



**DEPARTMENT  
of HEALTH  
and HUMAN  
SERVICES**

**Fiscal Year  
2012**

Health Resources and  
Services Administration

*Justification of  
Estimates for  
Appropriations Committees*

## **MESSAGE FROM THE ADMINISTRATOR**

I am pleased to present the FY 2012 Congressional Justification for the Health Resources and Services Administration (HRSA). This budget targets critical healthcare needs in underserved areas.

It is estimated that in FY 2012 approximately 24.4 million patients will receive access to high quality, comprehensive and cost-effective primary health care through HRSA's Health Center program. Additional resources are also provided for the Ryan White HIV/AIDS program to enhance prevention and treatment of people impacted by HIV/AIDS. Through the AIDS Drug Assistance Program, requested resources will provide life saving medications to 218,446 people infected with HIV. In July, 2010, the Obama Administration released the National HIV/AIDS Strategy (NHAS) and Implementation Plan for the United States. HRSA has an essential role to play in meeting the NHAS goals and is working across its Bureaus to fulfill the implementation plan activities. The budget also requests funding for other programs that play a key role in driving down costs and expanding healthcare access for the whole family.

The FY 2012 budget invests resources to increase the number of doctors, nurses and dentists in areas of the country experiencing shortages of health professionals. This will ensure that qualified clinicians will be available to serve underserved populations in the future. The budget also includes \$124 million to improve both access to and quality of health care in rural areas. This will strengthen regional and local partnerships among rural health care providers, expand community-based programs and promote the modernization of the health care infrastructure in rural areas.

This budget request supports achievement of the Agency's four strategic goals, which are to:

- Improve Access to Quality Health Care and Services
- Strengthen the Health Workforce
- Build Healthy Communities
- Improve Health Equity

Our FY 2012 budget request places a strong emphasis on investing in programs that improve access to health care in underserved areas and allows the Health Resources and Services Administration to take important steps toward achieving health care reform.

Mary K. Wakefield  
Administrator

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**Office of Pharmacy Affairs/340B Drug Pricing Program**

	<b>FY 2010 Actual</b>	<b>FY 2011 CR</b>	<b>FY 2012 Budget Request</b>	<b>FY 2012+/- FY 2010</b>
BA	\$2,220,000	\$2,220,000	\$5,220,000	+\$3,000,000
FTE	---	---	---	---

Authorizing Legislation - Section 340B of the Public Health Service Act as amended by the Affordable Care Act (P.L. 111-148), as further amended by the Health Care and Education Reconciliation Act (P.L. 111-152).

FY 2012 Authorization ..... Indefinite

Allocation Method ..... Contract

**Program Description and Accomplishments**

The 340B Drug Pricing Program requires drug manufacturers to provide discounts or rebates to a specified set of HHS-assisted programs and hospitals that meet the criteria in the Public Health Service Act and the Social Security Act for serving a disproportionate share of low income patients. The following health care providers are eligible to purchase outpatient drugs at 340B prices: all HRSA-assisted Federally Qualified Health Centers; Black Lung Clinics; Ryan White HIV/AIDS Programs including AIDS Drug Assistance Programs; Comprehensive Hemophilia Treatment Centers; Indian Health Service tribal organizations and Urban Indian Programs; Centers for Disease Control and Prevention- assisted sexually transmitted disease (STD) and tuberculosis (TB) clinics; Native Hawaiian Centers; Title X Family Planning Clinics; certain disproportionate share hospitals; children’s hospitals; Federally Qualified Health Center Look-A-Likes; Free-Standing Cancer Centers; Critical Access Hospitals; Rural Referral Centers; and Sole Community Hospitals.

The 340B Program requires drug manufacturers to give covered entities a discount that is at least 23.1 percent below Average Manufacturer Price (AMP) for brand name drugs; 13 percent below AMP for generic drugs; and 17.1 percent below AMP for clotting factor and pediatric drugs. From FY 2010 through FY 2011, covered entities will save an estimated \$3 billion on their \$6 billion outpatient drug expenditures by participating in the 340B Program. The total savings in FY 2012 are expected to increase as participation in the 340B Program increases. Drug purchases under the 340B Program represent approximately 2 percent of all U.S. drug purchases.

The Prime Vendor Program (PVP) established under Section 340B (a) (8) is responsible for the negotiation of pharmaceutical prices below the 340B ceiling price as well as contracting for wholesale distribution of pharmaceuticals to covered entities. The Program is free and

voluntary. The PVP contract was re-competed and awarded in 2009 to Apexus, a non-profit organization. As of May 2010, the PVP had over 3,600 drugs under contract with an estimated average savings of 15 percent below the 340B ceiling price. In addition, the PVP has contracts for other value-added pharmacy products and services such as vaccines, diabetic supplies, pharmacy software, and outpatient pharmacy automation. Historically, the PVP contracts provided over \$30 million in additional savings for covered entities enabling them to further expand their pharmacy programs and address growing patient needs during difficult economic times. Apexus has established “shareback” payments of \$5 million to participating covered entities. These funds allow the covered entities to purchase more medications at a reduced cost for their patients. The 340B Prime Vendor continues to build on the value that this public/private business arrangement brings to covered entities and the government. Current PVP trends are expected to continue, and savings are expected to increase substantially in subsequent years.

The Pharmacy Services Support Center (PSSC) was established in FY 2002 under a HRSA contract with the American Pharmacists Association to provide guidance and technical assistance to 340B covered entities. The PSSC contract was modified to accommodate the Office of Inspector General (OIG) recommendations that HRSA provide 340B Program education and training activities for covered entities. The PSSC assists the covered entities through the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) and the PVP to improve medication management, drug utilization, and patient safety, and to contain healthcare costs for their patients. The technical assistance is critical in assisting the newly eligible safety-net providers to fully utilize the 340B Drug Pricing Program. It also is important to maximize their savings through the use of all available tools, including multiple contract pharmacies since April 2010 and integrating leading patient safety practices to avoid serious adverse events.

HRSA has prepared a report, as requested in the 2007 and 2008 Senate Appropriations Committee Reports that identifies valuable lessons learned with recommendations for extending the services in which medications play an integral role in patient care. The Committee requested that HRSA submit a report that includes these recommendations and options for financing clinical pharmacy services in HRSA-supported programs, cost of such financing and opportunities for maintaining and building upon the relationships with colleges and schools of pharmacy.

### **Program Growth**

In FY 2010, 14,400 covered entities sites are expected to have registered in the 340B Program. The 340B Program is expected to continue experiencing a 3 percent growth per year. The number of contract pharmacies registered in the 340B Program serving covered entities has increased to over 3,000 and continues to grow since the final publication of guidance in March 2010.

## Funding History

<b>FY</b>	<b>Amount</b>
FY 2007	---
FY 2008	---
FY 2009	\$1,470,000
FY 2010	\$2,220,000
FY 2011 CR	\$2,220,000

## Budget Request

The FY 2012 Discretionary Budget Request for the Office of Pharmacy Affairs/340B Program is \$5,220,000 which is an increase of \$3,000,000 above the FY 2010 Actual Level. This funding will help to support verification of all HRSA-funded entities, ensuring accuracy and integrity of the 340B database over time.

From the inception of the 340B Program in 1992, the entire cost of administering the Program, including the development of guidelines and the provision of technical assistance to eligible grantees, has been borne by HRSA program management funds until FY 2009 when a line item of \$1,470,000 was established. The line item was expanded to \$2,220,000 in FY 2010 because of the need to make major improvements in program operations as identified by audits and evaluations conducted by the OIG. Continued and enhanced funding in FY 2012 is necessary to continue these major improvements in the 340B Program operations and to resolve identified deficiencies of the current level of operations. The areas of focus include:

Non-compliance with the 340B pricing requirements - 340B Program pricing errors are caused by a variety of problems including: incorrect package size data, omissions in data needed to compute 340B ceiling prices, and mistakes in 340B prices offered by drug manufacturers and/or wholesalers. As a first step in correcting these problems, HRSA negotiated an intra-agency agreement with CMS, permitting HRSA to compute the 340B ceiling prices using data that manufacturers' supplied to CMS. Funds from the FY 2012 appropriation request will continue to support publication of policies regarding the computation of 340B ceiling prices; implement a systematic quarterly comparison of 340B ceiling prices with the selling prices offered by manufacturers and drug wholesalers, and follow-up efforts to resolve problems wherever they arise in the data supply chain.

Errors and omissions in HRSA's covered entity database - HRSA's staff and its contractors have continued to take a number of steps to improve the integrity and reliability of the database of covered entities. This includes purging duplicate and obsolete entity records and adding updated entity information. While there have been great advances in improving the integrity and accuracy of the 340B database in response to deficiencies identified by the OIG, a sustained and systematic approach is needed to maintain this accuracy and integrity. HRSA will continue to require the verification of eligibility of entity types in FY 2012. In FY 2012, phased

implementation of a systematic verification system will begin to allow annual online verification of all records in the 340B database. HRSA considers the integrity of the 340B database to be a crucial responsibility that requires ongoing maintenance and development in order to effectively administer the 340B Program and meet the obligations of the Secretary and the law.

Program Regulations and Guidance - In FY 2012, HRSA will continue to support the implementation of program regulations and guidance to provide oversight to maintain the integrity of the 340B Program.

Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) - HRSA responded to the Senate Appropriations Committee's encouragement to establish a collaborative to identify and implement leading practices to improve patient care quality and avoid adverse events by establishing the pharmacist as an integral part of a patient-centered, inter-professional health care team. Collaborating with HRSA are external stakeholders including FDA's Office of Women's Health. FDA's interest was to reach underserved populations with medication safety and effectiveness information using specially trained health care professionals across the nation. Other partners include CMS, AHRQ, IHS, and more than 50 national organizations. The first PSPC cohort used a "collaborative care model" with 68 teams representing more than 200 safety net providers in 37 states to identify and disseminate best practices to other safety net providers. In the second cohort, more than 110 teams generated 54 percent improvement in health outcomes and a 49 percent decrease in adverse drug event rates. The fall of 2010 through 2011 marked the beginning of the third year of the Collaborative that continues and spreads throughout organizations nationwide. In this third cohort, there are 128 community-based, inter-professional teams comprised of 300+ organizations in 43 states. Schools and Colleges of Pharmacy have also adopted this model to increase their integration with safety-net partners to improve patient safety and patient health outcomes.

### **HRSA-Supported Performance Outcomes**

The primary products are the 340B online public access database, required by legislation, for use by stakeholders of the 340B Program, and the pricing module to be used to validate manufacturers' calculation of the 340B ceiling price. This investment allows OPA to improve its ability to respond to customer needs and improve 340B Program integrity. This project supports element 1.1 – to ensure accountability for business results by making sure stakeholders have accurate 340B Program data on which to base their sales projections or other business decisions.

Section 508 compliance of the PSSC/OPA Website was included in FY 2010 Planning. Implementation will continue in FY 2012. The purpose of this project is to make the PSSC Web-content 508 compliant and to establish a ".gov" domain. This project supports element 1.1 to strategically manage information technology to support the fair, consistent, transparent and efficient administration of the 340B Program.

## Outcomes and Outputs Tables

<b>Measure</b>	<b>Most Recent Result</b>	<b>FY 2010 Target</b>	<b>FY 2012 Target</b>	<b>FY 2012 +/- FY 2010</b>
Covered Entity Sites Served	FY 2009: 14,076	14,400	15,244	+844
TA Consultations	FY 2009: 3,408	1,000	4,885	+3,885
Program Level Funding (\$ in millions)	N/A	\$2.220	\$5.220	+\$3.000

**Office of Pharmacy Affairs/340B Drug Pricing Program User Fees**

	<b>FY 2010 Actual</b>	<b>FY 2011 CR</b>	<b>FY 2012 Budget Request</b>	<b>FY 2012+/- FY 2010</b>
BA	---	---	\$5,000,000	+\$5,000,000
FTE	---	---	5	+5

Authorizing Legislation - Section 340B of the Public Health Service Act as amended by the Affordable Care Act (P.L. 111-148), as further amended by the Health Care and Education Reconciliation Act (P.L. 111-152).

FY 2012 Authorization ..... Indefinite

Allocation Method ..... Contract

**Program Description and Accomplishments**

The 340B Drug Pricing Program (340B Program) is authorized by Section 340B of the Public Health Service Act (PHSA), and substantially reduces the cost of covered out-patient drugs to certain federally-supported entities and safety net hospitals. The 340B Program results in large cost savings for its participants and enables them “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384(II), at 12 (1992). Section 340B was amended by sections 7101 and 7102 of the Affordable Care Act (PPACA) which significantly expanded eligibility and increased HRSA’s oversight responsibilities and authorities. A sustainable funding source is needed to ensure the integrity of the Program under the demands of existing growth and the changing marketplace.

Newly eligible entities for the 340B Program are estimated to add 5,000 new sites to the Program. These new entities include: children’s hospitals (previously eligible under the Social Security Act), free standing cancer hospitals, critical access hospitals, sole community hospital, and rural referral centers. HRSA began enrolling these new covered entities beginning August 2, 2010. As of October 1, 2010, 337 hospitals out of approximately 1,500 eligible hospitals have enrolled in the Program.

HRSA has increased oversight responsibilities over 340B Program which will improve Program integrity, while adding a new level of complexity to program administration. The new authorities include pricing oversight, civil monetary penalties for manufacturers and covered entities, administrative dispute resolution process, and annual recertifications of all participants in the 340B Program.

HRSA requires significant additional ongoing funding sources to be able to administer the new authorities and responsibilities. Funds are also needed to address longstanding recommendations by the OIG to make major improvements in program integrity. Implementation of the cost recovery fee would address current information deficiencies as well as provide significant resources needed to address both long standing problems and expanded authority while reducing the government expenditure of taxpayer dollars.

The 340B cost recovery fee mechanism will permit a cost recovery fee initially set at 0.1 percent of the total 340B drug purchase paid by participating covered entities. These funds shall be available until expended. The fee will be collected from the covered entities by the manufacturers who will then deposit the cost recovery fee into a no year account established by the Secretary for use by the Secretary and designees in paying the total costs of the 340B Drug Pricing Program. HRSA's recovery fee model is based on the model utilized by the Veteran's Administration (VA) for its administration of the VA pharmaceutical discount program, which shares some aspects of the 340B Program. The VA pharmaceutical discount program operates with similar cost recovery fees commonly known as industrial funding fees.

The implementation of the cost recovery system will include the reporting of sales under the 340B Program and establishment of the cost recovery fee as a percent of the drug purchases under the Program paid to the manufacturer. The collected fee is in addition to the cost to purchase the drug at the 340B price. This fee will be paid by the entity and remitted by the manufacturer to the Secretary for use in administering operations of the 340B Program including integrity provisions and access to covered drugs and services for 340B eligible entities. The 340B entities receive a significant benefit and the cost recovery fee is designed to ensure the cost of administering the Program is paid for with a small fraction of the received benefit. Without the cost recovery fee, the funding necessary to administer this Program comes exclusively from the taxpayers. The cost recovery fee will create a sustainable funding source to meet the demands of the existing growth of the Program, the changing marketplace, and the new statutory program requirements.

## **Program Growth**

In FY 2011, approximately 1,000 newly eligible covered entity sites are expected to register in the 340B Program. While the 340B Program is expected to continue experiencing a 3 to 4 percent growth per year for existing categories of eligible entities, the covered entities that are newly eligible are expected to increase at an accelerated rate of at least 10 percent for the first two to three years. The number of contract pharmacies registered in the 340B Program serving covered entities has increased to over 3,000 and is expected to continue growing at an accelerated rate for the newly eligible covered entities.

## Funding History

FY	Amount
FY 2007	---
FY 2008	---
FY 2009	---
FY 2010	---
FY 2011 CR	---

## Budget Request

The FY 2012 Discretionary Budget Request of \$5,000,000 for the Office of Pharmacy Affairs/340B Drug Pricing Program User Fee is \$5,000,000 above the FY 2010 Actual Level. The 340B cost recovery fee will begin putting a cost recovery system in place and establish the necessary requirements for manufacturers and covered entities to efficiently implement this cost recovery system that will provide operations, oversight and integrity for the 340B Drug Pricing Program. The implementation of the cost recovery fee will support the natural growth of the 340B Program and fund new authority, responsibility, and oversight. The cost recovery fee will initially be set at 0.1 percent. During this first year of implementation for the cost recovery fee mechanism, an appropriation would still be necessary for the expanded functions until the regulations are published and funds are collected in sufficient manner to operate the Program.

Due to funding limitations, HRSA has not been able to fully implement the program integrity recommendations of the OIG or statutory requirements. Historically, the Program was supported with HRSA program management funds. Full implementation of the Program is resource dependent and is delayed due to insufficient resources. The lack of resources is partly due to the 340B Program's continuous adjustments to evolving Program needs including: normal Program growth of 3 to 4 percent a year on over 14,800 listed health care delivery sites; publishing guidelines and implementing various Program changes such as the addition of Children's Hospitals (added by the Deficit Reduction Act of 2005) and permitting multiple contract pharmacy arrangements. Full implementation of the cost recovery fee would address current information deficiencies as well as provide significant resources needed to address both long standing problems and expanded authority while reducing the government expenditure of taxpayer dollars.

Implementing the cost recovery fee will ensure a reliable and continuous funding source for HRSA to fully administer the 340B Program and will allow HRSA to better monitor compliance among both manufacturers and covered entities. The cost recovery fee will result in efficiency and fairness for the 340B Program overall. Having manufacturers collect the fees from covered entities as part of the payment process for covered drugs is the most efficient approach to ensure the accuracy and timeliness of the fee collection. In anticipation of expected further growth of the Program and additional responsibilities relating to increased eligibility and maintaining integrity and compliance, this funding mechanism will ensure the Program continues to operate successfully and effectively.

HRSA is required to develop and implement a system to verify accuracy of the 340B ceiling price in the marketplace. HRSA needs to develop and publish defined standards and methodology for the calculation of ceiling prices as well as put in place a new transparent system to calculate the official federal 340B ceiling price and make it available to the covered entities through the secured internet website that protects privileged pricing data. HRSA also needs to perform oversight activities such as spot checks of sales transactions by covered entities, selective auditing of manufacturers and wholesalers, inquire into the cause of any pricing discrepancies and take necessary corrective actions. The corrective actions include making sure the manufacturers issue timely refunds for routine retroactive adjustments and for exceptional circumstances such as erroneous or intentional overcharges. In addition, all covered entities are required to be recertified and their information must be updated on an annual basis or sooner to ensure the integrity of the system and information in the HRSA's database is accurate. These are all activities important to the integrity of the Program and it has not been possible to carry out them out due to insufficient resources.

Specifically, the activities that will be supported by this budget request include:

Cost Recovery System – The development and implementation of a comprehensive system to calculate fees and collect the appropriate amounts from manufacturers. The establishment of a cost recovery system for the 340B Program will help assure overall program integrity through systematic monitoring of compliance in accordance with 340B requirements and guidelines, by both covered entities and drug manufacturers. This can be achieved by updating the agreement between the Secretary and participating manufacturers with the following requirements: (1) to establish a cost recovery fee from participating 340B covered entities to pay for the total operating cost of the 340B Drug Pricing Program; (2) to give the Secretary discretion to require manufacturers to collect the fee at the time of sale of a covered outpatient drug to a 340B covered entity and remit that fee to the Secretary; (3) the fee initially will be 0.1 percent of the total 340B drug purchase paid by participating 340B covered entities to a manufacturer solely for drugs purchased by covered entities for 340B Drugs; (4) to incorporate the requirement that manufacturers report their calculated ceiling price with a supplemental report of the total amount obtained by the manufacturer for each covered outpatient drug sold to a covered entity (exclusive of non-discriminatory bona-fide service or administrative fees) and any additional information determined by Secretary necessary to administer the 340B Program; and (5) manufacturers would deposit the cost recovery fee into a no year account established by the Secretary for use by the Secretary and designees in paying the total costs of the 340B Drug Pricing Program. HRSA will need to issue regulatory and sub-regulatory guidance to manufacturers and covered entities to fully implement this provision. In addition to amending section 340B to authorize collection of fees from participating entities, it is imperative to add language to the legislation that gives the Secretary the authority to request participating manufacturers to sign a new Pharmaceutical Pricing Agreement that complies with the current law, or otherwise find them no longer in compliance with the requirements of 340B(a)(1).

Office of Pharmacy Affairs Information Systems (OPAIS) - Manufacturer's are required to report their 340B ceiling prices directly to HHS, HRSA must develop a system of verifying ceiling price calculations, post 340B ceiling prices to a secure website, utilize spot checks of

sales, and develop a system of refunds where appropriate. HRSA is also required to establish a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, and covered entities for purposes of facilitating ordering, purchasing, and delivery of covered drugs, including the processing of charge-backs for such drugs. In addition, HRSA is required to make system improvements and add procedures to enable and require covered entities to regularly update the information via the internet website. The system will verify the accuracy of information regarding covered entities that are listed on the website.

Compliance and Oversight - Compliance issues are addressed primarily when they emerge as complaints from manufacturers, covered entities, or non-governmental interest groups. HRSA currently has no systematic method of monitoring manufacturer or covered entity compliance with the 340B law and HRSA's published guidelines. OIG reports on October 18, 2005, titled "Deficiencies in the Oversight of the 340B Drug Pricing Program (OEI-05-02-00072)"; and on July 14, 2006, titled "Review of 340B Prices (OEI-05-02-00073)" have outlined recommendations for Program oversight and compliance. Among five recommendations to correct non-compliance among manufacturers, the OIG urged HRSA to institute oversight mechanisms to validate its 340B price calculations and the prices charged by manufacturers to participating entities. HRSA has not been able to fully implement these recommendations due to limited resources.

Technical Assistance - The newly eligible covered entity types to the 340B Program require technical assistance and access to the patient safety clinical pharmacy collaborative (PSPC) to improve operational performance and patient outcomes. The technical assistance includes the interpretation of applicable laws and statutes; the dissemination of information about the newly established cost recovery fee system; and guidance on system implementation for manufacturers. The technical assistance provided will also include recommendations to establishing affordable, high quality; comprehensive pharmacy services by the eligible entities using 340B purchased drugs. They also receive training and framework for peer to peer opportunities with other 340B safety-net providers for understanding 340B clinical and policy priorities to ensure compliance with law and guidelines. The technical assistance also includes support for implementing best pharmaceutical practices in the 340B Program to improve patient outcomes by measuring outcomes, reducing medication errors, and assisting in eliminating health disparities. These technical services are crucial to ensure participants are utilizing the 340B Program for maximum benefit. In addition, covered entities' access to PSPC will provide partnership opportunities to collaborate on leading clinical pharmacy practices to improve patient care quality and avoid adverse events.

Administrative Dispute Resolution Process - HRSA is authorized to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased and claims by manufacturers of violations, including appropriate procedures for the provision of remedies and enforcement of such process through mechanisms and sanctions. HRSA will designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and resolving claims by covered entities that they have been overcharged prices for covered drugs and claims by manufacturers that violations have occurred. HRSA will establish

deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously. The administrative resolution of claims under the regulations promulgated shall be a final agency decision and shall be binding, unless invalidated by an order of a court.

Civil Monetary Penalties - HRSA has new authority to impose sanctions in the form of civil monetary penalties for manufacturers and covered entities. HRSA will have the authority to impose up to \$5,000 of penalty to manufacturers for each instance of overcharging a covered entity knowingly and intentionally. In addition, HRSA will have the authority to require covered entities to pay monetary penalties to manufacturers in the form of compounded interest for knowing and intentional violations of diversion and/or removing and disqualifying the covered entity from the 340B Program for a designated period of time as penalty when violations are found to be systematic and egregious. These new authorities, responsibilities, and oversight are significant and will require sustainable funding resources to implement.

### **Outcomes and Outputs Tables**

The Program measures are under development.