the wholesaler-distributor sub-contractor, and will be exempted from this fill rate standard.
- 1.1.6 **Back-Ordered Item**: Member entities shall be notified, as soon as possible, of any manufacturer back ordered or canceled items. This shall free the member entity to seek the product from another source if the member entity has placed an order for the items with the 340B Prime Vendor's distributor subcontractors.

- 1.1.7 **Substitution:** The wholesaler-distributor sub-contractors may not make brand or generic product substitutions within a therapeutic category that do not comply with the terms of the Apexus' authorized distribution agreements.
- 1.1.8 **Expiration Date:** Any product bearing an expiration date/shelf life requirement shall have not less than six (6) months remaining upon delivery to the member entity. Notwithstanding the preceding sentence, products that are manufactured with less than a six (6) months expiration date/shelf life shall be delivered with the best available date.
- 1.1.9 **Returns:** The wholesaler-distributor sub-contractors shall be responsible for accepting returns, in accordance with applicable laws and regulations, for credit, at no charge to the member entity under the following conditions: (1) products shipped in error; (2) products damaged in shipment; (3) products with concealed shipping damages; (4) products that do not conform to the requirements in Section 1.1.8 above, unless otherwise authorized by the Chief Pharmacist of the member entity or designated representative; (5) recalled products, regardless of level of recall; (6) outdated products that were purchased from the wholesaler-distributor sub-contractor, are returnable to the manufacturer at a credit rate allowed by the manufacturer and are unopened; and (7) products which are no longer needed if they were purchased from the wholesaler-distributor sub-contractors, returnable to the manufacturer, and are unopened. Returned products shall be credited to the ordering member entity account.
- 1.1.10 Reports shall be provided to member entities upon their request, such as standard quarterly industry drug purchasing and utilization reports, as needed.
- 1.1.11 Annually convene customer consultation groups which are made up of select representative members which promote and support the interest of covered entities to assist in the implementation of the 340B Prime Vendor Program. Provide feedback to HRSA on success of the program.

1.2 **Price Negotiation Services:** The 340B Prime Vendor shall directly provide price negotiating services in accordance with standard business practices with the purpose of providing all member entities the most advantageous sub-ceiling prices.

1.3 **Billing:** The member entity shall be responsible for all payments for products and services provided by wholesaler-distributors. Under no circumstances will HRSA be responsible for such payments. The 340B Prime Vendor will not charge member entities a fee for enrollment or participation in the 340B Prime Vendor Program.

1.4 **Member Entity Contracts:** All 340B Prime Vendor contracts with member entities shall contain no terms and conditions that are inconsistent with the terms and conditions of this Agreement, the PPA, or Section 340B or its implementing regulations or guidelines.

1.5 **Implementation Plan:** The 340B Prime Vendor shall develop an implementation plan that addresses at minimum the following areas:

1.5.1 **Communication** – The 340B Prime Vendor must contact all covered entities to inform them of the new 340B Prime Vendor Agreement, how to participate in the 340B Prime Vendor Program, and the advantages of participation, within thirty (30) days of the effective date of this Agreement.

1.5.2 **Delivery** – The 340B Prime Vendor’s wholesaler-distributor sub-contractors must begin delivery of covered outpatient drugs to the member entity at or below the ceiling price established by Section 340B, within thirty (30) days after a covered entity has joined the 340B Prime Vendor Program and placed an order for one or more covered outpatient drugs.

1.5.3 **340B Program Policies and Guidelines** – The 340B Prime Vendor must ensure that staff representatives and all subcontractors are knowledgeable in the policies and guidelines of the 340B Program and the 340B Prime Vendor Program. To facilitate the collection of purchasing volume data for all covered entities, agreements with sub-contractors must include provisions protecting the confidentiality of the covered entities’ drug purchasing information.

1.6 **Stakeholder Education and Support**: The 340B Prime Vendor shall provide training and education opportunities to all 340B stakeholders. The 340B Prime Vendor and its wholesaler-distributor sub-contractors shall also provide or make available toll-free customer service lines for all 340B stakeholders. Through this mechanism, the 340B Prime Vendor shall provide technical assistance to all stakeholders and shall promptly respond to inquiries within 3 business days. Information provided to stakeholders shall be verified and coordinated with OPA in order to maximize the value to stakeholders in meeting compliance requirements per HRSA policy.

1.7 **Value to 340B Stakeholders**: The 340B Prime Vendor shall provide a summary of, and strategic plan of activities that improve the level of support to the 340B Program. The plan shall be included in the quarterly report described in Section 1.8.1 below.

1.8 **Reports**: The 340B Prime Vendor shall provide:

1.8.1 Quarterly reports and an annual summary report to the HRSA Staff or Prime Vendor Coordinator including the following elements: (1) a summary of accomplishments for the previous quarter and program plans for the next quarter, including changes from previous reports; (2) selling prices to member entities for the current quarter, including changes from previous reports; (3) a drug distribution performance report for the previous quarter, including changes from the previous reports that includes fill rates, member entity total dollar sales, and other data, as prescribed by HRSA; (4) the results of sub-ceiling price negotiations, including changes from the previous reports; (5) other catalog products and services by selling price and changes from last report; (6) a summary of wholesaler-distributor subcontractor audits conducted (see section 6 below), including any findings and corrective action; (7) 340B purchases per covered entity at the drug level; (8) resource investment demonstrating additional value to the 340B Program and program integrity; (9) pricing discrepancy reports based on evaluation of pricing data in the market and (10) implementation plan. This information shall be provided or made accessible electronically in a mutually agreed upon format with an appropriate security protocol.

1.8.2 Pricing integrity and discrepancy reporting: The 340B Prime Vendor shall work with HRSA to develop mechanisms to assess and validate pricing data and submit a quarterly Pricing Integrity and Discrepancy report.

1.9 Deliverables. The 340B Prime Vendor shall provide the following reports:

Deliverable	Quantity	Due Date
Implementation Plan	1	Within Thirty (30) days of Effective date of Award
Quarterly Report	1	Each quarter after agreement is signed
Plan to provide value to 340B Stakeholders	1	Each quarter after agreement is signed
Annual Report	1	One month after the end of the calendar year
Pricing Integrity and Discrepancy Report	1	Each quarter after agreement is signed
Standard industry drug purchasing and utilization report	1	Each quarter after agreement is signed
Number of reports provided to member entities	1	Annually

1.10 Standards of Performance: The 340B Prime Vendor shall adhere to the following performance standards:

Performance Element	Performance Standard	Method of Surveillance
Distribution services	See Section B.1.f	<ul style="list-style-type: none"> - Contract terms - see section B.1.f of proposal - Audits to ensure compliance with contract terms - Manage pricing integrity Benchmark generics pricing
Drug price negotiation	See section B.2.d	- Contract terms- see Tab II in

		<p>Appendix.</p> <ul style="list-style-type: none"> - Manage pricing integrity - Data confidentiality management - Data systems surveillance and compliance program reporting - Price trend analysis - Market pricing analysis
Value Provided to 340B Stakeholders	See section B.3.d	<ul style="list-style-type: none"> - Growth in savings goals for sub-340B, sub-WAC, and vaccine savings as established by Apexus' Advisory Board - Enrollment monitoring and monthly reports - Monitor Apexus website utilization - Evaluate Apexus Answers customer service trends - Utilize 340B satisfaction surveys to improve programing
340B Prime Vendor Participation (including education/support)	See sections B.4. a-d	<ul style="list-style-type: none"> - Monitor marketplace for distribution and pharmaceutical contracting opportunities - Continue to monitor HRSA registrants and ensure 340B PVP enrollment - Continue quality assurance of call center inquiries and performance metrics - Review and act on satisfaction surveys - Maintain Participant Advisory councils and utilize feedback to improve programs - Monitor stakeholder educational needs and incorporate into 340B University tools
Value Added Products and Services	See section B.6	<ul style="list-style-type: none"> - Monitor marketplace for contractual and educational opportunities - Improve services by assessing participants' feedback via stakeholder polling, satisfaction surveys, advisory boards and councils, and call center.

<p>Reports</p>	<p>Apexus will continue to grow the HRSA and Participant Dashboards that provide real time reports and data based on feedback from HRSA and 340B PVP participants to meet HRSA and other key stakeholders' needs. See section B.3.a and Tab IV.</p>	<p>– Act on request and feedback from HRSA and Advisory Board/Councils to optimize our data and reporting capabilities</p>
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Section 2. Promotion. HRSA will disseminate information about the 340B Prime Vendor Program to covered entities and encourage their participation in the 340B Prime Vendor Program.

Section 3. HRSA Prime Vendor Coordinator. HRSA has designated a HRSA Prime Vendor Coordinator to provide guidance to Apexus on how to improve services for covered entities. CDR Krista M. Pedley, Director of the Office of Pharmacy Affairs will serve in that capacity. HRSA may change the Prime Vendor Coordinator at any time and will notify Apexus in writing if such a change occurs.

Section 4. No Expectation of Payment. Apexus, LLC. agrees that any services provided pursuant to this Agreement are provided without any expectation of payment from HRSA or any third party acting on HRSA's behalf, and Apexus agrees that it will not seek reimbursement for performing such services. HRSA will have no financial liability to Apexus. Nothing in this Agreement shall be deemed to be a commitment or obligation of Federal funds.

Section 5. Term and Termination. This Agreement is effective upon execution by both parties and shall have a period of performance of five (5) years (September 30, 2014 to September 29, 2019, unless terminated as set forth in this paragraph. This Agreement may be terminated by: (a) mutual written agreement of the parties, at any time; (b) HRSA, for the Government's convenience, at any time; (c) HRSA, if Apexus has defaulted, 30 or more days after written notice of the default; or (d) either party, if Apexus is unable to perform its obligations under this Agreement due to insolvency, bankruptcy, or other extraordinary business or financial situations. Apexus must notify HRSA of its intent to terminate under (d) 60 or more days in advance of such a termination, unless 60 days' notice is impracticable, in which case Apexus must notify HRSA as far in advance as practicable. Any termination of this Agreement will be at no cost to HRSA.

Section 6. Retention of Records and Auditing. Apexus shall retain all records relating to compliance with this Agreement, including purchase transactions for member entities and work papers developed for price negotiations, for 5 years after the term of this Agreement ends. These records shall be made available for examination by authorized HHS employees, including staff of HRSA and the Office of the Inspector General, or their designees.

Section 7. Site Visits. HHS staff shall have the right to visit the premises of Apexus and its wholesaler-distributor subcontractors during normal business hours, and to inspect relevant

documents for the purpose of verifying vendor cost and ascertaining compliance with the terms of this Agreement. HHS staff shall give Apexus or its wholesaler-distributor subcontractors at least 24 hours advance notice of any site visit. Apexus must ensure that the substance of this clause is included in any agreements with its wholesaler-distributor subcontractors. HRSA will review, on an annual basis, Apexus' performance and its ability to meet the requirements of the Agreement.

Section 8. Compliance with Laws and Regulations. Apexus represents and warrants that as of the date and for the duration of this Agreement, it and its wholesaler-distributor subcontractors have obtained, and will maintain, all necessary Federal, State and local licenses and permits required to conduct business in all applicable jurisdictions, and will comply with all applicable Federal and State laws and regulations. Apexus shall provide timely written notice to HRSA of actions brought against it by any governmental agency, professional licensing or regulatory agency, or private party.

Section 9. Rights in Data. HRSA shall have unlimited rights in data first produced in the performance of this Agreement and data delivered under this Agreement. The terms "unlimited rights" and "data" shall be given the same meanings as are given to those terms in the Federal Acquisition Regulation clause 52.227-14, Rights in Data--General (May 2014). In addition to the data specified elsewhere in this Agreement to be delivered, HRSA may, at any time during performance of this Agreement or within a period of 5 years after the term of this Agreement ends, order any data first produced or specifically used in the performance of this Agreement at no cost to HRSA.

Section 10. Indemnification and Hold Harmless. Apexus shall indemnify and hold HHS harmless from any and all claims, losses, liabilities, costs and expenses (including, without limitation, attorneys' fees) arising out of the negligence or intentional acts or omissions of Apexus, its employees, officers and directors, and its agents and wholesaler-distributor subcontractors, in performance of this Agreement, provided that any intentional acts or omissions subject to this Section were not directed by HHS. This obligation will apply during the term of this Agreement and thereafter.

Section 11. Disputes.

11.1 The provisions of this section are distinct from the informal dispute resolution guidelines published in Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65412, December 12, 1996, the latter of which do not apply to this Agreement.

11.2 This Agreement is subject to 41 U.S.C. chapter 71, Contract Disputes. Except as provided in 41 U.S.C. chapter 71, all disputes arising under or relating to this Agreement shall be resolved under this clause. In interpreting 41 U.S.C. chapter 71, the term "claim" shall be given the same meaning as given to that term in Federal Acquisition Regulation clause 52.233-1, Disputes (May 2014).

Section 12. Confidentiality.

12.1 Confidentiality: Apexus shall guarantee strict confidentiality of all information or data provided by the Government, member entities, or covered entities, relating to the 340B Program (including the 340B Prime Vendor Program). All Apexus staff and any subcontractor or consultant

staff that is provided such information or data, including access to databases, shall sign a confidentiality agreement, and HRSA must approve the template for the confidentiality agreement. A copy of the signed agreement for each relevant staff member shall be submitted to the Prime Vendor Coordinator prior to receipt of relevant documents.

12.2 Disclosure of information or data covered by this Confidentiality provision may only be made: after Apexus receives prior written approval from HRSA; as permitted by the confidentiality agreement; or as required by a court order, law, or regulation, in which case Apexus must give HRSA sufficient notice of the required disclosure to allow HRSA to obtain a protective order. If Apexus is uncertain with regard to the proper handling of information or data under this Agreement, it must obtain a written determination from HRSA.

12.3 The obligations in this Confidentiality provision shall apply during the term of this Agreement.

Section 13. Employee Conflicts of Interest. Apexus shall maintain written standards of conduct governing the performance of its employees and subcontractors engaged in the administration of this Agreement. No employee, officer or subcontractor nor any member of his or her immediate family shall solicit nor accept gratuities, favors, or anything of monetary value from manufacturers or wholesalers. However, Apexus may set standards for situations in which the financial interest is not substantial or the gift is an unsolicited item of nominal value. The substance of this provision must be included in any subcontracts.

Section 14. Miscellaneous.

14.1 Authority to Bind. HRSA represents that the party or parties signing below on its behalf is or are authorized to bind HRSA to this Agreement. Apexus represents and warrants that the party signing below on its behalf is authorized to bind Apexus to this Agreement.

14.2 Governing Law. This Agreement shall be governed by Federal law. To the extent any term of this Agreement is inconsistent with Federal law or regulation, the applicable Federal law or regulation shall govern.

14.3 Assignment. Apexus may not assign this Agreement, or any of its rights and responsibilities under this Agreement, without the prior, written consent of HRSA, which may be withheld for any reason or for no reason at all.

14.4 Amendment. Changes to substantive terms and conditions of this Agreement may be effected only by a written bilateral modification to the Agreement signed by both parties. Changes that are merely administrative and do not affect substantive terms and conditions to the Agreement may be made on a unilateral basis by HRSA. HRSA shall provide written notification of said changes to Apexus.

14.5 Relationship Between Parties. Nothing in this Agreement is intended to create an employment or agency relationship between the parties. Neither party shall be deemed to be an employee or agent of the other.

14.6 Communications and Deliverables. Any written notice or communication pursuant to or

regarding this Agreement shall be in writing. All notices, communications, or deliverables should be sent to the following:

Notice to HRSA:

Health Resources and Services Administration
5600 Fishers Lane, Room 14W-26
Rockville, MD 20857
Attention: HRSA Prime Vendor Coordinator and HRSA Contracting Officer
E-mail: kpiedley@hrsa.gov or fmurphy@hrsa.gov

Notice to Apexus:

Attention:

14.7 Waiver. The waiver or failure of either party to enforce the terms of this Agreement shall not constitute a waiver of that party's rights under this Agreement with respect to any other violation.

14.8 Force Majeure. Neither party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the party failing to perform. Apexus shall not be excused from strict compliance with this Agreement due to errors, omissions or failures by its subcontractors.

14.9 Integration and Severability. This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof, and supersedes all prior agreements and understandings with respect to such subject matter. If any provision is waived, illegal, invalid, or unenforceable, the legality, validity, and unenforceability of the remaining provisions shall not be affected.

14.10 Counterparts. This Agreement may be executed in any number of counterparts, each of which, when executed, shall be deemed to be an original and all of which together shall constitute one agreement.

SIGNATURE PAGE FOLLOWS

IN WITNESS WHEREOF, the duly appointed representatives of the parties have executed this Agreement as of the date(s) provided below.

Apexus:

By: Christopher A. Hartwig
Printed: Christopher A. Hartwig
Title: President, Apexus LLC
Title: _____
Title: _____
Date: October 1, 2014

HRSA:

By: Francis R. Murphy
Printed: Francis R. Murphy
Title: Contracting Officer
Title: Health Resources
Title: and Services Administration
Date: 9/24/14

HRSA:

By: Kristin M. Pedley
Printed: Kristin M. Pedley
Title: Director
Title: Office of Pharmacy Affairs
Title: Health Resources and Services Administration
Date: 9/25/14