


Executive Resources, LLC
Healthcare Management Consultants

We know the business of healthcare

SECTION 340B COMPLIANCE REVIEW PROGRAM



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HRSA has been conducting audits of Section 340B covered entities since 2012 to determine if they are in compliance with Program requirements. While these audits and reviews have been conducted for some time they have intensified and focused on specific areas that may give rise to compliance concerns within the industry. It would appear that these audits were spurred on by the fact that HRSA has been under pressure and criticism by members of Congress, Drug Manufacturers and the media for its lack of oversight of the 340B program.

GOVERNMENT REPORTS

- In September, 2011, the GAO released its report “Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement” The GAO concluded that HRSA’s oversight of the 340B Program was inadequate to provide reasonable assurance of compliance with program requirements.
- In February, 2014 the HHS OIG issued a report “Contract Pharmacy Arrangements in the 340B Program” It stated that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. The OIG found that most covered entities did not conduct all of the oversight activities recommended by HRSA.

HRSA AUDITS OF COVERED ENTITIES

In order to ensure that covered entities are complying with the Section 340B requirements, HRSA initiated compliance audits of covered entities. These audits focused on drug diversion and duplicate discounts. The procedures utilized by HRSA auditors included, at a minimum, the following:

- Review of relevant policies and procedures and how they are operationalized;
- Verification of eligibility, including GPO and outpatient clinic eligibility;
- Verification of internal controls to prevent diversion and duplication;
- Review of contract pharmacy compliance; and
- Testing of 340B drug transaction records.

HRSA released the results of their audits the findings covered the following areas of non compliance (not all inclusive):

- 340B Drugs dispensed to non patient at the contract pharmacy;
- Incorrect 340B database record for the authorizing official;
- Covered entity was billing the Medicaid Program when it was excluded from doing so;
- Incorrect office location and contact information;
- Drugs dispensed to ineligible patient;
- Incorrect name listed in OPA database;
- Pharmacy listed as child site;
- Prescriptions written at ineligible site;

- Contract pharmacy arrangement did not include provision to prevent duplicate discounts;
- 340B drugs shipped to pharmacy not listed on OPA database;
- NPI numbers missing;
- Ineligible providers prescribing drugs;
- Incorrect codes;
- Missing modifiers; and
- Incorrect provider numbers.

SECTION 340B COMPLIANCE REVIEW PROGRAM

In response to the needs of our clients Executive Resources, LLC developed a “**Section 340B Compliance Review Program**” that is used to assist our clients in identifying those areas of compliance and potential areas of non-compliance that may require additional review and/or change. This compliance review program represents Executive Resources interpretation of those areas that we believe covered entities are most vulnerable and present areas of risk to all covered entities. Our interpretations are based upon our understanding and analysis of the latest releases by HRSA and Federal Register publications. HRSA through the OPA has repeatedly stated that the process and procedures used by covered entities in auditing compliance with the Section 340B requirements will be left entirely up to the discretion of the individual covered entities. Therefore, HRSA will not provide specific guidelines on how a covered entity should conduct an audit of its operations or contract Pharmacies and will leave it up to the covered entities to ensure compliance.

The only requirement that HRSA has maintained is that covered entities ensure that the following be performed:

- Compliance with all federal, state and local laws;
- Procedures be implemented to avoid diversion of drugs;
- Procedures be implemented to prevent duplicate discounts;
- Maintain auditable records;
- Maintain accurate information in the database;
- Ensure that new sites and contract pharmacies are registered; and
- Recertify eligibility on an annual basis.

Executive Resources “**Section 340B Compliance Review Program**” focuses on two specific areas of review. Each area includes a separate review program:

- Covered Entity Review; and
- Contract Pharmacy Review.

The Covered Entity Review focuses on the covered entity and specific requirements that it should adhere to. The Contract Pharmacy Review focuses on each separate contract that the Covered Entity has with each Contract Pharmacy, such as Diversion, Duplicate Discounts, Inventory and the 12 Compliance Elements listed in the March 10, 2010 Federal Register.



Section 340B Compliance Review

HRSA has made it quite clear that it will be conducting audits on all covered entities through its Division of Financial Integrity. It is not a matter of if, rather when a covered entity will be audited. We believe that these audits by HRSA will be used to determine the level of compliance and, ultimately could be used as a basis for sanctions of covered entities from participating in the Section 340B Drug Pricing Program.

HRSA has stated that the covered entities are responsible for compliance with the requirements of the program and must perform their own internal reviews to ensure compliance. These internal reviews act as a mechanism to uncover weaknesses within the organization and provide opportunities to address potential problems and correct them. Failure to be proactive could potentially place the

organization at risk and subject it to disenrollment from the Section 340B Program.

EXECUTIVE RESOURCES PROFESSIONAL TEAM

EXECUTIVE professionals have operational, financial, regulatory, auditing and clinical experience that span over four decades within the healthcare industry to assist them in complying with a myriad of federal and state regulatory issues. We are known throughout the industry as problem solvers and product developers. Our professionals can assist in the performance of a Section 340B Compliance Review for those covered entities that do not have available staff to do their own

internal review and, if necessary, are prepared to implement a corrective action plan.

A sample of some of the procedures that are performed are:

- Review policies and procedures;
- Interview select management personnel;
- Determine internal controls in place as they relate to
 - * Diversion of Drugs;
 - * Duplicate Discounts;
 - * 340B Purchasing Policies; and - Other Relevant Requirements.
- Determine internal reporting processes;
- Review Inventory Tracking System;
- Perform a site visit of the independent pharmacies;
- Perform a sample of transaction records;
- Determine that sites are properly registered location;
- Review the Medicaid exclusion file for compliance;
- Determine that OPA database is covered;
- Review independent pharmacy contracts to determine that they include the necessary compliance elements recommended by HRSA;
- Review status of health care professionals;
- Review 340B application and coordinate with scope of services included in the grant application.

OTHER EXECUTIVE RESOURCES 340B PRODUCT

In addition to our "Section 340B Compliance Review Program", Executive Resources has also developed another Section 340B related product the "Section 340B Policies and Procedures Manual". This product was designed to be used by Section 340B covered entities as a template that they can modify to meet the specific needs of their individual organization. It includes 19 policies and related procedures that can be used as a base to start your own manual. Each covered entity must first determine the needs of their organization and how this manual can be incorporated into their operations. It should be stressed that upon audit, HRSA will review the policies and procedures to ensure that they are actually followed by the covered entity.

We would like the opportunity to assist your organization and to discuss Executives' "Section 340B Compliance Review Program" or "Section 340B Policies and Procedures Manual" with you.

Contact us at (732) 974-7200.

Please send our organization a copy of Executive Resource's 340B Compliance Review Program. Enclosed is our payment of \$895.00 for one copy. Remit to: Executive Resources, LLC, 1955 Hwy. 34, Suite 3-B, Wall, NJ 07719. *All programs are sent via email download upon receipt of payment.

Organization Name: _____

Contact Person/Title: _____

Address: _____

Address: _____

City, State, Zip Code: _____

Phone/Fax: _____

*Email/Website: _____

Name of Covered Entity: _____

Name(s) of Contract Pharmacy (ies): _____

XXXXXX Covered Entity		Enter State Abbreviation of Each Pharmacy
Section 340B Compliance Review		N/A
XXXXXX Contract Pharmacy		Open
CONTRACT PHARMACY REVIEW		No Exemptions
PHARMACY CONTRACT		Exemption
Procedure		
Determine that the contract with the Contract Pharmacy includes the following compliance elements:		
The covered entity purchases the drugs, maintains title to the drugs and assumes responsibility for establishing its price, pursuant to the terms of the HHS grant (if applicable) and any applicable Federal, State and local laws.		
A "ship to, bill to" procedure is used in which the covered entity purchases the drugs but ships the drugs directly to the contract pharmacy.		
The manufacturer and/or wholesaler bills the covered entity for the drugs purchased.		
In cases where the covered entity has more than one site, it may choose between having each site billed individually or designating a single covered entity billing address for all 340B drug purchases.		
Determine if the covered entity has more than one clinical site.		
Describe how the manufacturer/wholesaler bills for these sites.		
The agreement specifies the responsibility of the parties to provide comprehensive pharmacy services:		
Dispensing		
Recordkeeping		
Drug Utilization Review		
Formulary maintenance		
Patient Profiles		
Patient Counseling		
Medication Therapy Management Services		
Other Clinical Pharmacy Services		
The patient will be informed of his or her freedom to choose a pharmacy provider.		
Determine if there is documentation in the Covered Entity's records that supports that the patient was informed.		
The contract pharmacy may provide other services to the covered entity or its patients at the option of the covered entity:		
Home Care		
Delivery		
Reimbursement Services		
The Contract Pharmacy and the Covered Entity will adhere to all Federal, State, and local laws and requirements.		
Determine if the Covered Entity and the Contract Pharmacy are aware of the potential for civil or criminal penalties if either violates Federal or State law and is this documented.		