

EXHIBIT 2



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Hemophilia Treatment Center Manual
for Participating in
the Drug Pricing Program
Established by Section 340B of
the Public Health Service Act**

July 2005



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Introduction

This manual has been prepared by the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Maternal and Child Bureau (MCHB), Division of Services for Children with Special Health Needs (DSCSHN), Genetic Services Branch (GSB) to provide guidance and reference material for Hemophilia Treatment Centers (HTCs) eligible to participate in the Drug Pricing Program authorized by section 340B of the Public Health Service Act (PHS Act). It provides information on the authorizing legislation, the program's method of operation, and specifics on how HTCs can become approved covered entities and make effective use of 340B discounts while complying with its statutory requirements. The manual does not establish policy for either the HTC Grant Program or the 340B Drug Pricing Program. Its purpose is to provide background information and practical advice on how HTCs can operate in compliance with 340B policy and related HTC program policy. Although GSB will update this manual to incorporate new policy developments, HTCs should make use of the information resources listed below to keep up to date with new developments as they occur, especially on the Web site for the Health Resources and Services Administration, Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA) (<http://www.hrsa.gov/opa>).

The manual is divided into three main sections:

- The first section provides a general description of the 340B program, its history and how it is administered by the OPA.
- The second section provides specifics on how the 340B program can be used by HTCs, emphasizing the aspects of the program which are most likely to concern them.
- The third section is made up of four appendices:
 - < The complete text of section 340B of the PHS Act
 - < The current version of the Pharmaceutical Pricing Agreement (PPA) which manufacturers must sign to continue to participate in the Medicaid program
 - < A compilation of all of HRSA's 340B program guidelines published to date
 - < Grants management guidance concerning program income.

General Information Resources

References are made throughout the manual to accessing information and advice from two key HRSA organizations, OPA in HSB and GSB in MCHB. In addition, through a contract managed by OPA, the HRSA Pharmacy Services Support Center (PSSC) is now handling routine inquiries about the 340B program. The following addresses should be used to acquire information from these organizations:

OPA:

Web site: <http://www.hrsa.gov/opa>

General phone number: (301) 593-4353

HRSA PSSC:

2215 Constitution Avenue, NW

Washington, DC 20037

Web site: <http://pssc.aphanet.org>

E-mail address: pssc@aphanet.org

Use the web site to register with the PSSC to receive information on new events and developments in the 340B program and gain access to other online resources.

General phone number: 1-800-628-6297

MCHB GSB:

General phone number: (301) 443-1080

MCHB Web site: <http://mchb.hrsa.gov>

Part I:
The Major Elements of the Public Health Service Drug Pricing Program

A. Brief history of the development of 340B

The 340B Drug Pricing Program was established by Section 340B of the PHS Act which requires drug manufacturers to provide discounts or rebates to a specified set of U.S. Department of Health and Human Services (HHS) assisted programs and hospitals that meet the criteria in the Social Security Act (SSA) for serving a disproportionate share of low income patients. It was enacted on November 4, 1992 as part of the Veterans Health Care Act of 1992 (VHCA92). This legislation was a follow-up to the Medicaid Drug Rebate Program (MDR Program) enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA90).

The MDR Program requires manufacturers to give Medicaid a rebate of 15.1 percent of the average manufacturer's price (AMP) or the AMP less the best manufacturer's price (BMP), whichever is lower. As originally enacted, the calculation of BMP included sales to directly operated Federal health care programs such as the medical systems operated by the Department of Veterans Affairs (VA) and the U.S. Department of Defense (DoD). As a result, drug manufacturers were reluctant to continue to sell drugs to direct Federal health care programs at the very advantageous prices they had in the past because it could increase the rebates they had to pay to Medicaid. Overall, prices paid for drugs by directly operated Federal health care programs rose after the enactment of OBRA 90.

Sections 601 and 603 of VHCA92 corrected the problem for direct Federal health care programs by removing their drug sales from the calculation of BMP and mandating minimum price reductions for purchases made by the VA for its own and other Federal health care operations. Section 602 of VHCA92 created section 340B of the PHS Act which provides ceilings on outpatient drug prices for certain HHS programs and disproportionate share hospitals. These sales were also excluded from the calculation of BMP. See Appendix A for the text of 340B.

B. Main Provisions of the 340B Legislation

Agreements with manufacturers

As a condition for continued participation in Medicaid, drug manufacturers must sign an agreement with the Secretary of HHS requiring their sales to the covered entities to be at or below the ceiling prices mandated by section 340B. Failure to sell covered drugs at these prices could result in a manufacturer being prohibited from receiving payments for its products from the Medicaid program.

Ceiling prices

For single source and innovator, multiple source drugs, the 340B ceiling price is the average manufacturer price (AMP) reduced by the Medicaid rebate percentage. For over-the-counter and generic drugs, the 340B ceiling price is the AMP reduced by 11 percent. The AMP is a term developed for the Medicaid Rebate Program (MR Program) and is defined in section 1927 of the Social Security Act (SSA). In general, the AMP is based on the weighted average of prices paid by wholesalers for drugs distributed to the retail pharmacy class of trade. It excludes sales to Federal health care systems and the covered entities.

The covered entities

The law designates the following selected grantees as eligible to be covered entities if they receive funds from the programs specified in 340B:

- Community Health Centers
- Migrant Health Centers
- Homeless Health Centers
- Public Housing Health Centers
- Black Lung Clinics
- Native Hawaiian Centers
- School-based Health Centers
- HIV Early Intervention Projects
- AIDS Drug Assistance Programs
- Other Ryan White AIDS Projects
- Hemophilia Treatment Centers (HTCs)
- Tribal Health Centers
- Urban Indian Health Centers
- Sexually Transmitted Disease Clinics
- Tuberculosis Clinics
- Title X Family Planning Clinics

The law also defines two types of non-grantees as eligible to be covered entities:

- Federally Qualified Health Center Look-Alikes recognized by HRSA
- Disproportionate Share Hospitals if they
 - < Carry out certain specified State or local government health care programs
 - < Have a disproportionate share adjustment percentage greater than 11.75 percent
 - < Do not participate in any group purchasing arrangements for covered outpatient drugs

Requirements for covered entities

A covered entity must comply with the following statutory requirements to access 340B discounts:

- Not request a discount for a drug subject to a Medicaid rebate; the Secretary established a mechanism to ensure compliance before the statutory deadline of one year after enactment (See page 23 for the details of how the mechanism works.)
- Not resell or otherwise transfer a discounted drug to a person who is not a patient of the entity
- Permit the Secretary and manufacturers to audit entity records pertaining to the drug in question, in accordance with procedures established by the Secretary, to ensure compliance with the first two requirements
- Repay the manufacturer the amount of 340B discounts received for any violations of the first two requirements, if the manufacturer seeks restitution

Other provisions

- The Secretary is required to
 - Develop and implement a process for the certification of certain eligible tuberculosis and sexually transmitted disease clinics and non-governmental entities participating in the programs established by Titles I and II of the Ryan White CARE Act, excluding AIDS Drug Assistance Programs (ADAPs)
 - Develop a prime vendor program to serve the covered entities
 - Notify manufacturers and State Medicaid agencies of the identity of the covered entities
- Manufacturers are not prohibited from charging a price for a drug that is lower than the maximum price that may be charged under 340B.

C. The Office of Pharmacy Affairs (OPA)

Shortly after the enactment of section 340B in 1992, the responsibility for administering the law was assigned to HRSA. To carry out this task, HRSA established the Bureau of Primary Health Care (BPHC), Office of Drug Pricing (ODP). In June, 2000, the mission of the office was broadened to include more general assistance for pharmacy programs and its name was changed to the Office of Pharmacy Affairs (OPA). In February 2003, OPA was moved to a new Division of Health Care Development (DHCD) and became the Pharmacy Affairs Branch (PAB). In September 2004, PAB was moved to the Healthcare Systems Bureau (HSB) as the Office of Pharmacy Affairs (OPA).

The mission and functions for OPA are as follows:

As the primary pharmacy resource for HHS health care programs, OPA promotes universal access to clinically and cost effective pharmacy services by:

- (1) maximizing the value of the 340B Program for eligible entities by
 - (a) managing the Pharmaceutical Pricing Agreement with pharmaceutical manufacturers who participate in the Medicaid program,
 - (b) maintaining a database of covered entities and organizations eligible to become covered entities, including status of certifications, where required,
 - (c) publishing guidelines and/or regulations to assist covered entities, drug manufacturers, and wholesalers to use the Drug Pricing Program (DPP) and comply with the requirements of section 340B,
 - (d) implementing and overseeing the 340B Prime Vendor Program (PVP) that provides drug distribution and price negotiation services for the covered entities,
 - (e) coordinating the 340B implementation activities of programs in HRSA, the Centers for Disease Control and Prevention (CDC), the Indian Health Service (IHS), and the Office of the Assistant Secretary for Health's (OASH) Office of Public Health and Science (OPHS) that provide support to entities eligible to access the DPP,
 - (f) providing a full range of technical assistance to eligible and participating entities,
 - (g) working with the Centers for Medicare and Medicaid Services (CMS) and the Department of Veterans Affairs (VA), which operate related drug rebate and discount programs, to coordinate policies and operations, and
 - (h) maintaining liaison with grantee associations, professional organizations, the pharmaceutical industry, and trade associations concerning drug pricing and pharmacy issues,
- (2) supporting HRSA health centers, States, and other delivery systems as they develop quality programs for affordable drug benefits through
 - (a) managing clinical pharmacy demonstration projects,
 - (b) assisting health centers and other grantees to make optimum use of resources available for pharmacy services,
 - (c) demonstrating innovative methods of delivering pharmacy services, and
 - (d) providing technical assistance to grantees, States, local governments, and other health care delivery systems to plan and implement pharmacy services,
- (3) serving as a Federal Government resource for pharmacy practice through
 - (a) developing and maintaining cooperative relationships with national pharmacy and governmental organizations to share information and build infrastructure for safety-net providers,
 - (b) compiling and marketing pharmacy "models that work" for States and communities, (c) developing a technical assistance center for pharmacy practice, and
 - (d) providing model pharmacy products (such as sample contracts and business plans) for safety-net health care providers, and
- (4) carrying out special projects as assigned by the Administrator.

Information about the 340B Program and other pharmacy program developments can be obtained from the OPA Web site at <http://www.hrsa.gov/opa>.

Pharmacy Services Support Center (PSSC)

OPA's ability to carry out its mission was enhanced through the award of a 5-year contract at the end of FY 2002 to the American Pharmacists Association (APhA) to operate the HRSA PSSC. APhA is the largest professional association of pharmacists in the United States with 50,000 members including practicing pharmacists, pharmaceutical scientists, students, pharmacy technicians, and others. The association provides professional information and education for pharmacists and is an advocate for improved health through the provision of comprehensive pharmaceutical care. Additionally, the American Association of Colleges of Pharmacy (AACCP) and other national pharmacy associations will participate in the contract to ensure that the new center is equipped to provide timely information on pharmacy practice.

Services to be provided by the PSSC include:

- Helping OPA conduct policy and pharmacoeconomic analyses on effective pharmacy practice and program needs of HRSA grantees;
- Providing information, evaluation, and recommendations to community health networks and community service organizations concerning innovative approaches in all practice settings for affordable, quality pharmaceutical services, including the effective use of the 340B drug pricing program; and
- Recruiting and managing a pharmacy consultant pool that will be available to provide on-site technical assistance to health centers and other providers supported by HRSA.

As the PSSC develops over the life of the contract, it is expected that its role in providing supporting professional services for providers eligible to participate in the 340B drug pricing program will grow. Check the PSSC web site (<http://pssc.aphanet.org>) for the latest developments. Eligible entities can obtain a PSSC ID to receive information on new events and developments in the 340B program and have access to other online resources.

D. The Pharmaceutical Pricing Agreement

Section 340B requires drug manufacturers, as a condition of continued participation in the Medicaid program, to sign an agreement with the Secretary of HHS to sell covered outpatient drugs to the covered entities at prices that do not exceed the limitations specified by the law. As of March 2005, there were 692 drug manufacturers participating in the 340B Program.

The full text of the current agreement is in Appendix B.

Manufacturers' responsibilities

- Adhere to the pricing limitations in section 340B
- Provide HRSA access to information needed to administer the 340B Program and retain supporting documentation for at least 3 years after its creation
- Permit HRSA to use Medicaid rebate data submitted by manufacturers to CMS that is needed for administering the 340B Program
- Participate in the PVP unless otherwise agreed to by the Secretary of HHS
- Use HRSA published procedures for resolving disputes with covered entities and conducting audits to determine if there has been any drug diversion
- Maintain the confidentiality of audit information obtained from the covered entities

Secretary's responsibilities

- Maintain accessible data on the identity of covered entities, updated quarterly
- Develop and implement a mechanism for preventing duplicate price reductions (see page 23 for how this works)
- Require covered entities to retain purchasing records and claims for Medicaid reimbursement for at least 3 years
- Maintain the confidentiality of information disclosed by the manufacturers, except as necessary to carry out Section 340B

E. The Covered Entity Database

As required by the Pharmaceutical Pricing Agreement (PPA) and Section 340B of the PHS Act, OPA maintains a database of covered entities authorized to purchase outpatient drugs at 340B prices. The data are updated quarterly and can be downloaded from the OPA Web site (<http://www.hrsa.gov/opa>) which is easily accessible by manufacturers, covered entities, State agencies, and any other parties interested in the administration of the PHS DPP. The data include multiple entries for covered entities that operate at more than one site.

The following Table I shows the trends in the number of covered entity sites registering as covered entities in the PHS DPP, broken down by type of program, since the end of its first full year of operation at the beginning of 1994. Over this period the number of sites has more than doubled. The program continues to grow at the rate of about 10 percent per year.

Table I
Number of Covered Entity Sites, 1994-2005

Type of Entity	Jan 94	Jan 96	Jan 98	Jan 01	Jan 03	Jan 04	Jan 05
Community Hlth. Ctrs.	342	451	670	1,064	1,412	1,805	2,301
Migrant Hlth. Ctrs.	69	99	122	165	182	178	113
Homeless Hlth. Ctrs.	39	105	84	118	155	171	128
Pub. Housing Hlth. Ctrs.	9	53	19	18	17	21	18
Fed. Qualified Hlth. Ctr. Lookalikes	56	34	92	96	130	146	163
Black Lung Clinics	1	1	1	4	5	5	10
Native Hawaiian Hlth. Ctrs.	0	0	0	0	0	0	5
School-based Hlth. Ctrs.	0	9	11	13	13	12	merged w/CHC
AIDS Drug Assistance Programs	1	26	25	49	52	54	54
Other Ryan White AIDS grantees	76	204	170	189	211	247	347
Hemo. Treatment Ctrs.	20	53	57	59	66	69	72
Subtotal, HRSA covered entity sites	613	1,035	1,251	1,775	2,243	2,708	3,211
Tribal Hlth. Ctrs.	0	34	45	64	86	92	100
Urban Indian Ctrs.	9	11	12	13	16	16	17
Subtotal, IHS covered entity sites	9	45	57	77	102	108	117
STD Clinics	162	236	459	688	916	1,154	1,342
TB Clinics	166	171	404	714	1,003	1,069	1,024
Subtotal, CDC covered entity sites	328	407	863	1,402	1,919	2,223	2,366
Title X Family Planning Clinics (OPHS)	4,068	4,607	4,773	4,768	4,928	5,269	5,190
Disproportionate Share Hospitals	122	160	238	332	446	578	1,026
Total, all covered entity sites	5,140	6,254	7,182	8,354	9,638	10,886	11,910

F. Program Guidelines

Since its inception, HRSA has used guidelines published in the *Federal Register* (FR) to administer the 340B Program.

Appendix C includes all of the guidelines published as final notices through mid 2005. The text includes only the final statement of the guidelines, not the responses to comments received on the proposed guidelines. The OPA Web site contains the complete text of the notices published in the *FR* including all of the responses to comments received.

The guidelines in Appendix C cover the following topics:

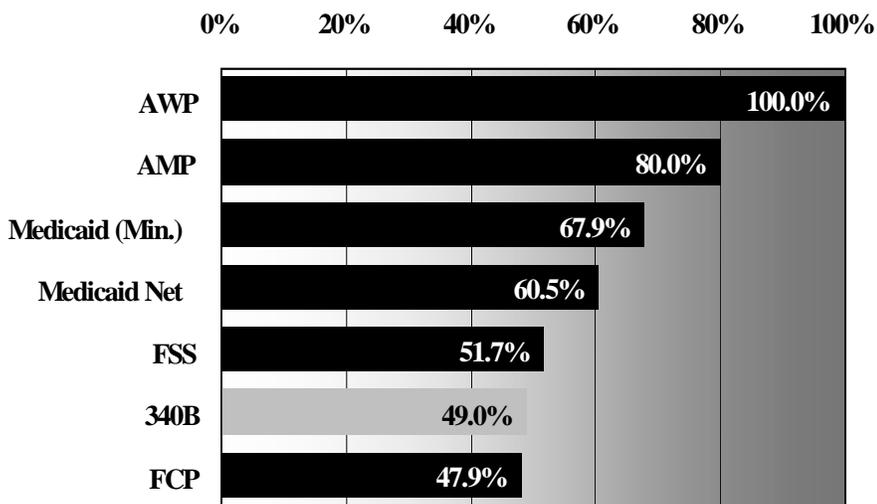
- General program guidance including eligibility criteria for covered entities, definition of a covered outpatient drug, calculation of the ceiling price, general information for manufacturers and covered entities, and confidentiality provisions
- The mechanism to prevent a Medicaid rebate on a 340B discounted drug
- Entity guidelines including procedures for avoiding drug diversion, requirements to maintain records of purchases of covered outpatient drugs and of any claims for Medicaid reimbursement for audit purposes, use of purchasing agents and wholesalers, and a clarification that manufacturers may not impose prior conditions, such as requiring their own assurance of action to prevent drug diversion, before selling drugs at the ceiling prices
- Eligibility of outpatient facilities of disproportionate share hospitals to be covered entities
- Guidelines for pricing new drugs introduced by manufacturers
- Definition of a patient of a covered entity
- Guidelines for contract pharmacy services, including a model agreement format and suggested contract provisions
- Guidelines for manufacturer audits of covered entities
- Recommended dispute resolution process
- Recognition of the State AIDS Drug Assistance Program rebate option
- Recognition of the option for covered entities to purchase outpatient drugs at regular market prices for their Medicaid patients

G. How 340B Discounts Help Covered Entities Improve Services

The purpose of the 340B Program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts or rebates. This permits HHS programs to provide additional financial capacity to assisted health care providers without increasing the Federal budget for the grant or other assistance programs that confer eligibility for the discounts. This method of augmenting their resources carries out the Congressional intent expressed in the House Commerce Committee's (HCC) report on the legislation (H.R. Report 102-384, 102nd Congress, 2nd Session, Part 2, page 12) which states, "In giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." If the covered entities were not able to access resources freed up by the drug discounts when they apply for grants and bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.

As required by the law and the PPA, drug manufacturers must charge covered entities a price for an outpatient drug that does not exceed the average manufacturer price (AMP) reduced by the Medicaid rebate percentage of 15.1 percent. Covered entities are free to negotiate lower prices if they have sufficient purchasing power. The chart below provides a general picture of how 340B prices compare to other Federal price reduction or discount programs in reference to average wholesale prices (AWP). It is based on a slide in a presentation entitled "State Opportunities under the 340B DDP" prepared by the Public Hospital Pharmacy Coalition (PHPC), a leading member of the 340B Coalition, a group of advocacy organizations representing the programs eligible to participate in 340B. It shows that the 340B prices are among the best available, coming in lower than the prices on the Federal Supply Schedule (FSS). However, they fall short of the discounts achieved by the VA's contract prices negotiated under the authority of section 603 of the Veterans Health Care Act for selected direct Federal health care programs. The complete presentation is available on the PHPC's web site, www.phpcrx.org.

Estimated Prices For Selected Public Purchasers, as a Percent of AWP



Covered entities use 340B income for a variety of purposes within their overall missions and the general purposes of the grants they receive. For example, community health centers use 340B income primarily to improve services for medically uninsured patients whose declared income is below 200 percent of the poverty line and pay for services on a sliding scale. Centers have increased the number of patients receiving discounted services and increased the discounts in the sliding scale fee schedule. Both community health centers and disproportionate share hospitals often use 340B income to offset unreimbursed costs of providing prescription drug services to under-insured or uninsured patients.

Most covered entities have used 340B income to provide services to more patients with little or no resources than they could otherwise afford to serve. Others have added services for their current service populations. Consistent with this overall pattern, hemophilia treatment centers (HTCs) use the extra income from the 340B discount to maintain or expand supporting services and as well as provide factor replacement products to uninsured patients.

H. Technical Assistance

Since the implementation of the 340B program in 1992, OPA, then the ODP, has placed a major emphasis on providing technical assistance to both eligible and participating entities. This assistance was provided primarily by phone consultations with in-house staff. However, during FY 1998, the Office expanded technical assistance resources by augmenting its in-house capacity with expert consultants. Since then the level of technical assistance has continued to grow.

With the broadening of OPA’s mission, technical assistance now includes advice on delivering effective clinical pharmacy services as well as making appropriate use of the 340B program. This

broadened technical assistance has been a critical component of OPA's support for clinical pharmacy demonstrations and comprehensive pharmacy assistance grants awarded to individual and networks of health centers. All eligible entities can request technical assistance from OPA on 340B operational issues or to obtain advice on efficient and effective pharmacy management.

The most efficient way to request technical assistance is to use the OPA Web site. Click on "Pharmacy Technical Assistance (PharmTA)" on the home page. This leads to the PharmTA page which contains a menu providing information about the services available. To request assistance on a specific topic, click on "Apply for Pharmacy TA." This leads to a form which can be used to request technical assistance online. E-mail responses are provided within 2 business days. You can also request assistance by phone, toll-free, at 1-866-PharmTA (1-866-742-7682).

I. Prime Vendor Program (PVP)

The 340B PVP has been developed to carry out section 340B(a)(8):

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

In the private sector, a prime vendor is an organization that provides total drug purchasing and distribution services for a single health care facility or network of facilities. PVs provide consolidated drug purchasing and frequent deliveries so that hospitals and clinics do not need to maintain large drug inventories. Health care facilities use prime vendors to lower distribution costs, reduce response times for making critical drugs available, and reduce inventory costs.

In designing the 340B PVP, HRSA included price negotiation services as an essential component to try to take advantage of the purchasing volume of the covered entities. As section 340B(a)(10) explicitly states, manufacturers are not prohibited from charging a price for a drug that is lower than the maximum price permitted by the 340B program. Including price negotiation in the PVP thus creates an opportunity to bring substantial additional value to the covered entities.

The current PV agreement, approved by the HRSA Administrator on September 10, 2004, designates Health Purchasing Partners International (HPPI) as the 340B PV. HPPI is a group purchasing organization serving more than 8,000 health care organizations by assisting them to lower and control their supply costs. Through its relationship with Novation, a supply chain management company which is responsible for negotiating a portfolio drug and medical supply pricing agreements, HPPI manages over \$20 billion in combined annual purchasing power in its non-PV business. The expectation is that HPPI can draw on this experience and its relationships with drug manufacturers to benefit the covered entities that join the PV program.

The previous PV agreement, approved by the Administrator on September 10, 1999, was with AmerisourceBergen, a national drug and medical supply wholesaler. The foundation of the agreement was drug distribution services with price negotiation as an additional service. This arrangement had limited success because covered entities using different wholesalers were reluctant to switch in order to join the PV program. Although AmerisourceBergen was able to negotiate additional discounts for a wide variety of generic drugs, it was unable to obtain additional discounts from brand name manufacturers.

The foundation of the current PV agreement is price negotiation and is structured so that a wide variety of drug wholesalers can participate. All three national wholesalers, AmerisourceBergen, Cardinal Health, and McKesson Pharmaceutical, participate in the PV program as well as several regional distributors. HPPI's PV operations are easily able to accommodate other distributors if requested to do so by prospective covered entity members.

HPPI has created a special Web site for the 340B PV program. It can be accessed at <http://www.340bpvp.com>. The phone number for the PV program is 1-888-340-2787. On the Web site, HPPI states its PV mission as serving covered entity members in 3 primary roles:

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

The Web site includes a link to instructions for completing the downloadable 3-page 340B Prime Vendor Participating Agreement. Prospective members need to print and complete two copies of the 340B Prime Vendor Participation Agreement and then submit two originals to HPPI by mail. The address is: 340B Prime Vendor Member Services/HPPI, Attn: 340B Prime Vendor, 125 East John Carpenter Freeway, Irving, TX 75062-2324. Once accepted as a member, the entity will receive one of the original agreements countersigned by HPPI. When the agreement is officially executed by both parties, the entity's distributor and contracted suppliers will be notified and instructed to use the prime vendor program contract pricing in all future covered outpatient drug transactions.

In its first 6 months of operation as the 340B PV, HPPI has made substantial progress in delivering services to covered entities. Participation has increased from 465 entities to 937. Annual sales volume increased to \$1.7 billion. Negotiations began with at least five brand name drug manufacturers. HPPI also offers discounts on a variety of other management and operational "value added" services such as patient assistance program software, contract pharmacy implementation and support services, and contract pricing on non-covered drugs and supplies.

J. Grant Statement

Although section 340B makes participation by the covered entities voluntary, other mandates for Federal fund managers and grantees require them to conduct operations at the lowest reasonable cost.

HRSA decided to include a statement in the Notice of Grant Award (NGA) requiring grantees to make an assessment of whether their drug purchasing practices meet Federal requirements regarding reasonable and cost effective purchasing. This policy was implemented during the FY 2000 grant award cycle by adding the following statement to the “Remarks” section of the HRSA NGA and the approval statements for Federally Qualified Health Center Look-Alikes:

If your organization purchases or reimburses for outpatient drugs, an assessment must be made to determine whether the organizations drug acquisition practices meet Federal requirements regarding cost-effectiveness and reasonableness (See 42 CFR Part 50, Subpart E, and OMB Circulars A-122 and A-87 regarding cost principles). If your organization is eligible to be a covered entity under section 340B of the PHS Act and the assessment shows that participating in the 340B DPP and its PVP is the most economical and reasonable manner of purchasing or reimbursing for covered outpatient drugs (as defined in section 340B), failure to participate may result in a negative audit finding, cost disallowance, or grant funding offset.

This requirement to make an assessment of drug acquisition practices is not based on anything in the 340B law or HRSA’s guidelines. It is based on Federal cost principles for grants and specific standards for the acquisition of drugs.

The general policy in the drug acquisition regulation in 42 CFR Part 50, Subpart E (Section 50.503) states:

It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible.

“Program funds” includes program income as well as Federal grant funds.

OMB Circular A-122, Cost Principles for Non-Profit Organizations, states the following regarding reasonable costs in Attachment A, section A-3:

A cost is reasonable if, in its nature or amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the costs. In determining the reasonableness of a given cost, consideration shall be given to:

- a. Whether the cost is of a type generally recognized as ordinary and necessary for the operation of the organization or the performance of the award.
- b. The restraints or requirements imposed by such factors as generally accepted sound business practices, arms length bargaining, Federal and State laws and regulations, and terms and conditions of the award.
- c. Whether the individuals concerned acted with prudence in the circumstances, considering their responsibilities to the organization, its members, employees, and clients, the public at large, and the Federal Government.
- d. Significant deviations from the established practices of the organization which may unjustifiably increase the award costs.

OMB Circular A-87, Cost Principles for State, Local, and Indian Tribal Governments, which applies to HTC's that are state agencies, contains a similar provision in section C.2 of Attachment A:

A cost is reasonable if, in its nature and amount, it does not exceed that which would be incurred by a prudent person under the circumstances prevailing at the time the decision was made to incur the cost. The question of reasonableness is particularly important when governmental units or components are predominately federally-funded. In determining reasonableness of a given cost, consideration shall be given to:

- a. Whether the cost is of a type generally recognized as ordinary and necessary for the operation of the governmental unit or the performance of the Federal award.
- b. The restraints or requirements imposed by such factors as: sound business practices; arms length bargaining; Federal, State and other laws and regulations; and, terms and conditions of the Federal award.
- c. Market prices for comparable goods or services.
- d. Whether the individuals concerned acted with prudence in the circumstances considering their responsibilities to the governmental unit, its employees, the public at large, and the Federal Government.
- e. Significant deviations from the established practices of the governmental unit which may unjustifiably increase the Federal award's cost.

Grantees that purchase or reimburse for drugs and fail to meet the standards in these policy documents could be subject to negative audit findings, cost disallowances, and future grant funding offsets. Annual audits conducted by public accounting firms are supposed to take account of the requirements of the grant statement as well as those conducted by HHS Office of Inspector General (OIG).

No additional instructions were issued to provide guidance on the scope and depth of the analysis that would constitute an assessment that would be satisfactory to HRSA.

K. Alternative Method Demonstrations

On June 18, 2001, then HHS Secretary Thompson announced a new initiative to help community health centers and other covered entities to develop methods of using the 340B Program to improve patient access to outpatient prescription drugs. Through demonstration projects, the initiative allows covered entities to reduce administrative costs and make acquiring drugs easier for patients. Entities approved for the demonstrations are able to do one or more of the following activities:

- Participate in single purchasing and dispensing systems that serve covered entity networks
- Contract with multiple pharmacy services providers; and
- Use contracted pharmacy services to supplement in-house pharmacy services.

Approved demonstration projects are time limited and must be evaluated on the basis of benefits provided as well as on compliance with requirements of the 340B law. They are focused exclusively on methods of using the 340B program and do not involve any increase in grant funds. If the demonstrations are successful, the new methods of accessing discounted drugs could be incorporated into HRSA's 340B guidelines.

Complete information about the Alternative Method Demonstration Projects is on the OPA Web site (<http://www.hrsa.gov/opa>).

Part II: Guidance for Hemophilia Treatment Centers

A. Deciding Whether to Submit the Necessary Information to Become a Covered Entity

A key element in the decision to register to become a covered entity is to make an estimate of the potential financial benefit of participating in the 340B program. This section presents guidance for making the assessment of drug purchasing practices required by the statement in the NGAs for organizations eligible to participate in 340B.

It is important to note at the outset that the grant statement **does not** require a hemophilia treatment center (HTC) or grantee to start purchasing or dispensing outpatient drugs if it does not already do so. It does not require an HTC to start acquiring and dispensing factor replacement products (FRP). However, if an HTC does operate an FRP program or makes a decision to start an FRP program, it must determine whether its acquisition practices meet the Federal requirements referenced in the grant statement.

OPA and GSB presume that HTCs participating in the 340B program and its PV are purchasing FRP in an economical and reasonable manner and do not need to make a new assessment of their purchasing practices. This includes HTCs that maintain separate purchasing records for FRP purchased outside of 340B for their Medicaid patients. However, an HTC that is participating in 340B but not its PV does need to make an assessment to determine whether joining the PV program would bring additional financial or program benefits.

OPA and GSB recognize that different HTCs may reach different conclusions regarding the most economical and reasonable manner to acquire FRP (e.g., to participate in both the 340B DPP and its PV, to participate in the 340B DPP but not its PV, or to participate in neither).

If the assessment shows that participating in the 340B program or using its PV would be financially beneficial, but the organization would prefer to adopt or retain a more costly alternative, it needs to document the reasons for reaching this conclusion.

The primary use of the assessments of drug purchasing practices is as input for HTC management during the process of determining whether to participate in the 340B program and its PV. Unless requested, they do not have to be submitted to GSB, OPA, or HRSA's grants management office. The assessments should be retained for examination during audits conducted by public accounting firms, the parent organizations oversight staff, or HHS OIG and for any site visits and reviews made by GSB or other HRSA field or headquarters staff.

With regard to becoming a customer of the PV, it does not appear to offer any significant value to HTCs, as of mid 2005. Although, to date, the PV has not been successful in lowering prices on FRP, it will continue to strive to negotiate advantageous pricing for 340B participating HTCs. To comply with the PV part of the assessment, check with OPA to determine whether this situation

has changed. If it has not, no further action needs to be taken. However, if the situation has changed, an analysis of the potential impact on the HTC's FRP acquisition operation should be undertaken. If the PV can guarantee timely delivery of FRP in the quantities required, a comparison needs to be made with the HTC's current suppliers and a judgement made concerning the value of becoming a PV customer.

B. Submitting the Necessary Information to Be a Covered Entity

OPA has standardized the registration process to ensure that eligible organizations submit the necessary information when they request to be recognized as covered entities. It includes the documentation that the entity meets the statutory requirements in subsections (5) (A) and (B) of section 340(b). To get the standard application form (340B Program Registration Form for Covered Entities), go to the OPA Web site and click on "Introduction to the 340B Program" on the home page. Click on "this form" which will open an Adobe Acrobat form which can be downloaded and printed.

Because GSB must verify an HTC's status before OPA adds the HTC to the covered entity database, HTCs should submit the completed form to GSB through the appropriate regional grantee. You may also fax an advance copy to OPA. GSB will provide the verification and forward the form to OPA. Following this process will speed up the verification and keep all involved parties informed of your request to become a covered entity.

This form can also be used to update entity information.

C. Confidential Drug Pricing Information

The need to protect confidential drug pricing information is a requirement of the Medicaid rebate program. For CMS to compute the rebates that manufacturers owe state Medicaid agencies, manufacturers must submit quarterly reports regarding their average manufacturer prices (AMP) and their best prices (BP). Section 1927 of the Social Security Act imposes strict confidentiality rules on HHS's use of this information.

Manufacturers determine the 340B discount or rebate by applying the statutory percentage to AMP or BP, whichever is lower. OPA gains access to these calculations through HRSA's interagency agreement with CMS and must also observe the confidentiality protections. The Entity Guidelines, published on May 14, 1994 (see guideline #3 in Appendix C), pass these protections on to the covered entities in section (1) but make it clear that 340B selling prices provided by wholesalers or manufacturers are not confidential:

"Confidential drug pricing information" includes both "BP" and "AMP." The quoted price and the actual price given by the manufacturer to the covered entity are not confidential.

In the normal course of operations, HTCs should have little difficulty maintaining the confidentiality requirements because they do not have access to AMP or BP data. OPA does not provide any restricted data to HTCs or any other covered entity. When inquiries are made concerning the accuracy of a 340B selling price, OPA never divulges AMP or BP data.

D. Avoiding Duplicate Discounts/Rebates

Subsection (5)(A)(ii) required the Secretary to establish a mechanism to ensure that covered entities do not request Medicaid reimbursement for a 340B drug for which a State agency requests a rebate under the Medicaid rebate program. The Secretary's final mechanism was published on June 16, 1993 and the full text is included in guideline #2 in Appendix C. The application of the mechanism was further clarified in a notice published on March 15, 2000 regarding the permissibility of the Medicaid carve-out. This is also included in guideline #11 in Appendix C.

The objective of the mechanism is to ensure that manufacturers are subject to only one price reduction for any outpatient drug sale: either a Medicaid rebate or a 340B discount, but not both. It also seeks to ensure that Medicaid State agencies do not miss out on rebates that they are entitled to.

If an HTC purchases all of its FRP at 340B prices, it is required to submit its Medicaid provider number to OPA when it registers as a covered entity. OPA then passes this number to the appropriate State agency for its exclusion file so that the HTC's FRP purchases are left out of the agency's rebate requests to manufacturers.

If an HTC purchases FRP for its Medicaid patients at regular market prices and maintains a dual inventory, it should not submit its Medicaid provider number when registering as a covered entity. In this way, the state agency can collect rebates on the HTC transactions. In either case, manufacturers are not exposed to more than one price reduction on each FRP purchase and reimbursement.

E. Avoiding Drug Diversion

Subsection (5)(B) of section 340B requires that a covered entity shall not resell or otherwise transfer a 340B drug to a person who is not a patient of the entity. Ensuring that 340B drugs are dispensed only to the patients of the covered entity is one of the most important requirements for participating in the 340B program. Some flexibility in carrying out this assurance is possible through participation in an alternative method demonstration project in which a network is permitted to be treated as a single covered entity.

Observance of the prohibition against drug diversion depends heavily on following the definition of a patient. This definition was published on October 24, 1996 (see guideline #6 in Appendix C) and reads as follows:

An individual is a “patient” of a covered entity (with the exception of State operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
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 (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

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.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the State program.

F. Audit Requirements

Section 340(b)(5)(C) gives manufacturers, at their own expense, the authority to audit covered entities that they suspect of non-compliance with the prohibitions on duplicate discounts/rebates or drug diversion. The authority must be carried out according to procedures established by the Secretary. [This section also refers to similar audits conducted by the Secretary. This does not supersede the much broader authority to conduct audits and investigations which other law provides to HHS OIG or Congress’s Government Accountability Office (GAO). Based on this law, the OIG and GAO have the authority to audit or investigate any aspect of a grantee’s operation.]

The procedures adopted by the Secretary to manage manufacturer audits have been published as a separate HRSA guideline. (See guideline #8 in Appendix C.) The procedures require the manufacturer to present “documentation which indicates that there is reasonable cause” to suspect non-compliance as well as a detailed audit workplan to HRSA before conducting an audit. As of mid 2005, no manufacturer has made a formal request to conduct an audit or presented any documentation to support a charge of drug diversion or actions leading to duplicate discounts/rebates.

Section (e) in guideline 1 in Appendix C requires covered entities to retain records of 340B drug purchases and any claims for reimbursement for these drugs submitted to Medicaid State agencies. These records must be retained and made available in case of an audit by a manufacturer or the OIG. The normal standard for how long the records need to be retained is 3 years from the end of the fiscal year during which the transactions occurred.

G. Dispute Resolution

HRSA has adopted formal procedures for resolving disputes that may arise among participants in the 340B program. (See guideline #9 in Appendix C.) Although these procedures have a broader scope than the audit guideline, to some extent, they are meant to provide an alternative to a manufacturer audit. One of the early steps in the audit process encourages the manufacturer and the covered entity to move to the dispute resolution process rather than proceeding with the development and implementation of a detailed audit work plan.

Most important, before the formal dispute resolution process begins, the parties must attempt, in good faith, to resolve the dispute informally. At this stage the disputing parties need to document the issues and the good faith attempt to resolve the problems. If this effort fails, this documentation becomes the starting of the formal resolution process, possibly leading to the convening of a committee appointed by the Associate Administrator for HSB to examine the issues and propose a determination.

Some of the disputes that could be resolved are:

- A concern that a manufacturer is charging a price that exceeds the 340B ceiling price
- An allegation that a manufacturer is conditioning the sale of 340B drugs on a covered entity meeting a requirement not based on the law
- A manufacturer concern that a covered entity is dispensing a covered outpatient drug in an unauthorized service such as inpatient care
- A covered entity concern that the auditors of the manufacturer have not abided by the approved workplan or audit guidelines
- A wholesaler or distributor will not sell drugs to a covered entity at 340B prices

As of mid 2005, no dispute has resulted in use of the formal resolution process or the establishment of a committee.

H. What to Do If Factor Replacement Products Are Not Available at 340B Prices

Since the 340B law was enacted in 1992, HTC's have sometimes experienced problems in acquiring factor at the 340B discount. Some of these problems are the result of production

difficulties such as the lead time needed to increase the supply of new products and others from a poorly worded provision in the first version of the PPA that manufacturers signed shortly after 340B was enacted.

The following is from a letter that the Office of Pharmacy Affairs (OPA) Director sent to an HTC in 2001 in response to a question about a problem acquiring factor at the 340B price from a distributor. It states HRSA's policy on delivering 340B priced products through the drug supply chain:

The concern that you raise may be the result of a provision in the PPA that manufacturers signed when the 340B program was first implemented in December, 1992. Section II (a)(3) of that PPA states:

A manufacturer may, at its option, make the price computed under this paragraph available either directly to the covered entity or to the wholesaler designated by such covered entity for covered outpatient drugs purchased by the covered entity.

The 1992 PPA was revised in 1995, and this provision was not retained. The wording of the 1992 provision led to some confusion about the manufacturer/wholesaler relationship. After the 1992 PPA was signed by most manufacturers, it came to our attention that manufacturers might be using the option of direct sale to single out covered entities from other customers for restrictive conditions that would undermine the statutory objectives of Section 340B. To clarify the manufacturer/wholesaler relationship, HRSA included the following section in the Entity Guidelines published in a final *FR* notice on May 13, 1994 (59 *FR* 25110, 25113):

Section (c)(10): Dealing Direct or through a Wholesaler

If a manufacturer has customarily dealt directly with a particular covered entity, then requiring the manufacturer to continue this form of purchasing with the covered entity is reasonable.

When dealing directly with a covered entity, manufacturers must offer covered outpatient drugs at or below the section 340B discount prices. If a manufacturer customarily uses a wholesaler as a means of distribution, then requiring the manufacturer to continue this form of purchasing with covered entities is also reasonable. If the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue. Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective. Manufacturers must not place

limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.

Thus, the covered entity may choose to utilize any purchasing system that a manufacturer may make available to its customers. It is program policy that a manufacturer should not single out covered entities through the use of restrictive conditions that may limit the entity's purchasing options, such as requiring direct from manufacturer purchasing when that manufacturer also utilizes wholesalers and distributors to deliver its products to other customers. The foregoing statement of 340B program policy has not changed since it was published in the May, 1994 *FR*.

In brief, HRSA's policy is that manufacturers must offer 340B prices to covered entities for their products no matter what route the payments take through the drug supply system from the covered entities to manufacturers. Distributors are subject to this policy as well as wholesalers.

If there are problems with a wholesaler or distributor refusing to provide FRP at 340B prices, the HTC should always deal with them in a way that does not jeopardize the health of the people that it serves. A patient's health or the quality of health care should never be compromised because of a pricing dispute with a drug manufacturer, wholesaler, or distributor. HRSA also recognizes that HTCs are not responsible for enforcing the 340B law and the associated pricing policy. However, an HTC that experiences a situation where a manufacturer, wholesaler, or distributor appears to be charging improper prices is responsible for bringing the facts of the situation to the attention of GSB and OPA.

An HTC observing potentially illegal pricing actions should record the facts of the situation in a written report to their grantee organization and to HRSA, MCHB, GSB along with any supporting documentation that might be available. GSB will review the report and, if the allegations appear credible, forward the report and documentation to OPA for appropriate action. OPA will attempt to resolve the problem. If that is not possible, OPA will consult with the Office of General Council (OGC) and/or the OIG to determine the appropriate course of action.

I. Freedom of Choice Regarding FRP and Avoidance of Conflict of Interest

It is a requirement of the MCHB National Hemophilia Program (NHP) that all MCHB funded hemophilia treatment centers have a "Freedom of Choice" policy where patients are informed of choices they have regarding factor replacement products and where these products might be purchased. It is important that this policy be exercised with all patients and it is especially important that this policy be exercised by MCHB funded hemophilia treatment centers that sell factor replacement products since income generated from this activity is used to further the provision of services by the hemophilia treatment center. To avoid any appearance of conflict of interest, patients must be informed about their choices and be encouraged to make whatever decision they desire.

J. Contract Pharmacy Services

In 1996, HRSA published detailed procedures for covered entities to use contracted pharmacy services to dispense their 340B drugs. (See Appendix C, guideline 7.) The guideline includes all of the steps needed to develop a contractual relationship, including a model contract agreement. A “ship to, bill to” procedure enables the covered entity to purchase the drug but have it shipped directly to the contract pharmacy.

For manufacturers to recognize the contract pharmacy as an authorized dispenser of drugs at 340B prices, it must be included in a OPA database separate from the covered entity database. To get its contracted pharmacy in that database, a covered entity must submit a notarized self certification that it has a contractual agreement in effect. A self-certification form is available on the OPA Web site to print or download. From the home page, click on “Contracted pharmacy” and then “Self-Certification Form.”

It is not necessary that the contract be with a commercial pharmacy. It is possible for the in-house pharmacy in one covered entity to be the contracted pharmacy for another covered entity. HTC networks or cooperative systems may find such an arrangement a useful tool in carrying out their programs.

In structuring the relationship between the HTC and the contract pharmacy, it is important to pay close attention to section 3 of the notice regarding compliance with the Federal Anti-Kickback statute. Careful adherence to these requirements will avoid many potential conflict of interest problems. In addition it is important to make sure that the management of the contract pharmacy be kept separate from the management of the hemophilia treatment center. No employee of the contract pharmacy should occupy any role or position of a policy making nature regarding policies of the hemophilia treatment center.

K. Billing Private Insurance Carriers

There is no HRSA guideline regarding billing private insurance carriers for the provision of 340B drugs including FRP. HTCs are free to use their own judgment as they work within the reimbursement policies of the public and private health insurance plans they work with. Some critics of HTCs have recommended that they bill insurance carriers at 340B prices. However, to do so would require HTCs to forgo the income that 340B was enacted to create. But there is another factor that also needs to be considered, the life-time limits that many private insurance plans place on reimbursements for FRP. In using their billing flexibility, the GSB recommends that HTCs carefully balance the opportunity for needed income against the value of extending the duration of the insurance benefit.

L. Using 340B Income

Guidance on the programmatic use of this income is the responsibility of the office administering the program and the office awarding the grant within the rules of the HHS Grants Management Regulation (GMR) (Part 74 of Title 45 of the Code of Federal Regulations) and HRSA's grants policy which is based on the PHS Grants Policy Statement (GPS). (This may be superseded in the future by the publication of a separate HRSA GPS.) These general rules may be supplemented by specific guidance in the NGA or by letter from the Grants Management Officer (GMO) and/or the Associate Administrator for the Maternal and Child Health Bureau (MCHB).

The grants awarded to HTC's do not provide funds for purchasing and dispensing FRP. This is an activity that many HTC's undertake in addition to the activities directly supported by their grant funding. Income received beyond FRP operating costs is then used to support activities of the same general type as those supported by the grant awards. In a letter to grantees dated May 23, 2003, the HRSA GMO and the Associate Administrator for MCHB clarified how the grants policy rules on program income affect the HTC's. In brief, FRP revenue, whether or not the HTC is a 340B covered entity, is program income and subject to the rules for that kind of income in the grant regulation and the policy statement. The rules apply to both HTC regional grantees and their affiliates. Program income needs to be reported on the Financial Status Report beginning with grant awards for FY 2003. Program income may be used to reimburse costs provided by HTC parent institutions. The program income sections of the regulation and policy statement are in sections 1 and 2 of Appendix D. The full text of the letter to grantees is in section 3 of Appendix D.

M. Role of the OPA

OPA has the broad responsibility for administering section 340B of the PHS Act and overseeing the use of the authority by the programs eligible for it and the grantees and other entitled organizations that become covered entities. OPA is responsible for developing and interpreting, in consultation with OGC, all official guidance that is published in the *FR*. As part of its policy development function, OPA coordinates with the CMS and the National Acquisition Center (NAC) of the VA regarding issues affecting the Medicaid rebate program and the statutory discount program for direct Federal health care programs, respectively.

Operationally, OPA maintains Pharmaceutical Pricing Agreements with drug manufacturers and databases of eligible entities, covered entities, and pharmacies having contracts with covered entities. Primarily through the PSSC, OPA provides technical assistance to PHS programs and their grantees to help them make the most effective use of the 340B authority and provides advice on effective pharmacy operations. OPA is also responsible for overseeing the integrity of the 340B program and carries out this function in concert with the programs eligible to use the authority.

In carrying out its responsibilities, OPA is cognizant of the responsibility of the program and

grants management offices to be the primary source of program guidance to their grantees. The resolution of 340B issues must be carried out within this context.

N. Role of the GSB

As the project office, the GSB is responsible for developing and overseeing the program policies governing HTC grants. With respect to 340B, GSB is responsible for managing the interface between that authority and HTC program policy and operations. GSB makes sure that the regional grantees and the affiliates are aware of the basic features and requirements of 340B and keep abreast of 340B program developments and is also a resource for technical assistance. It coordinates the presentation of issues that need to be resolved by OPA, HRSA grants management, or other oversight offices. As described on page 18 of this document, the general policy in the drug acquisition regulation in 42 CFR Part 50, Subpart E (Section 50.503) states: It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible. GSB expects HTCs to not only pay attention to the economical initial cost of FRP, but also to the economical operation of the FRP program whether operated through an in-house pharmacy or through a contract pharmacy. In addition, GSB has program responsibility to ensure that grantee/HTC performance including performance of a FRP program is effective in meeting the needs of HTC patients. HTCs that do not operate their FRP programs in an appropriate effective and economical manner are subject to program requirements being placed on them by means of conditions being placed on the Regional Grant.

O. Role of Regional Grantees

As the initial recipients of grants for hemophilia services, Regional Grantees have a general oversight responsibility for the program policies developed by MCHB and GSB as clarified by the May 23, 2003 letter to grantees (see Appendix D, section 3). They have a similar oversight responsibility for the use of the 340B authority. The Regional Grantees coordinate the provision of reports on 340B FRP operations by the HTCs using this authority. Regional Grantees have a responsibility to be informed regarding HTC FRP programs in terms of their general characteristics and have the same responsibility as GSB to foster the economical and effective operation of these programs. HTCs that are interested in looking into starting an FRP program should contact their Regional Grantee Program Director or Coordinator to discuss various possibilities regarding how such a program might operate. Regional Grantees in turn should contact their MCHB Grant Project Officer to discuss any plans for an HTC RFP Program.

Appendix A:
Section 340B of the Public Health Service Act

Title III, Part D, Subpart VII – Drug Pricing Agreements
Limitation on Prices of Drugs Purchased by Covered Entities

340B (a) Requirements for agreement with Secretary

(1) In general -- The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs [other than drugs described in paragraph (3)] purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

(2) Rebate percentage defined

(A) In general -- For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to-- (i) the average total rebate required under section 1927(c) of the Social Security Act with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by (ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general -- For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act is based on the applicable percentage provided under section 1927(c)(4) of such Act.

(ii) Definition -- The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans -- Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act.

(4) Covered entity defined -- In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256(a) of this title.

(C) A family planning project receiving a grant or contract under section 1000 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV of this chapter (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV of this chapter.

(F) A black lung clinic receiving funds under section 937(a) of this title.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXVI of this chapter [other than a State or unit of local government or an entity described in subparagraph (D)], but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247(c) of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital [as defined in section 1886(d)(1)(B) of the Social Security Act] that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage [as determined under section 1886(d)(5)(F) of the Social Security Act] greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

(5) Requirements for covered entities

(A) Prohibiting duplicate discounts or rebates

(i) In general – A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) Establishment of mechanism – The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

(B) Prohibiting resale of drugs – With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) Auditing – A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

(D) Additional sanction for noncompliance – If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug [as described in subparagraph (A)] provided under the agreement between the entity and the manufacturer under this paragraph.

(6) Treatment of distinct units of hospitals – In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

(7) Certification of certain covered entities

(A) Development of process – Not later than 60 days after November 4, 1992, the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

(B) Inclusion of purchase information – The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

(C) Criteria – The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

(D) List of purchasers and dispensers – The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

(E) Recertification – The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

(8) Development of Prime Vendor program – The Secretary shall establish a Prime Vendor program under which covered entities may enter into contracts with Prime Vendors for the distribution of covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

(9) Notice to manufacturers – The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

(10) No prohibition on larger discount – Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

(b) Other definitions – In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(c) References to Social Security Act – Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect November 4, 1992.

(d) Compliance with requirements – A manufacturer is deemed to meet the requirements of subsection (a) of this section if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after November 4, 1992), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after November 4, 1992.

Appendix B:
**Current Standard Pharmaceutical Pricing Agreement between the
Department of Health and Human Services and Drug Manufacturers**

PHARMACEUTICAL PRICING AGREEMENT
(hereinafter referred to as the "Agreement")
Between
THE SECRETARY OF HEALTH AND HUMAN SERVICES
(hereinafter referred to as the "Secretary")
and
THE MANUFACTURER
Identified in Section IX of this Agreement
(hereinafter referred to as the "Manufacturer")

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) **"Average Manufacturer Price (hereinafter referred to as the "AMP")"** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) **"Best Price"** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) "**Bundled Sale**" refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

(d) "**Covered Drug**" means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) "**Covered Entity**" means:

- (1) certain Public Health Service grantees, "look alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and
- (2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) "**Manufacturer**" has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the covered outpatient drug. The term includes:

- (1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and
- (2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) "**Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)**" means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) "**Medicaid Rebate Program and Medicaid Rebate Agreement**" mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) "**National Drug Code (NDC)**" means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) "**Over the Counter Drug**" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) "**Quarter**" means a calendar quarter unless otherwise specified.

(l) "**Rebate Percentage**" means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) "**the Secretary**" means the Secretary of Health and Human Services, or any successor or thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) "**Unit of the Drug**" means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) "**Wholesaler**" means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

II. Manufacturer's Responsibilities

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11 percent, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP, baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the Public Health Service Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site, or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c) to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in

an amount equal to the reduction in the price of the drug as described in section II(a) of the Agreement. Pursuant to section 340(B)(a)(4) which states that "the term "covered entity" means an entity that meets the requirements described in paragraph 5...". The covered entity could also be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section 340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement.

(e) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

V. CONFIDENTIALITY PROVISIONS

- (a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.
- (b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

VI. NONRENEWAL AND TERMINATION

- (a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.
- (b) The Manufacturer may terminate the Agreement for any reason. Such termination shall

become effective the latter of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

- (c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request, the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.
- (d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.
- (e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

VII. GENERAL PROVISIONS

- (a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.
 - (1) Notice to the Secretary will be sent to:
 - Health Resources and Services Administration
 - Attn: Office of Pharmacy Affairs
 - 5600 Fishers Lane, Room 10C-03
 - Rockville, Maryland 20857
 - (2) Notice concerning data transfer and information systems issues is to be sent to the same address listed above (section VII(a)(1) of this Agreement).
 - (3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.
- (b) The Manufacturer will be permitted to audit the records of each covered entity -
 - (1) that directly pertain to the entity's compliance with the prohibition on -
 - (A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

- (B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);
- (2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and
- (3) at the Manufacturer's expense.
- (c) No provision in the Agreement shall prohibit the Manufacturer from charging a price for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.
- (d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.
- (e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.
- (f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.
- (g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme. Except for changes of address, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.
- (i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between The Secretary of Health and Human Services and The Manufacturer.

IX. SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By:

Title: Administrator
Health Resources and Services Administration

Date:

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments, or other changes to this pricing agreement.

By:

(Type or print name)

Title:

Name of Manufacturer:

Manufacturer Address:

Phone Number:

Manufacturer Labeler Code(s):

Contact Person:

Title:

Phone No:

Date:

Appendix C:
Compilation of Published Guidelines for the Drug Pricing Program
(Dates indicate when final notices were published in the *Federal Register*)
(Excludes responses to comments on proposed notices)

1. General Guidance (February 11, 1993)

Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement (the "Agreement") with the Secretary of Health and Human Services (the "Secretary") in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed the average manufacturer price ("AMP") decreased by a rebate percentage. This notice advises manufacturers and covered entities of the terms of the Agreement, describes the criteria for the certification process required of certain entities, and alerts manufacturers who have not received an Agreement by mail of the manner in which to request one.

Section 340B was effective with respect to drug purchases on or after December 1, 1992. Agreements signed after that date are effective for purchases of covered outpatient drugs retroactive to December 1, 1992, for those entities included on the initial list of covered entities mailed to each manufacturer. For manufacturers that have not received an Agreement by mail, a written request for an Agreement should be submitted to the Drug Pricing Program within 30 days from the date of publication of this notice.

I. Introduction

The Act was designed to establish price controls to limit the cost of drugs to Federal purchasers and to certain grantees of Federal agencies. In 1990, Congress identified a problem with increasing drug prices and enacted the Omnibus Budget Reconciliation Act of 1990. This attempt at drug price control focused only on the Medicaid program and established a best-price policy. Under the Medicaid drug rebate program, pharmaceutical manufacturers initially gave State Medicaid agencies the greater of a minimum 12.5 percent flat rebate of the average manufacturer price (AMP) or the difference between the AMP and the best price paid by the customer for single source or innovator multiple source drugs. To provide a phase-in period, the rebate amount was capped at a specific percentage of the AMP which increased from 1991 through 1993. Generic manufacturers gave States a 10 percent of AMP flat rebate which will increase to 11 percent in 1994. The Veterans Health Care Act is an attempt to provide Federal purchasers with a process whereby they will receive drug discounts or rebates. Section 601 of Pub. L. 102-585 amends the Medicaid rebate program, section 602 provides drug discounts primarily to certain grantees of the Public Health Service, and section 603 enacts a drug discounting process administered by the Department of Veterans Affairs for the benefit of several Federal agencies. This guidance addresses the program enacted by section 602.

II. Covered Entities

(a) Current Covered Entities

Section 602 of Public Law 102-585 enacted a new section 340B of the Public Health Service Act. Pursuant to this new section, eligible entities are as follows (except as otherwise indicated, references are to sections of the Public Health Service Act):

1. Federally-qualified health centers (migrant, community and homeless health centers) as defined in section 1905(l)(2)(B) of the Social Security Act, 42 U.S.C. 1396(d).
 - (f) Health centers for residents of public housing funded under section 340A, 42 U.S.C. 256(a).
 - (g) Family planning projects receiving grants or contracts under section 1001, 42 U.S.C. 300.
 - (h) An entity receiving a grant for outpatient early intervention services for HIV disease under subpart II of part C of title XXVI, 42 U.S.C. 300ff-51 et seq.
 - (i) A State-operated AIDS drug purchasing assistance program receiving financial assistance under section 2616 of the Act, 42 U.S.C. 300ff-26.
 - (j) A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act, 30 U.S.C. 937(a).
 - (k) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act, 42 U.S.C. 701(a)(2).
 - (l) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988, 42 U.S.C. 11701 et seq.
 - (m) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act, 25 U.S.C. 1651 et seq.
 - (n) Any entity, certified by the Secretary, receiving assistance under title XXVI of the Act, 42 U.S.C. 300ff et seq., (other than a State or unit of local government or an entity described in #4).
 - (o) Any entity, certified by the Secretary, receiving funds relating to the treatment of sexually transmitted diseases under section 318, 42 U.S.C. 247(c), or relating to the treatment of tuberculosis under section 317(j)(2), 42 U.S.C. 247(b), through a State or unit of the local government.

- (p) A "disproportionate share" hospital as defined in section 1886(d)(1)(B) of the Social Security Act, which (for the most recent cost reporting period that ended before the calendar quarter involved) had a disproportionate share adjustment greater than 11.75 percent, and which is (1) owned or operated by a State or local government, (2) a public or private nonprofit corporation formally granted governmental powers by a State or local government, or (3) a private nonprofit hospital with a State or local government contract to provide health services to low income individuals who are not entitled to benefits under Medicare or eligible for assistance under the State plan. The discount need not be provided for drugs which the hospital obtains through a group purchasing arrangement.

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity unless the hospital is otherwise a covered entity, i.e., it meets the requirements of a disproportionate share hospital as determined by the Secretary under section 340B(a)(4)(L).

(b) Certification

Certain covered entities must be certified by the Secretary before they become eligible for the discount drug prices, section 340B(a)(7) of the Public Health Service Act. The entities requiring certification are those that -

- (a) receive grant funds related to the treatment of sexually transmitted diseases through a state or local government under section 318 of the Public Health Service Act, 42 U.S.C. 247(c),
- (b) receive grant funds related to the treatment of tuberculosis through a state or local government under section 317(j)(2) of the Public Health Service Act, 42 U.S.C. 247(b), and
- (c) are receiving assistance under title XXVI of the Public Health Service Act, 42 U.S.C. 300ff et seq., other than a State or unit of local government or grantee for HIV outpatient early intervention services (subpart II of part C of title XXVI of the Public Health Service Act).

The criteria for eligibility include State certification that the entity does receive Federal grant funds and is an entity described in (a), (b), or (c) above. Information concerning the amount each entity expended for outpatient drugs in the preceding fiscal year (October 1, 1991, to September 30, 1992) is also required. These amounts are necessary to assist the Secretary in evaluating the validity of subsequent purchases of outpatient drugs at the discounted prices.

The respective Public Health Service program directors for these entities have been asked to compile a list of the covered entities in their programs and include for each entity the estimated amount of outpatient drug purchases in the preceding year. They are asked to send this list and a form certification letter to the respective State program directors so that the State may certify the accuracy of the list.

The States are asked to return the certification letters to the respective Public Health Service program directors. These letters, along with the drug purchasing information, will be kept on file so that they can be used for audit purposes.

In addition, section 340B(a)(7)(E) of the Public Health Service Act requires a certification process of these same entities. The respective Public Health Service program directors will compile, on an annual basis, a list of eligible entities for the above categories (a), (b), and (c), will estimate the amount of outpatient drug purchases for each listed entity during the preceding fiscal year, and will include a recertification letter and the newly compiled list of entities in the grant renewal package for each State program director to complete and return.

(c) Possible Future Covered Entities

Section 340B also requires the Secretary to conduct a study concerning entities that receive funds from a State for mental health and substance abuse treatment services under subparts I or II of part B of title XIX of the Public Health Service Act or under title V of such Act; or receive funds from a State under title V of the Social Security Act for outpatient maternal and child health services. The Secretary is directed to determine the feasibility of awarding these entities eligibility status and to submit this report to Congress by November 4, 1993.

III. Covered Drugs

Covered drugs are outpatient drugs as defined in section 1927(k) of the Social Security Act. Section 1927(k)(2) generally includes within this term (a) a drug which can only be dispensed upon prescription, and (1) which has been approved for safety and effectiveness under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or (2) which was used or sold commercially in the United States before the enactment of the Drug Amendments of 1962 (or identical, related, or similar to such a drug) and which has not been the subject of a final determination by the Secretary that it is a "new drug," or (3) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined that there is a compelling justification of its medical need and for which the Secretary has not issued a notice of opportunity for hearing on a proposed order to withdraw approval of an application for such a drug because the drug is less than effective for some or all of its labeled indications; (b) a prescribed biological product other than a vaccine, licensed under section 351 of the Public Health Service Act, and produced at an establishment licensed under such section to produce such a product; (c) insulin, certified under section 506 of the Federal Food, Drug, and Cosmetic Act; and (d) an over-the-counter drug, if it is prescribed by a person authorized to prescribe such a drug under State law.

Pursuant to the limiting definition of section 1927(k)(3) of the Social Security Act, a covered outpatient drug does not include any drug, biological product, or insulin provided as part of, or incident to and in the same setting as, any of the following (and for which payment is made as part of payment for the following and not as direct reimbursement for the drug): (a) inpatient hospital services; (b) hospice services; (c) dental services, except drugs for which the State Medicaid plan authorizes direct reimbursement to the dispensing dentist; (d) physicians' services; (e) outpatient hospital service emergency room visits; (f) nursing facility services; (g) other laboratory and x-ray services; and (h) renal dialysis. A covered outpatient drug does not include any such drug or

product which is used when there is no medically accepted indication.

IV. Calculation of the Drug Price

To determine the price for a covered outpatient drug, the manufacturer shall calculate the average manufacturer price (AMP) for the drug and reduce it by the rebate percentage. Average manufacturer price is the average price paid to the manufacturer for the drug in the United States by wholesalers for the drug distributed to the retail pharmacy class of trade in the calendar quarter. The rebate percentage is the total per unit Medicaid rebate amount, section 1927(c)(1) and (2) of the Social Security Act, for the particular drug divided by the AMP. The Medicaid rebate calculation utilizes Best Price information which considers the lowest price available at which the manufacturer sells the covered outpatient drug to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States in any pricing structure (as defined in section I(b) of the Pharmaceutical Pricing Agreement).

To calculate the price for an over-the-counter or generic drug, the rebate percentage will be determined as if the rebate required under 1927(c) of the Social Security Act is based upon the percentages provided in section 1927(c)(4) of the same Act (i.e., calendar quarters between January 1, 1991 and December 31, 1993 = 10 percent and calendar quarters beginning on or after January 1, 1994 = 11 percent).

V. Manufacturers' Information

(a) Effective Date of Implementation

Because the effective date of section 340B of the Public Health Service Act with respect to drug purchases is December 1, 1992, and all Agreements signed with entities included on the initial list of covered entities are effective retroactive to that date, manufacturers should incorporate these pricing limitations in dealings with covered entities as of that date. If the manufacturer finds that a price adjustment is required, the manufacturer shall calculate any rebate (or credit) necessary to account for sales between December 1, 1992, and the date of the Agreement and shall either remit the rebate to the entity (or provide for the credit). Additional eligible entities, later included in the updated lists, will be eligible for drug discounts only for purchases on and after the date of their inclusion on the list.

(b) Definition of Manufacturer

The term "Manufacturer" has the meaning as set forth in section 1927(k)(5) of the Social Security Act and includes all entities engaged in -

- (1) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(2) the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. A manufacturer must hold legal title to or possession of the NDC number for the covered outpatient drug. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

"Manufacturer" also includes an entity, described in (1) or (2) above, that sells outpatient drugs to covered entities, whether or not the manufacturer participates in the Medicaid rebate program. Furthermore, the Pharmaceutical Pricing Agreement provides that the term also includes any contractor who fulfills the responsibilities pursuant to the Public Health Service drug pricing agreement.

The Department is aware that many covered entities purchase drugs from wholesalers, rather than directly from manufacturers. Manufacturers shall take the steps necessary to ensure that the discounts required by this legislation are passed through the wholesalers to the covered entities.

(c) Pharmaceutical Pricing Agreement

A manufacturer must sign an Agreement with the Department agreeing not to charge a covered entity a price for a covered outpatient drug exceeding the AMP of the drug decreased by the rebate percentage. Signing the Agreement does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the maximum price that can be charged.

The Department mailed the Agreements December 15, 1992, priority mail, and requested, for participation in the discount program, a return of the signed agreement by January 6, 1993. If a manufacturer did not receive a copy of the Agreement, it must contact OPA at the address specified in the "Further Information" section of this notice within 30 days from the date of publication of this notice.

(d) List of Eligible Covered Entities

A list of eligible covered entities has been mailed to each manufacturer along with the Agreement, and this list will be updated at least annually. Timely notification of additions to and deletions from the list of eligible covered entities will also be provided. A list of eligible subgrantees will be made available at a later date. The requirement for retroactive adjustments to December 1, 1992, will not apply to covered entities not included on the initial list.

(e) Drug Pricing Information Access

Those manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs must agree to submit, upon request, to the Department a list of all covered outpatient drugs purchased by covered entities, the average manufacturer prices (AMP), baseline AMP, Best Price calculations (if relevant), and information concerning the prices of the covered outpatient drugs distributed through a wholesaler. The manufacturer must further maintain all records relevant to the generation of

these reports for a period of 3 years from the date of their creation. The Department will have reasonable access to the records of all participating manufacturers relevant to the manufacturer's compliance with the terms of the Agreement. Upon request, the Centers for Medicare and Medicaid Services (CMS) will share AMP and (if relevant) Best price information submitted under the Medicaid Rebate Agreement on covered drugs with the Secretary or her designee for the purpose s of carrying out the agreement. (The reporting and record-keeping requirements of this section are subject to the Office of Management and Budget (OMB) clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501-3520, and will not be implemented until such clearance has been obtained.)

(f) Drug Utilization Information Access

A manufacturer will be permitted to audit the records of covered entities that directly pertain to a prohibition on the resale of drugs to persons not patients of the entity and a prohibition on possible duplicate discounts (i.e., Medicaid rebates, coupled with discounts allowable under the Act). This audit must be in accordance with procedures established by the Department relating to number, duration, and scope of audits and will be at the manufacturer's expense.

(g) Penalty Provisions

Pursuant to section 1927(a)(5)(A) of the Social Security Act, a manufacturer who does not sign, and keep in effect, an Agreement will not have met the requirements of section 1927(a)(5)(A). If the Department finds, after notice and a hearing, that a manufacturer has failed to comply with the pricing requirement of section II(a) of this Agreement, has refused to submit drug pricing information requested by the Department, or has submitted false information, the Agreement will be terminated. As applicable, other penalties will be imposed.

VI. Covered Entities' Information

(a) Effective Date of Implementation

Covered outpatient drugs purchased on or after December 1, 1992, by a covered entity included on the initial list must be discounted pursuant to the formula in section 340B(a)(1) and (2) of the Public Health Service Act. Agreements with manufacturers signed after December 1, 1992, will be effective retroactive to that date for covered entities included on the initial list; therefore, the manufacturer must calculate any price adjustments necessary and remit a rebate directly to the covered entity (or provide for a credit).

(b) Eligibility

The Department has provided a list of eligible entities to each manufacturer along with a copy of the Agreement and is notifying each covered entity of its eligibility to purchase drugs at the discounted prices. Each covered entity is encouraged to begin discussing the pricing provisions of section 340B of the Public Health Service Act with manufacturers so that potential problems can be identified early and resolved.

(c) Drug Price Negotiation

Although the Department signs the Agreement with each manufacturer, the entity itself may continue to negotiate individual drug pricing agreements with each manufacturer. Nothing in the statute precludes group purchasing agreements or other arrangements not inconsistent with the Agreement, except for disproportionate share hospitals.

(d) Penalty Provisions

A covered entity is prohibited from reselling or otherwise transferring a covered drug to a person who is not the patient of the entity [section 340B(a)(5)(B) of the Public Health Service Act]. The statute provides further the drug purchases will not be subject to both the discount under section 340B and the Medicaid rebate under section 1927 of the Social Security Act [section 340B(a)(5)(A) of the Public Health Service Act]. The Secretary has decided to establish a mechanism within 120 days after the effective date of the Agreement to ensure that covered entities comply with the prohibition on duplicate discounts and rebates. If the Secretary does not establish a mechanism within 120 days, the Secretary will apply the provisions of section 1927(a)(5)(C) of the Social Security Act.

If the Secretary finds, after notice and hearing, that a covered entity has violated either of these prohibitions, the covered entity shall be liable to the manufacturer of the covered drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as described in section 340B of the Public Health Service Act.

(e) Audit Provision

Each covered entity will be required to retain records of purchases of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act. When a covered entity is making purchases through a wholesaler, it will be required to provide the manufacturer with information necessary to arrange for such purchases consistent with the terms of the Agreement.

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is the subject of an Agreement to audit, at the Secretary's or manufacturer's expense, the records of the entity that directly pertain to the entity's compliance with the resale or duplicate discount prohibition.

VII. Confidentiality Provisions

Information disclosed by the manufacturer in connection with a request by the Department is confidential and, except as otherwise required, will not be disclosed by the Department in a form that reveals the manufacturer, or the prices charged by the manufacturer, except as necessary by the Department to carry out the provisions of the Act or to permit review by the Comptroller General.

The manufacturer shall hold audit information obtained from the covered entities confidential.

The Department shall require, under a reasonable schedule of implementation, that covered entities not reveal confidential drug pricing information.

VIII. Nonrenewal and Termination Provisions

Unless otherwise terminated by either party, the Agreement will be effective for a period of one year and will be renewed automatically for additional successive terms of one year, unless the manufacturer gives written notice of intent not to renew. The manufacturer may terminate the Agreement for any reason, and the Secretary, after notice and hearing, may terminate the Agreement for good cause or a violation of the Agreement.

2. Duplicate Discounts and Rebates on Drug Purchases (June 16, 1993)

Section 1927 of the Social Security Act provides that in order to receive payment under the Medicaid program for covered outpatient drugs, drug manufacturers must enter into and comply with rebate agreements with the Secretary on behalf of States or with States directly. Section 1927 was enacted by the Omnibus Budget Reconciliation Act of 1990 and was amended by section 601 of the Act. Section 602 of the Act creates a program under which drug manufacturers must provide discounts to "covered entities," which consist primarily of certain grantees of the Public Health Service and "disproportionate share" hospitals.

Section 340B(a)(5)(A) of the Public Health Service Act reflects Congress' recognition that there is a potential for drugs purchased by a covered entity with a discount to be subject to a Medicaid rebate, if the drug is reimbursed by the Medicaid program. Accordingly, this section directs the Department to establish a mechanism to avoid the combination of the discount and the Medicaid rebate for the same drug purchases.

The Public Health Service has consulted with the Health Care Financing Administration (HCFA), which is responsible for the Federal administration of the Medicaid program, and proposes the following as the mechanism to comply with section 340B(a)(5)(A):

I. All-Inclusive Rates Per Encounter or Visit

Under "all-inclusive rates" (either per encounter or visit), drug purchases are not billed as separate cost items, and, therefore, there is no opportunity for a Medicaid rebate to be sought for the drugs, even if purchased with a section 340B discount. [See, for example, the reimbursement methodology for Federally Qualified Health Centers, sections 1861(aa) and 1905 (l)(2) of the Social Security Act.] Accordingly, to the extent that covered entities develop all inclusive rates, there is no possibility that the duplicate discount and rebate can occur.

II. Drug Purchases Not Reimbursed Under All-Inclusive Rate

For those drug purchases which are not reimbursed by Medicaid under all-inclusive rates, the Department proposes the following mechanism to avoid the duplicate discount and rebate. The Public Health Service has provided manufacturers a list of covered entities eligible for the discounts. (This list will be updated periodically.) The Public Health Service will provide the list to State Medicaid agencies with the Medicaid provider numbers for each covered entity in the respective State. The covered entities will provide these numbers to the Public Health Service.

When a covered entity submits a bill to the State Medicaid agency for a drug purchase by or on behalf of a Medicaid beneficiary, the amount billed shall not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus a dispensing fee established by the State Medicaid agency. This will ensure that the discount to the covered entity will be passed on to the State Medicaid agency.

Based on the Medicaid provider number information furnished by the Public Health Service, the State Medicaid agency will create a separate provider file for claims from covered entities which are billing on a cost basis for drug purchases. The State Medicaid agency will exclude data from these provider files when generating the rebate bills to the manufacturers under the section 1927 program. Thus, the payment of duplicate discount and rebates by the drug manufacturer will be prevented.

This mechanism is consistent with the Veterans Health Care Act and the limitations established in the Medicaid regulations, 42 CFR sections 447.331- 447.334, which limit the amount the Medicaid States agency may reimburse providers. These regulations are designed to give States a certain amount of flexibility in administering their drug payment programs, while encouraging prudent purchasing. A mechanism whereby the amount billed by covered entities for prescription drugs cannot exceed the actual acquisition cost plus a reasonable dispensing fee allows States to retain flexibility in their drug payment programs and to obtain the benefit of the cost savings established under the Act.

3. Entity Guidelines (May 13, 1994)

(1) Confidential Drug Pricing Information

“Confidential drug pricing information” includes both “best price” and “average manufacturer price.” The quoted price and the actual price given by the manufacturer to the covered entity are not confidential.

(2) Duplicate Discount/Rebate Potential

First, a covered entity billing on a cost basis for drug purchases must provide the Office of Drug Pricing (ODP) with a pharmacy Medicaid number (the number which the entity uses to bill Medicaid for medications). [Note: The OPD is now the Office of *Pharmacy Affairs* in HRSA’s HSB.] Second, a covered entity using an all-inclusive rate (either per encounter or visit) must submit its all-inclusive Medicaid number (e.g., “FQ” number). Third, if a covered entity does not

bill Medicaid for outpatient drugs, then the entity must notify the Office of *Pharmacy Affairs* of this decision. Fourth, a large facility which houses many different clinics, only several of which are eligible, must obtain a separate Medicaid provider number for the eligible clinics. For those States which cannot generate additional Medicaid provider numbers for entities, covered entities must discuss an alternative arrangement with the States to accomplish this objective. This information will be posted on the Web site maintained by the Office of *Pharmacy Affairs* at www.hrsa.gov/opa, to indicate which covered entities have elected to participate in the program. If a drug is purchased by or on behalf of a Medicaid beneficiary, the amount billed may not exceed the entity's actual acquisition cost for the drug, as charged by the manufacturer at a price consistent with the Veterans Health Care Act of 1992, plus a reasonable dispensing fee established by the State Medicaid agency.

(3) Eligibility for Retroactive Discounts

Until 30 days after publication of this notice, eligible covered entities included on the initial eligibility list may request retroactive discounts (discounts, rebates, or account credit) for covered outpatient drugs purchased retroactive to December 1, 1992. Entities added to the eligibility list at a later date may only request discounts retroactive to the date of their inclusion on the list. Of the entities listed on the eligibility list, only the following may request these discounts: The covered entity that--(1) has billed for covered outpatient drugs using an all-inclusive rate (either per visit or per encounter), or (2) has not billed Medicaid for covered outpatient drugs since December 1, 1992, (or since its inclusion on the eligibility list), or (3) has submitted its Medicaid provider number and is requesting refunds for subsequent periods, or (4) has adequate documentation proving that drugs for which a retroactive discount is being requested have not generated Medicaid rebates. A Disproportionate Share Hospital (DSH) is not eligible for retroactive discounts for covered outpatient drugs purchased through a group purchasing organization (GPO) or any group purchasing arrangement. Any DSH outpatient clinic which is or will be eligible for retroactive discounts may preserve its rights by sending manufacturers a letter requesting such refunds and providing adequate documentation of purchases.

(4) Entity Guidelines Regarding Drug Diversion

Covered entities are required not to resell or otherwise transfer outpatient drugs purchased at the statutory discount to an individual who is not a patient of the entity. There are several common situations in which this might occur. First, if individuals other than patients of the covered entity obtain covered outpatient drugs from its pharmaceutical dispensing facility, the entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to individuals who are not eligible for the discount (e.g., separate purchasing accounts and dispensing records). Second, a larger institution which contains an eligible entity within its structure is required to establish separate purchasing accounts and maintain separate dispensing records for the eligible entity. Third, the covered entity itself may not use the covered outpatient drug in excluded services (e.g., inpatient services). If an entity offers services excluded from the drug discount program, the entity must develop a separate method for purchasing and dispensing drugs for excluded services. The covered entity may, at its option, develop an alternative system, short of tracking each discounted drug through the purchasing and dispensing process, by which it can prove compliance. If an alternate system of tracking is proposed to be used, this system must be

approved by the Drug Pricing Program. The Office of Pharmacy Affairs (OPA) will develop criteria for alternative systems at a later date and welcomes all suggestions.

(5) Audit Requirement

All entities receiving statutory prices are required to maintain records of purchases of covered outpatient drugs and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act. The entity must permit HHS and the manufacturer to audit any record of a covered drug purchase that was subject to the discount, as provided by section 340B(a)(5)(C) of the Public Health Service Act. Manufacturer audits will be conducted in accordance with procedures developed by the Secretary of HHS. The Office of Drug Pricing is developing proposed audit guidelines which will be published in the *Federal Register* with public comment invited. The notice will address only audits related to purchases as a covered entity; it does not address other audit requirements related to participation in State Medicaid programs or receipt of Federal funding.

(6) Entity Participation

Covered entity participation in the section 340B drug discount program is voluntary. Once an entity has elected to participate in the program, it must wait to enter or withdraw from the program until the next official updating of the eligible entity list. The Office of Drug Pricing will update this list two weeks before each calendar quarter. The entity must comply with all program guidelines until the date it is removed from the eligibility list.

(7) Group Purchasing

A DSH may participate in a group purchasing arrangement for inpatient drug use without affecting its eligibility to purchase section 340B discounted drugs. If a DSH participates in a GPO or other group purchasing arrangement for covered outpatient drugs, the DSH will no longer be an eligible covered entity and cannot purchase covered outpatient drugs at the section 340B discount prices. States, or other groups, which purchase drugs for covered entities (other than disproportionate share hospitals) are not included on the list of covered entities; however, they are eligible to purchase at the section 340B discount if the following requirements are met: (1) the group purchasing arrangement must be comprised of only covered entities, (2) if group purchasing arrangements contain entities which are not eligible for the discount, separate purchasing accounts and dispensing/distribution must be maintained, and (3) the purchasing group has written authority from the covered entity to purchase covered outpatient drugs on its behalf.

(8) Purchasing Agents

A covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts. If a purchasing agent is used, the arrangement must be in writing and the terms of the agent's relationship with the entity must be clearly defined. The entity and the agent should decide whether the agent simply negotiates the drug purchasing contracts on behalf of the entity or actually receives drug shipments for distribution to the entity. If the latter, the transfer of purchased pharmaceuticals from an agent to the entity would not be viewed as drug diversion. For

purposes of the DSH/GPO prohibition only, a purchasing agent may be distinguished from and would not be considered operating as a GPO or other group purchasing arrangement if the following conditions are met: (1) the purchasing agent is not associated with a GPO or other purchasing arrangement; (2) no collective bargaining by a group of hospitals occurs; (3) the negotiations for Public Health Service pricing are separate activities for each individual DSH; (4) a separate agreement with each DSH is executed; (5) as part of the agreement, there will be no sharing of pricing information; and (6) all final decisions concerning product and price acceptance will be made by each individual DSH.

(9) Definition of Covered Outpatient Drug

Section 1927(k)(2) of the Social Security Act defines "covered outpatient drug" to include most drugs and biologicals which may be dispensed only by prescription and which require approval by the Food and Drug Administration or a license under section 351 of the Public Health Service Act. Section 1927(k)(3) limits the definition of "covered outpatient drug" to exclude certain settings (e.g., such services as emergency room, hospice, dental, physician, nursing facilities, x-ray, lab, and renal dialysis) in some instances. In these settings, if a covered drug is included in the per diem rate (i.e., bundled with other payments in an all-inclusive, per visit, or an encounter rate), it will not be included in the section 340B discount program. However, if a covered drug is billed and paid for instead as a separate line item as an outpatient drug in a cost basis billing system, this drug will be included in the program.

(10) Dealing Direct or Through a Wholesaler

If a manufacturer has customarily dealt directly with a particular covered entity, then requiring the manufacturer to continue this form of purchasing with the covered entity is reasonable. When dealing directly with a covered entity, manufacturers must offer covered outpatient drugs at or below the section 340B discount prices. If a manufacturer customarily uses a wholesaler as a means of distribution, then requiring the manufacturer to continue this form of purchasing with covered entities is also reasonable. If the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue. Manufacturers may not single out covered entities from their other customers for restrictive conditions that would undermine the statutory objective. Manufacturers must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program.

(11) Manufacturer's Contracts Requiring Entity Compliance

A manufacturer may not condition the offer of statutory discounts upon an entity's assurance of compliance with section 340B provisions. Covered entity assurances regarding the following activities may not be required: (1) eligibility to participate in the program; (2) utilization of covered outpatient drugs only in authorized services; (3) maintaining the confidentiality of the drug pricing information; (4) permitting the manufacturers to audit purchase, inventory, and related records prior to the publication of approved Public Health Service guidelines; and (5) submitting information related to drug acquisition, purchase, and inventory systems. Entities are not required to sign agreements ensuring manufacturers of their compliance with section 340B

provisions. (If a manufacturer asks a covered entity whether the entity is in fact participating in the section 340B discount program, the entity must supply the manufacturer with this information). This prohibition does not include provisions that address customary business practice, request standard information, or include other appropriate contract provisions.

4. DSH Outpatient Facility Guidelines (September 19, 1994)

The outpatient facility is considered an integral part of the “hospital” and therefore eligible for section 340B drug discounts if it is a reimbursable facility included on the hospital's Medicare cost report. For example, if a hospital with one Medicare provider number meets the disproportionate share criteria and this hospital has associated outpatient clinics whose costs are included in the Medicare cost report, these clinics would also be eligible for section 340B drug discounts. However, free-standing clinics of the hospital that submit their own cost reports using different Medicare numbers (not under the single hospital Medicare provider number) would not be eligible for this benefit. A DSH, eligible for Public Health Service pricing, must first request that the Office of Drug Pricing include in the Public Health Service drug discount program the outpatient facilities that are included in its Medicare cost report. A list of these outpatient facilities along with Medicaid billing status information must be included with the request. Second, an appropriate official of the DSH must sign a statement that he/she is familiar with HCFA guidelines concerning Medicare certification of hospital components as one cost center, has examined the list of outpatient facilities, and certifies that the facilities are correctly included on the DSH's Medicare cost report. When these facilities are added to the master list of eligible and participating covered entities, the off-site facilities will be able to access Public Health Service discount pricing. On-site clinics that are not included on the Medicare cost report will not be eligible for Public Health Service discount pricing. This information will be posted on the Electronic Data Retrieval System (EDRS), maintained by the Office of Drug Pricing, on a quarterly basis.

5. New Drug Pricing (October 2, 1995)

Calculation of the current quarter Public Health Service ceiling price for each covered outpatient drug, as provided in section 340B(a)(1) of the Public Health Service Act, is based upon data supplied to the Medicaid Drug Rebate Program (i.e., AMP, baseline AMP and BP). The manufacturer calculates pricing information for all of its covered outpatient drugs and sends this pricing data to HCFA within 30 days after the end of the quarter. HCFA will provide the CMS with the data necessary for the Public Health Service to determine the ceiling price which will be used for resolving disputes, studies involving pricing data, auditing manufacturers, or other program purposes.

For calendar year 1995, the Medicaid rebate for single source and innovator multiple source drugs is the greater of 15.2 percent of the AMP or the AMP minus BP. In calendar year 1996, and thereafter, the rebate percentage decreases to 15.1 percent. An additional rebate must also be paid for single source and innovator multiple source drugs in the amount by which the increase in the baseline AMP exceeds the increase in the Consumer Price Index--Urban (CPI-U). The Public Health Service ceiling price is computed based on the combined basic and additional rebate amounts calculated for the Medicaid program. For noninnovator multiple source drugs, the rebate percentage is 11 percent of the AMP.

For Public Health Service pricing purposes, the timeframe for reporting the pricing data is a problem with respect to new drugs because there is a time lag for new drug pricing information. For new drugs, manufacturers are permitted to calculate the AMP using the pricing instituted in the first quarter; however, the baseline AMP is not available until the end of the first full quarter after the day on which the drug was first sold. For example, if a new drug was first sold on January 15, the quarterly AMP for the period 1/1 through 3/31 would be calculated using sales from 1/15 through 3/31 while the quarterly baseline AMP for the first full quarter would not be available. The baseline AMP must be determined for a full quarter; therefore, pricing data for the period 4/1 through 6/30 would be utilized. Thus, for the first and second quarter, the discount for the new drug would be a manufacturer's estimate and later adjusted using only the basic rebate amount.

This time lag is not a problem for the State Medicaid agencies because they bill manufacturers for a rebate after the covered outpatient drugs are dispensed to Medicaid beneficiaries. However, to comply with the requirements of section 340B of the Public Health Service Act, the Public Health Service ceiling price must be determined before the covered outpatient drug is sold to the covered entity.

Because there are no sales data for a new drug from which to determine the Public Health Service ceiling price, the Office of Drug Pricing is proposing to utilize a ceiling price estimated by the manufacturer until sufficient data is available to calculate the AMP and BP of the new drug. Any adjustments necessary to reconcile differences between the first and second quarter estimated ceiling price and the third quarter ceiling price will be in the form of a retroactive charge back or rebate.

Because the manufacturer calculates the Public Health Service ceiling price using a data lag, the manufacturer would estimate the new drug ceiling price for three quarters. For example, a new single source drug that enters the market in February (first quarter) will have an estimated Public Health Service ceiling price for that quarter. The manufacturer must submit AMP and BP pricing data for sales within that quarter to HCFA within 30 days from the end of the quarter (4/30). HCFA will use this pricing data to calculate the basic rebate amount.

The manufacturer must estimate the ceiling price for the second quarter (April 1-June 30). Sales during the quarter will constitute the baseline AMP and BP. The manufacturer must submit baseline AMP and BP for the second quarter to HCFA within 30 days from the end of the second quarter (7/30). The additional rebate amount does not apply to this quarter since there must be two full quarters of pricing data to generate an additional rebate amount when a price increase exceeds the increase of the CPI-U.

Because manufacturers must transmit pricing to wholesalers two weeks before the beginning of the quarter, the total rebate amount (basic plus additional rebate) for the third quarter (July 1-September 30) will not be available at that time.

Manufacturers must submit pricing data to HCFA by 10/30. Thus, the manufacturer must offer the third quarter discount using only the basic rebate amount.

Beginning with the fourth quarter (October 1-December 31), the manufacturer will have the necessary pricing data to calculate a total rebate amount. All retroactive charge backs or rebate adjustments necessary to reconcile the first, second, and third quarters estimated ceiling price must be completed by the end of the fourth quarter, i.e., December 31.

Example: Drug Enters Market February 15.

Calender quarter	Baseline AMP	Add'l rebate (if applicable)	Pricing due to HCFA	Actual basic amounts available from HCFA	Actual add'l amounts available from HCFA
1 (Jan-Mar)			35914	35929	N/A
2 (April-June)	X		36005	36021	N/A
3 (July-Sept)		X	36097	36113	36113
4 (Oct-Dec)		X	35824	35840	35840

6. Definition of a Patient (October 24, 1996)

An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
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 (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

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.

An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the Public Health Service Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

7. Contract Pharmacy Services (August 23, 1996)

Covered entities that wish to utilize contract pharmacy services to dispense section 340B outpatient drugs are encouraged to sign and have in effect a contract pharmacy service agreement between the covered entity and the pharmacy. This mechanism is designed to facilitate program participation for those eligible covered entities that do not have access to appropriate "in-house" pharmacy services. See Appendix for suggested contract provisions.

(1) The following is a suggested model agreement format:

- (a) The covered entity will purchase the drug and assume responsibility for establishing its price, pursuant to the terms of a Public Health Service grant (if applicable) and any applicable consumer protection laws.

A "ship to, bill to" procedure may be used in which the covered entity purchases the drug, the manufacturer bills the entity for the drug that it purchased, but ships the drug directly to the contract pharmacy. See section 1 of Appendix.

- (b) The contractor will provide all pharmacy services (e.g., dispensing, record keeping, drug utilization review, formulary maintenance, patient profile, counseling). Each covered entity which purchases its covered outpatient drugs has the option of individually contracting for pharmacy services with the pharmacy of its choice. The limitation of one pharmacy contractor per entity does not preclude the selection of a pharmacy contractor with multiple pharmacy sites, as long as only one site is used for the contracted services. [The Office of Drug Pricing will be evaluating the feasibility of permitting these covered entities to contract with more than one site and contractor.]
- (c) The covered entity health care provider will inform the patient of his or her freedom to choose a pharmacy provider. If the patient does not elect to use the contracted service, the patient may obtain the prescription from the covered entity and then obtain the drug(s) from the pharmacy provider of his or her choice.

When a patient obtains a drug from a retail pharmacy other than the entity contract pharmacy, the manufacturer is not required to offer this drug at 340B pricing.

- (d) The contractor may provide the covered entity services, other than pharmacy, at the option of the covered entity (e.g., home care, reimbursement services). Regardless of the services provided by the contractor, access to 340B pricing will always be restricted to only patients of the covered entity.
- (e) The contractor and the covered entity will adhere to all Federal, State, and local laws and requirements. Additionally, all Public Health Service grantees will adhere to all rules and regulations established by the grant funding office.

Both the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties if the covered entity and/or the contract pharmacy violate Federal or State law. [The

Department reserves the right to take such action as may be appropriate if it determines that such a violation has occurred.]

- (f) The contractor will provide the covered entity with reports consistent with customary business practices (e.g., quarterly billing statements, status reports of collections and receiving and dispensing records). See Section 2 of Appendix.
- (g) The contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340B discounted drugs to individuals who are not patients of the covered entity. Customary business records may be used for this purpose. The covered entity will establish a process for a periodic random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities. See Section 3 of Appendix.
- (h) The covered entity and the contract pharmacy will develop a system to verify patient eligibility. [The Department's draft guidance defining covered entity "patient" is set forth in an August 3, 1995, *Federal Register* notice. See 60 FR 39762.]

Both parties agree that they will not resell or transfer a drug purchased at section 340B pricing to an individual who is not a patient of the covered entity. See section 340B(a)(5)(B). The covered entity understands that it can be removed from the list of covered entities because of its participation in drug diversion, a 340B(a)(5) prohibition, and no longer be eligible for 340B pricing. See Section 4 of Appendix.

- (i) Both parties will not use drugs purchased under section 340B to dispense Medicaid prescriptions, unless the contract pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.
- (j) Both parties understand that they are subject to audits (by the Department and participating manufacturers) of records that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate Medicaid rebates and 340B discounts. See section 340B(a)(5).

The contractor will ensure that all pertinent reimbursement accounts and dispensing records, maintained by the contractor, will be separate from the contractor's own operations and will be accessible to the covered entity, the Department, and the manufacturer in the case of a manufacturer audit.

- (k) Upon request, a copy of this contract pharmacy service agreement will be provided to a participating manufacturer which sells covered outpatient drugs to the covered entity. All confidential proprietary information may be deleted from the document.

(2) *Certification*

Under section 340B, we believe that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price. If the entity directs the drug shipment to its contract

pharmacy, we see no basis on which to conclude that section 340B precludes this type of transaction or otherwise exempts the manufacturer from statutory compliance. However, the entity must comply, under any distribution mechanism, with the statutory prohibition on drug diversion and duplicating discounting.

To provide Office of Drug Pricing and manufacturers with assurance that the covered entity has acted in a manner which limits the potential for drug diversion, the covered entity is encouraged to submit to Office of Drug Pricing a certification that it has signed and has in effect an agreement with the contract pharmacy containing the aforementioned provisions. However, Office of Drug Pricing will review any alternative mechanism which is designed to reduce the potential for drug diversion. The names of those covered entities which submit a certification, or an alternate mechanism approved by Office of Drug Pricing, will be placed on the EDRS for the convenience of participating drug manufacturers.

(3) Anti-kickback Statute

Contractors and covered entities must be aware of the potential for civil or criminal penalties if the contractor violates Federal or State law. In negotiating and executing a contracted pharmacy service agreement pursuant to these guidelines, contractors and covered entities should be aware of and take into consideration the provisions of the Medicare and Medicaid anti-kickback statute, 42 U.S.C. 1320a-7b(b). This statute makes it a felony for a person or entity to knowingly and willfully offer, pay, solicit, or receive remuneration with the intent to induce, or in return for the referral of, Medicare or a State health care program business. State health care programs are Medicaid, the Maternal and Child Health Block Grant program, and the Social Services Block Grant program. Apart from the criminal penalties, a person or entity is also subject to exclusion from participation in the Medicare and State health care programs for a knowing and willful violation of the statute pursuant to 42 U.S.C. 1320a-7(b)(7).

The anti-kickback statute is very broad. Prohibited conduct covers not only remuneration intended to induce referrals of patients, but also includes remuneration intended to induce the purchasing, leasing, ordering, or arranging for any good, facility, service, or item paid for by Medicare or a State health care program. The statute specifically identifies kickbacks, bribes, and rebates as illegal remuneration, but also covers the transferring of anything of value in any form or manner whatsoever. This illegal remuneration may be furnished directly or indirectly, overtly or covertly, in cash or in kind and covers situations where there is no direct payment at all, but merely a discount or other reduction in price or the offering of a free good(s).

Arrangements between contractors and covered entities that could violate the anti-kickback statute would include any situation where the covered entity agrees to refer patients to the contractor in return for the contractor agreeing to undertake or furnish certain activities or services to the covered entity at no charge or at a reduced or below cost charge. These activities or services would include the provision of contracted pharmacy services, home care services, money or grants for staff or service support, or medical equipment or supplies, and the remodeling of the covered entity's premises. For example, if a contractor agreed to furnish covered outpatient drugs in return for the covered entity referring its Medicaid patients to the contractor to have their prescriptions filled, the arrangement would violate the anti-kickback statute. Similarly, if the contractor agreed

to provide billing services for the covered entity at no charge in return for the covered entity referring its patients to the contractor for home or durable medical equipment, the statute would be violated.

Pursuant to the authority in 42 U.S.C. 1320a-7b(b)(3), the Secretary of Health and Human Services has published regulations setting forth certain exceptions to the anti-kickback statute, commonly referred to as "safe harbors." These regulations are codified at 42 CFR 1001.952. Each of the safe harbors sets forth various requirements which may be met in order for a person or entity to be immune from prosecution or exclusion.

Appendix--Suggested Contract Provisions

- (1) "The covered entity will order covered drugs directly from the manufacturer, from a designated sales representative, or a drug wholesaler and arrange to be billed directly for such drugs. The covered entity will arrange for shipment of such drugs directly to the pharmacy. The pharmacy will compare all shipments received to the orders and inform the covered entity of any discrepancy within five (5) business days of receipt. The covered entity will make timely payments for such drugs delivered to the (pharmacy) pursuant to the entity's order."
- (2) "The covered entity will verify, using the contractor's (readily retrievable) customary business records that a tracking system exists which will ensure that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. Such records can include: prescription files, velocity reports, and records of ordering and receipt. These records will be maintained for the period of time required by State law and regulations."
- (3) "Prior to the pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures. The pharmacy will permit the covered entity or its duly authorized representatives to have reasonable access to pharmacy's facilities and records during the term of this agreement in order to make periodic checks regarding the efficacy of such tracking systems. The pharmacy agrees to make any and all adjustments to the tracking system which covered entity advises are reasonably necessary to prevent diversion of covered drugs to individuals who are not patients of the covered entity."
- (4) "The pharmacy will dispense covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is

for an eligible patient. The covered entity will furnish a list to the pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. If a contract pharmacy is found to have violated the drug diversion prohibition, the pharmacy will pay the entity the amount of the discount in question so that the entity can reimburse the manufacturer.”

8. Manufacturer Audit Guidelines (December 12, 1996)

Covered entities which choose to participate in the section 340B drug discount program shall comply with the requirements of section 340B(a)(5) of the Public Health Service Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity. The participating entity shall permit the manufacturer of a covered outpatient drug to audit its records that directly pertain to the entity's compliance with section 340B(a)(5) (A) and (B) requirements with respect to drugs of the manufacturer. Manufacturer audits shall be conducted in accordance with guidelines developed by the Secretary, as required by section 340B(a)(5)(C). Not only will the records of any organization working with a covered entity to purchase or dispense covered drugs, or to prepare Medicaid reimbursement claims for the covered entity be subject to the same audit requirement, but also any primary record that could be part of a reasonable audit trail.

This notice does not include the complete audit guidelines to be used by Government auditors in cases where the Government performs its own audit. Federal auditors shall perform audits in accordance with the Government Auditing Standards. The Government auditors' authority to audit the covered entity's compliance with the requirements of section 340B(a)(5) (A) and (B) shall not be limited by the manufacturer's audit guidelines.

The following is the “Compliance Audit Guide” concerning manufacturer audit guidelines as developed by the Secretary pursuant to section 340B(a)(5)(C): (These guidelines do not preclude the entity and the manufacturer from voluntarily developing mutually beneficial audit procedures.)

I. General Guidelines

The manufacturer shall submit a work plan for an audit which it plans to conduct of a covered entity to the Department. (See section III for suggested audit steps.) The manufacturer's auditor shall be an independent public accountant employed by the manufacturer to perform the audit. The auditor has an ethical and legal responsibility to perform a quality audit in accordance with Government Auditing Standards, Current Revision, developed by the Comptroller General of the United States. Patient confidentiality requirements also must be observed. At the completion of the audit, the auditors must prepare an audit report in accordance with the reporting standards for performance audits in Government Auditing Standards, Current Revision. The cost of a manufacturer audit shall be borne by the manufacturer, as provided by section 340B(a)(5)(C) of the Public Health Service Act.

(a). Number of Audits

A manufacturer shall conduct an audit only when it has documentation which indicates that there is reasonable cause. "Reasonable cause" means that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B) of the Public Health Service Act (i.e., accepting a 340B discount on a covered outpatient drug at a time when the covered entity has not submitted its Medicaid billing status to the Department or transferring or otherwise reselling section 340B discounted covered drugs to ineligible recipients).

Consistent with Government auditing standards, the organization performing the audit shall coordinate with other auditors, when appropriate, to avoid duplicating work already completed or that may be planned. Only one audit of a covered entity will be permitted at any one time. When specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's compliance with section 340B(a)(5) (A) and (B), the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer.

(b). Scope of Audits

The manufacturer shall submit an audit work plan describing the audit to the Department for review. The Department will review the work plan for reasonable purpose and scope. Only those records of the covered entity (or the records of any organization that works with the covered entity to purchase, dispense, or obtain Title XIX reimbursement for the covered drug) that directly pertain to the potential 340B violation(s) may be accessed, including those systems and processes (e.g., purchasing, distribution, dispensing, and billing) that would assist in determining whether a 340B violation has occurred.

(c). Duration of Audits

Normally, audits shall be limited to an audit period of one year and shall be performed in the minimum time necessary with the minimum intrusion on the covered entity's operations.

II. Procedures To Be Followed

- (a). The manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B. The manufacturer and the covered entity shall have at least 30 days from the date of notification to attempt in good faith to resolve the matter.
- (b). The manufacturer has the option to proceed to the dispute resolution process described later in the notice without an audit, if it believes it has sufficient evidence of a violation absent an audit. If the matter is not resolved and the manufacturer desires to perform an audit, the manufacturer must file an audit work plan with the Department. (See section For Further Information for address.) The manufacturer must set forth a clear description of why it has reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, along with sufficient facts and evidence in support of the belief. In addition, the manufacturer shall provide copies of any documents supporting its claims.

- (c). The Department will review the documentation submitted to determine if reasonable cause exists. If the Department finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene. In cases where the Department determines that the audit shall be performed by the Government, the Department will so advise the manufacturer and the covered entity within 15 days of receipt of the audit work plan.
- (d). The filing of a audit work plan does not affect the statutory obligations of the parties as defined in section 340B of the Public Health Service Act. During the audit process, the manufacturer must continue to sell covered outpatient drugs at the section 340B ceiling price to the covered entity being audited, and the covered entity must continue to comply with the requirements of section 340B(a)(5).
- (e). Upon receipt of the manufacturer's audit work plan, the Department, in consultation with an appropriate audit component, will review the manufacturer's proposed work plan. As requested by GAS, the audit work plan shall describe in detail the following:
 - (1). audit objectives (what the audit is to accomplish), scope (type of data to be reviewed, systems and procedures to be examined, officials of the covered entity to be interviewed, and expected time frame for the audit), and methodology (processes used to gather and analyze data and to provide evidence to reach conclusions and recommendations);
 - (2). skill and knowledge of the audit organization's personnel to staff the assignment, their supervision, and the intended use of consultants, experts, and specialists;
 - (3). tests and procedures to be used to assess the covered entity's system of internal controls;
 - (4). procedures to be used to determine the amounts to be questioned should violations of section 340B(a)(5) (A) and (B) be discovered; and
 - (5). procedures to be used to protect patient confidentiality and proprietary information.
- (f). Within 15 days of receipt of the proposed audit work plan, the Department shall review the work plan. If after this review the Department has concerns about the work plan, it will work with the manufacturer to incorporate mutually agreed-upon revisions to the plan. The covered entity will have at least 15 days to prepare for the audit.
- (g). At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the GAS. The manufacturer shall submit the audit report to the covered entity. The covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 30 days from the date of receipt of the audit report. When the covered entity agrees with the audit report's findings and recommendations either in full or in part, the covered entity shall

include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report's findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.

- (h). The manufacturer shall also submit copies of the audit report to the Department (see section For Further Information Contact for the address) and the Office of Inspector General, Office of Audit Services, Public Health Service Audits Division at Room 1-30, Park Building, 12420 Parklawn Drive, Rockville, MD 20857.
- (i). If a dispute concerning the audit findings and recommendations arises, the parties may file a request for dispute resolution with the Department. All dispute resolution procedures developed by the Department shall be followed.

III. Suggested Audit Steps

Suggested audit steps include the following:

- (a). Review the covered entity's policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs.
- (b). Obtain an understanding of internal controls applicable to the policies and procedures identified above (step a) when necessary to satisfy the audit objectives.
- (c). Review the covered entity's policies and procedures to prevent the resale or transfer of drugs to a person or persons who are not patients of the covered entity.
- (d). Test compliance with the policies and procedures identified above (step c) when necessary to satisfy the audit objectives.
- (e). Review the covered entity's records of drug procurement and distribution and test whether the covered entity obtained a discount only for those programs authorized to receive discounts by section 340B of the Public Health Service Act.
- (f). If a covered entity does not use an all inclusive billing system (per encounter or visit), but instead bills outpatient drugs using a cost-based billing system, determine whether the covered entity has provided its pharmacy Medicaid provider number to the Department and test whether the covered entity billed Medicaid at the actual acquisition cost. The auditor is permitted to contact the Office of Drug Pricing (at the number in the For Further Information Contact section) to determine if the entity--(1) has provided its pharmacy Medicaid provider number, (2) does not bill Medicaid for covered outpatient drugs, (3) uses an all-inclusive rate billing system, or (4) is an entity clinic eligible for the discount pricing but located within a larger medical facility not eligible for the drug discounts and has provided the Office of Drug Pricing a separate pharmacy Medicaid provider number or an agreement with the State Medicaid Agency regarding an operating mechanism to prevent duplicate discounting.

- (g). Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5) (A) or (B), identify (1) the procedures or lack of adherence to existing procedures which caused the violation, (2) the dollar amounts involved, and (3) the time period in which the violation occurred.
- (h). Following completion of the audit field work, provide an oral briefing of the audit findings to the covered entity to ensure a full understanding of the facts.

9. Dispute Resolution Process (December 12, 1996)

The Department, acting through the Office of Drug Pricing (ODP), is proposing a voluntary process for the resolution of certain disputes between manufacturers and covered entities concerning compliance with the provisions of section 340B of the Public Health Service Act. Covered entities or manufacturers are not required to enter this informal process for resolution of disputes regarding section 340B. However, the Department expects parties to utilize the process before resorting to other remedies which may be available under applicable principles of law.

I. Types of Disputes Covered

Disputes resolved by these procedures include:

- (a) A manufacturer believes a covered entity is in violation of the prohibition against resale or transfer of a covered outpatient drug (section 340B(a)(5)(B) of the Public Health Service Act), or the prohibition against duplicate discounts or rebates (section 340B(a)(5)(A) of the Public Health Service Act).
- (b) A covered entity believes that a manufacturer is charging a price for a covered outpatient drug that exceeds the ceiling price as determined by section 340B(a)(1) of the Public Health Service Act.
- (c) A manufacturer is conditioning the sale of covered outpatient drugs to a covered entity on the entity's provision of assurances or other compliance with the manufacturer's requirements that are based upon section 340B provisions.
- (d) A covered entity believes that a manufacturer has refused to sell a covered outpatient drug at or below the ceiling price, as determined by section 340B(a)(1) of the Public Health Service Act.
- (e) A manufacturer believes that a covered entity is dispensing a covered outpatient drug in an unauthorized service (e.g., inpatient services or ineligible clinics within the same health system).
- (f) A manufacturer believes that a covered entity has not complied with the audit requirements under section 340B(a)(5)(c) of the Public Health Service Act or the audit guidelines as set forth in this notice.

- (g) A covered entity believes that the auditors of the manufacturer have not abided by the approved work plan or audit guidelines.
- (h) A covered entity is unable to obtain covered outpatient drugs through a wholesaler because the manufacturer will only sell section 340B discounted drugs directly from the manufacturer to the entity.
- (i) A manufacturer or covered entity wants to verify the accuracy of the master list of covered entities.

II. Dispute Resolution Process

Prior to the filing of a request for dispute review with the Department, the parties must attempt, in good faith, to resolve the dispute. All parties involved in the dispute must maintain written documentation as evidence of the good faith attempt to resolve the dispute. Such evidence includes documentation of meetings, letters, or telephone calls between the disputing parties that concern the dispute.

If the dispute has not been resolved after a good faith attempt, a party may submit a written request for a review of the dispute to the Director of the Office of Drug Pricing within 30 days.

The party requesting the review may not rely only upon allegations but is required to set forth specific facts showing that there is a genuine and substantial issue of material fact in dispute that requires a review.

The request for review shall include a clear description of the dispute, shall identify all the issues in the dispute, and shall contain a full statement of the party's position with respect to such issue(s) and the pertinent facts and reasons in support of the party's position. In addition to the required statement, the party shall provide copies of any documents supporting its claim and evidence that a good faith effort was made to resolve the dispute. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.

The filing of the dispute does not affect any statutory obligations of the parties, as defined in section 340B of the Public Health Service Act. During the review process, for example, a manufacturer must continue to sell covered outpatient drugs at or below the section 340B ceiling price to all covered entities, including the covered entity involved in the dispute. Only when the entity is found guilty of prohibited activity and a decision is made to remove the entity from the list of covered entities, is the manufacturer no longer required to extend the discount.

The Director, Bureau of Primary Health Care, shall appoint a committee to review the documentation submitted by the disputing parties and to make a proposed determination. A minimum of three individuals shall be appointed (one of whom shall be designated as a chairperson) either on an ad hoc, case-by-case basis, or as regular members of the review committee. The chairperson shall be from the Office of Drug Pricing and the committee members shall be from other sections of Public Health Service (e.g. chief pharmacist, auditor).

Upon receipt of a request for a review, the chairperson of the review committee, within 30 days, will send a letter to the party alleged to have committed a violation. The letter will include (1) the name of the party making the allegation(s), (2) the allegation(s), (3) documentation supporting the party's position, and (4) a request for a response to or rebuttal of the allegations within 37 calendar days of the receipt of the letter (7 days from the date of the postmark of the letter being allowed for mailing and processing through the organization).

Upon receipt of the response or rebuttal, the review committee will review all documentation. The request and rebuttal information will be reviewed for (1) evidence that a good faith effort was made to resolve the dispute, (2) completeness, (3) adequacy of the documentation supporting the issues, and (4) the reasonableness of the allegations. If the documentation meets these requirements, the review committee will consider the matter.

The reviewing committee may, at its discretion, invite parties to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

The reviewing committee will propose to dismiss the dispute, if it conclusively appears from the data, information, and factual analyses contained in the request for a review and rebuttal documents that there is no genuine and substantial issue of fact in dispute. Within 30 days, a written decision of dismissal will be sent to each party and will contain the committee's findings and conclusions in detail, and, if the committee decided to dismiss, reasons why the request for a review did not raise a genuine and substantial issue of fact.

With all other proposed findings, within 30 days, the review committee will prepare a written document containing the findings and detailed reasons supporting the proposed decision. The document is to be signed by the chairperson and each of the other committee members. The committee's written decision will be sent with a transmittal letter to both parties. If the committee finds the covered entity guilty of prohibited activity and a decision is made to remove the entity from the covered entity list, then the manufacturers will no longer be required to extend the discount. If the covered entity or the manufacturer does not agree with the committee's determination, the covered entity or the manufacturer may appeal within 30 days after receiving such a determination to the Administrator of the Health Resources and Services Administration, who will appoint a review official or committee. The review official or committee will respond to appeal requests within 30 days from the receipt of the request.

III. Penalties

If the final determination is that a manufacturer has violated the provisions of section 340B of the Public Health Service Act or the Public Health Service Pharmaceutical Pricing Agreement, the manufacturer's agreement with HHS could be terminated or other actions taken, as deemed appropriate. If the final determination is that an entity has violated section 340B prohibitions against the resale or transfer of covered outpatient drugs or the prohibition against duplicate discounts and rebates (or billing Medicaid more than the actual acquisition cost of the drug), the entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug for the period of the violation, as provided by section 340B(a)(5)(D) of the Public Health Service Act. After the dispute is

resolved, any disputed amounts must be paid or credited to an account balance no later than 30 days following a final determination. The entity may also be excluded from the drug discount program, if the conduct warrants such a sanction. Such penalties do not preclude the imposition by the Government of other penalties or remedies under other statutes such as the Federal False Claims Act. A copy of the findings may be sent to the Office of the Inspector General for further action. If it is documented that several manufacturers have been wronged by the same prohibited entity behavior, corrective action will be afforded such manufacturers. (The reporting and record keeping requirements of this document are subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501-3520, and have OMB clearance through 9/30/97 (OMB Control No. 0915-0176). The Paperwork Reduction Act of 1995 added disclosure requirements to the list of items needing OMB approval. The disclosure requirements in the audit guidelines include: section II(a)--the manufacturer shall notify the covered entity in writing when it believes the covered entity has violated provisions of section 340B; section II(g)--the manufacturer shall submit the audit report to the covered entity, and the covered entity shall provide its response to the manufacturer on the audit report's findings; and section III(h) the manufacturer shall provide an oral briefing of the audit findings to the covered entity. The disclosure requirements in these sections will not be in force until OMB approval has been obtained.

10. The State ADAP Section 340B Rebate Option (June 29, 1998)

HRSA recognizes rebates obtained by the State ADAPs or their components that equal or exceed the 340B discount provided by the statutory ceiling price as a method of participating in the 340B program, subject to compliance with other requirements for participation. Standard business practices, such as those reflected in the Medicaid Rebate Program and current voluntary manufacturer rebate programs (consistent with the requirements of section 340B and all program guidance published in the Federal Register) are appropriate for the development of rebate contracts and agreements between State ADAPs and manufacturers.

State ADAPs or their components and manufacturers wishing technical assistance in developing a rebate program and rebate agreements should contact HRSA's Office of Drug Pricing at (301) 594-4353 or (800) 628-6297. State ADAPs or their components determined to be eligible for participation in the State ADAP 340B rebate program will be listed on the Office of Drug Pricing (ODP) Electronic Data Retrieval System (EDRS) on the first quarterly update of the EDRS which occurs 30 days following the effective date of this Federal Register notice. State ADAPs or their components listed on this update may submit rebate claims to participating manufacturers for covered drugs that are purchased starting 30 days after the date of this final notice publication. State ADAPs or their components listed on a later EDRS update may claim rebates only on purchases made after their effective date of listing on the EDRS.

Section 340B(a)(5)(A) reflects Congressional recognition that there is a potential for a covered drug purchased by a covered entity at the 340B discount price to be subject to a Medicaid rebate, if the drug is reimbursed by the Medicaid program. All program guidance regarding the prevention of such duplicate discounting must be followed by ADAPs participating in the rebate program as well as those participating in the discount program. Guidance regarding billing State Medicaid Agencies at actual acquisition cost plus a dispensing fee (established by the State Medicaid agency) and the prevention of duplicate discounting was published in the Federal Register on May

7, 1993 (58 FR 27293) entitled "Duplicate Discounts and Rebates on Drug Purchases." Further guidance was published in the Federal Register on May 13, 1994 (59 FR 25112). State ADAPs may find it necessary to work with State Medicaid Agencies to adapt these guidelines to meet the unique circumstances of each individual State, such as provisions permitting retroactive reimbursement of drug purchases while Medicaid eligibility was pending.

The HRSA is sensitive to concerns about diversion of covered drugs to individuals who are not patients of the covered entities. Guidelines have been issued to minimize this potential, and manufacturers have available to them specified remedies if they believe diversion has occurred. These guidelines and remedies will apply fully to drugs purchased under a rebate option, and we believe that instituting rebates will not increase the potential for diversion.

11. Program Guidance Clarification re Mechanism to Prevent Duplicate Discounts (March 15, 2000)

SUMMARY: Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act, "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible (covered) entities must sign a pharmaceutical pricing agreement with the Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula.

The purpose of this notice is to clarify section 340B program guidance related to the mechanism to prevent duplicate discounts (i.e., the generation of a Medicaid rebate on a section 340B discounted drug). Any covered entity that purchases its non-Medicaid drugs through the 340B program but its Medicaid drugs through other avenues must provide the Office of Drug Pricing (ODP) notice of this type of dual purchasing activity. The Office of Drug Pricing will place a notation "non-applicable" (N/A) by the covered entity name on the eligibility list so that any reimbursement requests for its Medicaid drugs will continue to generate manufacturer rebates. For appropriate Medicaid drug reimbursement procedures, the Health Resources and Services Administration (HRSA) refers the covered entity to its respective State Medicaid agency for guidance.

SUPPLEMENTARY INFORMATION: Section 340B(a)(5)(A) required HHS to develop a mechanism to prevent a section 340B drug discount and a Medicaid rebate on the same drug (i.e., prevention of double discounting). HRSA, together with the Medicaid Rebate Program, Health Care Financing Administration, developed a process to prevent this potential double price reduction and published the final notice of this mechanism on June 23, 1993, at 58 FR 34058. The mechanism, which focuses only on 340B covered outpatient drugs, requires a covered entity that bills Medicaid on a cost basis (e.g., community health centers using fee for service and not all inclusive rates) to submit to the Office of Drug Pricing its Pharmacy Medicaid Number (i.e., the number used to bill Medicaid for the drugs). This information is placed by the name of the covered entity on the master electronic eligibility list. Using this Medicaid number, the State Medicaid agency creates a separate provider file for claims from that covered entity. This computer file then excludes data from this provider file when generating the rebate bills to the manufacturers. In this way, the mechanism prevents double discounting. An entity which utilizes

a Medicaid billing system that includes pharmacy in an all-inclusive rate or does not submit Medicaid claims for covered outpatient drugs would not generate Medicaid rebates. Consequently, these entities do not have to provide their pharmacy numbers (58 FR 34059). However, such entities were instructed to provide the Office of Drug Pricing with notice of such purchasing practices so that this information could be provided to participating manufacturers and appropriate State Medicaid agencies (59 FR 25112, May 13, 1994). It has come to our attention that there may be some confusion concerning the appropriate reporting procedures for an entity not participating in the 340B Program for its Medicaid drugs (i.e., purchasing its non-Medicaid drugs through the 340B Program and its Medicaid drugs outside the Program). Because drugs purchased outside of the 340B Program are not considered covered 340B outpatient drugs, an entity that only purchases non-Medicaid drugs through the 340B Program would not request Medicaid reimbursement for its covered outpatient drugs (i.e., non-Medicaid drugs discounted through the 340B program). Consequently, the covered entity would not provide Office of Drug Pricing its Medicaid Pharmacy number. However, this entity still must notify Office of Drug Pricing of this type of purchasing practice. Office of Drug Pricing will place N/A by the name of the covered entity, signaling no Medicaid reimbursement requests on drugs purchased with discounts under section 340B. In this way, Medicaid rebates will continue to be generated on its Medicaid drugs purchased outside the 340B program. Covered entities that have submitted Medicaid Pharmacy provider numbers now included in the covered entity database but are purchasing drugs for their Medicaid patients on the open market should contact Office of Drug Pricing as soon as possible to request that their Medicaid Pharmacy numbers be replaced by N/A in the covered entity database. An entity that has purchased Medicaid drugs outside of the 340B Program but submitted its Medicaid provider number to Office of Drug Pricing should attempt to preserve any documentation of such purchasing activity. The entity should contact its State Medicaid agency about these past drug purchases so that the agency can bill manufacturers for rebates that were excluded from past rebate claims. On behalf of the Medicaid Drug Rebate Program, HRSA provided notice to covered entities regarding appropriate procedures for requesting Medicaid reimbursement for covered outpatient drugs (58 FR 27293 and 59 FR 25112 regarding “actual acquisition cost”). Currently, HRSA is reviewing that portion of the guidance and recommends that covered entities refer to their respective Medicaid State agency drug reimbursement guidelines for applicable billing limits.

**Appendix D:
Grants Management Documents re Program Income**

1. Sections of the HHS Grants Management Regulation (Part 74 of Title 45 of the Code of Federal Regulations) providing general rules for managing program income

Sec. 74.2 Definitions

Program income means gross income earned by the recipient that is directly generated by a supported activity or earned as a result of the award [see exclusions in Sec. 74.24 (e) and (h)]. Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under federally-funded projects, the sale of commodities or items fabricated under an award, license fees and royalties on patents and copyrights, and interest on loans made with award funds. Interest earned on advances of Federal funds is not program income. Except as otherwise provided in the terms and conditions of the award, program income does not include the receipt of principal on loans, rebates, credits, discounts, etc., or interest earned on any of them. Furthermore, program income does not include taxes, special assessments, levies, and fines raised by governmental recipients.

Sec. 74.5 Subawards

(a) Unless inconsistent with statutory requirements, this part (except for Sec. 74.12 and the forms prescribed in Sec. 74.22) shall apply to--

(1) Except for subawards under block grants (45 CFR part 96), all subawards received by institutions of higher education, hospitals, other nonprofit organizations, and commercial organizations from any recipient of an HHS award, including any subawards received from States, local governments, and Indian tribal governments covered by 45 CFR part 92; and

(2) All subawards received from States by any entity, including a government entity, under the entitlement programs identified at 45 CFR part 92, Sec. 92.4 (a), (a)(7), and (a)(8), except that Secs. 74.12 and 74.25 of this part shall not apply.

(b) Except as provided in paragraph (a)(2) of this section, when State, local, and Indian Tribal government recipients of HHS awards make subawards to a government entity, they shall apply the regulations at 45 CFR part 92, "Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments," or State rules, whichever apply, to such awards.

Sec. 74.24 Program income

(a) The standards set forth in this section shall be used to account for program income related to projects financed in whole or in part with Federal funds.

(b) Except as provided below in paragraph (h) of this section, program income earned during the project period shall be retained by the recipient and, in accordance with the terms and conditions of the award, shall be used in one or more of the following ways:

- (1) Added to funds committed to the project or program, and used to further eligible project or program objectives;
- (2) Used to finance the non-Federal share of the project or program; or

- (3) Deducted from the total project or program allowable cost in determining the net allowable costs on which the Federal share of costs is based.
- (c) When the HHS awarding agency authorizes the disposition of program income as described in paragraph (b)(1) or (b)(2) of this section, program income in excess of any limits stipulated shall be used in accordance with paragraph (b)(3) of this section.
- (d) In the event that the HHS awarding agency does not specify in the terms and conditions of the award how program income is to be used, paragraph (b)(3) of this section shall apply automatically to all projects or programs except research. For awards that support performance of research work, paragraph (b)(1) of this section shall apply automatically unless Social Security Act:
 - (1) The HHS awarding agency indicates in the terms and conditions of the award another alternative; or
 - (2) The recipient is subject to special award conditions under Sec. 74.14; or
 - (3) The recipient is a commercial organization (see Sec. 74.82).
- (e) Unless the terms and conditions of the award provide otherwise, recipients shall have no obligation to the Federal Government regarding program income earned after the end of the project period.
- (f) Costs incident to the generation of program income may be deducted from gross Social Security Act income to determine program income, provided these costs have not been charged to the award.
- (g) Proceeds from the sale of property shall be handled in accordance with the requirements of the Property Standards. (See Secs. 74.30 through 74.37, below).
- (h) The Patent and Trademark Laws Amendments, 35 U.S.C. section 200-212, apply to inventions made under an award for performance of experimental, developmental, or research work. Unless the terms and conditions for the award provide otherwise, recipients shall have no obligation to HHS with respect to program income earned from license fees and royalties for copyrighted material, patents, patent applications, trademarks, and inventions made under an award. However, no scholarship, fellowship, training grant, or other funding agreement made primarily to a recipient for educational purposes will contain any provision giving the Federal agency rights to inventions made by the recipient.

2. Public Health Service Grants Policy Statement, Section 8: Postaward Administration, policy regarding program income

PROGRAM INCOME

Recipients are accountable to Public Health Service for certain kinds of program income in accordance with 45 CFR Part 74, Subpart F, and 45 CFR Part 92.25. Contracts under a grant are subject to the terms of the contract with regard to the income generated by the activities. Program income includes general program income (see 45 CFR Part 74.42); proceeds from the sale of assets acquired with project funds; royalties from copyrights on publications developed under, or patents and inventions conceived or first actually reduced to practice under, a grant-supported project; and interest and investment income. These requirements are set forth in 45 CFR Part 74, Subpart F, and in 45 CFR Part 92.25 and are summarized below.

Each NGA will provide information as to the treatment of program income for each funded project.

General Program Income

All general program income, as defined in 45 CFR Part 74.42 and program income as defined in 45 CFR Part 92.25, earned during the period of Public Health Service grant support shall be retained by the recipient and shall be treated in accordance with one or a combination of the following options:

1. *Deduction Alternative*--Deducted from total allowable costs and third-party in-kind contributions for the purpose of determining the net costs on which the Federal share will be based. When this alternative applies, the deduction must be made from current costs unless the terms of the NGA authorize deferral to a later period. General program income subject to this alternative shall be reported on lines 10c and 10q of the FSR (Long Form).
2. *Matching Alternative*--Used to satisfy all or part of a matching requirement. General program income subject to this alternative shall be reported on lines 10g and 10q of the FSR (Long Form).
3. *Additional Costs Alternative*--Used for costs that are in addition to the allowable costs of the project for any purposes that further the objectives of the legislation under which the grant was made. General program income subject to this alternative shall be reported on lines 10r and 10s, as appropriate, of the FSR (Long Form).

Option 1 above may always be selected by recipients and must be used if neither of the other alternatives is specified by the Public Health Service awarding office in regulations or on the NGA. A subgrantee may not be permitted to use an option not permitted by the terms of the award to the grantee.

For information on treatment of program income by--

- State and local governments and federally recognized Indian tribes, see 45 CFR Part 92.25.
- Recipients of research grants,
- All other nonprofit grantees, see 45 CFR Part 74, Subpart F.
- For-profit organizations, see appendix 6

Interest earned by recipients as a result of a permissible use of general program income, e.g., where a statute or other grant term provides for the use of income to be deferred to a later period, shall be retained by the recipient and treated as general program income.

Treatment of General Program Income Under Research Grants

Recipients of certain Public Health Service research grants have been extended the authority to use the Additional Costs Alternative (see "Special Provisions for Research Grants"). Each NGA will provide information as to the treatment of program income for each funded project.

For research grants not included in the special grant provisions (expanded authorities), general program income shall be used as follows unless specified otherwise by the awarding office:

1. The first \$25,000 of program income is to be used in accordance with the Additional Costs Alternative and shall be reported on lines 10r and 10s of the FSR (Long Form). However, this option may not be authorized for-profit grantees (however, see also appendix 6), grantees designated as exceptional organizations, or where the principal investigator has a history of frequent, large annual unobligated balances on previous grants or has requested multiple extensions of the budget/project period.
2. Amounts in excess of \$25,000 are to be used in accordance with the Deduction Alternative, unless another alternative is specified on the NGA, and shall be reported on lines 10c and 10q of the FSR (Long Form).

Sale of Real Property, Equipment, and Supplies

Sale of Property

45 CFR Part 74.134 states that the disposition instructions of the granting agency shall be followed when real property is no longer to be used by the grantee or transferred to an eligible third party.

Sale of Equipment

Grantees subject to the requirements in 45 CFR Part 74.139, Disposition of Equipment, shall report income earned from the sale of equipment on the FSR if the grantee's project or program for which equipment was acquired is still receiving grant support. If authorized by the awarding unit, grantees may use the income for allowable costs of the project. This income would be reported on lines 10c, 10r, or 10s of the FSR (Long Form) in accordance with the Public Health Service awarding office's authorized disposition. There are no reporting requirements for nonprofit institutions of higher education or nonprofit organizations whose primary purpose is the conduct of scientific research, since they are not subject to the requirements in 45 CFR Part 74.139.

Unused Supplies

Grantees subject to the requirements in 45 CFR Part 74.141, Unused Supplies, shall reflect any credit to the grant on line 10c of the FSR (Long Form). There are no reporting requirements for nonprofit institutions of higher education or nonprofit organizations whose primary purpose is the conduct of scientific research, since they are not subject to the requirements in 45 CFR Part 74.141.

Other Income

Royalties From a Copyrighted Work

Where the terms of the NGA do not specify disposition, no reporting of income is required on the FSR. Where the terms of the NGA govern disposition, this kind of income shall be reported on lines 10c, 10r, or 10s of the FSR (Long Form), in accordance with the Public Health Service

awarding office's authorized disposition.

Royalties From Patents or Inventions

Where the terms of the NGA govern disposition, this kind of income would be reported on lines 10c, 10r, or 10s of the FSR in accordance with the Public Health Service awarding office's authorized disposition. Where the terms of the NGA do not specify disposition, Public Health Service awarding office instructions for reporting this kind of income shall be followed.

Interest and Investment Income

Except as provided immediately below, grantees shall remit to the Federal Government any interest or other investment income earned on advances of Public Health Service grant funds. This includes any interest or investment income earned by subgrantees and cost-type contractors on advances to them that are attributable to advances of Public Health Service grant funds to the grantee. However, States shall not be accountable to the Federal Government for interest or investment income earned by the State itself, or by its subgrantees, where this income is attributable to Federal grants.

Income After the Grant or Subgrant Support Not Otherwise Treated

Unless specified in the terms of the NGA, there are no reporting requirements for income accrued after the period of grant support ends.

3. Guidance re Program Income from a Letter to HTC Grantees dated May 23, 2003

The Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), is continuing its grant monitoring procedures concerning program income. We would like to take this opportunity to inform you and your affiliates of the reporting requirements and governing policies in reference to program income. As specified in 45 C.F.R. 74.2, program income is that “gross income earned by the [grant or subaward] recipient that is directly generated by a supported activity or earned as a result of the award.” Costs incident to the generation of program income may be deducted from the gross income to determine the net program income, provided those costs have not been charged to the grant. 45 C.F.R. 74.24(f).

All Federal grants are subject to regulation under the “Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations.” 45 C.F.R. Part 74. These same requirements are passed down from the grant recipient to the subawardee. 45 C.F.R. § 74.5. A “subaward” means the “award of financial assistance...made under an award by a recipient to an eligible subrecipient or by a subrecipient to a lower tier subrecipient...even if the agreement is called a contract.” 45 C.F.R. § 74.2. Grant recipients are “responsible for managing and monitoring each project, program, subaward, function or activity supported by the award.” 45 C.F.R. § 74.51. Consequently, it is incumbent upon you to share this information with appropriate individuals/entities within your institution and affiliates.

Part 74 requires program income to be used in one or more of three ways: (1) added to funds committed to the project or program and used to further eligible project or program objectives; (2) used to finance the non-federal share of the program; or (3) deducted from the total program allowable costs. 45 C.F.R § 74.24(b). As provided on the Notice of Grant Award (Item #15), the MCHB requires the HTC grantees and their affiliate institutions to use the program income to “further eligible project and program objectives.” Therefore, the program income is to be used for patient care and supportive services necessary to provide comprehensive care to patients. This is consistent with the purpose of section 340B which is to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” H.R. Rep. No. 102-384, at 12 (1992). Note that the grants awarding office may, on a case-by-case basis, allow a grantee to use the income for eligible costs of the project that might not be expressly allowable costs under the terms and conditions of the award. Such cases require prior written approval from the grants awarding office.

Many HTCs are Title V grantees, and are eligible to access section 340B drug ceiling prices as a result of receiving these grant awards. Section 340B(a)(4)(G) of the Public Health Service Act designates a “comprehensive hemophilia diagnostic treatment center receiving a grant under [Title V] section 501(a)(2) of the Social Security Act” as eligible for drug ceiling prices. Certain HTC grantees are participating in the 340B drug program and accessing such pricing. It is our understanding that these centers are purchasing certain drugs at the ceiling prices and selling these drugs at a mark-up to their patients. Net income realized from the sale of 340B drugs purchased under the 340B program is considered to be program income. In addition, those grantees and affiliates that have factor programs that are non-participants in the 340B Program and those who have factor programs as a result of participation in the 340B Program must consider all sales of drugs, including Medicaid sales, as program income.

Program income from hemophilia treatment center (HTC) grant projects must be managed in accordance with the requirements of Part 74 and must be reported on the Financial Status Report (FSR) SF 269 (long form) within 90 days after the end of each budget period (form enclosed). It is the responsibility of the grantees to monitor the program income generated by the subawardees. To remind grantees of this reporting requirement, the Notice of Grant Award for the FY 2003 budget year (June 1, 2003 – May 31, 2004) will have a term award pertaining to the accurate reporting of the net program income on the FSR form. Focusing on a prospective application, starting with FY 2003 funding cycle, the reporting of net program income on the FSR form is due in the HRSA Division of Grants Management Operation (DGMO) on August 31, 2005, 90 calendar days after the close of the budget period end date. [Note: The Notice of Grant Award for the FY 2004 budget year (June 1, 2004 - May 31, 2005) had a term award regarding the reporting of net program income on the FSR due on August 31, 2005.]

