Recent Changes to HRSA 340B Pharmacy Program

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Prime Vendor Program (PVP)

- No cost to participate/voluntary
- Drug price negotiation services
  - > 3000 drug items average 10% below 340B ceiling price
  - > $2 billion in purchase volume
- Multiple wholesale distributor agreements
  - All national and most regional wholesalers
  - Favorable distribution costs
- Other value added products/services

What is the 340B Drug Pricing Program?

- Section 340B of the Public Health Service Act
- Provides discounts on *outpatient* drugs to certain safety-net covered entities
- Covered drugs are **only** for covered entity patients
- Manufacturers that participate in Medicaid must also participate in the 340B program

340B Eligible Entities

- Federally Qualified Health Centers (FQHC)
- Comprehensive Hemophilia Treatment Centers
- Ryan White Programs (Parts A, B, C, D)
- Sexually Transmitted Disease/Tuberculosis Programs (STD/TB)
- Title X Family Planning Clinics
- Urban / 638 Tribal Programs
- Federally Qualified Health Center Look-Alikes (FQHC-LA)
- Disproportionate Share Hospitals (DSH)
- *Children's Hospitals (Pending)*

Program Benefits

- Average savings of 25-50% on outpatient drug purchases for 340B covered entities

- Savings may be used to:
  - Reduce price of pharmaceuticals for patients
  - Expand drug formularies
  - Expand services offered to patients

Slides 2-5 from HRSA Primary Care Grantee Mtg June 2008

New Interpretations of “patient”

- Federal Register: January 12, 2007
  (Volume 72, Number 8)
  Page 1543-1546

- ftp://ftp.hrsa.gov/bphc/pdf/opa/frn011207va.pdf

Rationale for clarifications

- "However, it is possible that some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program"
- "Therefore, HRSA finds it necessary to issue this Notice, and to include several ***examples*** that further illustrate the guidance"

Definition

- **Definition of a Patient**
  Under these proposed guidelines, the criteria determining whether an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) are:
- 1. The covered entity has established responsibility for the outpatient health care services it provides to the individual, such that the covered entity maintains ownership, control, maintenance, and possession of records of the individual's health care, including records that appropriately document health care services that result in the use of, or prescription for, 340B drugs;
  2. The individual receives outpatient health care services that result in the use of, or a prescription for, 340B drugs as part of the diagnosis and treatment from a health care provider who is employed by the covered entity, or provides health care to patients of the covered entity under a valid, binding, and enforceable contract. If the individual received health care services from a health care provider employed by or under contract with the covered entity, then the individual may be referred for follow up care for the same condition by that health care provider, to an outside health care provider and still remain a patient of the covered entity for purposes of this guidance, so long as ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs, remains with the covered entity; and
  3. The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, 340B drugs are:
- a. Part of a health care service or range of services for which grant funding or Federally-Qualified Health Center look-alike status has been provided to the covered entity; or
  b. Provided by a Disproportionate Share Hospital (DSH) or by a location that qualified as a provider-based facility within a DSH under 42 CFR 413.65. If the individual received care from such DSH or qualifying provider-based facility, then the individual may be referred for followup care for the same condition by such a health care provider to an outside health care provider and still remain a patient of the covered entity for purposes of this rule, so long as the covered entity (either the DSH or a qualified provider-based facility) retains ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs. To demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility of the DSH within 12 months after the time of referral.

Functional Definition

- For IHS funded health programs the definition of “patient” is an eligible Indian patient who receives regular care at the facility

Federal Register Notice Indian health example

- “**Example 5: Indian Tribes and Tribal Organizations**
  In the case of Indian tribes or tribal organizations, any attempt to serve non-Indian Health Service beneficiaries must receive prior formal approval by the Indian Health Service. “

“Formal approval”

- Agency not in position to grant formal approval for provision of 340B pharmaceuticals to non-Indians unless conditions of IHCIA section 813 met:
  - Tribe makes determination (with IHS agreement) that
    - No reasonable alternative service available
    - No diminution of services to Indian patient will occur
    - Would need to go into contract/ compact

Additional consideration for HRSA Rural Health Centers

- A HRSA 330 health facility may have contract that includes provision of health services to all 330 eligible patients in their catchment area

Reconciling and drawing within the lines

- Non-Indians cannot be provided 340B medications.
- If health programs are going to provide pharmaceuticals to non-Indians, then should have systems in place to account for the 340B and non-340B medications separately
- Even for 330 designated clinics, should keep separate records for 340B and non-340B as designation as IHS funding reason for 340B eligibility