EXECUTIVE RESOURCES, LLC

COMPLIANCE ASSESSMENT PROGRAM

(EXCAP-340B)

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COMPLIANCE ASSESSMENT PROGRAM
340B PROGRAM EVALUATION
(EXCAP-340B)

I. INTRODUCTION

Executive Resources, LLC designed this **Compliance Assessment Program (EXCAP-340B)** © 2015 v.2 in order to obtain a better understanding of a client's compliance with the Section 340B Drug Pricing Program requirements and to identify potential areas of weakness and deficiencies that will be used in developing a focused program of review. This assessment tool is used in conjunction with Executive Resources, LLC **Compliance Assessment Review Program (EXCARP-340B)** © 2015 v.2 to assist in modifying our focused review compliance program and Executive Resources, LLC **Compliance Policy and Procedure Model (EXCoPP-340B)** © 2015 v.2. The questions listed herein have been selected to address issues raised on the following HRSA and affiliated sites and/or published documents:

- HRSA web site **(HRSA Website)**;
- Apexus web site **(APX)**;
- 340B University published documents **(UNIV)**;
- Covered Entity Audit findings **(AUDIT)**;
- Office of the Inspector General Reports and Web site **(OIG)**;
- Federal register Notices **(FR);**
- Program/Pricing Policy Notices **(PPN);**
- United States Code **(USC);**
- Section 340B Statute **(STAT);**
- Frequently Asked Questions (FAQ) listed on the HRSA web site **(HRSA FAQ);** and
- Frequently Asked Questions (FAQ) listed on the Prime Vendor web site **(PVP)**;
- Other Relevant Documents (OTH).

The questions in this Compliance Assessment Program (EXCAP-340B) © 2015 v.2 are followed by a reference to an official source document that can be located on the HRSA or Prime Vendor sites. HRSA has stated that Apexus, the 340B Program Prime Vendor, is authorized to release information on the 340B program requirements and provide answers to questions asked by the

industry **(FAQ # 1580)**. The responses from Apexus can be used by industry covered entities as guidance in complying with 340B requirements **(HRSA Website – OPA)**.

There are numerous questions posed to both HRSA and Apexus on a continuous basis and the FAQ's listed on the various sites represent those questions that have been asked with the most frequency and are, therefore, listed on the sites. There may be questions that are no longer included on the web sites of either HRSA or Apexus. The removal of an FAQ does not suggest that it is no longer supported by HRSA **(APX – Home Page)**. Covered Entities should still pay heed to the responses for any question that may have been published unless it has been withdrawn by regulation or other form of guidance.

HRSA has stated in its many releases that its primary concern in the security of the program is to prevent unauthorized diversion of 340B drugs and to prevent duplicate discounts. It has also stated that it is the responsibility of the covered entity to ensure compliance with the program and, therefore, is reluctant to provide specific recommendations on how to accomplish this.

The 340B database is the official list of covered entities eligible to purchase or use 340B drugs for its patients. The 340B database provides the most current information HRSA has on participating covered entities, contract pharmacy arrangements, and drug manufacturers. In addition, the 340B database signals whether covered entities bill Medicaid for 340B drugs. The 340B database gives manufacturers and wholesalers positive assurance that the purchasing/receiving site is eligible to obtain 340B drugs.

Generally, the 340B Program includes the following outpatient drugs:

- FDA-approved prescription drugs;
- Over-the-counter (OTC) drugs written on a prescription;
- Biological products that can be dispensed only by a prescription (other than vaccines); or
- FDA-approved insulin.

Participating covered entities report savings that range between 25-50% of Average Wholesale Price (AWP) for covered outpatient drugs as a result of 340B discounts.

An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

To be eligible to receive 340B-purchased drugs, patients must receive health care services other than drugs from the 340B covered entity. The only exception is patients of State operated or -funded AIDS drug purchasing assistance programs. An individual is a patient of a 340B covered entity only if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;

- The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and

- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity, with the exception of Disproportionate share hospitals.

Covered entities must have mechanisms in place to prevent duplicate discounts and should address prevention of duplicate discounts in their policies and procedures. Covered entities must choose whether they will use 340B drugs for their Medicaid patients. If they choose to do so, they must provide the HRSA Office of Pharmacy Affairs (OPA) with their pharmacy Medicaid provider number or National Provider Identifier (NPI), which is placed in the 340B Medicaid Exclusion File.

As noted in the Prime Vendor Questions and Answers section **(PVP # 1524)**, HRSA and its contracted 340B Prime Vendor Program (PVP) are the only sources of information related to the 340B program that is verified and endorsed by HRSA. The responsibility to ensure compliance with 340B program requirements remains with covered entities and manufacturers that participate. Information received from vendors, consultants and other third parties cannot be assumed to be compliant with HRSA policy. HRSA uses the HRSA contracted 340B Prime Vendor Program, managed by Apexus, to assist in communicating that policy. HRSA cannot ensure the accuracy of information provided by other sources beyond Apexus. Liability for compliance with 340B program requirements resides with the covered entity. **(PVP # 1580)** The Prime Vendor works closely with the OPA in promoting the 340B Drug Pricing Program and improving access to affordable medications for covered entities and the patients they serve. Apexus routinely reports on the program's progress to the OPA.

II. GENERAL OVERVIEW

Is the covered entity aware of the fact that it must comply with all federal, state and local laws and requirements not specifically included under a safe harbor publication (FR March 5, 2010, Page 10273, Part A, PVP # 1688), in addition to, 340B requirements?

a. **Anti-Kickback Regulations?**

b. **OIG LEIE exclusion list?**

c. **Prudent business practices (ie, paying for reasonable costs)?**

d. **Etc.?**

Is the Covered Entity aware of its obligations under the 340B Drug Program for the following (FR March 5, 2010, Page 10273, Part A & Part C (3))?

e. **It is responsible for the purchase of all 340B drugs (HRSA FAQ – 1, PPN-1)?**

f. **It must maintain title to all purchased 340B drugs (HRSA FAQ – 1, PPN-1)?**

g. **It must assume responsibility for establishing the price charged for 340B drugs (pursuant to the terms of an HHS grant, if applicable)?**

h. **It is required to follow all applicable Federal, State and local laws, in addition, to the 340B drug Program regulations and guidelines?**

Does the covered entity purchase all its covered outpatient drugs through the 340B program (PVP # 1323)?

i. **Does the covered entity search for prices that are lower than the 340B drug program, outside of the PVP?**

Has the covered entity worked with its manufacturer for repayment issues when violations are found (PVP # 1429, PVP # 1453)?

j. **Were the discussions positive?**

k. **Was the HRSA notified and provided with the following information?**

   i. **340BID;**

   ii. **The violation that occurred;**

   iii. **Scope of the problem;**

   iv. **A corrective action plan (CAP) to fix the problem moving forward;**

   v. **A strategy to inform the affected manufactures (if applicable); and**

   vi. **A plan for financial remedy if repayment is owed.**

l. **Provide copies of documentation?**

III. CONTRACT PHARMACY AND ARRANGEMENTS

How are payments made by the Contract Pharmacy to the Covered Entity?

a. **How often are payments remitted to the Covered Entity?**

b. **Are dispensing fess deducted from these remittances?**

c. **Does the Contract Pharmacy bill separately for dispensing fees?**

Do all the pharmacy contracts contain the twelve essential elements as required by the 340B Drug Program guidelines (FR March 5, 2010, Page 10277, Part C (3) (a-k))?

d. **The agreement specifies the responsibility of the parties to provide the following (FR March 5, 2010, Page 10277, Part C) (3) (b)):**

   i. **Dispensing?**

   ii. **Recordkeeping?**

iii. **Drug utilization review?**

iv. **Formulary maintenance?**

v. **Patient profile?**

vi. **Patient counseling?**

vii. **Medication therapy management services?**

viii. **Other clinical pharmacy services?**

e. **The agreement specifies that the contract pharmacy with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B drugs to individuals who are not patients of the covered entity (42 U.S.C.256b(a)(5)(B)), (FR March 5, 2010, Page 10277, Part C) (3) (g))?**

i. **Did the covered entity establish a process for periodic comparison of its prescribing records with the contract pharmacy's dispensing records to detect potential irregularities?**

ii. **Did the covered entity and the contract pharmacy develop a system to verify patient eligibility, as defined by HRSA guidelines?**

iii. **The agreement specifies that both parties agree that they will not resell or transfer a drug purchased at section 340B prices to an individual who is not a patient of the covered entity**?

Does the Covered Entity perform routine oversight of its contract pharmacy relationships? (HRSA Website – 1 & 2, HRSA FAQ - 1, PVP # 1976, PVP # 1422)

f. **Have any violations of 340B Program requirements been noted?**

g. **Were these findings disclosed to HRSA?**

h. **Was a corrective action plan prepared to address the violation?**

Does the pharmacy provide the covered with, at a minimum, reports for the following (PVP # 1450)?

i. **Quarterly Billing Statements?**

j. **Collection Reports?**

k. **Receiving Report?**

l. **Dispensing Reports?**

Does the covered entity have any contract pharmacies that use a repackager to process 340B prescriptions (PVP # 1496)?

m. **Does the covered entity retain ownership and title of the drugs that the repackager processes?**

n. **Did the covered entity sell or transfer ownership of the 340B Drugs to the repackager?**

o. **Is the repackager authorized to dispense 340B Drugs?**

IV. HRSA AND 340B DATA BASE

Does the Covered Entity regularly review the 340B data base to ensure its accuracy (AUDIT-1, AUDIT-2)?

a. **How often is this review performed?**

b. **Are these reviews documented?**

Has the covered entity reviewed the Electronic Handbook data for compliance with the 340B database? (PVP # 1463)?

c. **Have any discrepancies been noted?**

V. SOFTWARE, INTERNAL CONTROL SYSTEMS AND MANAGEMENT OF INVENTORY

What type of inventory model does the Covered Entity use with its contract pharmacies?

a. **Replenishment Inventory Model**

b. **Pre-Purchased Inventory Model**

Does the covered entity replenish at the 11 digit NDC level (PVP # 1222)?

a. **Has the covered entity replenished at the 9 digit NDC level?**

   i. **Explain the circumstances?**

   ii. **Was this documented?**

b. **Does the covered entity have a policy that addresses this situation?**

c. **Is this consistently used in contracts with Contract Pharmacies?**

Does the Covered Entity include the 340B Inventory held by the Contract Pharmacy on its Balance Sheet (HRSA FAQ Contract Pharmacy - 1, HRSA Website – 1, PVP # 1456)?

d. **If not, what is reason?**

e. **What is amount?**

f. **When was last physical inventory taken?**

   i. **Any discrepancies noted?**
   ii. **How were they resolved?**
   iii. **Did this result in 340B drugs being diverted?**

iv. **Did Covered Entity self-report to HRSA?**
v. **Was a corrective action plan developed?**

VI. EXTERNAL RELATIONSHIPS WITH CONTRACTORS

The 340b Drug Discount Program requires that the Covered Entity comply with all local, state and federal regulations. Did the Covered Entity confirm that the following contractors were not listed on the OIG's LEIE System (FR March 5, 2010, Page 10273, Part A):

a. **Eligible Professional?**

b. **Physician Assistants?**

c. **Professional Clinical Staff?**

d. **Pharmacists?**

e. **Pharmacy Staff?**

Do contracts with health care professionals include the following elements (PVP # 1213)?

f. **Provision of services regarding a legitimate medical service?**

g. **The covered entity maintains records of the eligible patient's health care services?**

h. **The responsibility for care of the eligible patient resides with the covered entity?**

VII. ELIGIBILITY

Is the covered entity classified as a "Pickle Hospital"? (PVP # 1217)

a. **Does the Hospital have the authorization letters to support the classification?**

Does the covered entity prescribe 340B Drugs to its employees (PVP # 1435)?

b. Does the covered entity maintain records of care of the individual's health care (HRSA Website - 3)?

c. Does the individual receive health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity (HRSA Website - 3)?

d. Relative to Non DSH hospitals - Does the individual receive a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity (HRSA Website - 3)?

Does the covered entity have written policies and procedures that describes the process in place to identify 340B eligible patients (PVP # 1383, UNIV-5, UNIV-6)?

e. Are there records supporting the eligible patient's medical care?

f. Are the health care services provided by a health care professional who is

i. Employed by?

ii. Under contract with?

iii. Other contractual arrangement, i.e. Referral?

g. The covered entity has responsibility for the medical care of the eligible patient?

h. The medical care is and service received is consistent with funding or designation status (hospitals are exempt)?

i. The medical services are for more than the dispensing of drugs?

VIII. NON DSH COVERED ENTITIES

Does the covered entity only prescribe 340B drugs to eligible patients who fall under the scope of the grant program approved by HRSA (PVP # 1230, PVP # 1285, PVP # 1565)?

a. **If 340B Drugs are prescribed to eligible patients who fall outside the scope of services approved by HRSA – What is the reason?**

Does the covered entity encounter situations where eligible patients, on occasion, are admitted as inpatients (PVP # 1657)?

b. **Are 340B drugs provided to these patients as a continuation of their treatment regimen while residing as an inpatient?**

c. **If so, what is the reason?**

IX. POLICIES AND PROCEDURES

Does the organization have an updated set of policies and procedures that address the Section 340B Program requirements?

a. **Reviewed on an annual basis?**
b. **Approved by the governing board?**
    i. **Are they signed?**
    ii. **Are they dated?**
c. **Approvals noted in the minutes of the board?**
d. **Are the procedures included in the policies or are they separate and distinct?**

Does the organization have policies that address the following situations?

a. **Section 340B Audit Policy**
    i. **Internal Review**
    ii. **External Review**

b. Responsibility for Section 340B Compliance

- **Section 340B Internal Reporting Process**
- **Maintenance of OPA Database**
- **Drug Diversion Prohibition**
- **Duplicate Discounts Prohibition and Medicaid Exclusion File (PPN-2)**
- **Use of Section 340B Revenues**
- **Agreements with Contract Pharmacies**
- **Excluded Providers**
- **Health Care Professionals**
- **Section 340B In Service Training**
- **Section 340B Pharmacy Policy**
- **Section 340B Inventory Tracking System**
- **Prescription Dispensing Patterns**
- **Home Deliveries of Prescriptions**
- **Compliance and Ethics Concerns**
- **Section 340B Covered Drug Shortages**
- **Compliance and Eligibility Requirements**
- **Patient Eligibility**
- **Patient Confidentiality – E Prescribing, Faxes, etc**
- **Section 340B Audit Response**
- **Section 340B Material Breach**
- **Referral Relationships**
- **Relationships with Wholesalers**
- **Others – List**
-

X. RELATIONSHIPS WITH WHOLESALERS AND MANUFACTURERS

Has Covered Entity encountered a situation where a Manufacturer denied a chargeback from a wholesaler? (PVP # 1228)

a. What was the reason?

b. Was it resolved?

i. Favorably

ii. Unfavorably

Has the covered entity experienced a situation whereby a 340B drug price was not made available by the manufacturer (APX-1, HRSA-1)?

a. Did the covered notify HRSA using the "HRSA Notification Template"?

b. **Did the covered entity document its communication with the manufacturer or wholesaler regarding the reason why the drug was not available at the 340B ceiling price?**

c. **Did the covered entity use an alternative method to purchase this drug at a non 340B price?**

d. **What type of contract was used?**

   i. **GPO?**

   ii. **WAC?**

   iii. **Special Limitation?**

   iv. **Other?**

XI. RECERTIFICATION

Did the covered entity recertify for the current fiscal year in accordance with the 340B requirements (UNIV-3, UNIV-4, STAT-1)?

a. **The database entry is complete, accurate and correct?**

b. **The Covered Entity meets 340B eligibility requirements?**

c. **The Covered Entity is in compliance with 340B requirements/restrictions?**

d. **The Covered Entity maintains auditable records?**

e. **Systems are in place to ensure compliance?**

f. **The Covered Entity obtains required information to ensure contract pharmacy compliance?**

g. **The Covered Entity will contact HRSA for any breach of the above?**

h. **The Covered Entity acknowledges the possibility of repayment to manufacturers for failure to notify HRSA in timely fashion?**

XII. DIVERSION

Does the covered entity perform periodic reviews of prescriptions issued to eligible patients to ensure that they are documented in the patients' records (AUDIT-1, Audit-2, Stat-1)?

XIII. HIPAA AND DATA SECURITY

Does the covered entity require a business associates agreement to be executed by:

a. **Wholesalers?**

b. **Vendors?**

c. **Contractors?**

d. **Consultants?**

e. **Others?**

XIV. ELIGIBILITY

Does the covered entity confirm that patients prescribed 340B Drugs meet the definition of an eligible patient as published in the Federal Register October 24, 1996 (FR October 24, 1996)?

XV. AUDIT COMPLIANCE

Does the covered entity periodically compare its prescription records with the pharmacy's dispensing records to determine if there are any discrepancies (PVP # 1450)?

a. **Prescription files?**

b. **Velocity/Inventory Reports?**

c. **Drug Orders?**

d. **Drug Receipts from manufacturer/wholesaler?**

e. **How differences are resolve?**

f. **Are violations reported to HRSA?**

Does the covered have a policy and procedure that addresses a material breach (PVP # 1539)?

g. **Has the covered entity encountered a situation whereby it has noted a material breach within its system audits?**

h. **How was this material breach addressed?**

i. **Was a correction action repot prepared?**

j. **Was the HRSA notified?**

k. **Were violations resolved with the manufacturer?**

XVI. DUPLICATE DISCOUNTS, MEDICAID PROGRAM AND EXCLUSION FILE

Does the covered have child sites with Medicaid provider numbers that are different from the parent (PVP # 1369)?

a. **Does the covered entity have child sites with multiple NPI numbers (PVP # 1495)?**

b. **Do all child sites handle Medicaid patients on a consistent basis (PVP # 1495)?**

c. **Are multiple provider numbers listed on the OPA data base (PVP # 1495, PVP #1520, PVP # 1475)?**

XVII. GROUP PURCHASING ORGANIZATION

Does the covered entity use a Group Purchasing Organization (GPO) to purchase non covered outpatient drugs (PVP # 1535, # PVP 1276)?

d. **Has the covered entity set up controls in its system to ensure that the GPO does not purchase covered outpatient drugs (AUDIT-1)?**

e. **Does the covered entity have documentation that supports its conclusion that the drugs purchased are non-covered 340B drugs?**

f. **Are the documents available upon audit?**

g. **Has the covered entity been found to be in violation of the GPO Prohibition (PVP # 1216, PVP # 1453)?**

i. **Was this reported to the manufacturer?**

ii. **Was the HRSA notified and provided with the following information?**

iii. **340BID;**

iv. **The violation that occurred;**

v. **Scope of the problem;**

vi. **A corrective action plan (CAP) to fix the problem moving forward;**

vii. **A strategy to inform the affected manufactures (if applicable); and**

viii. **A plan for financial remedy if repayment is owed.**

XVIII. DSH HOSPITALS

Does the DSH Hospital meet the requirements to be an eligible covered entity which are supported by the Medicare Cost Report submission (PVP # 1295, UNIV-1, UNIV-2)?

a. **Worksheet A, Clinics should be recorded as a separate line item;**

b. **Worksheet E, Part A, Line 33, Should reflect DSH rate greater than 11.75%;**

c. **Worksheet S-2, line 21, Should show hospital as not for profit;**

d. **Worksheet S, Should show date of eligibility; and**

e. **Worksheet C, Should show charges for operation of clinic.**

XIX. CHILDREN's HOSPITALS

Does the Children's Hospital have a CMS 3300 number (PVP # 1282)?

XX. CRITICAL ACCESS HOSPITALS

Does the CAH have a CAH designation issued by CMS?

a. **Provide a copy of the most recent designation**

XXI. FREE STANDING HOSPITAL

XXII. RURAL REFERRAL CENTER (RRC)

Does the hospital use a GPO for the purchase of 340B covered outpatient drugs (PVP # 1669)?

XXIII. SOLE COMMUNITY HOSPITAL (SCH)

Does the hospital use a GPO for the purchase of 340B covered outpatient drugs (PVP # 1669)?