



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Health Resources and Services Administration

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Office of Acquisition Management and Policy  
Rockville, MD 20857-5600

**HRSA 340B Prime Vendor Agreement  
HRSA-250-2019-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 with primary mailing address 290 East John Carpenter Freeway, Irving, TX. 75062.

WHEREAS, HRSA, Healthcare Systems Bureau, 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, as amended) ("340B Program");

WHEREAS, HRSA is the HHS operating division 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 offer covered entities covered outpatient drugs for purchase at or below the applicable 340B ceiling price;

WHEREAS, HRSA is responsible for the establishment of a prime vendor program as mandated by Section 340B(a)(8) ("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 implement the 340B Prime Vendor Program via this Agreement;

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

**Section 1. 340B Prime Vendor Status and Responsibilities.** Independently and not as an agent of the Federal Government, Apexus, LLC will perform the 340B Prime Vendor Program services set forth in Section 1 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. The Prime Vendor shall provide the following services:

1.1 Distribution services for all covered outpatient drugs shall be provided to member entities. In addition, other value-added catalog items and services may be offered to member

entities. HRSA 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(a)(4). This list will be made available to the 340B Prime Vendor. 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 340B 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 Equipment shall be provided, 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 equipment and appropriate training in its use shall be provided. A contact person with all related contact information must be provided to member entities in the event that additional instruction is necessary.
- 1.1.3 Drug distribution shall be conducted in a manner that meets standard business practices with respect to fill rates, delivery schedules, returns and other routine services necessary to ensure 340B drugs and the support services related to distribution are available to member entities to optimize operations.
- 1.1.4 Reports shall be provided to member entities, upon their request, such as standard industry drug purchasing, and quarterly and utilization reports.
- 1.1.5 The 340B Prime Vendor shall annually convene customer consultation groups comprised of select representative members of covered entities to assist in the implementation of the 340B Prime Vendor Program and provide feedback to HRSA on consultation group consensus responses.
- 1.1.6 The 340B Prime Vendor shall conduct routine audits of any sub-contractor fulfilling roles as set forth in this section.

1.2 340B Price Negotiation Services: The 340B Prime Vendor shall provide 340B price negotiating services in accordance with standard business practices as detailed in Volume II, Section B2– 340B Price Negotiation Services of the 340B Prime Vendor's Revised Proposal dated on November 18, 2019, with the purpose of providing all member entities the most advantageous pricing on outpatient covered drugs that may not exceed the 340B ceiling price. Reports produced under this section (1.2) shall be submitted to HRSA to ensure adherence to HRSA policy.

1.3 Billing/Compensation: The 340B Prime Vendor shall be responsible for all payments for products and services provided by sub-contractors. Under no circumstances will HRSA or HHS be responsible for such payments. The 340B Prime Vendor is prohibited from charging member entities a fee for enrollment or participation in the 340B Prime Vendor Program; however fees may be collected from other parties.

1.4 Member Entity Contracts: 340B Prime Vendor contracts with member entities shall not contain terms and conditions that are inconsistent with the terms and conditions of this Agreement, the PPA, or Section 340B of the Public Health Service Act or its implementing regulations or guidelines.

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

- 1.5.1 Communication -- The 340B Prime Vendor must contact all covered entities to inform them of this 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 Distribution -- The 340B Prime Vendor must establish the ability to distribute covered outpatient drugs to member entities through existing channels at or below the 340B ceiling price, within thirty (30) days after a covered entity has joined the 340B Prime Vendor Program.
- 1.5.3 340B Program Policies and Guidelines -- The 340B Prime Vendor must ensure that staff representatives and all subcontractors are trained and knowledgeable about the HHS requirements and guidelines governing the 340B Program and the 340B Prime Vendor Program.
- 1.5.4 Data Collection -To facilitate the collection of purchasing volume data for all covered entities, agreements with organizations, vendors or sub-contractors must include provisions protecting the confidentiality of the covered entities' drug purchasing information from unauthorized disclosure to third parties.

1.6 340B Education and Support: The 340B Prime Vendor shall provide 340B education opportunities, call center services, technical assistance and value-added activities and services.

1.6.1 The 340B Prime Vendor shall provide or make available a call center (hereby referenced as Apexus Answers) to provide technical assistance and shall respond to inquiries within 3 business days. The 340B Prime Vendor shall verify information provided with HRSA to ensure compliance with 340B statutory requirements and HRSA policy.

1.6.2 The 340B Prime Vendor shall establish training and education opportunities such as a website, FAQs, in-person trainings, and tools and resources (including social media) in alignment with HRSA policy.

1.6.3. The 340B Prime Vendor shall provide or make available value-added activities and services; which shall include the following:

**(b) (4)**

**(b) (4)**

- 340B University/Customized Training for Manufacturers and other 340B stakeholder groups
- Providing a manufacturer refund service

1.7 **Reports:** The 340B Prime Vendor shall provide the following in a mutually agreed upon format:

- 1.7.1 Quarterly reports and an annual summary report to HRSA including the following elements: (1) a summary of accomplishments from 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 price negotiations including new contracts awarded, terminated contracts, and any changes to the terms of the contracts from previous quarters including copies of reports reference in section 1.2 above; (5) other catalog products and services by selling price and changes from last report; (6) a summary of distribution audits conducted (as outlined in section 1.1), 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; and (9) pricing discrepancy reports based on evaluation of pricing data in the market. This information shall be provided or made accessible electronically in a mutually agreed upon format with an appropriate security protocol.
- 1.7.2 Final implementation plan that outlines how the terms of the agreement will be implemented and how HRSA will be informed as the activities are initiated and implemented.
- 1.7.3 Pricing integrity and discrepancy reporting: The 340B Prime Vendor shall work with HRSA to develop mechanisms to assess and validate 340B pricing data and submit a quarterly Pricing Integrity and Discrepancy report.

1.8 **Deliverables:** The 340B Prime Vendor shall provide the following reports:

<b>Deliverable</b>	<b>Quantity</b>	<b>Due Date</b>
Implementation Plan	1	Within thirty (30) days of effective date of Award
Quarterly Report	1	Each quarter after Agreement is signed

Report on Education and T.A. provided	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
Report on value added activities	1	Each quarter after Agreement is signed

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

Performance Element	Performance Standard	Method of Surveillance
Distribution Oversight	(b) (4)	Quarterly Reports. Annual Reports.
Pricing Integrity		Quarterly Reports.
340B Drug Price Negotiation		Quarterly Reports.
Data Confidentiality		Annual Report. Annual Report.
Covered Entity Enrollment		Annual Report.
Stakeholder 340B Education and Support		Call center survey consolidated annually. Learning management system and University

	<b>(b) (4)</b>	registration enrollment reports annually.
		Quarterly Reports.
Value Added Products and Services		Quarterly Reports.
Reports to HRSA		Annual Report.

**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 340B Prime Vendor Coordinator and Contracting Officer Representative.** HRSA will designate a HRSA 340B Prime Vendor Coordinator and a Contracting Officer Representative to provide guidance to the 340B Prime Vendor on how to improve services for covered entities. HRSA shall notify the 340B Prime Vendor in writing when the HRSA Prime Vendor Coordinator and the Contracting Officer Representative have been designated. HRSA may change the 340B Prime Vendor Coordinator and/or the Contracting Officer Representative at any time and will notify the 340B Prime Vendor in writing if such a change occurs.

**Section 4. No Expectation of Payment.** The 340B Prime Vendor agrees that any services provided pursuant to this Agreement are provided without any expectation of payment from either HHS, HRSA, or any third party acting on HHS or HRSA's behalf, and the 340B Prime Vendor agrees that it will not seek reimbursement from HHS or HRSA for performing such services. Neither HHS nor HRSA will have any financial liability to the 340B Prime Vendor. 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 December 31, 2019 and shall be for a three (3) years base period, followed by two (2) three (3) year option periods and one (1) one (1) year option period, for a potential term of ten years, unless terminated as set forth in this paragraph. HRSA may terminate the Agreement for any reason at any time. Any termination of this Agreement will be at no cost to HRSA or HHS.

**Section 6. Retention of Records and Auditing.** The 340B Prime Vendor 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 or audit 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 the 340B Prime Vendor and any of its 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 and/or HRSA staff shall give the 340B Prime Vendor or subcontractors at least 24 hours advance notice of any site visit. The 340B Prime Vendor shall ensure that the substance of this clause is included in any agreements with its subcontractors. HRSA will review, on an annual basis, the 340B Prime Vendor's performance and its ability to meet the requirements of the Agreement.

**Section 8. Compliance with Laws and Regulations.** The 340B Prime Vendor represents and warrants that as of the date and for the duration of this Agreement, the 340B Prime Vendor and its subcontractors have obtained, and shall maintain, all necessary Federal, State and local licenses and permits required to conduct business in all applicable jurisdictions, and shall comply with all applicable Federal and State laws and regulations. The 340B Prime Vendor shall provide timely written notice to HRSA of actions brought against the 340B Prime Vendor by any governmental agency, professional licensing or regulatory agency, or private party.

**Section 9. Rights in Data.** HHS will 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" will 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, require delivery of and/or provide access to any data first produced or specifically used in the performance of this Agreement.

**Section 10. Indemnification and Hold Harmless.** The 340B Prime Vendor 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 the 340B Prime Vendor, its employees, officers and directors, and its agents and subcontractors, in performance of this Agreement. This obligation will apply during the term of this Agreement and thereafter.

**Section 11. Disputes.**

- (a) Application. 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.
- (b) Applicable Law. This Agreement is subject to 41 U.S.C. chapter 71, Contract Disputes Act. 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.**

- (a) Confidentiality: The 340B Prime Vendor shall guarantee strict confidentiality of all Confidential Information (defined below) provided by the Government, manufacturers, member entities, or covered entities, relating to the 340B Program (including the 340B Prime Vendor Program) consistent with the terms of this Agreement. Any Confidential Information developed or provided under this Agreement shall be used only for the purpose of carrying out the provisions of this Agreement and shall not be disclosed or made known in any manner to any persons or other parts of the 340B Prime Vendor's organization that are unrelated to the performance of this Agreement. All 340B Prime Vendor staff and any subcontractor or consultant staff that are provided such Confidential Information, 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 340B Prime Vendor Coordinator prior to receipt of relevant documents.

"Confidential Information" includes, but is not limited to, drug pricing information, call center information identifiable by stakeholders, and any sales data identifiable by covered entity, information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

- (b) Disclosure of information or data covered by this Confidentiality provision may only be made: after the 340B Prime Vendor receives prior written approval from HRSA; as permitted by the confidentiality agreement; as permitted by the terms of this Agreement; or as required by a court order, law, or regulation, in which case the 340B Prime Vendor must give HRSA sufficient notice of the required disclosure to allow HRSA to obtain a protective order. If the 340B Prime Vendor is uncertain with regard to the proper handling of information or data under this Agreement, it must obtain a written determination from HRSA.
- (c) The obligations in this Confidentiality provision shall apply during the term of this Agreement and thereafter.

## **Section 13. Conflicts of Interest.**

- (a) Employee Conflict of Interest – The 340B Prime Vendor 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 other parties (including subcontractors) with a business or financial interest relating to the 340B Prime Vendor Program. Operational processes, systems and information assigned to



the Prime Vendor agreement shall operate independently from any other business operations, and firewalls should be established to ensure information is protected.

(b) Organization Conflict of Interest (OCI)--

1. **Purpose.** The purpose of this clause is to ensure that the 340B Prime Vendor and its subcontractors:
  - a) Are not biased because of their financial, contractual, organizational, or other interests which relate to the work under the Agreement, and
  - b) Do not obtain any unfair competitive advantage over other parties in other Federal acquisitions by virtue of performance of this Agreement.
2. **Scope.** The restrictions described here shall apply to performance or participation by the 340B Prime Vendor, its parents, affiliates, divisions and subsidiaries, in the activities covered by this clause. For purposes of this clause, affiliation occurs when a business concern is controlled by or has the power to control another or when a third party has the power to control both.
3. **Warrant and Disclosure.** The 340B Prime Vendor warrants that, to the best of its knowledge and belief, there are not facts or circumstances which would give rise to an organizational conflict of interest as defined by FAR Subpart 9.5 (48 CFR 9.5), and that the 340B Prime Vendor has disclosed all relevant information regarding any actual or potential conflict. The 340B Prime Vendor agrees it shall make an immediate and full disclosure, in writing, to the Contracting Officer, of any potential or actual organizational conflict of interest or the existence of any facts that may cause a reasonably prudent person to question the 340B Prime Vendor's impartiality because of the appearance or existence of bias or an unfair competitive advantage. Such disclosure shall include a description of the actions the 340B Prime Vendor has taken or proposes to take in order to avoid, neutralize, or mitigate any resulting conflict of interest.
4. **Remedies.** The Contracting Officer may terminate this Agreement, in whole or in part, if the Contracting Officer deems such termination necessary to avoid, neutralize or mitigate an actual or apparent organizational conflict of interest. If the 340B Prime Vendor fails to disclose facts pertaining to the existence of a potential or actual organizational conflict of interest, or misrepresents relevant information to the Contracting Officer, the Government may terminate the Agreement for breach or pursue other remedies as permitted by law or this contract.

5. Subcontracts. The 340B Prime Vendor shall include a clause substantially similar to this OCI clause in all subcontracts or other types of organizational agreements at any tier, and the terms will apply to the subcontractors or other related organizations in the same manner as to the 340B Prime Vendor.
6. 340B Prime Vendor Responsibilities. The 340B Prime Vendor shall obtain from its subcontractors or consultants the same disclosures required by the 340B Prime Vendor under (3), above.

**Section 14. Miscellaneous.**

- (a) Authority to Legally Bind. HRSA represents that the party or parties signing below on its behalf is or are authorized to legally bind HRSA to this Agreement. The 340B Prime Vendor represents and warrants that the party signing below on its behalf is authorized to legally bind the 340B Prime Vendor to this Agreement.
- (b) 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.
- (c) Assignment. The 340B Prime Vendor shall 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.
- (d) 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 the 340B Prime Vendor.
- (e) 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.
- (f) 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  
Rockville, MD 20857  
Attention: HRSA Contracting Officer and HRSA Contracting Officer Representative

Notice to 340B Prime Vendor:

Attention:  
Apexus, LLC  
290 East John Carpenter Freeway  
Irving, Texas 75062  
Attention: President

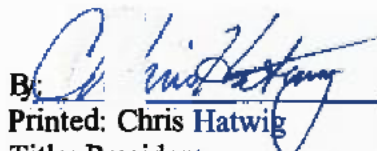
With a copy to:  
Apexus, LLC  
290 East John Carpenter Freeway  
Irving, Texas 75062  
Attention: Chief Legal Officer

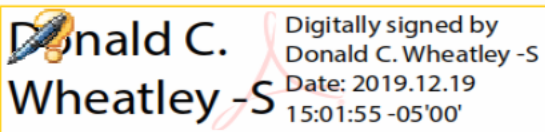
- (g) Waiver. The waiver or failure of either party to enforce the terms of this Agreement shall not constitute a waiver of that party's rights under this Agreement with respect to any other violation.
- (h) Force Majeure. Neither party shall be considered to have failed in the performance of this Agreement if such failure arises out of causes beyond the control and without the fault or negligence of the party failing to perform. The 340B Prime Vendor shall not be excused from strict compliance with this Agreement due to errors, omissions or failures by its subcontractors.
- (i) 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 in this Agreement is waived or deemed illegal, invalid, or unenforceable, the legality, validity, and enforceability of the remaining provisions shall not be affected.
- (j) 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.

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

Apexus, LLC (340B Prime Vendor):

HRSA:

By:   
Printed: Chris Hatwig  
Title: President  
Date: 12/19/19

By:   
Printed: Donald C. Wheatley, Jr.  
Title: Contracting Officer  
Date: 12/19/19