



*Strengthening Oklahoma's Safety Net,
One Community At A Time*

Board Bulletin

Volume 9, Number 9 • September 2011

340B Drug Pricing Program

Access to affordable pharmaceutical services is a must to prevent patient 'churning' - seeing the same patients repeatedly who never seem to get well. A non-CHC clinic experiencing this problem found that patients left with 'scripts' in hand but never filled the prescription as there was no means to pay full price for medicine. CHCs have access to a benefit that helps prevent this type of scenario – the 340B Drug Pricing Program which provides discounts on outpatient drugs to eligible entities. While the 340B program is quite helpful in providing patients with affordable drugs, CHCs must understand requirements and avoid prohibited practices.

Improving Patient Outcomes via 340B

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585 (the Veterans Health Care Act of 1992 codified as Section 340B of the Public Health Service Act). The Health Services and Resources Administration (HRSA) Office of Pharmacy Affairs (OPA) manages the program. OPA's mission - "to promote access to clinically and cost effective pharmacy services" – is achieved by maximizing the value of participation in 340B, developing innovative pharmacy services, and serving as a federal resource for pharmacy practice.

- **Program Benefits** – 340B covered entities realize an average savings of 25-50% on outpatient drug purchases. This allows CHCs to reduce the price of pharmaceuticals for patients, expand services and increase access as well as using savings to offset the cost of providing care on a sliding fee scale.
- **Eligible Entities** – CHCs are eligible including federally qualified health center (FQHC) Look-alikes, special population health centers (migrant, homeless and public housing), recipients of healthy schools/health communities, and tribal/urban Indian organizations. The Affordable Care Act of 2010 expanded eligibility to Critical Access Hospitals, Rural Referral Centers, Sole Community Hospitals, Free Standing Cancer Hospitals, and Children's Hospitals (all of which have specific statutory definitions and must further demonstrate service to low income individuals). A complete listing of other entities can be accessed at www.hrsa.gov/opa.
- **Enrollment Process** – Eligible entities must complete appropriate registration forms (in entirety) and submit to OPA. The quarterly deadlines for application submission to OPA are December 1, March 1, June 1 and September 1 (completed applications must be received 1 month before the start of the quarter). Once enrolled, an approved entity must abide by all prohibitions and requirements of Section 340B, notify its wholesaler of the 340B ID and eligibility, and determine if contract pharmacy services are appropriate.
- **Prohibitions** – There are two program prohibitions of which to be keenly aware – diversion and duplicate discount. Diversion occurs when dispensing 340B drugs to individuals who are not CHC patients or for services not included in project scope. The other program prohibition – duplicate discount – involves receiving both a 340B discount and a Medicaid rebate on the same drug. If the CHC, as a covered entity, receives a 340B discount when purchasing the drug from the manufacturer then later the state Medicaid agency also claims a rebate from the manufacturer, a duplicate discount would have occurred and would result in Medicaid exclusion. Since Medicaid makes up 30% of Oklahoma CHC revenues, exclusion from that program due to a duplicate discount mistake would be quite costly – potentially making it impossible for a CHC to sustain operations.
- **Program Requirements** – CHCs must maintain auditable records that demonstrate 340B compliance, which may be subject to audit by the manufacturer or the government. Additionally, CHCs must notify OPA immediately if there are changes in eligibility, location, operating status, and authorizing official/contacts.
- **Contract Pharmacy Services** – CHCs can work with local pharmacies under a 'ship to bill' arrangement – the CHC retains legal title to and must pay for the 340B drugs but has them shipped directly to the contract pharmacy. The contract pharmacy is subject to audits designed to prevent diversion and duplicate discounts.

CHC boards must work with senior management to design pharmaceutical services that yield positive patient outcomes while ensuring proper 340B risk management is exercised to protect organizational resources. Additional 340B Drug Pricing Program resources can be found at www.hrsa.gov/opa. To review the entire series, visit www.okpca.org and click on the home page *Board Bulletin* link.

Oklahoma Primary Care Association
4300 N. Lincoln Blvd., Ste 203, OKC, OK 73105
(405) 424-2282, Ext. 104 • Fax (405) 424-1111 • www.okpca.org