



NATIONAL ASSOCIATION OF
Community Health Centers



Understanding the 340B Program: A Primer for Health Centers

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Introduction

The 340B Drug Pricing Program (340B program) was created in 1992 to provide discounts on outpatient prescription drugs to select safety net providers, including among others, Federally Qualified Health Centers, which include centers receiving grant funds under Section 330 of the Public Health Service (PHS) Act and look-a-like health centers.ⁱ The program promotes: 1) access to affordable medications, 2) efficient business practices, 3) outcomes-driven pharmacy services, and 4) quality assurance.ⁱⁱ The intent of the program is to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”ⁱⁱⁱ

The 340B program was developed in response to unintended consequences stemming from the Medicaid Drug Rebate program that began in 1990. Under that program, drug manufacturers were required to enter into a rebate agreement with the U.S. Department of Health and Human Services (HHS) to provide drugs to state Medicaid programs. The required rebate was based on the drug manufacturers’ “best price,” and thus, manufacturers had little incentive to reduce their prices in non-Medicaid markets because doing so could lead to larger rebates in the Medicaid market. As a result of the rebate program, non-Medicaid patients may have been charged higher rates than they otherwise would have been charged. From the federal and state governments’ point of view, this was not productive because savings to the Medicaid program were offset by higher costs to other providers.^{iv} To address this situation, Congress established the 340B program, requiring drug manufacturers to enter into a pharmaceutical pricing agreement with HHS to provide discounts to certain safety net providers.

Under the 340B program, drug manufacturers that participate in the Medicaid Drug Rebate program must also provide a reduced 340B price for covered outpatient drugs to select safety net providers that choose to participate in the program. The 340B discount is the same discount that manufacturers are required to provide to state Medicaid agencies.

Use of the 340B program can lead to significant cost savings and revenue generation for health centers. The National Association of Community Health Centers (NACHC) found that health centers save between 15%-60% on their prescription drug costs by using the 340B program.^v The amount of savings per health center depends on the volume and type of drugs that are purchased. Health centers may use the savings in a variety of ways, such as providing medications at a reduced cost or at no cost to some patients, expanding their formulary, reaching additional low-income patients, or offering new services. As part of the original 340B legislation, the government was also required to establish a prime vendor program (PVP). The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract with the Office of Pharmacy Affairs. The PVP serves its participants in three primary roles:

- Negotiating sub-340B pricing on pharmaceuticals
- Establishing distribution solutions and networks that improve access to affordable medications
- Providing other value-added products and service.

The program is a voluntary program of 340B-covered entities. The PVP also provides technical assistance in implementing the program, and conducts health center specific costs analyses upon request.

The 340B Program is administered by the Office of Pharmacy Affairs (OPA) in the Health Resources and Services Administration (HRSA). OPA is part of HRSA's Healthcare Systems Bureau and has three primary functions: 1) administer the 340B program, 2) develop innovative pharmacy delivery models and provide technical assistance, and 3) act as a federal resource for pharmacy issues.^{vi} OPA focuses on patient access, best practices, and outcome-driven pharmacy management. HRSA has contracted with the American Pharmacists Association to administer the Pharmacy Services Support Center (PSSC) to assist health centers and other eligible entities in enrolling and using the program. PSSC's mission is to "provide information, education, and policy analysis to help eligible entities optimize the value of the 340B program and provide clinically and cost effective pharmacy services that improve medication use and advance patient

care.”^{vii} PSSC offers general guidance as well as PharmTA, a technical assistance group knowledgeable about 340B program requirements and various aspects of operating a pharmacy.

While the 340B Program can provide health centers with the opportunity for substantial cost savings, health centers have often found the program difficult to navigate. Concerns have been expressed regarding issues such as deciding what kind of pharmacy service to establish in a health center, understanding how 340B interacts with Medicaid and Medicare, and knowing how to comply with auditing and tracking requirements. This primer is designed to help health centers take advantage of this program by providing an overview of issues related to the program, clarifying federal regulations and guidelines, and explaining various options health centers have when using the program. Section I outlines program benefits and provides instructions for enrolling in the 340B Program and the PVP. Section II provides an in-depth discussion of program details, such as how 340B interacts with Medicaid and rules health centers must abide by when participating in the program. Section III lists additional resources that health centers may find useful when participating in the program.

This primer is intended for health center personnel who want to learn about the 340B program and understand some of the specific rules and issues associated with using the program. Other resources identified here are available to health centers interested in assessing what strategy to use to provide pharmaceutical services or learning about operational details when setting up and running the 340B program.

SECTION I: GETTING STARTED

A. 340B Benefits and Pricing

Under the 340B program, drug manufacturers provide front-end discounts to health centers and other covered entities, meaning that the health center receives a discount at the outset when it purchases the drug rather than a rebate later on in the payment process. “Covered entity” is a term used in the 340B law to define the various safety-net providers that qualify for 340B discounts. FQHCs are listed in the statute as one of these covered entities.^{viii} The 340B program covers all of a participating manufacturer’s outpatient prescription drugs provided to the health center, including over-the-counter drugs if a prescription is written for the drug. The program does not cover vaccines.^{ix}

Health centers may use their 340B-purchased drugs for all of their patients. However, their charge to their patients for these drugs must be compliant with Section 330 of the PHS Act, meaning full pay for those with income at or above 200% of the Federal Poverty Level (FPL), application of a sliding fee scale for those with income between 100%-200% of the FPL, and a minimal charge at most for those with income below 100% of the FPL. Consequently, before using the 340B program, health centers should consider how the program will be financed and how that financing interacts with the requirement of Section 330 of the Public Health Service (PHS) Act to provide services to health center patients regardless of ability to pay; thereby ensuring decisions are made that protect health centers’ overall financial health.

The 340B price is the *ceiling price*, meaning that it is the highest price that 340B covered entities would have to pay for a drug. Health centers also may negotiate prices with manufacturers that are below the 340B prices. The 340B ceiling price is set according to a complex formula based on the Average Manufacturer Price (AMP), less a discount that is generally equivalent to the state Medicaid drug discount program rebates.

The AMP is the average price wholesalers pay for drugs distributed to retail pharmacies. The AMP is calculated excluding prompt pay discounts, but including other standard discounts or rebates.^x The AMP is defined by federal statute and regulation and is based on actual drug transactions.^{xi} For most drugs, the 340B discount was increased in the Affordable Care Act (ACA)^{xii} to AMP less 13% for generic and over-the-counter drugs, and the lower of AMP less 23.1% or best available price for brand name drugs.^{xiii} The best available price is the lowest price given by the manufacturer to any private sector entity. Additional discounts are available if the drug's AMP has risen faster than inflation, although the ACA limits the rebate to 100% of AMP. 340B prices are recalculated quarterly and may be lowered during a quarter, but manufacturers or wholesalers may not apply any increase in price to health centers until the next quarter begins. Any price increase must not exceed the 340B ceiling price for that quarter.

The box below provides examples of 340B pricing. As discussed in Section II, health centers that use a wholesaler or distributor may face additional fees; therefore, the final cost to the health center may be higher than the 340B ceiling price.

Calculating 340B Prices

Generic/over-the-counter drugs: Average Manufacturer Price (AMP) minus 13%

List price for a month supply is \$15 (for a twice a day drug at \$.25 per unit). AMP is \$10. 340B ceiling price is AMP-13% or \$8.70, which is 58% of the list price.

Brand name (single source) drugs: AMP minus 23.1% OR best price, which is the “lowest price available to any private entity”

List price for a month supply is \$30 (for a twice a day drug at \$.50 per unit). AMP is \$20. 340B ceiling price is AMP-23.1% or \$15.38, which is 51.3% of the list price. If the manufacturer’s best price is \$17, the 340B ceiling price remains \$15.83 because it is the lower of the two prices. If the manufacturer’s best price is \$15, the 340B ceiling price is \$15 because that is the lower of the two prices.

Cases where AMP has risen faster than inflation

List price for a month supply is \$15 (for a twice a day drug at \$.25 per unit). AMP is \$10. 340B ceiling price is AMP-13% or \$8.70, which is 58% of the list price. When the drug was originally introduced, adjusted for inflation, the AMP was \$7. Because this amount is lower than the calculated 340B price of \$8.70, the manufacturer must apply an additional discount, which is equal to the difference between the current AMP (\$10) and the inflation-adjusted baseline AMP (\$7). This additional discount of \$3 is applied to the calculated 340B price (\$8.70). The final ceiling price is \$8.70-\$3.00 or \$5.70.

In cases where the additional inflation adjusted discount would bring the cost to less than zero, the ceiling price is set a \$.01. Manufacturers may place quantity limits on drugs priced at that level.

There have been concerns about the 340B program regarding the availability of pricing information to health centers. This has been one of the major complaints about the program. The recent health reform law addresses this issue by including a number of manufacturer and covered entity compliance requirements intended to improve HRSA’s collection and reporting of 340B prices, as well as ensuring that covered entities are being charged the correct price.^{xiv} The regulations and/or guidelines relating to these requirements have not been published at this time. The new compliance requirements are described in the box below.

New Compliance Requirements

The Affordable Care Act requires HRSA to improve 340B compliance by manufacturers and covered entities.

Manufacturer compliance requirements:

- ⇒ HRSA must publish standards and methodology for calculating ceiling prices;
- ⇒ HRSA must compare ceiling prices calculated by HRSA with quarterly pricing data supplied by manufacturers;
- ⇒ HRSA must perform spot checks of drug sales;
- ⇒ HRSA must take or order manufacturers to take corrective action if price disparities are discovered;
- ⇒ HRSA may impose civil monetary penalties on manufacturers for intentional overcharging;
- ⇒ Manufacturers must issue refunds in a timely manner;
- ⇒ Manufacturers must report rebates given to other entities and make refunds to 340B entities if these rebates alter the 340B discount; and
- ⇒ HRSA must perform increased auditing of manufacturers and wholesalers.

Covered entity compliance requirements:

- ⇒ HRSA must develop a system that requires covered entities to update their information on HRSA's database at least annually;
- ⇒ HRSA must develop a system to verify the accuracy of its database;
- ⇒ HRSA must develop guidance to help covered entities understand their options for billing Medicaid agencies while remaining in compliance with the program;
- ⇒ HRSA must develop a single, standardized system for identifying covered entities in its database; and
- ⇒ HRSA may impose civil monetary penalties on covered entities that do not comply with program requirements.

In addition to these compliance requirements, the ACA also mandates that HHS establish a dispute resolution process for covered entities and manufacturers.^{xv} Health centers may avail themselves of the dispute resolution process if they believe they have been overcharged for drugs purchased through the 340B program, and manufacturers may use the process if they believe health centers are violating the program rules

relating to duplicate discounts or drug diversion (discussed in Section II). HHS has not developed the dispute resolution process at this time. The agency is currently seeking comments regarding the best way to proceed in meeting this requirement.

B. 340B Enrollment

As of July 2010, almost all eligible health centers (94%) had enrolled in the 340B program.^{xvi} Both the promise of savings on drug purchases and a federal requirements relating to enrollment in the 340B program have boosted participation in the program. Since 2000, the Notice of Grant Award for HRSA-funded health centers has included language stating the need for health centers to review whether their drug purchasing practices meet applicable cost principles.^{xvii} If a health center that provides pharmacy services does not participate in the 340B Program and it is found that participating in that program would be the most economical way for the health center to purchase outpatient drugs, the health center may receive a negative audit finding, cost disallowance, or grant funding off-set.

Health centers must enroll with OPA to participate in the 340B program. Enrollment in the program is a fairly simple process.

⇒ Health centers must complete a short, health center-specific enrollment form.

- This form is available on the OPA website, psscwww.hrsa.gov/opa/legalresources.htm
- Every health center site (main and satellite sites) that will be dispensing drugs acquired under the 340B program must be enrolled in the 340B program. Each satellite site should find out whether the main site enrolled all of the sites or whether the sites are expected to enroll individually.
- Health centers must indicate whether the health center will dispense drugs acquired under 340B pricing to its Medicaid clients (see Section II for details on the interaction of 340B and Medicaid).

- ⇒ A health center can verify that it is enrolled and active in the 340B program by checking OPA's covered entity database, found at opanet.hrsa.gov/opa/CE/CEExtract.aspx<http://opanet.hrsa.gov/opa/CE/CEExtract.aspx>.
- ⇒ Once the health center's application is processed, OPA will contact the health center and provide the start date and a 340B identification number.
- OPA updates the database for new entities four times per year and requires a minimum of one month to process an application. The enrollment due dates for each quarter are as follows:
 - December 1 for quarter beginning Jan. 1
 - March 1 for quarter beginning April 1
 - June 1 for quarter beginning July 1
 - September 1 for quarter beginning Oct 1
- ⇒ **Health centers must inform manufacturers and distributors that they are participating in the 340B program and should verify that they receive the 340B price when placing orders.**
- Manufacturers and suppliers must provide health centers with the 340B price once they verify that a health center is enrolled in the program through the covered entity database.
- ⇒ Health centers must inform OPA if there are any changes in to their 340B sites, such as site address or authorized contact, by completing the 340B Participant Change form, which is found at www.hrsa.gov/opa/legalresources.htm.
- Completed forms should be emailed to OPA at opastaff@hrsa.gov. Health centers will be notified when changes have been processed.

Need help?

Contact the Pharmacy Services Support Center

Call 1-800-628-6297

Email PSSC@aphanet.org

Visit <http://pssc.aphanet.org/>

C. Prime Vendor Program Benefits and Pricing

As already noted, as part of the original 340B legislation HHS was required to establish a prime vendor program (PVP). The 340B Prime Vendor Program (PVP) is managed by Apexus through a contract with the Office of Pharmacy Affairs (OPA). Enrollment in the PVP program is voluntary to 340B-covered entities. The program provides sub-340B discounts and value added services to participating entities. Health centers may enroll in the PVP at no cost; the program is financed by fees paid by suppliers and distributors.

The PVP maintains that it is able to use its status as the preferred organization to increase its collective purchasing volume, allowing it to obtain sub-340B prices on select pharmaceuticals and to provide longer term pricing. Since the PVP includes all types of covered entities, they state that it has significant market power to use as leverage in negotiations with suppliers. The PVP provides additional services to covered entities such as assisting health centers with the implementation of the 340B program, establishing distribution networks, providing information regarding software options, conducting educational seminars, and analyzing health center-specific prescription drug needs and costs. Although PVP-negotiated prices are not publicly available, health centers enrolled in the PVP have access to the PVP price list. The PVP points out that it provides ceiling price verification so health centers can be assured they are receiving the appropriate price on drugs purchased through the PVP.^{xviii}

The PVP notes that it has arrangements with over a dozen wholesalers and more than 60 suppliers. Overall, it offers discounts on 3,300 items and provides health centers with an average savings of 11% as compared to 340B ceiling prices. Participants must use PVP's distribution agreements to obtain PVP pricing. If a covered entity has negotiated a distribution fee that is lower than the PVP distributor agreement, the lower fee will remain in place.

Unlike the 340B program, the PVP also provides discounts on vaccines and non-pharmaceutical medical items such as diabetic meters, prescription vials, and syringes. While the 340B program covers all outpatient drugs from a participating manufacturer (except vaccines), the PVP maintains that it is able to obtain a sub-340B price by negotiating discounts with manufacturers of select drugs within a class of drugs. For example, PVP may offer lower prices on some, but not all, types of anti-depressants. A full list of the drugs in the PVP catalogue is available on the Apexus website, www.340bpvp.com/public/.

D. Prime Vendor Enrollment

Health centers must first complete the 340B enrollment process with OPA since only 340B-enrolled entities are eligible to participate in the PVP. To enroll in the PVP, the health center should:

- ⇒ Go to the 340B PVP website, www.340bpvp.com/public/registration/default.aspx, and click on the Participation tab on the left side menu. The website provides a step-by-step process for enrollment,
 - The health center will be asked for its 340B ID to begin enrollment.
 - The health center will be asked to designate an authorized signer and provide details about the clinic.

- ⇒ PVP enrollment is activated on the 1st of each month. Enrollment may take up to two weeks to process, so applications submitted before the 15th of any given month will be activated on the 1st of the following month while applications submitted after the 15th will have to wait until the month after. For example, an application submitted on July 7 will be

activated on August 1, while an application submitted on July 25 will be activated on September 1.

- ⇒ PVP will send the health center an email and welcome letter indicating when its application is active and outlining ways the health center can make the most effective use of the program.
- A health center should share its welcome letter with its PVP participating distributor to ensure that it is clear the health center is participating in the PVP.
- ⇒ PVP will send health centers a monthly newsletter with catalogue updates and other useful information. In addition, technical assistance information is available on their website, www.340bpvp.com.
- ⇒ Health centers may update their file on the 340B PVP website. Go to www.340bpvp.com and click on My Profile and then “continue to My Profile” to make needed changes.

Need help?
Contact Apexus/340B Prime Vendor Program
Call 888-340-BPVP (888-340-2787)
Email 340TechSupport@340bpvp.com or
340CustomerServices@340bpvp.com
Visit <https://www.340bpvp.com/public/>.

SECTION II: PROGRAM DETAILS

A. Purchasing Pharmaceuticals

Health centers may offer pharmacy services through various strategies or combinations of strategies, such as running an in-house pharmacy, contracting for pharmacy services, and using provider dispensing in-house. The exact nature of pharmacy purchasing will depend, in part, on which configuration a health center uses. For example, health centers with in-house pharmacies purchase, own, and dispense the drugs themselves. In comparison, health centers that contract for pharmacy services purchase and own the drugs, but pay a dispensing fee to the contracted pharmacy (or arrange for patients to pay the fee to the pharmacy). Health centers using contracted pharmacy services will have to stock the pharmacy with sufficient inventory to cover their patients' needs. This initial inventory investment may be substantial, though it may be possible to make a payment arrangement with a contract pharmacy to help spread out the costs to the health center.

Since 1996, HRSA has allowed health centers to contract with outside pharmacies to provide 340B services. At that time, health centers were only allowed to use one pharmacy site to serve all of their patients. The pharmacy could be either in-house pharmacy or an outside contract pharmacy. The single pharmacy restriction was in place in an attempt to limit fraud and ease auditing and inventory tracking burdens. Health centers that wished to use a different pharmacy arrangement could only do so through the use of an Alternative Methods Demonstration Project discussed below in sub-section E.

Many health centers strongly opposed the single pharmacy restriction because it was difficult to steer all of their patients to a one pharmacy, especially for health centers with multiple sites over a large geographic area. As of April 5, 2010, **this restriction has been lifted and health centers may now contract with**

multiple pharmacies. Health centers must register each of their contracted pharmacies with HRSA and adhere to several requirements when working with multiple pharmacies. See the box below for details.

Multi-Contract Pharmacy

Multiple pharmacy site strategies may combine in-house pharmacy and contract pharmacy or include multiple contract pharmacies.

Health centers must abide by the following rules when using multiple sites:

- ⇒ There must be a written contract between the health center and each pharmacy site. The contract can cover multiple health center sites or individual contracts may be used for each site. A model contract agreement is available at <http://www.hrsa.gov/opa/contractedmodel.htm>;
- ⇒ Health centers using a contract pharmacy arrangement must register as a contract pharmacy entity with OPA. Go to <http://www.hrsa.gov/opa/contractpharmacy.htm> for details and forms;
- ⇒ Health centers must buy, maintain title, and assume pricing responsibility for the drugs;
- ⇒ A ship to/bill to procedure must be used where the health center buys the drug, but the drug is shipped to the pharmacy sites (may ship to a central site or to multiple sites);
- ⇒ The contract must specify responsibilities of the parties for providing comprehensive pharmacy services;
- ⇒ Health centers must inform patients of their site options for purchasing pharmaceuticals;
- ⇒ Contracting pharmacies may provide additional services such as home care and delivery;
- ⇒ Contracting pharmacies must provide health centers with industry standard reports;
- ⇒ Health centers must meet all of the same compliance rules when using multiple pharmacy sites and have the appropriate tracking, inventory, and auditing systems to maintain compliance; and
- ⇒ Health centers and contracting pharmacies must comply with all federal, state, and local laws.

75 Fed. Reg. 10272 (March 2010)

An excellent resource for health centers considering their pharmacy options is *The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations* by Katheryne Richardson available at www.medpin.org/docs/bridge-340B.pdf. This document provides a comprehensive discussion of different pharmacy strategies, worksheets to conduct needs assessments, and case studies reflecting the various options. In addition, for those health centers considering a contracted pharmacy option, NACHC's *Contracting with a Pharmacy Management Services Company to Operate a Center's Licensed, In-House Pharmacy* provides important and practical information. This issue brief is available at www.nachc.org/Section-340b-Drug-Pricing-Program.cfm. **Whichever method a health center uses to provide pharmacy services, the health center, as the covered entity, is responsible for ensuring compliance with 340B requirements.**

While the 340B program sets rules about the price health centers will pay for drugs, it has not established a method for drug purchasing. Health centers may purchase drugs directly from the manufacturer, from a distributor, with the assistance of a Pharmacy Benefit Manager (PBM), from the PVP if enrolled, or through a group purchasing organization (GPO). The drug manufacturer is the entity that makes the drug and sets the initial price. A distributor purchases drugs from the manufacturer at a price less than the list price and sells them to retail pharmacies and other entities. Distributors may work with multiple manufacturers, allowing health centers to compare different products and consolidate purchasing. Purchasing through a distributor, however, may be more expensive than purchasing directly from the manufacturer because of distribution fees that are charged to health centers.

The PVP does not offer all outpatient drugs, but does offer discounts on select drugs and other medical supplies. Also, it is necessary to use PVP distribution agreements to obtain PVP pricing. Health centers generally will not have to change their current purchasing arrangement, however, because PVP

works with many different suppliers. A list of participating suppliers and distributors is available on the PVP website, www.340bpvp.com.

Given the complexity of providing pharmacy services, health centers may also engage the services of a Pharmacy Benefit Manager (PBM). PBMs are organizations that provide a host of administrative services for processing prescription claims. These services include designing formularies, contracting with manufacturers and suppliers, negotiating discounts, checking eligibility, paying claims, collecting data, etc. For their services, PBMs charge a fee to health centers.^{xix}

Some pharmacy solutions groups have specific programs geared to assist health centers with the 340B program. These groups provide standard PBM functions as well as additional services such as inventory management to help health centers run their 340B program. For example, WellPartner has established a 340B distribution network, 340B Access Solution, which administers and manages the 340B program for health center members.^{xx} Similarly, Rx Strategies provides turn-key 340B support for health centers, including negotiation of relationships with suppliers, program registration, staff training, etc.^{xxi} Other organizations, [such as Maxor](#), offer a variety of services, including but not limited to 340B implementation.^{xxii} Note: NACHC's reference to the above organizations does not reflect endorsement of the organization or of its products or services.

Health centers also have the option of joining a 340B group purchasing organization. Group purchasing organizations use the market power of collective negotiation to achieve reduced prices and provide other services to their members. For example, the Texas Association of Community Health Centers (TACHC) has developed a program called 340Better. Any health center can join the program, which focuses on securing long-term contracts for the most frequently dispensed high cost and high volume drugs.^{xxiii} In addition, its distributor, Cardinal Health, provides a web-based ordering application to assist

health center purchasing. Council Connections is another group purchasing organization founded by health centers that provides 340B related services as well as a variety of other services, products, and supplies.^{xxiv} Some group purchasing organizations may be set up to work with the PVP while others may require health centers to use their services exclusively. See Appendix A for a more extensive list of organizations that provide services related to the 340B program. Please note, NACHC provides the names of these organizations (and those in Appendix A) solely for informational purposes and is neither endorsing nor otherwise recommending their services.

B. Patient Definition

One of the key prohibitions in the 340B program is the requirement that discounted drugs may be furnished only to patients of a covered entity. There are several scenarios where a health center could inadvertently furnish products to a consumer who is not a patient. For example, a health center that runs an in-house pharmacy may have non-patient members of the community purchase drugs from their pharmacy. Contracted pharmacies will certainly serve both health center patients as well as other consumers. Health centers will need to ensure that systems are in place to guarantee that only patients of the health center receive 340B priced drugs while others receive non-340B priced drugs.

According to HRSA, an individual is not considered a patient of the health center if the only health care services provided by the health center to the individual is the dispensing of drugs. In addition, OPA policy is that a health center patient is one who has an established relationship with the health center and who receives typical health care services by a health center provider.

340B Patient Definition

An individual is a patient of a health center for 340B purposes if the following criteria are met:

- ⇒ The health center has established a relationship with the individual, such that the center maintains records of the individual's health care; and
- ⇒ The individual receives health care services from a health care professional who is either employed by the health center or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the health center; and
- ⇒ The individual receives a health care service or range of services from the health center that is consistent with the service or range of services for which grant funding for Federally-qualified health center or look-alike status has been provided to the center

⇒

61 Fed. Reg. 55156 (Oct. 1996)—this chart reflects the current version of HRSA's patient policy. However, HRSA is expected to publish soon a **proposed** revision to this policy

The selling or transferring of a 340B priced drug to a non-patient is referred to as drug diversion. Health centers are responsible for ensuring such diversion does not occur by developing appropriate tracking systems. Health centers must have some way to track drug purchasing and dispensing separately for their 340B patients and their non-340B patients. Health centers are required to maintain both purchasing and dispensing records and make those records available for audit by HHS.^{xxv} In addition, states may place requirements on health centers regarding separating 340B and non-340B inventory or recording keeping.

C. 340B Interaction with Medicaid

A second key prohibition in the 340B program relates to Medicaid reimbursement, and requires that health centers keep track of which program is paying for the drugs to maintain compliance with 340B rules.

The Medicaid Drug Rebate Program requires participating drug manufacturers to provide drugs to state Medicaid agencies at a low cost. Drug manufacturers that participate in the rebate program must also participate in the 340B program. The amount of the 340B discount is the same as the discount that is required in the Medicaid drug rebate program. While drug manufacturers participate in both programs, they are only required to provide a single discount on a drug given to a Medicaid patient. In other words, either the state Medicaid agency receives the rebate price for drugs provided to Medicaid patients or the health center receives the 340B discounted price for its Medicaid patients, but both the state and the health center cannot take a discount on the same transaction. This practice is referred to as “double dipping” or “duplicate discount”.

Health centers have two primary ways to avoid violating the double dipping rule. One option is to purchase drugs for Medicaid patients at the 340B price and then inform the state Medicaid agency not to seek a rebate for those transactions. To ensure the Medicaid agency does not seek a rebate, a health center must indicate on its 340B application that it intends to bill Medicaid for drugs purchased through the 340B program. This arrangement may involve special operational or financial requirements, which vary by state. OPA maintains a “Medicaid Exclusion” file that lists health centers using this option.

Whether this option makes sense for a particular health center will depend on the state Medicaid reimbursement level, which varies from state to state. Since 2001, health centers have been reimbursed for their Medicaid patients through the Prospective Payment System (PPS). Each health centers has

its own PPS rate, which is defined as the average per visit cost for health centers in 1999 and 2000. Pursuant to Federal Medicaid law, PPS rates are increased each year by the Medicare Economic Index and should be adjusted for any change in scope of services. Many states choose, however, to exclude the cost of pharmaceuticals from their PPS rate, and to set separate pharmaceutical reimbursement levels for Medicaid reimbursement. Health centers should contact their State Primary Care Association (PCA) or their State Medicaid officer for additional information on which approach their state has taken.

In addition, health centers and states have the choice to implement an Alternative Payment Methodology (APM). This methodology can take a variety of forms, including keeping the prior cost-based reimbursement system, as long as the APM results in payments at least as high as the statutorily defined PPS methodology and as long as **both** parties (the State Medicaid agency and the health center) agree to the APM. As with PPS, some states using an APM have chosen (presumably with the FQHC's agreement) to exclude the cost of drugs from an APM per visit rate.

Regardless of whether a state is applying PPS or an APM in paying FQHCs, inclusion or exclusion of the cost of pharmaceuticals in that payment is an important issue, since inclusion would likely mean that the health center is being paid only an amount approximating its actual costs. This means that the 340B discounts would be passed on entirely to the state, producing no direct benefit for the health center. In short, given the options available when implementing PPS, it is difficult to make a generalization about PPS and drug reimbursement. Health centers must become familiar with how their state has chosen to implement PPS, especially regarding pharmaceutical reimbursement.

Questions About PPS?

You can find annual PPS state-by-state reports as well as general PPS information on NACHC's website, <http://www.nachc.org/medicaid-prospective-payment-system.cfm>

Drug prices under Medicaid have three general components: the amount paid to the pharmacist for the drug (acquisition cost), an amount paid to the pharmacist to dispense the drug (dispensing fee), and the rebate paid to the state. In some states, Medicaid reimbursement for drugs may not exceed the *estimated* acquisition costs for the drug and a dispensing fee, or the providers' usual and customary charge to the general public.^{xxvi} States have discretion when setting reimbursement levels and many states use the Average Wholesale Price (AWP), which is the list price set by manufacturers, less a certain percentage to set the acquisition cost. This reimbursement level should be higher than the actual acquisition cost paid by a pharmacy, even one not involved with the 340B program. In 2000, HRSA issued guidance that stated that covered entities should refer to their respective state Medicaid agency drug reimbursement policies for applicable billing procedures specific to their state.^{xxvii} Several Medicaid agencies have recently taken the position that health centers are limited to being reimbursed their *actual* acquisition cost plus a dispensing fee. In these instances, where health centers are billing Medicaid their actual acquisition cost, the state Medicaid agency is essentially receiving the benefit of the 340B drug discount savings.

States also have broad discretion when setting the dispensing fee, and these vary widely by state. Even within states, dispensing fees may depend on volume of purchase, purchasing method (mail-order or in-person), type of drug, type of pharmacist (retail, institutional, for-profit, non-profit), location (urban, rural), and whether the drug is purchased through the 340B program.^{xxviii} Many states set nominal dispensing fees that are not sufficient to cover a provider's actual cost of filling the prescription, but assume the provider is covering costs through a markup on the ingredient cost. Because several state Medicaid agencies limit health center reimbursement to the actual acquisition cost plus the dispensing fee, it may be economically disadvantageous for a health center to take the 340B discount for its Medicaid patients unless a state's Medicaid

program agrees to a shared savings arrangement. The concept of a shared savings approach is that because 340B prices are significantly below the net Medicaid payments for outpatient drugs, both the state and health center can benefit from the savings opportunities. Shared savings can take the form of enhanced dispensing fees, product markups, or additional fees for serving high cost Medicaid patients, such as those participating in a disease management program. Many states have instituted such shared savings arrangements for 340B pharmacies. For health centers that participate in the PVP, the discounts available on PVP-contracted drugs also must be included when calculating the actual acquisition cost passed to Medicaid.

A second option is for health centers to “carve out” their Medicaid patients from the 340B program. In other words, health centers may purchase and bill non-340B drugs for the normal reimbursement for Medicaid patients, while still purchasing 340B drugs for non-Medicaid patients. Depending on the state and health center’s expected claims, this may be a better option for health centers financially. Under this model, the health center would only receive the nominal dispensing fee but should be able to cover costs through a markup on the ingredient cost, in much the same way as a retail provider. Even if the dispensing fee is low, the overall rate may be high enough for health centers to make a profit. Health centers must investigate prices available in the market and understand their state’s Medicaid reimbursement level to determine whether it makes sense to include or carve-out its Medicaid patients from the 340B program.

Reimbursement rules are different for patients in Medicaid who are enrolled in Medicaid Managed Care Organizations (MCO). While the Affordable Care Act (ACA) mandates that drugs purchased and covered through Medicaid MCOs are now subject to the Medicaid drug rebate program, 340B drugs purchased by Medicaid MCOs are exempt from this requirement.^{xxix} States must include utilization data from each Medicaid MCO when requesting a rebate from

manufacturers and when they submit quarterly reports to the Centers for Medicare and Medicaid Services. As a result of this exemption, health centers may be able to collect higher reimbursement for outpatient drugs given to their patients in Medicaid MCOs as compared to their other Medicaid patients. In other words, because States cannot collect rebates for 340B drugs purchased by FQHCs and furnished to their Medicaid managed care patients, there is no duplicate discount if the health center negotiates a payment from the MCO above the center's actual acquisition cost for these drugs. Health centers must consult their Medicaid MCO contracts to determine the reimbursement level for pharmaceuticals.

D. 340B Interaction with Medicare

Health centers may use 340B discount drugs for all of their patients regardless of payor source or income level. Thus, drugs prescribed for **Medicare** patients are also eligible for 340B pricing.

Medicare Part D is the prescription drug benefit in the Medicare program. As the Medicare Part D program is administered by contracted Part D plans, which take many forms, health centers must contract individually with each of the plans in their region in order to accept these patients. Each plan sets its own requirements for participation and reimbursement levels within Medicare guidelines. Most plans have special requirements and/or contract provisions for 340B providers or other safety net providers. Before executing an agreement, it is important in reviewing contracts with Part D plans to ensure that the use of 340B –purchased drugs is not prohibited and that reimbursement offered is acceptable.

Medicare Part D can be a significant revenue source for health centers, but only if health centers monitor the contracts. Particularly important, a health center must watch for contracts offered by Part D plans that provide the center a

lower reimbursement due to the center's ability to purchase drugs at 340B prices. In these instances, the plan is benefitting from the 340B discount that was intended for the health center.

Medicare Part D is financed, in part, by an annual deductible, monthly premiums, and cost-sharing paid by beneficiaries. The amount of the deductible, premiums, and cost-sharing varies from year to year because the benefit amount is adjusted to reflect per capita Part D spending growth. In 2010, the annual deductible was \$310. After meeting the deductible, Medicare beneficiaries pay 25% of drug costs for spending up to \$2,830 and pay 5% of drug costs after they reach \$6,440 in spending. The gap between the \$2,830 and \$6,440 in spending is referred to as the "doughnut hole" because Medicare beneficiaries pay 100% of drug costs in that spending range. The ACA reduced some of the financial burdens on Medicare patients under Part D by:

- ⇒ providing beneficiaries with a \$250 check towards costs incurred in the doughnut hole in 2010; and
- ⇒ providing a 50% discount on brand name purchased in the doughnut hole in 2011. This discount will reach 75% by 2020 and will also include generic drugs.^{xxx} Medicare beneficiaries will pay the remaining 25%.

E. Alternative Methods Demonstration Projects

Health centers that find that the 340B program restrictions inhibit their ability to serve their mission may consider applying for an Alternative Methods Demonstration Project (AMDP). These are not grant-funded opportunities, but projects approved by HRSA that allow health centers to use the 340B program in a manner that would otherwise not be allowed under program rules. AMDPs are intended to have the goal of increasing access to 340B pharmaceuticals. These projects will be approved for no more than six years and are designed to allow HRSA to observe the effects of possible program changes.^{xxx}

AMDPs have been used for a variety of purposes. Several AMDPs were developed to allow covered entities to use multiple pharmacy options. Given the new rule allowing for multiple contract pharmacy options, it is no longer necessary to seek an AMDP for this purpose. Health centers in Michigan, Vermont, and Washington have AMDPs that allow them to create a network of covered entities that are working together to provide pharmaceutical services.^{xxii} Health centers may also consider AMDPs that address other concerns such as high administrative costs or providing services over an extensive geographical area.

Health centers may submit an AMDP proposal at any time. HRSA provides guidance about what should be included in an AMDP proposal on its website at <ftp://ftp.hrsa.gov/bphc/pdf/opa/AltMethCriteria.pdf>. This guidance is also available in Appendix C. In general, a proposal application should include:

- ⇒ Identification of the problem being addressed by the proposal;
- ⇒ A detailed description of the area and population covered;
- ⇒ A detailed description of the project design and implementation;
- ⇒ Evaluation methodology and reporting plan;
- ⇒ Identification of participating members;
- ⇒ A plan for inventory control and dispensing; and
- ⇒ A plan for adhering to 340B requirements such as avoiding drug diversion or double dipping.

F. Split-Billing Software

Given the prohibitions relating to drug diversion (selling 340B drugs to individuals who are not patients of the health center) and double dipping (when both Medicaid and the health center take the 340B discount), as well as federal auditing requirements, it is essential that health centers or their contract pharmacies have a management information system that is able to distinguish

individuals who should be receiving 340B pricing from those who should not. In addition, health centers may want to be able to track pricing for their drug sales to help ensure they are receiving 340B prices. These concerns are magnified when health centers contract with outside pharmacies to provide 340B services. The health center and contract pharmacy must agree which party is responsible for tracking inventory and sales to ensure that the health center remains in compliance with 340B rules. Regardless of how an agreement with a contract pharmacy may be structured, the health center is ultimately responsible for staying in compliance with the program and will suffer any repercussions for violating program rules.

There are a variety of software programs available that can help health centers with these concerns. Split-billing software packages are designed to help pharmacies that see mixed groups of patients (both 340B eligible and ineligible) track purchasing, manage inventory, increase savings, create reports, and conduct audits. Software programs may be able to identify replenishment needs, submit claims, and verify pricing. These programs reduce the need for redundant databases and dual inventories for the pharmacist.

There are a variety of software options available to health centers, some of which are identified in Appendix A. The PVP has contracts with three software companies: AutoMed SupplyWorks®, eAudit Solutions®, and Talyst®. A comparison chart of several software options is available on the PVP website at https://www.340bpvp.com/public/agreements/services/340B_Split_Billing_Software_Comparison_Chart.pdf. Note: by listing these companies in this paragraph and in Appendix A, NACHC is not endorsing these companies nor their products.

III. ADDITIONAL RESOURCES

While this manual is intended to be a primer to help health center personnel understand the 340B program, health centers may want to consult additional resources as well. This section identifies additional resources for health centers and key information that they provide.

A. Agencies and Non-Profits

Title: Office of Pharmacy Affairs (HRSA)

Description: The Office of Pharmacy Affairs runs the 340B program for HRSA.

Phone: (301) 594-4353

Website: <http://www.hrsa.gov/opa/> and www.hrsa.gov/patientsafety

Available Information:

- ⇒ General information about the 340B Program, PSSC and PVP;
- ⇒ Database of covered entities;
- ⇒ Charts and reports relating to program participation;
- ⇒ Legal resources, including relevant notices from the Federal Register;
- ⇒ Registration forms for health centers with contract pharmacy services;
- ⇒ Information on contract pharmacy services;
- ⇒ Information on patient safety and clinical pharmacy services: and
- ⇒ Glossary of pharmacy terms.

Title: HRSA Pharmacy Services Support Center

Description: PSSC is a resource established by HRSA through a contract with the American Pharmacists Association to help 340B entities optimize the use of the program.

Phone: 1-800-628-6297

Website: <http://pssc.aphanet.org/>

Available Information:

- ⇒ General information about the 340B Program;
- ⇒ PharmTA, consultants available to help health centers with providing pharmacy services and implementing programs;
- ⇒ Federal Register notices;
- ⇒ Overview of registration process and enrollment forms for the 340B Program
- ⇒ Registration forms for health centers with contract pharmacy services; and
- ⇒ Policy newsletters and news alerts.

Title: 340B Prime Vendor Program

Description: The Prime Vendor Program is managed by Apexus through a contract with OPA. As part of the original 340B legislation, the government was required to establish a prime vendor program (PVP) to provide additional discounts on prescription drugs and other medical items and well as other value-added services.

Phone: 1-888-340-BPVP (1-888-340-2787)

Website: <https://www.340bpvp.com/public/>

Available Information:

- ⇒ General information about the 340B program (including a web-based tutorial) and the PVP;
- ⇒ Answers to Frequently Asked Questions;
- ⇒ Step-by-step enrollment in the PVP;
- ⇒ Lists of agreements with suppliers, distributors, vaccines, split-billing software companies, Pharmacy Benefit Managers and more;
- ⇒ PVP covered drug catalogue;
- ⇒ Customer service (340CustomerService@340bpvp.com); and
- ⇒ Technical assistance (340TechSupport@340bpvp.com)

Title: Medicine for People in Need (Medpin)

Description: An organization dedicated to providing information and collaborative opportunities for providing pharmaceutical services to low-income patients.

Website: <http://www.medpin.org/>

Information Available: Publications and resources to assist organizations in providing pharmaceutical services to low-income populations.

B. Publications

Commonwealth Medicine, University of Massachusetts, Massachusetts League of Community Health Centers, and Office of Clinical Affairs, MassHealth. *A guide to best practices for the federal 340B program*. Available at http://www.mass.gov/Eeohhs2/docs/masshealth/pharmacy/phm-340b-bpg_guide.pdf. This publication provides best practices and operational guidance for participating in the 340B program.

Congressional Budget Office. (2005). *Prices for Brand Name Drugs Under Selected Federal Programs*. Available at <http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf>. This publication analyzes price paid to manufacturers under several federal programs. It found that the 340B ceiling price averages to be 51% of the list price.

Department of Health and Human Services, Office of the Inspector General. (2006). *Review of 340B Prices*. Available at <http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf>. This publication reviews whether and why 340B covered entities pay more than the statutory ceiling for 340B drugs.

Department of Health and Human Services, Office of the Inspector General. (2005). *Deficiencies in the Oversight of the 340B Drug Pricing Program*. Available at <http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf>. This publication assesses the ability of HRSA to enforce compliance with drug pricing rules in the 340B program.

National Association of Community Health Centers. (2001). *Health Center Reimbursement for Prescription Drugs: Medicaid PPS and Section 340B Drug Pricing Considerations*. Available at <http://www.nachc.org/Section-340b-Drug-Pricing-Program.cfm>. This publication provides an analysis about how PPS reimbursement choices may affect health center decision making about using the 340B program.

National Association of Community Health Centers. (1999). *Contracting with a Pharmacy Management Services Company to Operate a Center's Licensed, In-House Pharmacy*. Available at <http://www.nachc.org/Section-340b-Drug-Pricing-Program.cfm>. This publication provides important and practical information about setting up a contract pharmacy arrangement.

Richardson, K. (2004). *The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations*. Available at <http://www.medpin.org/docs/bridge-340B.pdf>. This publication includes and extensive discussion of various pharmacy options for health centers, contains worksheets to assist health center decision making, and details 340B and PVP program benefits and requirements.

Richardson, K. (2004). *Implementing a Comprehensive 340B Contracted Pharmacy Service: Information and Tools for Community Pharmacists*. Available at <http://www.medpin.org/docs/pharmacy.pdf>. This publication provides

background information about the 340B program as well as planning and implementation tools for establish a contract pharmacy arrangement.

C. Select Purchasing Groups/Services

** These listing are provided to give health centers information and options.

Inclusion in this list does not indicate that NACHC endorses an organization or specific services or products, or makes any representation as to the quality of such services or products.

Title: 340Better

Description: Program established by the Texas Association of Community Health Centers and Cardinal Health to make effective use of the 340B program.

Phone: Lynn Ford, (512) 329-5959

Website: <http://www.340better.org>

Information Available: Overview of the services 340Better provides.

Title: Maxor National Pharmacy Management Services

Description: Maxor provides a wide range of services to manage pharmacies and provide services, including implementing the 340B and PVP programs.

Phone: 1-800-687-8629

Website: <http://www.maxor.com/>

Information Available: Overview of the variety of services Maxor provides.

Title: RxStrategies

Description: Provides health centers with full support for implementing the 340B program and running a pharmacy program.

Phone: Sales – 1-877-GoGetRx (1-877-464-3879) option 4

Website: <http://www.340bplus.com/>

Information Available: Overview of the services RxStrategies provides.

Title: Council Connections

Description: A group purchasing organization providing discounts on pharmaceutical purchasing and other items.

Phone: 1-800-640-1662

Website: <http://www.councilconnections.com/site/>

Information Available: Overview of the services Council Connection provides.

Title: WellPartner 340B Access Solution

Description: Provides health centers with full support for implementing the 340B program and running a pharmacy program.

Phone: 1-877-231-6346

Website: <https://www.wellpartner.com/Corp340BAccessSolutions.aspx>

Information Available: Overview of the services WellPartner provides.

Appendix A.

340B Related Organizations

This table identifies various organizations that offer services related to the 340B program. This is not an exclusive list of organizations. Inclusion in this table does not indicate that NACHC endorses an organization or its services.

Service Provider	Category of Service						
	Distrib.	Pharmacy Oper.*	Data Manag.	Consult	Disease Manag.	Pharm. Dispense	Provider Dispense
RX Blue Star Solutions, LLC (800-985-7950)			x	x	x	x	
340bvm.com (800-521-1635)			x	x	x		
340B Partners Pharmacy					x	x	
American Health Care			x		x		
AmeriChoice		x					
AmeriSource Bergen	x		x				
APS Pharmacy					x	x	
A-S Medication Solutions	x						x
Capture Rx			x				
Cardinal	x	x	x				
Centric Health Resources				x			
Coordinated Care Network			x	x	x	x	x
CVS Caremark	x				x	x	x
eAudit Solutions			x				
eRx			x				
EquiScript			x				
Global Pharm. Solutions			x	x			

Good Health Systems				X			
Hudson Headwaters				X			
Huron				X			
Innovation Associates		X					
McKesson	X	X	X	X	X		X
Morris & Dickson	X						
National Direct Home Pharmacy					X	X	
Navigant				X			
NEC Networks			X	X			
Net-Rx			X	X			
PDX		X	X	X	X		
Pharmacy HealthCare Solutions				X			
PSSC				X			
Qs1		X	X				
Ramsell Public Health Rx			X	X			
Rx Strategies			X	X			
S/T Health Group Consulting			X	X			
ScriptPro		X					
Sentry Data Systems			X	X			
Speed Script			X				
SunRx			X	X			
Talyst			X				
WellPartner			X			X	
Wilkinson Benefit Consultants				X			

* Pharmacy Operations includes both hardware and software

Source: Richardson, K (2010). How to sift through 340B references. *Clinical Oncology News*. 5:06.

Retrieved October, 5 2010

http://www.clinicaloncology.com/index.asp?section_id=151&show=dept&issue_id=640&article_id=1529

[9](#)

Appendix B.

Alternative Methods Demonstration Project Proposal Guidance

INFORMATION REQUIRED FOR THE APPROVAL OF AN ALTERNATIVE METHOD DEMONSTRATION PROJECT

The following criteria are used to evaluate Alternative Methods Demonstration Project (AMDP) proposals. This information may be useful in developing a proposal for a covered entity as a guide, it is not a template.

1. Need

The main purpose of AMDP is to increase access to 340B priced pharmaceuticals. Describe in depth why current methods of utilizing the 340B program are not adequate.

Examples:

- a. Inconvenient hours of operation for current pharmacy site
- b. Wide geographic expanse of patients served
- c. High administrative costs
- d. Pharmacy services for 340B covered entities currently do not exist

The proposal should also include a detailed description of need for the demonstration project. This can be shown through demographic data, current access data or with the use of maps.

Examples:

- a. Map of site and / or pharmacy locations – showing proximity
- b. Description of area served
- c. Demographic description of patients served.

Examples:

- i. Poverty status
 - ii. Insurance status (i.e. % uninsured)
 - iii. Population of target area
 - iv. Number of prescriptions dispensed
 - v. Noncompliance rates
 - vi. Notable prevalence of disease in area served
- d. Most importantly, justify statements of need with data.

2. Description of the Method

Describe in as much detail, what the participants plan to do and how it will be accomplished.

3. Methods of Evaluation

In order to make a decision about the overall success of the demonstration projects, the Office of Pharmacy Affairs (OPA) will rely on approved sites to provide reliable data so

that an appropriate decision can be made in the future on including these practices into the 340B guidelines. Please provide valid and reliable methods of evaluation to determine effectiveness of the proposal to improve access to drug therapy and comprehensive pharmacy services for the uninsured or underserved patients of the covered entity.

These reports should document progress by addressing the following topics:

1. Evaluate the impact of the project on improving access to prescription drugs.
2. Explain actions to reduce administrative costs and expand access to prescription drugs.
3. Evaluate procedures to prevent drug diversion and Medicaid rebates on drugs purchased at 340B prices.
4. Demonstrate the value of participating in the 340B program in order to make these medications available to greater numbers of network patients.

Other important areas to address: additional costs incurred as a result of the demonstration project, how those costs are being defrayed or funded, cost/benefit ratios, number of medications ordered, and number of patients being served. The inclusion of best practices, keys to success, or helpful hints for other health centers that may want to replicate the model are also very valuable.

4. Participating Covered Entities

All participant(s) must be identified and eligible for the 340B program and must be listed in the OPA database. If a participant is not in the database, they are eligible and made application. The proposal should further document the commitment of the participating entities to take the necessary actions to implement the proposal. This should include current letters of support and/or contracts or agreements. Contracts do not have to be signed and in place to submit proposals but they should be ready for signature and implementation upon approval of the demonstration project.

For Disproportionate Share Hospital applicants, it must be understood that the entire hospital cannot claim to be a participant if the covered entity is a distinct part of the hospital. Only clinics on the Medicare cost report will be considered as part of the covered entity.

5. Duration of Project

The maximum duration of time that a project may apply for is six years.

6. Inventory Control and Dispensing

Please provide a detailed description of how and when medications will be ordered and who will be (i.e. the entity, purchasing group, contract pharmacy, etc).

Does the proposal comply with all State pharmacy laws? Certain states may require separate *physical* inventories (i.e. Florida)

Describe in detail the method for ordering and purchasing medications. Description of the record system Description of procedures taken for medications not picked up by eligible

patients. Describe how 3rd Party reimbursements will be handled.

How will the covered entity ensure they will be filling prescriptions for eligible patients by eligible prescribers?

How will eligible patients and prescribers be identified?

How will this data be updated? Clarify Medicaid billing procedures for all participating entities. Will prescriptions to Medicaid patients be carved-out?

Describe the financial relationships between all parties. Include: - How are 340B medications paid for, i.e., who is paying the bills? - What will reimbursements be? Will separate physical inventories be used or a replenishment model? If using a replenishment model, what are the procedures?

7. Compliance with 340B statutory and Program Requirements

Does the proposal comply with all 340B statutory and program requirements?

8. Drug Diversion

Medicaid

- The Office of Pharmacy Affairs has the pharmacy Medicaid number, if Medicaid carve out is not being utilized.
- An appropriate system is in place to prohibit a request for a Medicaid rebate from the manufacturer on a drug purchased using 340B pricing.

Auditing

These demonstration projects require annual audits following standard business practices. These audits must be performed by an independent, outside auditor with experience auditing pharmacies. The proposal should provide:

- Identification of the auditor and his/her experience in pharmacy auditing
- What will be audited?
- What audit trails will be provided to the auditor by the entity?
- What kind(s) of reports will be utilized to audit the pharmacy?

Drug diversion and duplicate discounts are a primary concern of OPA and all efforts to avoid these potential problems should be well explained.

Patient Eligibility

Does an in-house pharmacy serve the general (non-eligible) patients? If so, what are the procedures to ensure compliance with program requirements? Please ensure and explain how the proposal meets the three criteria for the “definition of a patient”:

1. Covered entity has a relationship with the individual that includes the maintenance of individual’s health care record.
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that the responsibility for the care provided remains with

the covered entity.

3. The individual receives a health care service or range of services from the covered entity which is consistent with the grant funding or Federally-qualified look-alike status (DSHs are exempt from this).

An individual ADAP client receiving financial assistance for payment of drugs under Title XXVI of the PHS Act will be considered a patient of the payor state ADAP. An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Information Necessary for Networks of Covered Entities

- Is the applicant defined as a network for other purposes or by other organizations?
- Approval of overseeing State administrative bodies, if necessary.
- Identification of the lead entity, if one exists.
- Identification of which entity, if not all, will be driving income from sale of the medications, and consideration of how this reportable income will affect grants (if the covered entity is a grantee).
- Medication ordering, billing and distribution procedures.
- Medicaid billing procedures.

General Information to Consider

- Do the patients of the covered entity have the choice to receive medications (not at 340B discounts) and services from other pharmacies?
- Do all aspects of the proposal meet State Board of Pharmacy regulations?
- Include all contracts or agreements with parties involved. These do not have to be signed but do need to be ready for implementation upon proposal approval.
- Does the proposal violate the Anti-kickback statute?
- Please include a statement acknowledging that if the proposal is approved, it is subject to audit by manufacturers and the Healthcare Systems Bureau.

OPA Website, <ftp://ftp.hrsa.gov/bphc/pdf/opa/AltMethCriteria.pdf>

Revised: 3/8/2010

ⁱ Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585) codified as section 340B of the Public Health Service Act. Initial federal regulations, 57 Fed. Reg. 27289 (May 7, 1993).

ⁱⁱ Pharmacy Services Support Center. *The 340B integrity and quality leading practice achievement peer-to-peer program*. Retrieved November 12, 2010. Available at <http://pssc.aphanet.org/documents/P2POnePager20100716.pdf>.

ⁱⁱⁱ H.R. Rep. No. 102-384(II), at 12 (1992)

^{iv} Safety Net Hospitals for Pharmaceutical Access. (2008). *An overview of the section 340B drug discount program*. Retrieved November 11, 2010. Available at http://www.snhpa.org/public/340b_overview.cfm.

^v National Association of Community Health Centers (2009). *Section 340B Drug Pricing Program*. Accessed September 3, 2010 <http://www.nachc.org/Section-340b-Drug-Pricing-Program.cfm>

^{vi} Department of Health and Human Services. *Offices of Pharmacy Affairs, Health Care Systems Bureau/HRSA*. Retrieved on November 12, 2010. Available at <http://www.healthfinder.gov/orgs/hr3390.htm>.

^{vii} Pharmacy Services Support Center. (2010). *Need technical assistance?* Retrieved on September 15, 2010 <http://pssc.aphanet.org/askpssc/needtechassistance.htm>.

^{viii} Section 340B(a)(4)(A) of the PHS Act

^{ix} Pharmacy Services Support Center, Health Resources and Services Administration. (2010). *What drugs are covered?* Retrieved Sept. 14, 2010 <http://pssc.aphanet.org/about/whatdrugsarecovered.htm>

^x PPACA, § 2503(a)(2)(B).

^{xi} Department of Health and Human Services, Office of Inspector General. (2005). *Medicaid drug price comparisons: Average manufacturer price to published prices*. Retrieved Sept. 8, 2010 <http://oig.hhs.gov/oei/reports/oei-05-05-00240.pdf>. Brand name drugs receive a discount of only AMP less 17.1% for clotting factor drugs reimbursed under Medicare Part D and for drugs approved by the FDA exclusively for pediatric indicators, and different discount for line extensions of brand name drugs. ACA, P.L. 111-148 and Centers for Medicare and Medicaid Services, State Medicaid Director Letter #10-006. (2010). *Medicaid prescription drug rebates*. Retrieved Sept. 14, 2010 <http://www.cms.gov/smdl/downloads/SMD10006.pdf>

^{xii} P.L. 111-148 and 111-152 consolidated.

^{xiii} ACA, §2501.

^{xiv} ACA, § 7102.

^{xv} Advanced notice of proposed rulemaking. *340B drug pricing program alternative dispute resolution process*. 75 Fed. Reg. 57233 (Sept. 20, 2010).

^{xvi} Pharmacy Services Support Center, Health Resources and Services Administration. (2010). *Consolidated health center grantee (not site) participation in 340B and the prime vendor program as of 7/1/2010*. Retrieved on September 3, 2010. ftp://ftp.hrsa.gov/bphc/pdf/opa/July_charts.pdf

^{xvii} *Notice regarding HRSA grant requirement; participation in the 340B drug pricing program*. 65 Fed. Reg. 6383 (Feb. 9, 2000).

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- ^{xviii} Chris Hatwig. (2009). *Apexus and 340B PVP Update – PowerPoint presentation*.
- ^{xix} Richardson, K. (2004). *The bridge to 340B comprehensive pharmacy services solutions in underserved populations*. Retrieved September 15, 2010
<http://www.medpin.org/docs/bridge-340B.pdf>.
- ^{xx} Wellpartner. (2010). *Community pharmacy: 340B Access Solution*. Retrieved on September 15, 2010 <https://www.wellpartner.com/Corp340BAccessSolutions.aspx>
- ^{xxi} Rx Strategies. (2010). About us – overview of Rx Strategies the 340B provider. Retrieved on September 15, 2010 <http://www.340bplus.com/about-us>.
- ^{xxii} Maxor. (2010). Welcome to Maxor. <http://www.maxor.com/> Retrieved on September 15, 2010.
- ^{xxiii} Texas Association of Community Health Centers. (2010). *340Better Overview*. Retrieved on September 15, 2010.
<http://www.340better.org>
- ^{xxiv} Council Connections. (2010).
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