

340B Drug Pricing Program 340B Contract Pharmacy

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340B Resources

The Office of Pharmacy Affairs (OPA) - www.HRSA.gov/OPA

340B PRIME VENDOR PROGRAM (APEXUS) – [WWW.340BPVP.COM](http://www.340BPVP.COM)

Healthcare Communities - www.healthcarecommunities.org

2010 Notice Regarding 340B Drug Pricing Program - Contract
Pharmacy Services

<http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>



Agenda

340B Contract Pharmacy Background

- Elements of compliance
- Responsibilities
- Recertification

340B Contract Pharmacy Registration

- Process
- Entity selection
- System features

Live demonstration



340B Contract Pharmacy

Background:

- 1992 Enactment of Public Law 102-585, the Veterans Health Care Act: The 340B Program enables covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.
- 1995 Notice Regarding 340B Drug Pricing Program Contract Pharmacy Services: Covered entities allowed to contract with a single pharmacy.
- 2010 Notice Regarding 340B Drug Pricing Program Contract Pharmacy Services: Final guidelines, replaces all previous 340B Program guidance regarding contract pharmacy services. Covered entities allowed to contract with multiple pharmacies.



340B Contract Pharmacy

Compliance elements:

- Must have a written contract in place between itself and a specified pharmacy
- Full listing of all pharmacy locations that may be utilized under that agreement
- A “ship to, bill to” procedure is used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity for the drug that it purchased, but ships the drug directly to the contract pharmacy.
- Patient freedom to choose
- Annual audits are expected



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Covered entity and Contract pharmacy responsibilities:

- Responsibility to ensure against illegal diversion and duplicate discounts; maintain readily auditable records; and meet all other 340B Drug Pricing Program requirements.
- The operation under the contract continues to meet all 340B Drug Pricing Program requirements,
- Safeguards against diversion of covered drugs
- Adherence to all Federal, State, and local laws and requirements
- Anti-Kickback Statute



340B Contract Pharmacy

Medicaid Exclusion File:

- Neither party will use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the covered entity, the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounts. Any such arrangement shall be reported to the OPA, HRSA, by the covered entity.



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Recertification:

- information listed on the database for that covered entity is complete, accurate, and correct
- the covered entity met the 340B eligibility requirements throughout the prior year and continues to do so
- contract pharmacy arrangement was actually performed in accordance with specified requirements including, but not limited to, that the covered entity obtained sufficient information from the contractor to ensure compliance with applicable policy and legal requirements
- The methodology utilized to ensure compliance



340B Contract Pharmacy

GPO prohibition

Implications for contract pharmacies:

Organizations that are not part of the 340B covered entity are not subject to the GPO prohibition; however, the 340B covered entity is still prohibited from having organizations purchase covered outpatient drugs through a GPO on its behalf or otherwise receive covered outpatient drugs purchased through a GPO. A 340B covered entity purchases and maintains title to the drugs, not a contract pharmacy (see 75 Fed. Reg. 10272, 10277 (March 5, 2010)).

Therefore, a hospital subject to the GPO prohibition cannot use a GPO for covered outpatient drugs, even if the drugs are dispensed at a contract pharmacy. (see policy release regarding GPO prohibition for more information)

<http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpo-participation020713.pdf>



340B Contract Pharmacy Registration

How do I register my contract pharmacy?

- Register at <http://opanel.hrsa.gov/OPA/Default.aspx> during an open registration period
- Must have a fully executed written contract, do not register the contract arrangement prematurely
- Entity must be approved to participate and have a 340B ID
- Newly registered entities that have not been assigned a 340B ID, please email 340Bcontractpharmacy@HRSA.gov for further instructions.



340B Contract Pharmacy Registration

How do I register my contract pharmacy if I have multiple sites? (Parent vs child site)

- A single covered entity that has more than one 340B eligible sites at which it provides health care may have individual contracts for each such site or include multiple sites within a single pharmacy services contract.
- In cases where a 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
- More complex arrangements should be registered in the same manner as defined in the written contract.



340B Contract Pharmacy Registration

New Contract Pharmacy Registration Process

Notable changes:

- DEA register integration
- Electronic certification
- Termination requests
- Automatic address updates (in most cases)



Live Demo



Contact Information

Contract pharmacy related questions/concerns
340Bcontractpharmacy@HRSA.gov

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Change Request:
<http://www.hrsa.gov/opa/programrequirements/forms/index.html>

