



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

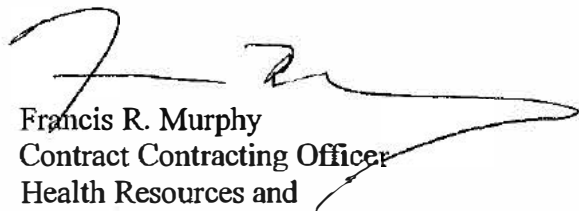
Attention: Christopher  
President, Apexus

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 I. 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 wholesale-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"> <li>- Contract terms - see section B.1.f of proposal</li> <li>- Audits to ensure compliance with contract terms</li> <li>- Manage pricing integrity Benchmark generics pricing</li> </ul>
Drug price negotiation	See section B.2.d	<ul style="list-style-type: none"> <li>- Contract terms- see Tab II in</li> </ul>

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

Reports	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.	- Act on request and feedback from HRSA and Advisory Board/Councils to optimize our data and reporting capabilities
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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: kpedley@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: \_\_\_\_\_  
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