Prime Vendor Program Update
340B Coalition Annual Conference
July 15, 2013

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Founded in 2007, Apexus Inc., a non-for-profit corporation, is the Health Resources and Services Administration’s (HRSA) Office of Pharmacy Affairs (OPA) awarded contractor to serve as the prime vendor for the 340B Program.

Through HRSA’s bid process, Apexus has been consecutively awarded as HRSA’s Prime Vendor in managing the 340B Prime Vendor Program (2004-2009, 2009-2014)

Apexus represents over 15,000 340B covered entities representing 90% of 340B related purchases
340B Prime Vendor Role

- Establishes distribution solutions and networks that improve access to affordable medications

- Negotiates sub-ceiling 340B pricing on branded and generic pharmaceuticals

- Negotiates other contract pricing for entities subject to the GPO Prohibition, and contracting for other value-added pharmacy related products and services

- Provides support and education services to improve program compliance for all stakeholders
Free-Standing Cancer Hospitals (CAN) 5
Others (BL/UI/NH) 22
Hemophilia Centers (HM) 64
Rural Referral Centers (RRC) 128
Children's Hospitals (PED) 160
Sole Community Hospitals (SCH) 275
HIV Programs (Ryan White/HV) 336
Tuberculosis Clinics (TB) 766
Critical Access Hospitals (CAH) 933
Sexually Transmitted Disease (STD) 912
Title X Family Planning (FP) 2767
Community Health Centers (CHC/FQHC) 4254
Disproportionate Share Hospitals (DSH) 5019
PVP Participants by Pharmacy Distributor
15,641 Participants (July 2013)

- AmerisourceBergen: 24%
- Cardinal: 37%
- McKesson: 17%
- HD Smith: 4%
- Morris & Dickson: 4%
- R&S Sales: 7%
- Others: 7%
PVP Sub-Ceiling Savings by Entity Type 2012

- Ryan White/HIV: 7.06%
- Cancer Hospital: 3.04%
- Hemophilia Centers: 6.36%
- Children's Hospital: 5.18%
- Rural Referral Centers: 7.02%
- Critical Access Hospital: 5.52%
- Urban Indian Clinic: 9.31%
- Native Hawaiian: 8.63%
- Hospitals (DSH): 9.29%
- Tuberculosis Clinic: 17.03%
- Community Health: 17.69%
- Black Lung: 11.84%
- Sexually Transmitted: 9.54%
- Title X Family Planning: 30.25%
Policy Release: GPO Prohibition

- Published February 7, 2013
- Represents clarification of OPA policy; not new policy
- Comply by: August 7, 2013
GPO Prohibition Clarification – Purchase Flow for Some Hospitals

- **Noncompliant State**
  - 340B Registered Hospital
  - All Other (Default to GPO) (Inpatient or Non-Covered Drugs (GPO))

- **Compliant State**
  - 340B
  - All Other Out-Patient Covered Drugs (Default to Non GPO Account)
Compliant 340B In Mixed-Use Areas

Mixed-Use Inventory

Drug Order

Drug Administration

Accumulator

GPO

Non-GPO/WAC

340B
Mixed-Use Setting Accumulators and Eligibility

**Accumulator: GPO Account #1**
- Inpatients or Non-Covered Drugs

**Accumulator: Non-GPO/WAC Account #3**
- **340B ineligible outpatients:**
  - Medicaid carve-out
  - Clinics within 4-walls but not 340B eligible
  - In-house pharmacy open to public
  - Lost charges
  - PAR Level Increases

**Accumulator: 340B Account #2**
- **340B eligible outpatients only**
  - (patient meets the 340B patient definition rule)
## Wholesaler Account Setup

**-DSH/PED/CAN with GPO Prohibition**

### Inpatient
- **GPO**
  - GPO Contract
  - DSH Inpatient GPO Contracts (DSH only)
  - GPO or Wholesaler Generic Source Program
  - Individual Hospital Agreement

### Outpatient
- **Non-GPO/WAC**
  - WAC Pricing
  - PVP Sub-WAC *(if enrolled in PVP)*
  - Apexus Generic Portfolio (AGP) *(if enrolled in PVP)*
  - Individual Hospital Agreement *(single entity only)*

### Outpatient
- **340B**
  - PHS/340B *(if enrolled in PVP)*
  - Apexus Generic Portfolio (AGP) *(if enrolled in PVP)*
  - Individual Hospital Agreement *(single entity only)*
Implications for 340B Stakeholders

• **Hospitals** are setting up Non-GPO accounts, upgrading split billing systems, and updating P&Ps
  – Most incurring additional inventory expense on initial setup until PVP can establish a complete sub-WAC portfolio for Non-GPO/WAC account

• **Wholesalers** are creating the non-GPO/WAC accounts and restructuring accounts and contract loads to support compliance

• Some **split billing vendors** are modifying systems to accommodate the clarification
  – Customers converted or in the queue for conversion
• **Manufacturers** assessing their contracting options and how they will respond
  – Take no action (customer to pay WAC), engage in independent contracting with each hospital, or contract via Federal 340B PVP

• **340B PVP** working with authorized wholesalers on appropriate account setup and manufacturers to contract for the Non-GPO/WAC accounts
  – Expanded value of Apexus Generics Portfolio
  – Established new PVP Sub-WAC portfolio

• **Consultants and law firms** – new business opportunities with clients
More Challenging Product Categories

- IVIG
  - PVP compliant agreements available
- Anesthesia gases*
  - PVP compliant agreements available
- Contrast media*
  - PVP agreement pending
- IV solutions and additives*
  - PVP agreement pending

* Defined as outpatient covered drug or not within facility?
Apexus Answers Call Center

• Supporting all stakeholders and HRSA with integrity initiatives
• Supported by 6.0 FTE’s and 3 consultants
• Comprehensive Quality assurance program
• 13,508 inquiries YTD through June 25, 2013 (averaging 2251/month)
• Staff worked with HRSA to publish over 300 FAQs on 340B PVP website
• 93% client satisfaction rating YTD
Call Center: Recent Hot Topics

• How should we appropriately interpret and apply the definition of covered outpatient drug?

• What should we do about manufacturers’ decisions regarding specialty pharmacy or interpretations of covered outpatient drug?

• How can we implement the GPO prohibition in a compliant manner, esp. regarding contract and in-house pharmacies?
Apexus offers 340B University, an in-depth educational program designed for all 340B stakeholders to learn 340B compliance from industry experts. Topics covered in the training include fundamentals in implementing a compliant pharmacy program from basics to drug pricing and hands on training with tools and resources available to assist with program integrity.
What Sets the 340B U Apart?

• Works closely with HRSA to develop the content to ensure it presents the most current, conservative policy

• Selects industry experts and leading practices, including recently audited entities with no findings, to serve on its faculty

• Develops tools entities can apply to their practice setting to improve compliance
  – Partners with covered entity groups to develop customized programming
340B U Supports Compliance


- Educational: https://www.340bpvp.com/resource-center/other-resources/other-tools/

- FAQs: https://www.340bpvp.com/resource-center/faqs/
• Remaining 2013 Events
  – Chicago, Aug 24 at NACHC – CHI Institute (for CHCs)
  – Chicago, Oct 20 at ASHP Annual Leadership Conference
  – Dallas (Grapevine), Nov 7-8
  – Orlando, Dec 8 at ASHP Midyear

• 1657 graduates YTD

• 2600 graduates by year end

• Does your 340B solution vendor or consultant have a 340B U certificate of completion?
Supporting 340B and Medicaid Programs

• CMS is strongly encouraging state Medicaid agencies to develop 340B policy (access and rebate related issues)

• Apexus is facilitating education of entities and state Medicaid agencies by assisting with the development of win-win reimbursement strategies

• Key areas for the use of 340B drugs for Medicaid recipients
  – Outpatient Fee-for-service programs
  – Outpatient managed care programs
  – Outpatient physician and clinic 340B drug use on procedure based services

• Medicaid resource database

• For questions or to seek individual targeted support please call the Apexus Answers at 888-340-BPVP (2787)
Apexus Supports Compliance

- LinkedIn Groups
  - 340B University Alumni
  - 340B PVP (open)
- Twitter: https://twitter.com/Apexus340B
- YouTube: http://www.youtube.com/user/Apexus340BPVP?feature=CAQQwRs%3D
- Apexus Answers Call Center
  - Mon-Fri 8:00-5:00 CT
  - Phone: (888) 340-BPVP (340-2787)
  - Email: ApexusAnswers@340bpvp.com
  - Live Chat
Questions?