OVERVIEW OF THE 340B PROGRAM

In 1992, Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992. Section 340B requires pharmaceutical manufacturers to enter into an agreement with the Department of Health and Human Services Secretary in exchange for having their drugs covered by Medicaid and Medicare. Under the agreement, the manufacturers agree to provide significant discounts on covered outpatient drugs purchased by specified providers, called "covered entities," that serve the nation's most vulnerable patient populations. According to congressional report language, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

The 340B program is administered by the Office of Pharmacy Affairs (OPA), within the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. OPA is charged with designing and implementing necessary policies and procedures to enforce agency objectives and assess program risk.

42 USC 256b(a)(5)(A)(i) prohibits manufacturers from providing a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

Covered entities must ensure that the numbers it uses to bill 340B drugs to Medicaid (i.e., national provider identifier (NPI) and/or state-specific billing numbers) are listed in OPA's Medicaid Exclusion File. This allows state Medicaid agencies to exclude claims billed under those numbers from their rebate invoicing. Some states, like Florida, impose additional notification requirements, such as requiring.

340B BILLING REQUIREMENTS FOR COVERED ENTITIES/PROVIDERS

- **<u>For fee-for-service 340B pharmacy claims:</u>**
  - Providers dispensing 340B outpatient drugs must be registered as a 340B provider.
  - Submit a value of **"08"** in **Basis of Cost Determination field (NCPDP field #423-DN)**
    (Basis of Cost Determination "**05"** will no longer be accepted.)
  - Amount submitted in the **Ingredient Cost Submitted field (NCPDP field #409-D9)** must be less than the reference price as provided by Centers for Medicare and Medicaid Services.
  - Submit a value of **"20"** in the **Submission Clarification Code field (NCPDP field #420-DK)**

  In the fee-for-service delivery system, Florida Medicaid reimburses for drugs purchased under the 340B program at the actual purchased drug price, which cannot exceed the 340B ceiling price, plus a dispensing of $10.24.
  (Link: https://www.flrules.org/gateway/ruleno.asp?id=59G-4.251)

- **<u>For entities providing outpatient services (not retail pharmacies nor inpatient):</u>**
  The provider's Medicaid ID number(s) must be posted on the HRSA website. The Agency's rebate collection vendor can identify claims submitted by those providers and

not collect rebates. Currently, if that entity's number appears on the HRSA website, ALL of their claims will be excluded from rebate collection.

- **HEALTH PLANS (ENCOUNTER CLAIMS) 340B CODES:**

- The Submission Clarification Code field (420-DK) must be populated with a **20** and **9.**

D.0 Payer Specifications or Encounter D.0 Payer Specifications can be found on the FL Medicaid Web Portal.

Link to all of the Florida Medicaid health plan contacts: http://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/SMMC_Provider_Plan_Contacts_External.pdf.