

(Insert Name of Covered Entity)

Section 340B Compliance Review

N/A

(Insert Name of Contract Pharmacy)

Open

CONTRACT PHARMACY REVIEW

No
Exception

PHARMACY CONTRACT

Exception

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/wholesale 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

(Insert Name of Covered Entity)

Section 340B Compliance Review

N/A

Open

No
Exception

Exception

COVERED ENTITY REVIEW

GENERAL ISSUES

Procedure

Obtain a copy of the Covered Entity's Table of Organization to determine those employees of the Covered Entity who are responsible for the Section 340B Drug Pricing Program

Obtain listing and position of all covered entity employees

Determine if the Covered Entity confirmed that its employees are not included on the following government exclusion lists

OIG List of Excluded Individuals Entities (LEIE)

GSA Excluded Parties List System (EPLS)

GSA System of Awards Management (SAM)

Determine how often the Covered Entity accesses the exclusion lists

Perform a test sample of the Covered Entity's employee list

Perform a cross check with the exclusion lists

Obtain a screen shot of the result from the exclusion list

Follow up with the Covered Entity on any exceptions noted

Determine the process used by the Covered Entity if an employee is found to be on the above lists

Determine if the Covered Entity confirmed that its Health Care Professionals and/or contractors are not included on the following government exclusion lists

OIG List of Excluded Individuals Entities (LEIE)

GSA Excluded Parties List System (EPLS)

GSA System of Awards Management (SAM)

Determine how often the Covered Entity accesses the exclusion lists

Perform a test sample of the Covered Entity's Health Care Professionals and/or contracts

Perform a cross check with the exclusion lists

Obtain a screen shot of the result from the exclusion list

Follow up with the Covered Entity on any exceptions noted

Determine the process used by the Covered Entity if a Health Care Professional and/or contractor is found to be on the lists