IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

DEFENDANTS' MOTION TO DISMISS

Pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), Defendants Alex M. Azar II and Department of Health and Human Services respectfully move to dismiss Plaintiffs' Complaint. In support of this Motion, Defendants respectfully refer the Court to the attached Memorandum of Points and Authorities.

Date: September 14, 2018

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Congress granted the Secretary of Health and Human Services (the "Secretary") broad authority to administer Medicare Part B's system for prospective payment of hospital outpatient services (known as the "Outpatient Prospective Payment System" or "OPPS"). That authority extends to setting payment rates for certain outpatient drugs, and making annual adjustments that are budget neutral. *See* 42 U.S.C. § 1395l(t)(2), (9) The Medicare statute provides that, once the Secretary calculates an OPPS drug payment rate, that rate may be "adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II). This broad and unequivocal grant of discretion reflects Congress's judgment that the Secretary needs flexibility to effectively administer the OPPS. Further demonstrating this congressional intent, the Medicare statute expressly precludes "administrative or judicial review" of the Secretary's development of the OPPS, including adjustments within that system. *See id.* § 1395*l*(t)(12). Both the D.C. Circuit and this Court have construed § 1395*l*(t)(12) to "clearly preclude judicial review of the Secretary's adjustments to prospective payment amounts." *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (Contreras, J.) (citing *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004)).

At issue here is the OPPS payment rate for drugs procured under the 340B Program, a program separate from Medicare that allows certain health care providers to obtain drugs at significantly discounted prices. From 2013 to 2017, the Centers for Medicare & Medicaid Services ("CMS") within Health and Human Services ("HHS") used a payment rate of average sale price ("ASP") plus 6% for all OPPS drugs, including drugs purchased under the 340B Program. Recent reports, however, have highlighted that providers have been receiving remarkably deep discounts on outpatient drugs under the 340B Program and, consequently, have reaped substantial profits on each drug they prescribe. By one measure, providers received Medicare payments for drugs

acquired under the 340B Program that were on average *58% higher* than what the provider paid for the drug.

This discrepancy is troubling for several reasons. First, because the Secretary administers the OPPS in a budget-neutral manner, providers outside the 340B Program have subsidized drug payments to 340B Program participants that bear no actual relation to the participants' acquisition costs. Second, Medicare beneficiaries' out-of-pocket payments, such as copayments or coinsurance, are tied to the amount that Medicare—not the provider—pays for the drug. As a result, beneficiaries have been paying artificially high rates for drugs that their providers received at a significant discount. Third, perhaps quite predictably, reports show that 340B hospitals tend to prescribe more drugs, or more expensive drugs, than hospitals outside the program – and they do so at the government's and beneficiaries' expense.

To address this issue, the Secretary issued a final rule that exercises his authority under § 1395*l*(t)(14)(A)(iii)(II) to "adjust[] . . . as necessary" the OPPS payment rate for 340B drugs. *See* 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) ("2018 OPPS Rule"). The Rule reduces the OPPS payment rate for 340B drugs to ASP minus 22.5%, which reflects the "minimum" or "lower bound of the average discount received by 340B hospitals," thus allowing 340B providers to retain some profit margin. *Id*. at 52,496. The payment adjustment is intended to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program," ensuring that beneficiaries "share in the savings on drugs acquired through the 340B Program." *Id.* at 52,362, 52,495-97. The Rule exempts from the payment adjustment "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals." *Id*. at 52,362. The payment adjustment also does not affect 340B providers that

are paid under a separate payment scheme outside of the OPPS, such as critical access hospitals. In total, at least 52% of the 340B providers are not affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS. The Secretary estimated that the payment adjustment would save Medicare $1.6 billion on OPPS drug expenditures for 2018. *Id.* at 52,509. In accordance with the Medicare statute's budget neutrality requirements, these savings already have been and will continue to be "redistributed in an equal offsetting amount to all hospitals paid under the OPPS," *id.*, including Plaintiffs.

Plaintiffs brought this suit under the Administrative Procedure Act ("APA"), seeking the extraordinary remedy of a preliminary injunction to enjoin the application of the 2018 OPPS Rule, among other things. Compl.; Plaintiffs' Memorandum in Support of their Motion for a Preliminary and Permanent Injunction ("Pls.'Mem."), ECF No. 2, Sept. 5, 2018. They claim that the Secretary's payment adjustment exceeded his authority under the Medicare statute. Compl. ¶¶ 67-78.

Plaintiffs' Complaint should be dismissed for four independent reasons. First, as indicated above, judicial review of the Secretary's adjustment of OPPS payment rates under § 1395*l*(t)(14)(A)(iii)(II) is expressly precluded by § 1395*l*(t)(12). Second, the Secretary's payment adjustment is an agency action that is "committed to agency discretion by law" and thus unreviewable under the APA. Third, Plaintiffs failed to exhaust their administrative remedies. Fourth, Plaintiffs' claim fails on the merits because their various theories as to why the Secretary's actions exceeded his statutory authority rest on misinterpretations of the Medicare statute.

Plaintiffs also fall far short of the extraordinary showing necessary to obtain a preliminary injunction. For the reasons outlined in support of Defendants' motion to dismiss, Plaintiffs are not likely to succeed on the merits. Moreover, the requested injunction would significantly disrupt

operation of the Medicare system, to the detriment of its participants and Defendants. Indeed, the Agency has processed millions of claims under the 2018 OPPS rule, and a preliminary injunction increasing the payment rate for drugs purchased through the 340B program would raise significant and difficult questions about how to handle claims related to other components of the OPPS that, as a result of the budget neutrality requirement, were paid under rates that were increased to offset the decrease to the payment rate for drugs acquired through the 340B program.

For all these reasons, Defendants respectfully request that the Court grant Defendants' motion to dismiss, and deny Plaintiffs' motion for a preliminary injunction.

BACKGROUND

I. The Medicare Outpatient Prospective Payment System

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.* (the "Medicare statute"). HHS administers Medicare through CMS. Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Part B of Medicare, at issue here, provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k.

A component of Medicare Part B is the OPPS, which pays hospitals directly to provide outpatient services to beneficiaries. *See* 42 U.S.C. § 1395*l*(t) (establishing the OPPS). Under the OPPS, hospitals are paid on prospectively-determined rates for their services in each upcoming year, thus requiring payments for outpatient hospital care to be determined in advance. *See id.* The Medicare program currently processes more than 100 million outpatient hospital claims per year. *See, e.g.*, 2016 CMS Statistics, at 42, Table V.6 (outpatient hospital claims represent 59.7% of 214.1 million total claims received) (attached as Exh. 1).

The Medicare statute confers broad authority on the Secretary to make adjustments to the OPPS. For instance, the Secretary is charged with annually updating the OPPS payment

classifications, relative payment weights, and other components of the OPPS, "to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A). Such adjustments must be made in a "budget-neutral" manner—*i.e.*, "the adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." *Id.* § 1395*l*(t)(9)(B). Further demonstrating the flexibility Congress intended to confer upon the Secretary in administering the OPPS, the Medicare statute expressly precludes "administrative or judicial review" of the Secretary's "development of" and "adjustments" to the OPPS system, including payment adjustments. *See id.* § 1395*l*(t)(12) (subsection titled "Limitation on review").

In 2003, Congress amended the Medicare statute to require the Secretary to set Medicare payment rates for "specified covered outpatient drugs" ("SCODs"). *Id.* § 1395*l*(t)(14). SCODs are a category of "separately payable" drugs—*i.e.*, drugs that are not bundled with other outpatient services, and for which a "separate ambulatory payment classification group" has been established. *Id.* § 1395*l*(t)(14)(B). Of particular relevance here, SCODs include some outpatient drugs that are subject to discounts under the 340B Program.

For 2004 and 2005, the Medicare statute gave the Secretary specific instructions on how to set payment rates for SCODs. *Id.* § 1395*l*(t)(14)(A)(i)-(ii). But for 2006 and beyond, Congress eschewed these specific instructions and instead expressed a preference for payment rates to align with acquisition costs. Specifically, Congress directed the Secretary to set payment rates for SCODs to be equal to either:

> (I) . . . the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on volume of covered [outpatient department ("OPD")] services or other relevant

> characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); *or*
>
> (II) if hospital acquisition cost data are not available, the average price for the drug in the year established under . . . section 1395w-3a of this title . . . *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.*

Id. § 1395*l*(t)(14)(A)(iii)(I)-(II) (emphasis added).[1] For purposes of subclause (II) of § 1395*l*(t)(14)(A)(iii), the cross-referenced statute establishes that the default payment rate shall be "106 percent" of "average sales price," or "ASP+6%." *See id.* § 1395w-3a(b)(1). As subclause (II) provides, however, this rate may be "adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* § 1395*l*(t)(14)(A)(iii)(II).

As explained in detail below, judicial review of the Secretary's payment adjustments under § 1395*l*(t)(14)(A)(iii)(II) is expressly precluded by three subsections of § 1395*l*(t)(12). First, § 1395*l*(t)(12)(A) provides that "there shall be no . . . judicial review . . . of" the "*development of the [OPPS] classification system* under paragraph (2), *including* the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, *other adjustments*, and methods described in paragraph (2)(F)." (emphasis added). This provision bars suits challenging the Secretary's adjustment of payment rates under § 1395*l*(t)(14)(A)(iii)(II), because such action is part of the Secretary's "development of" the OPPS, and is likewise an "adjustment[]" to that system. Second, § 1395l(t)(12)(C) states that there shall be no administrative or judicial review of "the periodic adjustments made under paragraph [9]"[2];

[1] Not all separately payable drugs qualify as statutory SCODs to which the payment methodologies of § 1395*l*(t)(14)(A)(iii) apply. Nonetheless, CMS applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). This "is a policy choice rather than a statutory requirement." *Id.*

[2] Although subsection 1395*l*(t)(12)(C) refers to "periodic adjustments made under paragraph (6)," the statutory history makes clear that Congress in fact meant the Secretary's authority to make

paragraph nine addresses periodic adjustments to "components of [the] prospective payment system" to "take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." 42 U.S.C.A. § 1395l(t)(9)(A). Third, § 1395*l*(t)(12)(E) provides that "there shall be no . . . judicial review . . . of" the "portion of the medicare [outpatient department] *fee schedule amount associated with particular . . . drugs*" (emphasis added). Because a payment adjustment under § 1395*l*(t)(14)(A)(iii)(II) necessarily alters the "fee schedule amount associated with particular … drugs," such an adjustment falls within § 1395*l*(t)(12)(E)'s bar on judicial review.

II. The 340B Program

Enacted by Congress in 1992, the 340B Program allows participating healthcare providers, known as "covered entities," to purchase "covered outpatient drugs" at discounted prices from drug manufacturers. *See* Public Health Service Act, § 340B, 42 U.S.C. § 256b. The Program initially applied to federal health care grant recipients and to hospitals that met a threshold disproportionate share hospital ("DSH") percentage. In 2010, Congress amended the Program to include additional types of hospitals. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821 (2010). Currently, about 40% of all U.S. hospitals participate in the 340B Program. U.S. Gov't Accountability Off., GAO-15-442, *Medicare Part B Drugs: Action*

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periodic adjustments under paragraph (9). *Compare* Pub L. No. 105-33, 111 Stat. 251, 448-49 (Aug. 5, 1997), *with* 42 U.S.C. § 1395*l*(t)(9) & (12). In the 1997 statutes at large, the preclusion-of-review provision—which was then in subsection (t)(9)—expressly precluded administrative and judicial review of "periodic adjustments made under paragraph (6)." 111 Stat. at 449. The provision providing for "periodic review and adjustments [to] components of [the] prospective payment system" was then found at subsection (t)(6) and was materially identical to the provision that is now in subsection 1395*l*(t)(9). *Id.* at 448. In 1999, Congress added what are now provisions (t)(5) through (t)(8). *See* Pub. L. No. 106-113, div. B., 113 Stat. 1501, 1501A-336-342 (Nov. 29, 1999). Although it "redesignat[ed]" the other provisions in section 1395*l*(t), Congress neglected to update the number of the provision cross-referenced in what is now (t)(12)(C). *Id.* at 1501A-336, 1501A-342.

Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals at 1 (June 2015), https://www.gao.gov/assets/680/670676.pdf ("GAO-15-442").

Participating drug manufacturers must agree to offer covered outpatient drugs to covered entities at or below a "maximum" or "ceiling" price, which is calculated pursuant to a statutory formula. 42 U.S.C. § 256b(a)(1)-(2). The program is designed to insure that participating grant recipients and hospitals obtain drugs at affordable prices. *See* Public Health Service Act, § 340B; *see also* H.R. Rep. No. 102-384, pt. 2, at 12 (explaining that the 340B Program allows participating grant recipients to "stretch scarce Federal resources as far as possible" by enabling them to purchase drugs at discounted prices). Nowhere in the enacting legislation does it indicate that a purpose of the Program is to allow providers to generate large profits on drug purchases, through differentials between purchase prices and reimbursement rates, which will subsidize other aspects of the grant recipient's or hospital's activities. *See* Public Health Service Act, § 340B. Indeed, reimbursements are not ever addressed under the § 340B program. Medicare payment amounts, for drugs administered to Medicare patients, are addressed through the OPPS. The 340B Program is distinct from Medicare: it is governed by a separate statutory scheme, and is administered by the Health Resources and Services Administration ("HRSA"), a component within HHS that is separate from CMS.

Notably, covered entities are often able to obtain outpatient drugs below the already-discounted 340B ceiling price. For instance, through the Prime Vendor Program, covered entities may contract with a prime vendor, which may negotiate even steeper, "subceiling" discounts from drug manufacturers. 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017). By the end of FY 2015, this program "had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent

below the [already-discounted] 340B ceiling price." *Id.* Participation in the Prime Vendor Program is voluntary and free. *Id* .

III. CMS's Prior OPPS Drug Payment Methodologies

CMS publishes an annual rule addressing the outpatient prospective payment system. In the OPPS rules for 2006 through 2012, CMS used what is called "standard drug payment methodology" to determine OPPS payment rates for separately payable drugs and biologicals. 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012). Under this methodology, CMS paid the average sales price plus a fixed, add-on percentage, which was intended to reflect "hospitals' acquisition costs for drugs and biologicals while taking into account relevant pharmacy overhead and related handling expenses." *Id.* at 68,385. Application of this methodology between 2006 and 2012 "yielded a finalized payment rate in the range of ASP+4 percent to ASP+6 percent." *Id.* at 68,386.

In CMS's 2013 OPPS Rule, the agency noted that there was "continuing uncertainty about the full cost of pharmacy overhead and acquisition cost, based in large part on the limitations of the submitted hospital charge and claims data for drugs." *Id.* In light of these concerns, CMS decided that for 2013, it would invoke the payment methodology set forth in subclause (II) of § 1395*l*(t)(14)(A)(iii) and "pay for separately payable drugs and biologicals at ASP+6 percent," which is the "statutory default" under § 1395*l*(t)(14)(A)(iii)(II). *Id.* CMS found it appropriate "at this time" to use the ASP+6% statutory default rate because, among other things, it yielded "increased predictability in payment for separately payable drugs and biologicals under the OPPS." *Id.* CMS applied this ASP+6% rate from 2013 until 2017, when it issued the 2018 OPPS Rule.

IV. The 2018 OPPS Rule

In its proposed OPPS rule for 2018, CMS noted recent studies indicating wide discrepancies between the amounts that 340B Program participants paid for covered outpatient

drugs and the amounts that Medicare reimbursed hospitals for those drugs, and proposed to adjust OPPS drug payment rates to correct these discrepancies. 82 Fed. Reg. 33,558, 33,632-33 (July 20, 2017). CMS adopted this proposal in its final 2018 OPPS Rule, at the outset of which the Secretary made clear that he was relying on his authority under 42 U.S.C.A. § 1395l(t)(9)(A) to "review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors." 82 Fed. Reg. 52,356, 52,356 (Nov. 13, 2017). The 2018 OPPS Rule also announced that CMS was exercising the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) "to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." 82 Fed. Reg. at 52,356.

In explaining this payment adjustment, CMS highlighted recent data showing that Medicare reimbursements for 340B drugs have substantially exceeded providers' costs for those drugs as a result of deep discounts providers receive from drug manufacturers, thus allowing providers to reap significant profits from the 340B Program discounts. For example, the Rule cites:

- A report by the Medicare Payment Advisory Commission ("MedPAC"),[3] citing data showing that "discounts across all 340B providers (hospitals and certain clinics) average *33.6 percent* of ASP, allowing these [340B] providers to generate significant profits when they administer Part B drugs." *Id.* at 52,494 (emphasis added).

[3] MedPAC is an independent congressional agency established by the Balanced Budget Act of 1997 to advise Congress on issues affecting the Medicare program.

- A report by the Government Accountability Office ("GAO"), titled "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals," finding that "the amount of the 340B discount ranges from an estimated *20 to 50 percent discount*, compared to what the entity would have otherwise paid to purchase the drug." *Id.* (emphasis added).
- A MedPAC report estimating that, "on average, hospitals in the 340B Program receive a *minimum discount* of *22.5 percent* of the [ASP] for drugs paid under the [OPPS]." *Id.* (emphasis added). MedPAC emphasized this was a "minimum" discount that reflected the "lower bound of the average discount received by 340B hospitals." *Id.* at 52,496.
- HRSA's FY 2018 Budget Justification, which notes that 340B providers participating in the HRSA's Prime Vendor Program "often . . . pay[] a subceiling price on some covered outpatient drugs." *Id.* at 52,494. As previously noted, by the end of FY 2015, the Prime Vendor Program "had nearly 7,600 products available to participating entities below the 340B ceiling price, including 3,557 covered outpatient drugs with an estimated average savings of 10 percent below the 340B ceiling price." *Id.*
- An HHS Office of Inspector General ("OIG") report, finding that Medicare payments "were *58 percent more than* 340B ceiling prices, which allowed covered entities to retain approximately *$1.3 billion* in 2013." *Id.* at 52,495 (emphasis added).

The 2018 OPPS Rule also notes the rapid and substantial growth of Medicare spending for 340B drugs. It highlights MedPAC's findings in its May 2015 report that "the number of hospitals participating in the [340B] program has grown from 583 in 2005 to 1,365 in 2010 and 2,140 in 2014." *Id.* at 52,495. In other words, the number of hospitals participating in the program more than tripled over a nine year period. MedPAC added that "Medicare spending grew faster among

hospitals that participated in the 340B Program for all five years than among hospitals that did not participate in the 340B Program." *Id.* at 52,494. CMS cited this as "just one example of drug spending increases that are correlated with participation in the 340B Program and calls into question whether Medicare's current policy to pay for separately payable drugs at ASP+6 percent is appropriate in light of the discounted rates at which 340B hospitals acquire such drugs." *Id.*

CMS also emphasized GAO's finding in its June 2015 report that "in both 2008 and 2012, per beneficiary Medicare Part B drug spending … was substantially higher at 340B DSH than at non-340B hospitals." *Id.* In 2012, for example, GAO found that the "average per beneficiary spending at 340B DSH hospitals was $144, compared to approximately $60 at non-340B hospitals"—*i.e.*, per beneficiary spending was more than double at 340B hospitals. *Id.* These "differences did not appear to be explained by the hospital characteristics GAO examined or patients' health status"; rather, the data indicated that, "on average, beneficiaries at 340B DSH hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other non-340B hospitals in GAO's analysis." *Id.*

CMS also explained that higher Medicare payment rates for 340B drugs results in higher drug costs for beneficiaries, because a beneficiary's copayment is tied to the Medicare payment rate, not the drug's actual purchase price. The Rule notes that "Medicare beneficiaries are liable for a copayment that is equal to 20 percent of the OPPS payment rate, which is currently ASP+6 percent (regardless of the 340B purchase price for the drug)." *Id.* at 52,495. It adds that "[b]ased on an analysis of almost 500 drugs billed in the hospital outpatient setting in 2013, the [HHS] OIG found that, for 35 drugs . . . in at least one quarter of 2013, the beneficiary's coinsurance alone … was greater than the amount a covered entity spent to acquire the drug.'" *Id.* CMS further explained that it is not possible to tie a beneficiary's copayment to the drug's 340B ceiling price,

because "ceiling prices are confidential" and CMS is thus "unable to publicly disclose those prices or set payment rates in a way that would allow the public to determine the ceiling price for a particular drug." *Id.* at 52,496.

In light of these findings, the 2018 OPPS Rule announced that CMS was exercising the Secretary's authority under § 1395*l*(t)(14)(A)(iii)(II) "to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through payment status and vaccines) acquired under the 340B Program from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent." *Id.* at 52,362. CMS arrived at the ASP minus 22.5% figure based on MedPAC's 2015 report, which, as noted above, found that "on average, hospitals in the 340B Program 'receive a *minimum* discount of 22.5 percent of the [ASP] for drugs paid under the [OPPS].'" *Id.* at 52,494 (emphasis added). CMS noted that this figure was "conservative" because it estimated the "lower bound" or "minimum" "average discount received by 340B hospitals for drugs paid under the [OPPS]" and found that it is "likely that the average discount is higher, potentially significantly higher, than the average minimum of 22.5 percent that MedPAC found through its analysis." *Id.* at 52,496. Thus, even after the payment adjustment, 340B providers would be able "to retain a profit on these drugs." *Id.* at 52,497. CMS reasoned that the payment adjustment will "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "lower drug costs for Medicare beneficiaries for drugs acquired by hospitals under the 340B Program," ensuring that beneficiaries "share in the savings on drugs acquired through the 340B Program." *Id.* at 52,362, 52,495-97. CMS expressly exempted from the payment adjustment "[r]ural sole community hospitals (SCHs), children's hospitals, and [prospective payment system]-exempt cancer hospitals," *id.* at 52,362, because of concerns about access to care and the different payment model employed in children's hospitals and PPS-exempt

cancer hospitals, *id.* at 52,505-52,506. The payment adjustment also does not affect covered entities that are paid under a separate payment scheme outside of the OPPS, such as critical access hospitals. *Id.* at 52,495. In total, at least 52% of the 340B covered entities are not affected by the payment adjustment, either because they are specifically exempted, or because they are not paid under the OPPS.[4]

CMS estimated that this payment adjustment would save Medicare $1.6 billion. 82 Fed. Reg. at 52,509. Critically, these savings are being redistributed within the OPPS system (including to Plaintiffs). That is because the CMS made the payment adjustment pursuant to § 1395*l*(t)(9)(B), which requires that adjustments be made in a "budget-neutral" manner within OPPS. As CMS explains in the Rule, "the reduced payments for separately payable drugs purchased through the 340B Program w[ould] *increase* payment rates for other non-drug items and services paid under the OPPS by an offsetting aggregate amount." *Id.* at 52,623 (emphasis added). CMS "project[ed] that reducing payment for 340B drugs to ASP minus 22.5 percent will increase OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018." *Id.*

The 2018 OPPS Rule became effective January 1, 2018.

V. This Case

Plaintiffs—three hospital associations and three of their member hospitals[5]— challenge, under the APA, 5 U.S.C. § 706(2), the 340B-related provisions of the 2018 OPPS Rule. The Complaint includes four counts, all of which are premised on the assertion that the 2018 OPPS

[4] *See* MedPac Report to Congress, *Overview of the 340B Drug Pricing Program*, at 20 n.22 & 10, Figure 1 (May 2015), http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf.

[5] The three hospital association plaintiffs are the American Hospital Association, the Association of American Medical Colleges, and America's Essential Hospitals. The three hospital plaintiffs are Eastern Maine Healthcare Systems, Henry Ford Health System, and Fletcher Hospital, Inc.

Rule's reduction of the payment rate for drugs purchased through the 340B Program was arbitrary and capricious and contrary to law, in violation of the APA. Compl. ¶¶ 67-78. More specifically, Count 1 challenges the OPPS Rule itself, while Counts 2 through 4 attack payment decisions made under the Rule with respect to Medicare claims submitted by the Plaintiff hospitals. *Id.*

As relief, Plaintiffs seek a declaration that the reduction of the payment rate for drugs purchased under the 340B program is unlawful, and an injunction requiring the Agency to: (i) use the payment rate from the 2017 OPPS Rule for drugs purchased through the 340 Program, (ii) reimburse the hospital Plaintiffs for their supposed underpayment with respect to the claims for payment referenced in Counts 2 through 4, (iii) reimburse the hospital Plaintiffs and any other members of the association Plaintiffs for any other alleged underpayments that occurred as a result of the agency's adherence to the 340B-related provisions of the 2018 OPPS; and (iv) follow the law (namely the Social Security Act) in the 2019 OPPS and beyond, and not rely on the payment approach adopted in the 2018 OPPS with regard to the 340B-related provisions. Compl., Prayer for Relief, ¶¶ A-E. Together with their Complaint, Plaintiffs moved for a preliminary injunction. Pls.' Mem. at 1. It seeks all of the relief sought in the Complaint. Pls.' Memo. at 35.

At bottom, this suit is a near carbon copy of a suit Plaintiffs filed last year in this Court. *See AHA v. Hargan*, 17-cv-2447 (DDC) (RC). The Court dismissed that case for lack of subject matter jurisdiction because Plaintiffs had not presented their claims to the agency as required under 42 U.S.C. § 405(g), *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 55 (D.D.C. 2017), and the D.C. Circuit affirmed the decision, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 2018).[6]

[6] Defendants do not dispute that the hospital Plaintiffs have now presented claims to the Agency, though they have not otherwise exhausted their administrative remedies.

ARGUMENT

I. Defendants' Motion To Dismiss Should Be Granted

Defendant moves to dismiss the Complaint for lack of subject-matter jurisdiction under Rule 12(b)(1), and failure to state a claim under Rule 12(b)(6). Dismissal for lack of subject-matter jurisdiction is appropriate when a statute precludes judicial review. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 118 (D.C. Cir. 2004) (court "lack[ed] jurisdiction" where § 1395*l*(t)(12) precluded review); *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20 (D.D.C. 2014) (same). To survive a Rule 12(b)(1) motion, the plaintiff bears the burden of establishing that the court has subject matter jurisdiction over its claim. *Moms Against Mercury v. FDA*, 483 F.3d 824, 828 (D.C. Cir. 2007). The Court may "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003). To survive a Rule 12(b)(6) motion, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

A. The Medicare Statute Expressly Precludes Judicial Review Of The Secretary's Payment Adjustments Under § 1395*l*(t)(14)(A)(iii)(II)

The Medicare statute expressly precludes judicial review of Plaintiffs' APA claims challenging the Secretary's exercise of his payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). Although the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action," the "APA does not apply . . . to the extent that . . . statutes preclude judicial review." *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012); *see* 5 U.S.C. § 701(a)(1). To determine "[w]hether and to what extent a particular statute precludes judicial

review," a court must look to the statute's "express language . . . the structure of the statutory schemes, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

Subsection (t)(12) of 42 U.S.C. § 1395*l* establishes strict limitations on judicial review of the Secretary's administration of the OPPS. Most pertinent here, the statute provides:

> ***There shall be no*** administrative or ***judicial review*** under section 1395ff of this title, 1395oo, of this title, or otherwise ***of***—
>
> > (A) ***the development of the [OPPS] classification system under paragraph (2), including*** the establishment of groups and relative payment weights for covered OPD services, of wage adjustment factors, ***other adjustments***, and methods described in paragraph (2)(F);
> >
> > * * *
> >
> > (C) ***periodic adjustments*** made under paragraph [9];
> >
> > * * *
> >
> > (E) . . .***the portion of the medicare OPD fee schedule amount associated with particular*** *devices,* ***drugs****, or biologicals,* and the application of any pro rata reduction under paragraph (6).

42 U.S.C. § 1395*l*(t)(12)(A), (C), (E) (emphasis added). The legislative history confirms that Congress intended § 1395*l*(t)(12) to broadly preclude judicial review—under the Medicare statute "or otherwise"—of the Secretary's "adjustment" of OPPS payments. *See* H.R. Rep. No. 108-391, at 599 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1965 (the "provisions concerning *Medicare's determination of payment amounts,* methods or *adjustments . . . will not be subject to* administrative or *judicial review*," and the "provisions concerning *Medicare's determination of the budget neutral adjustments, adjustments to* the practice expense relative value units for certain drug administration services and *other drug administration services* will not be subject to administrative or judicial review." (emphasis added)); *see also* H.R. Rep. No. 105-149

at 724 (1997) ("The provision would prohibit administrative or judicial review of the prospective payment system.").

In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), the D.C. Circuit construed § 1395*l*(t)(12), and concluded that the fact that "Congress intended to preclude judicial review of the Secretary's adjustments to prospective payment amounts *is 'clear and convincing' from the plain text of § (t)(12) alone*." *Id.* at 112 (emphasis added). The Circuit found "unsurprising" Congress's preclusion of review, given that "piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system."[7] *Id.* The court recognized that "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Id.* Moreover, as the court explained, "[p]ayments to hospitals are made on a prospective basis, and given the length of time that review of individual payment determinations could take, review could result in the retroactive ordering of payment adjustments after hospitals have already received their payments for the year." *Id.*

The D.C. Circuit is not alone in recognizing "the havoc that piecemeal review of OPPS payments could bring about." *Id.* (citing *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996); *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 454 (7th Cir. 2002)); *accord Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012). And this Court has acknowledged *Amgen*'s breadth, describing the decision as

[7] Recall, the Medicare program currently processes more than 100 million outpatient hospital claims per year. Since we are already three-quarters of the way through 2018, this means that Medicare providers have already furnished services related to tens of millions of claims that have been or will be reimbursed based on interdependent rates set in the 2018 OPPS.

holding that § 1395*l*(t)(12) "clearly preclude[s] judicial review of the Secretary's adjustments to prospective payment amounts." *Organogenesis Inc.*, 41 F. Supp. 3d at 20 (citing *Amgen*, 357 F.3d at 112).

The bottom line is this: subsections (A), (C) and (E) of § 1395*l*(t)(12) foreclose judicial review of Plaintiffs' APA claims.

1. Section 1395*l*(t)(12)(A) Precludes Judicial Review

As explained above, subsection (A) of § 1395*l*(t)(12) broadly precludes judicial review of the Secretary's "development of" the OPPS "classification system under paragraph (2)," including any "adjustments" to that system. This "classification system" refers to the general system of "classification for covered [outpatient department] services" that the Secretary is required to "develop" under § 1395*l*(t)(2)(A), which is better known as the ambulatory payment classification ("APC") system. *See* 42 C.F.R. § 419.60 (parallel regulation to § 1395*l*(t)(12), which forbids judicial review of the "development of the APC system"). When Congress added the OPPS drug payment provision at issue here—subsection (t)(14)—in 2003, it made clear that it was adding to the APC system by titling the new subsection "Drug *APC* payment rates." 42 U.S.C. § 1395*l*(t)(14) (emphasis added); *see also id.* § 1395*l*(t)(14)(B)(i) (drug is eligible for OPPS payment only if it is a drug "for which a separate ambulatory payment classification group (APC) has been established"). Thus, it is beyond dispute that the setting of drug payment rates under subsection (t)(14) is a component of the APC system, and the broader OPPS. It follows that the Secretary's *adjustment* of those rates for 340B drugs was part of his "development of" the APC system, and likewise qualifies as an "adjustment" to that system. In particular, it was an adjustment to the fee schedule amounts associated with particular drugs within the APC system. In light of this, as well as the case law holding that § 1395*l*(t)(12)(A) "clearly preclude[s] judicial review of the

Secretary's adjustments to prospective payment amounts," *Organogenesis*, 41 F. Supp. 3d at 20 (citing *Amgen*, 357 F.3d at 112), Plaintiffs' claims are statutorily barred by § 1395*l*(t)(12)(A).

2. Section 1395*l*(t)(12)(C) Precludes Judicial Review

Subsection (C) of § 1395*l*(t)(12) bars judicial review of the "periodic adjustments made under paragraph [9]." 42 U.S.C. § 1395*l*(t)(12)(C). The reference to "periodic adjustments made under paragraph [9]" is a reference to the statute's requirement that the Secretary make periodic adjustments to the components of the prospective payment systems. *Id.* § 1395l(t)(9)(A) ("The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors."). The reimbursement rate for drugs purchased through the 340B program is a component of the prospective payment system, as explained in the previous paragraph. And the Secretary invoked this authority when promulgating the final 2018 OPPS Rule, noting that "the Act requires the Secretary to review certain components of the OPPS not less often than annually, and to revise the groups, relative payment weights, and other adjustments that take into account changes in medical practices, changes in technologies, and the addition of new services, new cost data, and other relevant information and factors." 82 Fed. Reg. at 52,356. Accordingly, this provision also precludes review of Plaintiffs' claims.

3. Section 1395*l*(t)(12)(E) Precludes Judicial Review

Plaintiffs' APA claims are separately barred by subsection (E) of § 1395*l*(t)(12). That subsection provides that "there shall be no . . . judicial review . . . of" the "portion of the medicare [outpatient department ("OPD")] fee schedule amount associated with particular . . . drugs." The "OPD fee schedule" is a listing of Medicare payment rates for "each covered OPD service (or

group of such services), furnished in a year," including separately payable drugs. 42 U.S.C. § 1395*l*(t)(3)(D). Here, in exercising his authority under § 1395*l*(t)(14)(A)(iii)(II) to adjust the payment rate for 340B drugs, the Secretary necessarily changed the "fee schedule amount associated with" those "particular . . . drugs." *See* 82 Fed. Reg. at 52,503 (noting that hospitals can discern reduced payment rates for 340B drugs by using the fee schedule in Addendum B to the 2018 OPPS Rule). Thus, Plaintiffs' claim that the Secretary's adjustment of the payment rate for 340B drugs violates the APA, *see, e.g.*, Compl. ¶ 69, is necessarily a challenge to the "fee schedule amount associated with" those drugs. Based on § 1395*l*(t)(12)(E)'s plain statutory text, and the governing precedent, *see Amgen*, 357 F.3d at 112; *Organogenesis*, 41 F. Supp. 3d at 20, Plaintiffs' APA claims are also barred by § 1395*l*(t)(12)(E).

It bears emphasizing that Congress's rationale for precluding judicial review of the Secretary's administration of the OPPS—*i.e.*, to avoid "wreaking havoc" on the carefully-calibrated and interdependent system—is directly implicated here. *See Amgen*, 357 F.3d at 112. To achieve budget neutrality, the 2018 OPPS Rule offsets the savings from the 340B drug payment reduction by "increas[ing] OPPS payment rates for non-drug items and services by approximately 3.2 percent in CY 2018." 82 Fed. Reg. at 52,623 (noting that revised payment rates for non-drug items and services were reflected in the Addenda to the Rule). So, if the Court were to grant Plaintiffs' requested relief and require CMS to revert to its prior OPPS payment rate for 340B drugs (ASP+6%), *see* Compl. at 23, this could have repercussions throughout the OPPS, including perhaps forcing CMS to recalculate the revised payment rates for all non-drug items and services to ensure budget neutrality. (And as set forth earlier, the Medicare program currently processes more than 100 million outpatient claims pre year.) Permitting review here would, moreover, open the floodgates for other providers to challenge the OPPS payment rates for any number of drugs

or biologics, creating instability and uncertainty in the payment system. Congress did not intend such a "severe[] disrupt[ion of] this complex and delicate administrative scheme," and so it included statutory language expressly precluding judicial review to avoid such disruption. *Block*, 467 U.S. at 348; *see Amgen*, 357 F.3d at 112; *Paladin*, 684 F.3d at 531 n.3; *Skagit County*, 80 F.3d at 386; *Am. Soc'y of Cataract*, 279 F.3d at 454. This Court's review of Plaintiff's APA claims accordingly is precluded by statute.

4. The Preclusion Provisions Apply to Plaintiffs' Claims

Plaintiffs argue in support their motion for a preliminary injunction that "neither [§ 1395l(t)(12)(A) nor §1395l(t)(12)(E)] applies to agency action under subsection (t)(14), which is the authority HHS relied on in adopting its near 30% reduction in reimbursements." Pls.' Mem. at 20. Plaintiffs continue: "Subsection (t)(12)(A) precludes judicial review under paragraph (2) of subsection (t), but does not bar judicial review of agency action under (t)(14). Similarly, (t)(12)(E) only precludes judicial review of agency action under (t)(5) and (t)(6)." *Id.* at 20.

This argument lacks merit. As an initial matter, Plaintiffs do not address preclusion under § 1395*l*(t)(12)(C). In any case, Plaintiffs' argument fails to demonstrate the inapplicability of the two preclusion provisions that it addresses. By Plaintiffs' own admission, subsection (t)(12)(A) bars judicial review of the Secretary's action under Paragraph (t)(2). As explained above, Paragraph (t)(2) establishes general "[s]ystem requirements" for the *entire* OPPS. The paragraph begins as follows:

> **(2) System requirements**
> Under the payment system--
> **(A)** the Secretary shall develop ***a classification system for covered OPD [i.e., outpatient department] services***

42 U.S.C. § 1395*l*(t)(2)(A) (emphasis added). Section (t)(1)(B), in turn, defines "covered OPD services" to include all "hospital outpatient services designated by the Secretary." *Id.* § 1395*l*(t)(1)(B). Thus, § (t)(2)(A)'s reference to the "classification system for covered OPD services" plainly refers to the ***overall*** payment classification system for the OPPS, better known as the "APC system."[8] And when Congress added § (t)(14) to the Medicare statute in 2003, it made clear in several respects that it was adding a new payment methodology ***within*** the overall APC system described in § (t)(2)(A). First, Congress titled the new paragraph "Drug *APC* payment rates." 42 U.S.C. § 1395*l*(t)(14) (emphasis added). Second, a drug is eligible for OPPS payment only if it is a drug "for which a separate ambulatory payment classification group (APC) has been established." *Id.* § 1395*l*(t)(14)(B)(i). Third, the APC system described in § (t)(2)(A) applies to all "covered OPD services," and the specified covered outpatient drugs ("SCODs") subject to payment under § (t)(14)(A) are, by definition, drugs that are "furnished as part of a covered OPD service." *Id.* § 1395*l*(t)(14)(A). Viewed together, then, these provisions make clear that a drug's payment rate is necessarily part of the overall APC system described in § (t)(2)(A). It follows that the Secretary's adjustment here of the 340B drug payment rate under § (t)(14)(A)(iii)(II) was part of his "development of" the overall APC system described in § (t)(2)(A), and was likewise an "other adjustment[]" to that system, subject to the judicial review preclusion provision of § (t)(12)(A).

Subsection (t)(12)(E) also precludes judicial review. That provision precludes review of

> the determination of the fixed multiple, or a fixed dollar cutoff amount, the marginal cost of care, or applicable percentage under paragraph (5) or the determination of insignificance of cost, the duration of the additional

[8] By contrast, the remaining subsections of § (t)(2)—subsections (B) through (H)—describe specific types of payment methodologies and adjustments ***within*** the overall APC system. *See* 42 U.S.C. § 1395*l*(t)(2)(B)-(H).

> payments, the determination and deletion of initial and new categories (consistent with subparagraphs (B) and (C) of paragraph (6)), the portion of the medicare OPD fee schedule amount associated with particular devices, drugs, or biologicals, and the application of any pro rata reduction under paragraph (6).

42 U.S.C. § 1395*l*(t)(12)(E). As is relevant to this case, Plaintiffs contend that the provision precludes review only under paragraph 6. But Plaintiffs' reading disregards the "last antecedent rule" of statutory construction, under which "qualifying words or phrases modify the words or phrases immediately preceding them and not words or phrases more remote, unless the extension is necessary from the context or the spirit of the entire writing." *Lockhart v. United States*, 136 S. Ct. 958, 962-63 (2016) (quoting Black's Law Dictionary 1532-1533 (10th ed. 2014)). Applying that rule here, the "under paragraph (6)" language in § (t)(12)(E) only modifies the phrase immediately preceding it—i.e., "the application of any pro rata reduction." *See id.* at 962-69 (applying last antecedent rule). This reading makes sense in light of the rest of the statutory scheme, because the only place in § 1395*l*(t) where a "pro rata reduction" is mentioned is indeed in § (t)(6). *See* 42 U.S.C. § 1395*l*(t)(6)(E). By contrast, the "medicare OPD fee schedule" is mentioned repeatedly throughout § 1395*l*(t), undermining any inference that § (t)(12)(E)'s reference to the "medicare OPD fee schedule" is somehow limited to § (t)(6) alone. Indeed, it would be nonsensical for Congress to have barred review of "the portion of the medicare OPD fee schedule amount associated with particular . . . drugs" in some contexts, but not in others; there is only one OPD fee schedule in the OPPS system, and thus a claim, such as Plaintiffs', that challenges fee schedule amounts necessarily implicates each of the provisions in § 1395*l*(t) referencing the OPD fee schedule.

B. The Secretary's Payment Adjustment Under § 1395*l*(t)(14)(A)(iii)(II) Is Not Reviewable Because It Is Committed To Agency Discretion By Law

The Secretary's exercise of his payment adjustment authority is unreviewable for an additional reason: it is "committed to agency discretion by law" and thus exempt from judicial review under the APA. *See* 5 U.S.C. § 701(a)(2). A matter is "committed to agency discretion" where "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

Such is the case here. The Medicare statute provides that, if sufficient hospital acquisition cost data are not available, the Secretary must set the payment rate for SCODs at "the average price for the drug . . . *as calculated and adjusted by the Secretary as necessary for purposes of this paragraph*." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). The statute imposes no limitation on the Secretary's "adjust[ment]" of the payment rate for SCODs. It instead allows the Secretary to adjust that rate "as necessary for purposes of this paragraph," without imposing any "meaningful standard against which to judge the agency's exercise of discretion." *Heckler*, 470 U.S. at 830. The legislative history, moreover, confirms what the statute's text makes plain: that Congress wished to confer unreviewable discretion on the Secretary to adjust OPPS payment rates. *See* H.R. Rep. No. 108-391, at 599 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1965 (the "provisions concerning Medicare's determination of payment amounts, methods or adjustments…will not be subject to administrative or judicial review"); *see also* H.R. Rep. No. 105-149, at 1323 (1997) ("The Committee has given the Secretary discretion in determining the adjustment factors that will be applied to the OPD prospective rates."); H.R. Rep. No. 105-217, at 785 (1997) (Conf. Rep.), *as reprinted in* 1997 U.S.C.C.A.N. 176, 406 (same).

Consistent with this reasoning, courts routinely hold that where, as here, a statute authorizes an agency to take certain action whenever deemed "necessary" by the agency, such

action is committed to agency discretion by law. *See, e.g.*, *Webster v. Doe*, 486 U.S. 592, 600 (1988) (action unreviewable where statute allowed termination of employee whenever the agency Director "'shall deem such termination necessary or advisable in the interests of the United States,' not simply when the dismissal is necessary or advisable to those interests."); *Sierra Club v. Jackson*, 648 F.3d 848, 856 (D.C. Cir. 2011) (action unreviewable where "Congress's mandate to the Administrator is that she shall 'take such measures, including issuance of an order, or seeking injunctive relief, as necessary. . . ."); *Wendland v. Gutierrez*, 580 F. Supp. 2d 151, 153 (D.D.C. 2008) (action unreviewable where directive provided that agency director shall convene Record Examination Board "[a]t such times as he/she may deem necessary"). This Court should reach the same conclusion.

C. Plaintiffs Failed To Exhaust Administrative Remedies Under The Medicare Statute

The Court lacks jurisdiction for an additional reason: Plaintiffs have not exhausted their administrative remedies as required by 42 U.S.C. § 405(g). *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992). Exhaustion may be excused, but "only under rather limited conditions." *National Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992). As the Supreme Court has explained, Section 405(g)'s final decision requirement is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). Thus, Plaintiffs' contention that administrative review would be futile, Pls.' PI Mem. at 17-20, does not excuse compliance with the exhaustion requirement, *Shalala v. Illinois Council on Long Term Care, Inc*. ("*Illinois Council"*), 529 U.S. 1, 23 (2000) (channeling required even where agency lacks authority to consider certain questions). "The fact that the agency . . . may lack the

power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Id.*

Congress provided a "special review route," *Illinois Council*, 529 U.S. at 23, in Section 1395ff(b) which sets out an abbreviated administrative review process that establishes a path to expedited judicial review for those cases in which the administrative appeals tribunal "does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute." 42 U.S.C. § 1395ff(b)(2)(A).[9] (Plaintiffs have not received a determination that their claims are fit for expedited review.) Plaintiffs are not entitled to forgo administrative review and go straight to court merely because they wish to "resolve [a] statutory or constitutional contention that the agency . . . cannot[] decide." *Illinois Council*, 529 U.S. at 23. So long as plaintiffs can channel the "action" through the agency, a court may later consider "any statutory . . . contention that the agency . . . cannot[] decide." *Id.* (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 & n. 20 (1994); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *Salfi*, 422 U.S. at 762).

D. Plaintiffs' APA Claims Fail On The Merits

Even assuming Plaintiffs' APA claims were not statutorily precluded and Plaintiffs had exhausted their administrative remedies, the claims fail on the merits and thus should be dismissed

[9] Section 1395ff(b) provides that "[t]he Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B of this subchapter, or both, who has filed an appeal . . . may obtain access to judicial review when a review entity . . . , on its own motion or at the request of the appellant, determines that the Departmental Appeals Board does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute." 42 U.S.C. § 1395ff(b)(2)(A); *see also* 42 C.F.R. § 405.990 (expedited access to judicial review). Once that determination has been made, or if it is not made within 60 days after receipt of the request, "the appellant may bring a civil action" within 60 days in district court either in the judicial district in which the appellant is located or in the District Court for the District of Columbia. *Id.* § 1395ff(b)(2)(C).

under Rule 12(b)(6). In evaluating the merits, the Court must assess the parties' competing readings of the Medicare statute under the familiar two-step *Chevron* framework, under which the court first determines whether the statute is ambiguous, and if it is, upholds the agency's interpretation if reasonable. *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). Plaintiffs advance three theories for why the Secretary's payment adjustment exceeded his statutory authority under 1395*l*(t)(14)(A)(iii)(II), but each theory is foreclosed by the statute's unambiguous text. Insofar as the Court finds any relevant ambiguity in § 1395*l*(t)(14)(A)(iii)(II), however, the Secretary's interpretation is, at minimum, a reasonable one that is entitled to *Chevron* deference.[10]

1. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii) By Considering Acquisition Costs

Plaintiffs first argue that the Secretary is precluded from considering "acquisition costs" in adjusting the payment rate pursuant to subsection 1395*l*(t)(14)(A)(iii)(II). Pls.' Mem. at 22. Plaintiffs point to subclause (II)'s cross-reference of Section 1395w-3a to argue that the statute obligates the Secretary to set the payment rate based only on average sales price when exercising his authority under subclause (II). Pls.' Mem. at 22. Plaintiffs contend that the agency can rely on acquisition costs "only if" it has certain statutorily defined acquisition cost data, and is thus, exercising authority to set payment rates under subsection 1395*l*(t)(14)(A)(iii)(I). *Id.*

[10] Because Plaintiffs' APA claims raise pure legal questions regarding the scope of the Secretary's statutory authority, the Court may reach the merits of those claims on a Rule 12(b)(6) motion. *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993) (noting in Medicare case that "a court can fully resolve any purely legal question on a motion to dismiss," and thus "there is no inherent barrier to reaching the merits at the 12(b)(6) stage"). Relatedly, it is unnecessary for the Court to consider the administrative record in evaluating Plaintiffs' claim, since the claims present pure questions of statutory interpretation.

Plaintiffs are mistaken in two respects. First, subclause (II)'s text does not mandate "payment" based on ASP. While it requires that the Secretary "calculate[]" ASP, it also authorizes the Secretary to "adjust[]" that calculation "as necessary"—which is what the Secretary did here. So it is not accurate to say that the ultimate "payment" must be based strictly on ASP. If that were true, then the Secretary's adjustment authority would be rendered meaningless. *See Corley*, 556 U.S. at 314 ("[O]ne of the most basic interpretive canons . . . [is] that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant.'").

Second, and relatedly, nothing in subclause (II) or elsewhere in the Medicare statute precludes the Secretary from considering "acquisition cost" in adjusting the payment rate. As noted, the statute imposes no limitation on what the Secretary may consider in exercising his adjustment authority under subclause (II); it instead vests him with discretion to make such adjustments "as necessary for purposes of this paragraph." Moreover, subsection 1395l(t)(14)(A)(iii) itself specifically identifies "acquisition cost[s]" as a valid reference point for drug payments, 42 U.S.C. § 1395l(t)(14)(iii)(I). Even under the prior payment methodology that Plaintiffs endorse and request that the Secretary reinstate, CMS recognized that adjustments might be necessary to account for "acquisition" costs. *See* 77 Fed. Reg. at 68,383. Plaintiffs apparently believe that the Secretary is powerless to adjust OPPS payment rates for 340B drugs to account for evidence showing (1) providers are reaping substantial profits from Medicare payment amounts from the program, and (2) beneficiaries are paying unduly high copayments tied to Medicare payment rates. But that is an overly restrictive view of the Secretary's adjustment authority. The

Secretary permissibly considered both providers' acquisition costs and Medicare beneficiaries' copayments in exercising his adjustment authority under § 1395*l*(t)(14)(A)(iii)(II).[11]

2. The Secretary Did Not Exceed His Authority To "Calculate And Adjust" OPPS Payment Rates Under § 1395*l*(t)(14)(A)(iii)(II)

Plaintiffs' next argument is that "Defendants' near-30% reduction in payments is not an 'adjustment' to ASP [under § 1395*l*(t)(14)(A)(iii)(II)] because it is too large to be an 'adjustment' and because it bears no coherent relationship to Average Sales Price, the thing being 'adjusted.'" Pls.' Mem. at 24. As to the relationship point, Plaintiffs explain that "[t]he adjustment to the average sales price must more accurately reflect that price. The Secretary may not 'adjust' the ASP to more closely reflect another way of valuing the drug, such as acquisition costs." *Id.* at 26. Lastly, Plaintiffs contend, citing § 1395*l*(t)(14)(E), that the adjustment can take account only of overhead costs. Pls.' Mem. at 26-27. None of these arguments is persuasive.

Plaintiffs' argument that the reduction of the payment is too large to qualify as an "adjustment" is foreclosed by the statute's text. The statute does not impose any restriction on the Secretary's discretionary "adjustment" of OPPS drug payment rates under § 1395*l*(t)(14)(A)(iii)(II), including any restriction on the *amount* of that adjustment. Plaintiffs contend that the Secretary's adjustments must be "minor," Pls.' Mem. at 24, but no such qualifier

[11] Plaintiffs also claim that GAO agrees with this limited view of CMS's authority. Pls.' Mem. at 30. But GAO's interpretation of the Secretary's statutory authority is not binding on this Court (or the Secretary), and, in any event, provides little support for Plaintiffs' position. The 2015 GAO report cited by Plaintiffs—which, it bears emphasizing, is titled "Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals" and was one of the bases for the Secretary's decision to adjust the OPPS payment rate for 340B drugs—simply stated that "Medicare uses a statutorily defined formula to pay hospitals at set rates for drugs, regardless of their costs for acquiring them, which CMS cannot alter based on hospitals' acquisition costs." GAO-15-442 at 29. The report also opines that CMS and HRSA lack "statutory authority" to "limit[] hospitals' Medicare Part B reimbursement for 340B discounted drugs." *Id.* at 30. GAO did not engage in any substantive statutory analysis to support these conclusions, nor did it address the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii).

appears in the statutory text. To the contrary, Congress stated that adjustments will be made "by the Secretary *as necessary* for purposes of this paragraph." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Congress's inclusion of this language explicitly vesting the Secretary with discretion to make payment adjustments "as necessary" negates any inference that Congress intended to *implicitly* limit the Secretary's payment adjustment authority. Plaintiffs are, in essence, reading the statute to say that the payment rate may be adjusted by the Secretary as necessary "so long as that adjustment is only slight." Congress included no such express limitation on the Secretary's discretion, and this Court should not write one into the statute.

This conclusion is bolstered by the surrounding statutory text. In subsection (A) of § 1395*l*(t)(14), Congress provided specific instructions for how the Secretary should calculate drug payments rates for the years 2004 and 2005, and did not include any provision granting the Secretary discretion to adjust those rates. *See id.* § 1395*l*(t)(14)(A)(i)-(ii). By contrast, for 2006 and beyond, Congress eschewed these specific instructions and instead directed the Secretary to set payment rates for SCODs using one of the methodologies set forth in subclauses (I) and (II) of § 1395*l*(t)(14)(A)(iii). Thus, Congress demonstrated in § 1395*l*(t)(14)(A)(i)-(ii) that it knew how to impose express restrictions on the Secretary's setting of OPPS drug payment rates. But Congress omitted such restrictions in § 1395*l*(t)(14)(A)(iii)(II), and instead authorized the Secretary to make such adjustments "as necessary." This supports an inference that Congress did not intend to restrict the Secretary's payment adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). *See King v. St. Vincent's Hosp.*, 502 U.S. 215, 220-21 (1991) ("Given the examples of affirmative limitations on reemployment benefits conferred by neighboring provisions, we infer that the simplicity of subsection (d) was deliberate, consistent with a plain meaning to provide its benefit without conditions on length of service.").

Plaintiffs cite *Amgen v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004), and *MCI Telecommunications Corp. v. AT&T*, 512 U.S. 218, 225 (1994), in support of their argument that the Secretary's rate reduction does not qualify as an adjustment. *Amgen* and *MCI* stand for the proposition that the Secretary may not rely upon his adjustment authority to eliminate payments altogether, or "severe[ly] restructur[e] . . . the statutory scheme" in a manner that would "violate the Secretary's statutory obligation to make such payments and cease to be an 'adjustment.'" *Amgen*, 357 F.3d at 117 (alteration omitted).

These decisions do not support Plaintiffs' argument. The adjustment at issue here does not remotely approximate a "total elimination or severe restructuring of the statutory scheme." *Amgen*, 357 F.3d at 117. To understand the relative significance of the payment adjustment, one cannot look at the rate reduction in isolation—context is critical. The Secretary adjusted the payment rate for 340B drugs from average sales price plus six percent to average sales price minus 22.5% in order to "better, and more appropriately, reflect the resources and acquisition costs that [340B] hospitals incur," as well as "allow the Medicare program and Medicare beneficiaries to pay less for drugs . . . that are purchased under the 340B Program," ensuring that beneficiaries "share in the program savings realized by hospitals and other covered entities that participate in the 340B Program." 82 Fed. Reg. at 52,495. Although Plaintiffs characterize this adjustment as substantial, they overlook that it was intended to address an enormous disparity between Medicare payment rates and 340B drug acquisition costs when the average sales price plus six percent payment rate was employed. *See id.* (noting that the HHS Inspector General Report found that the Medicare payments "were 58 percent more than [already-discounted] 340B ceiling prices"). Indeed, in establishing the 340B Program and in granting the Secretary authority to set payment rates for what Medicare pays for drugs, Congress did not demonstrate an intent for 340B providers to reap

huge profits from the Medicare program. In fact, Congress specifically contemplated that where "average acquisition cost" data is available, the Secretary would rely on that data to set payment rates, likely resulting in little to no profit for providers participating in the 340B program. *See* 42 U.S.C. § 1395l(t)14(A)(iii)(I). Thus, the Secretary plainly did not exceed his authority in considering acquisition costs in adjusting the payment rate in the 2018 OPPS Rule.

Nor did the Secretary eliminate entirely the disparity between acquisition costs and Medicare payment rates. As the Secretary explained, 22.5% below the average sales price represented, on average, the highest amount that 340B providers were paying for drugs. *See* 82 Fed. Reg. at 52,496. In the majority of cases, "the average discount is higher, potentially significantly higher, than . . . 22.5 percent." *Id.* The Secretary chose a "conservative" number in order to ensure both that beneficiaries "share in the savings on drugs acquired through the 340B Program" and also that 340B providers would "retain a profit on these drugs." *Id.* at 52,496-97, 52,502. [12]

[12] Plaintiffs' reliance on dictionary definitions, Pls.' Mem. at 25 n.23, is unpersuasive because numerous dictionaries define "adjust" without using the word "slight" or any other term that could be construed to impose a quantitative limitation. *See, e.g.*, *Adjust*, Merriam-Webster, https://www.merriam-webster.com/dictionary/adjust ("a: to bring to a more satisfactory state … b: to make correspondent or conformable … c: to bring the parts of to a true or more effective relative position … 3: to determine the amount to be paid under an insurance policy in settlement of (a loss)."); *Adjust*, American Heritage Dictionary, https://ahdictionary.com/word/search.html?q=adjust ("1.a. To move or change (something) so as to be in a more effective arrangement or desired condition … b. To change so as to be suitable to or conform with something else… 3. To decide how much is to be paid on (an insurance claim)."); *Adjust*, Random House Dictionary, http://www.dictionary.com/browse/adjust ("1. to change (something) so that it fits, corresponds, or conforms; adapt; accommodate … 2. to put in good working order; regulate; bring to a proper state or position … 4. *Insurance*. to determine the amount to be paid in settlement of (a claim)."); *Adjust*, Black's Law Dictionary Free (2d ed.), https://thelawdictionary.org/adjust/ ("To bring to proper relations; to settle; to determine and apportion an amount due.").

Plaintiffs' argument that the adjustment is inadequately connected to the ASP is also unconvincing. Under the 2018 OPPS Rule, the Secretary continues to "calculate[]" ASP in the same manner as in calendar years 2013 through 2017—the difference is that *after* calculating ASP, the Secretary "adjusts" the payment rate to ASP minus 22.5%. *See* 82 Fed. Reg. at 52,496 (CMS will "*continue to pay for these drugs* under our authority at section [1395*l*](t)(14)(A)(iii)(II) of the Act *at ASP, and then . . . adjust that amount* by applying a reduction of 22.5 percent") (emphasis added). And as discussed earlier, the statute does not prohibit the Secretary from considering acquisition costs when making adjustments under this provision. *See* § I.D.1.

Plaintiffs' reliance on subparagraph (E) of § 1395*l*(t)(14) is similarly unpersuasive. Section 1395*l*(t)(14)(A)(iii) provides that the Secretary's determination of OPPS payment rates for SCODs is "subject to subparagraph (E)." Subparagraph (E), in turn, authorizes a separate "[a]djustment in payment rates for overhead costs." 42 U.S.C. § 1395*l*(t)(14)(E). Specifically, subparagraph (E) directs MedPAC to "submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs." *Id.* § 1395*l*(t)(14)(E)(i). Subparagraph (E) further provides, in a provision titled "Adjustment authorized," that the "Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account" MedPAC's recommendations. *Id.* § 1395*l*(t)(14)(E)(ii). Because subparagraph (E) concerns adjustments to account for "overhead costs and related expenses," and because § 1395*l*(t)(14)(A)(iii) incorporates subparagraph (E), Plaintiffs assert that the term "adjusted" as used in § 1395*l*(t)(14)(A)(iii)(II) must be limited to alterations for "overhead costs.'" Pls.' Mem. at 27.

Plaintiffs' convoluted statutory analysis overlooks that subparagraph (E) of § 1395*l*(t)(14) "authorize[s]" a *separate* adjustment specifically to account for "overhead and related expense" based on MedPAC's findings. This adjustment authority is wholly distinct from the Secretary's broader authority to adjust OPPS drug payment rates "as necessary" under § 1395*l*(t)(14)(A)(iii)(II). Indeed, whereas Congress titled subparagraph (E) "[a]djustment in payment rates *for overhead costs*," 42 U.S.C. § 1395*l*(t)(14)(E) (emphasis added), it included no similar qualifying language in describing the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). Congress's omission of such language in § 1395*l*(t)(14)(A)(iii)(II) indicates that the "adjustments" described in the two provisions are distinct. *See Am. Forest & Paper Ass'n v. FERC*, 550 F.3d 1179, 1181 (D.C. Cir. 2008) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion."); *see also Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1130 (D.C. Cir. 2017) (rejecting argument that the term "process" had same meaning throughout section of Medicare statute, because "there is more than one 'process' in [42 U.S.C] section 1395nn(i)(3)"). Moreover, if Plaintiffs were correct that the adjustment authority conferred by § 1395*l*(t)(14)(A)(iii)(II) and § 1395*l*(t)(14)(E) are coextensive, then it would have been unnecessary for Congress to separately "authorize" adjustment authority in § 1395*l*(t)(14)(E)(ii), because such authority would have already been available under § 1395*l*(t)(14)(A)(iii)(II).

3. The Secretary Did Not Exceed His Authority Under § 1395*l*(t)(14)(A)(iii)(II) By Limiting Application of the Rate Reduction or by Allegedly Undermining The 340B Program

Plaintiffs' final argument is that the Secretary exceeded his authority under § 1395*l*(t)(14)(A)(iii)(II) because he exempted certain providers from the adjustment and because

the 2018 OPPS Rule "undermines the basic purposes of the 340B Program." Pls.' Mem. at 27-30. Both parts of Plaintiffs' argument are flawed.

First, the 2018 OPPS Rule exempted certain providers from the rate reduction because other parts of the Medicare statute treat those types of providers differently. For example, subsection 1395*l*(t)(13) provides that the Secretary can treat rural hospitals differently, and the Secretary relied on this authority to exempt rural sole community hospitals from the 340B payment adjustment. *See* 42 U.S.C. § 1395*l*(t)(13); *see also* 82 Fed. Reg. at 52,505-06 (explaining differential treatment of rural sole community hospitals, and setting forth statutory basis). Likewise, children's hospitals and cancer hospitals are treated differently under subsection (t)(7)(D)(ii). *See* 42 U.S.C. § 1395*l*(t)(7)(D)(ii). And there are good reasons for treating these sorts of hospitals differently, including reasons related to access-to-care concerns. 82 Fed. Reg. at 52,505-52,506. Plaintiffs point to no statutory provision that would require the Secretary to ignore his authority to treat different types of providers differently merely because they might also have 340B agreements in place.

Second, the 2018 OPPS Final Rule does not undermine the purpose of the 340B Program. As Plaintiffs state, "[t]hat Program envisioned that eligible hospitals and clinics – i.e., those that served a disproportionately large share of persons who cannot afford to pay medical bills – would receive drug price discounts from pharmaceutical companies." Pls.' Mem. at 28. Of course, nothing in the 2018 OPPS Rule prohibits 340B Program participants from receiving drug price discounts. Indeed, the 2018 OPPS Rule addresses only the amount 340B participants will be reimbursed for these drugs (with respect to the treatment of covered Medicare patients). And nothing in the statute creating the 340B Program indicates that it was designed to make drug purchasing a huge profit center from which other activities could be subsidized. *See* Public Health

Service Act, § 340B.[13] Indeed, contrary to such a purpose, the law creating the 340B Program prohibited the resale of drugs by program participants to non-patients, cutting off an obvious source of such profits. *Id.* § 340B(a)(5)(B). Finally, the structure for reimbursing providers for drugs contemplates that there may be no profits from drug purchases, as Congress permits CMS to reimburse providers for the actual acquisition costs of the drugs. 42 U.S.C.A. § 1395*l*(t)(14)(A)(iii)(I).

In any case, the Rule was not intended (and is not likely) to *eliminate* providers' profit margin on 340B drugs, but was intended to make Medicare payment for these drugs "more aligned" with providers' acquisition costs. Indeed, CMS set the payment rate at ASP minus 22.5% because it determined (and several commenters agreed) that this was "an amount that allows hospitals to retain a profit on [340B] drugs." 82 Fed. Reg. at 52,497; *see id.* at 52,496 (noting that ASP minus 22.5% is a "conservative" payment rate because it reflects the "lower bound" or "minimum" "average discount received by 340B hospitals for drugs paid under the [OPPS]," and it is "likely that the average discount is higher, potentially significantly higher, than the average

[13] Plaintiffs cite a 2005 HRSA manual for the proposition that Congress intended for the 340B Program to become a profit center for providers. Pls.' Mem. at 28 (citing HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act 14 (July 2005) (attached as Exh. 2)). But what the manual actually says is "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." HRSA Manual at 14. Thus, HRSA recognizes that the purpose of 340B is facilitate the acquisition of low cost drugs, not to create a profit – that is an ancillary benefit to providers of a misalignment between acquisition costs and reimbursements, rather than a purpose of the 340B Program.

minimum of 22.5 percent that MedPAC found through its analysis."). Thus, Plaintiffs' assertion that the 340B drug payment reduction "undermines" the 340B Program is flawed.[14]

* * *

For all these reasons, the Medicare statute's plain text unambiguously forecloses each theory Plaintiffs assert in support of their APA claim. But even if there were any ambiguity in the statutory text, the Secretary's interpretation of the statute is eminently reasonable, was extensively explained in the 2018 OPPS Rule, *see* 82 Fed. Reg. at 52,493-511, and is bolstered by the legislative history, *see* H.R. Rep. No. 108-391, at 599 (2003) (Conf. Rep.), *as reprinted in* 2003 U.S.C.C.A.N. 1808, 1965; H.R. Rep. No. 105-149, at 1323 (1997); H.R. Rep. No. 105-217, at 785 (1997) (Conf. Rep.), *as reprinted in* 1997 U.S.C.C.A.N. 176, 406. Thus, if the Court deems it necessary to reach *Chevron* step two, the Court should defer to the Secretary's reasonable reading of § 1395*l*(t)(14)(A)(iii). Plaintiffs' APA claims should therefore be dismissed.

II. Plaintiffs' Motion For A Preliminary Injunction Should Be Denied

If the Court deems it necessary to reach Plaintiffs' motion for a preliminary injunction, that motion should be denied. "A preliminary injunction is 'an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.'" *Sherley v. Sebelius*, 644 F.3d 388, 392 (D.C. Cir. 2011) (quoting *Winter v. NRDC*, 555 U.S. 7 (2008)). "A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Id.* Moreover, a plaintiff

[14] Plaintiffs make much of the fact that in the Patient Protection and Affordable Care Act of 2010, Congress expanded the "covered entities" under the 340B Program. Pls.' Mem. at 30. But this has no bearing on the scope of the Secretary's adjustment authority under § 1395*l*(t)(14)(A)(iii)(II). That Congress wanted to increase access to low-cost drugs says nothing about its desire to make the purchasing of drugs a profit center for some providers under the Medicare program.

seeking an injunction that would alter the status quo – as Plaintiffs do here – must satisfy a heightened standard. *Paleteria La Michoacana, Inc. v. Productos Lacteos Tocumbo S.A. de C.V.*, 901 F. Supp. 2d 54, 56 (D.D.C. 2012) ("If the requested relief would alter, not preserve, the status quo, the court must subject the plaintiff's claim to a somewhat higher standard . . . [D]efendant thus seeks to alter—not preserve—the status quo. Accordingly, the court will exercise extreme caution in assessing the defendant's invitation to invoke the court's extraordinary equitable powers."). Plaintiffs would not satisfy the standard that applies to a request for a preliminary injunction that seeks to maintain the status quo, as they cannot establish that they are likely to succeed on the merits, that the equities tip in their favor, or that an injunction is in the public interest. And since Plaintiffs seek to alter the status quo, their arguments fall even further short of the mark.

A. Plaintiffs Are Unlikely To Succeed On The Merits

For the reasons outlined above in support of Defendants' motion to dismiss, Plaintiffs are not likely to succeed on their APA claims because: (1) they are statutorily precluded by § 1395*l*(t)(12); (2) they challenge agency action that is "committed to agency discretion by law" and thus unreviewable under the APA; (3) Plaintiffs have failed to exhaust administration remedies; and (4) the claims fail on the merits. Thus, Plaintiffs' motion for a preliminary injunction should be denied. *See U.S. Ass'n of Reptile Keepers, Inc. v. Jewell*, 103 F. Supp. 3d 133, 153 (D.D.C. 2015) (even if likelihood of success on the merits is not "an independent, free-standing requirement for a preliminary injunction," it is at least "a key issue and often the dispositive one"). At minimum, this factor weighs heavily against granting a preliminary injunction.

B. The Balance Of Equities And The Public Interest Weigh Strongly Against Granting A Preliminary Injunction

A party seeking a preliminary injunction must also demonstrate "that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20. "These factors merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). These factors weigh heavily against granting a preliminary injunction here.

As explained above, the D.C. Circuit and other courts have repeatedly recognized that "piecemeal review of individual [OPPS] payment determinations could frustrate the efficient operation" of the Medicare scheme, and "judicially mandated changes in one payment rate would affect the aggregate impact of the Secretary's decisions by requiring offsets elsewhere, and thereby interfere with the Secretary's ability to ensure budget neutrality in each fiscal year." *Amgen Inc.*, 357 F.3d at 112; *see, e.g.*, *Paladin*, 684 F.3d at 531 n.3 ("Judicial determinations forcing the Secretary to retroactively alter payment rates for various covered services—e.g., payment rates that are adjusted annually and are required to remain budget neutral—would likely wreak havoc on the already complex administration of Medicare Part B's outpatient prospective payment system."); *Skagit*, 80 F.3d at 386 (judicially mandated change in one payment rate would affect the "aggregate impact" of the Secretary's decisions and make it impossible for the Secretary to comply with his "duty to ensure budget neutrality in each fiscal year"); *see also Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1233 (D.C. Cir. 1994) (noting "significant, if not debilitating, disruption" that would be caused by retroactive corrections under the prospective payment system for inpatient care under Medicare Part A). Moreover, numerous payments have already been made under the 2018 OPPS Rule for drugs purchased under the 340B Program – and for other components of the OPPS that had their reimbursement rates altered to render the changes to the drug reimbursement rate budget neutral. Thus, a preliminary injunction increasing the

payment rate for drugs purchased through the 340B program would raise significant and difficult questions about how to handle claims related to other components of the OPPS that, as a result of the budget neutrality requirement, were paid under rates that were increased to offset the decrease to the payment rate for drugs acquired through the 340B Program. And it is precisely because of the interdependence of the Secretary's determinations, and dependence on payments already made by CMS, that Congress precluded judicial review of the Secretary's OPPS payment rate determinations. *See* 42 U.S.C. § 1395*l*(t)(12). Such concerns caution strongly against *any* judicial involvement—let alone the extraordinary remedy of a status-altering preliminary injunction—in the Secretary's administration of the OPPS.

In sum, each of the preliminary injunction factors weighs strongly against granting injunctive relief. Plaintiffs' motion for a preliminary injunction should therefore be denied.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion to dismiss and deny Plaintiffs' motion for a preliminary injunction.

Date: September 14, 2018

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EXHIBIT 1

2016 CMS Statistics

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U.S. DEPARTMENT OF
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Preface

This reference booklet provides summary information about health expenditures and Centers for Medicare & Medicaid Services (CMS) programs. The information presented was the most current available at the time of publication and may not always reflect changes due to recent legislation. Similar reported statistics may differ because of differences in sources and/or methodology.

The data are organized as follows:

Glossary of Acronyms

AFDC	**Aid to Families with Dependent Children**
BETOS	**Berenson-Eggers Type of Service**
CAHs	**Critical Access Hospitals**
CBC	**Community-Based Care**
CCPs	**Coordinated Care Plans**
CCW	**Chronic Conditions Data Warehouse**
CHIP	**Children's Health Insurance Program**
CM	**Center for Medicare**
CMCS	**Center for Medicaid and CHIP Services**
CMS	**Centers for Medicare & Medicaid Services**
DHHS	**Department of Health & Human Services**
DME	**Durable Medical Equipment**
DME MACs	**DME Medicare Administrative Contractors**
DMEPOS	**Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**
ESRD	**End Stage Renal Disease**
FFS	**Fee-For-Service**

Glossary of Acronyms (continued)

GDP	**Gross Domestic Product**
HCPP	**Health Care Prepayment Plan**
HI	**Hospital Insurance (Part A)**
HIT	**Health Information Technology**
HMO	**Health Maintenance Organization**
ICF/IID	**Intermediate Care Facility for Individuals with Intellectual Disabilities**
ICF-MR	**Intermediate Care Facility for Mentally Retarded**
IPAB	**Independent Payment Advisory Board**
MA	**Medicare Advantage**
MACs	**Medicare Administrative Contractors**
MA-PD	**Medicare Advantage Prescription Drug Plan**
MIF	**Medicare Improvement Fund**
MSA	**Medical Savings Account**
MSIS	**Medicaid Statistical Information System**
NF	**Nursing Facility**
NHE	**National Health Expenditures**
OACT	**Office of the Actuary**

Glossary of Acronyms (continued)

PACE	**Program of All-Inclusive Care for the Elderly**
PCCM	**Primary Care Case Management**
PDP	**Prescription Drug Plan**
PFFS	**Private Fee for Service Plan**
PHP	**Prepaid Health Plan**
PPS	**Prospective Payment System**
QIO	**Quality Improvement Organization**
RDS	**Retiree Drug Subsidy**
RPPOs	**Regional Preferred Provider Organizations**
SMI	**Supplementary Medical Insurance (Part B)**
SNF	**Skilled Nursing Facility**
SSA	**Social Security Administration**
TANF	**Temporary Assistance for Needy Families**
VA	**Veteran's Affairs**

Populations

Information about persons covered by Medicare, Medicaid, or CHIP

For Medicare, statistics are based on persons enrolled for coverage. Original Medicare enrollees are also referred to as fee-for-service enrollees. Historically, for Medicaid, recipient (beneficiary) counts were used as a surrogate for persons eligible for coverage, as well as for persons utilizing services. Current data systems now allow the reporting of total eligibles for Medicaid and for Children's Health Insurance Program (CHIP). Statistics are available by major program categories, by demographic and geographic variables, and as proportions of the U.S. population. Utilization data organized by persons served may be found in the Utilization section.

Table I.1
Medicare Enrollment/Trends

	Total Persons	Aged Persons	Disabled Persons
July		In millions	
1966	19.1	19.1	--
1970	20.4	20.4	--
1975	24.9	22.7	2.2
1980	28.4	25.5	3.0
1985	31.1	28.1	2.9
1990	34.3	31.0	3.3
1995	37.6	33.2	4.4
Average monthly			
2000	39.7	34.3	5.4
2005	42.6	35.8	6.8
2010	47.7	39.6	8.1
2013	52.5	43.6	8.9
2014	54.1	45.1	9.0
2015	55.3	46.3	9.0
2016	57.1	48.1	9.0

NOTES: Represents those enrolled in HI (Part A) and/or SMI (Part B and Part D) of Medicare. Data for 1966-1995 are as of July. Data for calendar years 2000-2016 represent average actual or projected monthly enrollment. Numbers may not add to totals because of rounding. Based on 2016 Trustees Report.

SOURCE: CMS, Office of the Actuary.

Table I.2
Medicare Enrollment/Coverage

	HI and/or SMI	HI	SMI		HI and SMI	HI Only	SMI Only
			Part B	Part D			
			In millions				
All persons	56.6	56.3	51.7	42.9	51.4	4.9	0.3
Aged persons	47.6	47.3	43.5	--	43.2	4.1	0.3
Disabled persons	9.0	9.0	8.2	--	8.2	0.8	0.0

NOTES: Projected average monthly enrollment during fiscal year 2016. Aged/disabled split of Part D enrollment not available. Based on 2016 Trustees Report. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of the Actuary.

Table I.3
Medicare Enrollment/Demographics

	Total	Male	Female
		In thousands	
All persons	55,584	25,276	30,308
Aged	46,728	20,716	26,012
65-74 years	26,209	12,338	13,871
75-84 years	13,975	6,117	7,858
85 years and over	6,543	2,261	4,283
Disabled	8,856	4,560	4,297
Under 45 years	1,902	1,024	878
45-54 years	2,420	1,233	1,187
55-64 years	4,534	2,303	2,231
Non-Hispanic White	41,726	18,932	22,794
Black (or African-American)	5,759	2,484	3,274
All Other	7,458	3,441	4,017
Am. Indian/Alaska Native	250	112	139
Asian/Pacific Islander	1,720	770	950
Hispanic	5,017	2,329	2,688
Other	471	230	240
Unknown Race	642	419	223

NOTES: Person-year enrollee counts for 2015. Numbers may not add to totals because of rounding. Race information is based on Research Triangle Institute (RTI) race codes.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.4
Medicare Part D Enrollment/Demographics

	Total	Male	Female
		In thousands	
All persons	39,509	16,773	22,736
Aged			
65-74 years	17,657	7,646	10,011
75-84 years	10,405	4,305	6,100
85 years and over	4,689	1,475	3,214
Disabled			
Under 45 years	1,551	813	738
45-54 years	1,865	931	934
55-64 years	3,343	1,603	1,740

NOTES: Person-year enrollee counts for 2015 as reported in the CMS Chronic Conditions Data Warehouse. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.5
Medicare ESRD Enrollment/Trends

	HI and/or SMI	HI	SMI
		In thousands	
Year			
1985	110.0	109.1	106.5
1990	172.1	170.6	163.7
1995	255.7	253.6	243.8
2000	290.9	290.4	272.8
2005	369.9	369.8	351.6
2010	427.5	427.3	405.6
2015	507.6	504.1	483.3

NOTES: Data as of July 1 for years 1985-2010. Enrollee counts for 2015 are determined using a person-year methodology.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.6
Medicare ESRD Enrollment/Demographics

	Number of Enrollees (in thousands)
All persons	557.5
Age	
Under 35 years	23.7
35-44 years	40.2
45-64 years	213.5
65 years and over	280.1
Sex	
Male	318.5
Female	239.0
Race	
Non-Hispanic White	232.4
Black (or African-American)	187.9
Other	132.5
Unknown	4.7

NOTES: CMS Chronic Conditions Data Warehouse. Represents persons with ESRD ever enrolled during calendar year 2015.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.7
Medicare Advantage, Cost, PACE, Demo, & Prescription Drug

	Number of Contracts	MA only	Drug Plan	Total
		(Enrollees in thousands)		
Total prepaid[1]	694	2,034	16,571	18,604
Local CCPs	464	1,430	14,510	15,940
PFFS	7	79	149	228
1876 Cost	16	340	280	619
1833 Cost (HCPP)	9	60	--	60
PACE	122	--	37	37
Other plans[2]	76	124	1,595	1,719
Total PDPs[1]	72	--	24,988	24,988
Total	766	2,034	41,559	43,592

[1]Totals include beneficiaries enrolled in employer/union-only group plans (contracts with "800 series" plan IDs). Where a beneficiary is enrolled in both an 1876 cost or PFFS plan and a PDP plan, both enrollments are reflected in these counts. [2]Includes MSA, Medicare-Medicaid Plans, and RPPOs.

NOTE: Data as of November 2016.

SOURCE: CMS, Center for Medicare.

Table I.8
Medicare Enrollment/CMS Region

	Resident U.S. Population[1]	Medicare Enrollees[2]	Enrollees as Percent of Population
	In thousands		
All regions	321,419	54,348	16.9
Boston	14,728	2,760	18.7
New York	28,754	4,844	16.8
Philadelphia	30,654	5,506	18.0
Atlanta	64,302	11,896	18.5
Chicago	52,277	9,240	17.7
Dallas	41,114	6,081	14.8
Kansas City	14,015	2,512	17.9
Denver	11,687	1,704	14.6
San Francisco	50,295	7,491	14.9
Seattle	13,593	2,314	17.0

[1]Preliminary annual estimate July 1, 2015 resident population.
[2]Medicare enrollment data for 2015 are determined using a person-year methodology. Excludes beneficiaries living in territories, possessions, foreign countries or with residence unknown.

NOTES: Resident population is a provisional estimate based on 50 States and the District of Columbia. Numbers may not add to totals because of rounding. For regional breakouts, see Reference section.
SOURCES: CMS, Office of Enterprise Data and Analytics; U.S. Bureau of the Census, Population Estimates Branch.

Table I.9
Medicare Enrollment by Health Delivery/CMS Region

	Total Enrollees	Original Medicare Enrollees	MA and Other Health Plan Enrollees
		In thousands	
All regions	55,584	37,786	17,799
Boston	2,760	2,163	596
New York	5,621	3,577	2,044
Philadelphia	5,506	4,007	1,499
Atlanta	11,896	8,051	3,845
Chicago	9,240	6,065	3,176
Dallas	6,081	4,308	1,773
Kansas City	2,512	1,991	520
Denver	1,704	1,204	500
San Francisco	7,512	4,458	3,054
Seattle	2,314	1,528	786

NOTES: Person-year enrollee counts for 2015. Numbers may not add because of rounding. Foreign residents and unknowns are not included in the regions, but included in the total figure.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.9a
Medicare Enrollment by Health Delivery/Demographics

	Total	Original Medicare	MA and Other Health Plans
		In thousands	
All persons	55,584	37,786	17,799
Aged	46,728	31,324	15,404
65-74 years	26,209	17,720	8,489
75-84 years	13,975	9,040	4,935
85 years and over	6,543	4,564	1,980
Disabled	8,856	6,462	2,395
Under 45 years	1,902	1,542	359
45-54 years	2,420	1,808	613
55-64 years	4,534	3,111	1,423
Male	25,276	17,557	7,719
Female	30,308	20,229	10,079
Non-Hispanic White	41,726	29,359	12,367
Black (or African-American)	5,759	3,708	2,051
All Other	7,458	4,228	3,229
Am. Indian/Alaska Native	250	215	36
Asian/Pacific Islander	1,720	1,082	638
Hispanic	5,017	2,616	2,400
Other	471	315	156
Unknown Race	642	490	151

NOTES: Person-year enrollee counts for 2015. Numbers may not add to totals because of rounding. Race information based on Research Triangle Institute race codes.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.10
Medicare Part D Enrollment by CMS Region

	Total Medicare Enrollees	Total Part D Enrollees	% of Total Enrollees
		In thousands	
All regions[1]	55,584	39,509	71.1
Boston	2,760	1,920	69.6
New York	5,621	4,187	74.5
Philadelphia	5,506	3,738	67.9
Atlanta	11,896	8,601	72.3
Chicago	9,240	6,780	73.4
Dallas	6,081	4,173	68.6
Kansas City	2,512	1,821	72.5
Denver	1,704	1,162	68.2
San Francisco	7,512	5,605	74.6
Seattle	2,314	1,509	65.2

[1]Foreign residents and unknowns are not included in the regions but are included in the total figure.

NOTE: Data for calendar year 2015 as reported in the CMS Chronic Conditions Data Warehouse.
SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.11
Medicare Part D Enrollment by Plan Type/CMS Region

	Total Part D Enrollees	Total PDP Enrollees	Total MA-PD Enrollees
		In thousands	
All regions[1]	39,509	24,101	15,408
Boston	1,920	1,371	549
New York	4,187	2,294	1,893
Philadelphia	3,738	2,494	1,244
Atlanta	8,601	5,033	3,568
Chicago	6,780	4,602	2,178
Dallas	4,173	2,692	1,480
Kansas City	1,821	1,357	464
Denver	1,162	726	436
San Francisco	5,605	2,703	2,902
Seattle	1,509	819	691

[1]Foreign residents and unknowns are not included in the regions but are included in the total figure.

NOTE: Data for calendar year 2015 as reported in the CMS Chronic Conditions Data Warehouse.
SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.12
Medicare Part D and RDS Enrollment/CMS Region

	Total Part D and RDS Enrollees	Total Part D Enrollees	Total RDS Enrollees
		In thousands	
All regions[1]	41,764	39,509	2,255
Boston	2,102	1,920	182
New York	4,452	4,187	265
Philadelphia	3,963	3,738	225
Atlanta	8,996	8,601	396
Chicago	7,206	6,780	426
Dallas	4,416	4,173	243
Kansas City	1,884	1,821	63
Denver	1,207	1,162	45
San Francisco	5,862	5,605	256
Seattle	1,660	1,509	150

[1] Foreign residents and unknowns are not included in the regions but are included in the total figure.

NOTES: Data for calendar year 2015 as reported in the CMS Chronic Conditions Data Warehouse. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table I.13
Projected Population[1]

	2010	2020	2040	2060	2080	2100
			In millions			
Total	315	342	396	437	481	526
Under 20	86	87	99	107	115	125
20-64	188	199	215	236	257	277
65 years and over	41	56	82	94	108	124

[1] As of July 1.

NOTE: Numbers may not add to totals because of rounding.

SOURCE: Social Security Administration, Office of the Chief Actuary, based on the 2016 Trustees Report Intermediate Alternative.

Table I.14
Period Life Expectancy at Age 65,
Historical and Projected

	Male	Female
Year	In years	
1965	12.9	16.3
1980	14.0	18.4
1990	15.1	19.1
2000	15.9	19.0
2010	17.6	20.2
2020[1]	18.6	21.0
2030[1]	19.3	21.6
2040[1]	19.9	22.2
2050[1]	20.5	22.7
2060[1]	21.1	23.2
2070[1]	21.6	23.7
2080[1]	22.1	24.1
2090[1]	22.6	24.6
2100[1]	23.0	25.0

[1] Projected.

SOURCE: Social Security Administration, Office of the Chief Actuary, based on the 2016 Trustees Report Intermediate Alternative.

Table I.15

Life Expectancy at Birth and at Age 65 by Race/Trends

Calendar Year	All Races	White	Black
		At Birth	
1960	69.7	70.6	63.6
1980	73.7	74.4	68.1
1990	75.4	76.1	69.1
2000	76.8	77.3	71.8
2005	77.6	78.0	73.0
2010	78.7	78.9	75.1
2012	78.8	79.1	75.5
2013	78.8	79.1	75.5
2014	78.8	79.0	75.6
		At Age 65	
1960	14.3	14.4	13.9
1980	16.4	16.5	15.1
1990	17.2	17.3	15.4
2000	17.6	17.7	16.1
2005	18.4	18.5	16.9
2010	19.1	19.2	17.8
2012	19.3	19.3	18.1
2013	19.3	19.3	18.1
2014	19.3	19.3	18.2

SOURCE: Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System.

Table I.16
Medicaid and CHIP Enrollment

	Fiscal Year					
	1995	2000	2005	2010	2015	2016
	Average monthly enrollment in millions					
Total	34.2	34.5	46.5	53.5	68.5	70.9
Age 65 years and over	3.7	3.7	4.6	4.8	5.5	5.7
Blind/Disabled	5.8	6.7	8.1	9.3	10.5	10.6
Children	16.5	16.2	22.3	26.4	28.0	28.0
Adults	6.7	6.9	10.6	13.1	15.4	15.5
Expansion Adults	NA	NA	NA	NA	9.1	11.2
Other Title XIX[1]	0.6	NA	NA	NA	NA	NA
Territories	0.8	0.9	1.0	1.0	1.5	1.4
CHIP	NA	2.0	5.9	5.4	5.9	6.5

[1]In 1997, the Other Title XIX category was dropped and the enrollees therein were subsumed in the remaining categories.

NOTES: Aged and Blind/Disabled eligibility groups include Qualified Medicare Beneficiaries (QMB) and Specified Low-Income Medicare Beneficiaries (SLMB). Children and Adult groups include both AFDC/TANF and poverty-related recipients who are not disabled. Medicaid enrollment excludes Medicaid expansion and CHIP programs. CHIP numbers include adults covered under waivers. Medicaid and CHIP figures for FY 2015-2016 are estimates from the Midsession Review of the President's FY 2017 budget. Enrollment for Territories for FY 2000 and later is estimated. Numbers may not add to totals because of rounding.

SOURCES: CMS, Office of the Actuary, and the Center for Medicaid and CHIP Services.

Table I.17
Medicaid Eligibles/Demographics

	Medicaid Eligibles	Percent Distribution
	In millions	
Total eligibles	72.2	100.0
Age	72.2	100.0
Under 21	37.2	51.5
21-64 years	28.1	38.9
65 years and over	6.9	9.5
Unknown	0.1	0.1
Sex	72.2	100.0
Male	30.3	41.9
Female	41.9	57.9
Unknown	0.1	0.1
Race	72.2	100.0
Non-Hispanic White	29.1	40.3
Black, (or African-American)	15.7	21.7
Am. Indian/Alaskan Native	0.9	1.2
Asian	2.5	3.4
Hawaiian/Pacific Islander	0.6	0.9
Hispanic	17.7	24.5
Other	0.4	0.6
Unknown	5.4	7.5

NOTES: Fiscal Year 2013 data derived from MSIS Granular Database. The percent distribution is based on unrounded numbers. Totals do not necessarily equal the sum of rounded components. Eligible is defined as anyone eligible and enrolled in the Medicaid program at some point during the fiscal year regardless of duration of enrollment, receipt of a paid medical service, or whether or not a capitated premium for managed care or private health insurance coverage has been made. Age groups are determined using the eligible's age at the end of the fiscal year. Excludes beneficiaries ever enrolled in separate Title XXI Children's Health Insurance Program (CHIP). Excludes data for Colorado, Idaho, and Rhode Island, and includes partial data for Kansas and North Carolina.

SOURCE: CMS, Center for Medicaid and CHIP Services.

Table I.18
Medicaid Eligibles/CMS Region

	Resident U.S. Population[1]	Medicaid Enrollment[2]	Enrollment as Percent of Population
	In thousands		
All regions	316,205	72,228	22.8
Boston	14,635	3,212	21.9
New York	28,573	7,671	26.8
Philadelphia	30,403	5,948	19.6
Atlanta	62,892	13,776	21.9
Chicago	52,079	11,995	23.0
Dallas	39,996	9,195	23.0
Kansas City	13,896	2,532	18.2
Denver	11,336	838	7.4
San Francisco	49,153	14,807	30.1
Seattle	13,243	2,252	17.0

[1]Estimated July 1, 2013 population.

[2]Persons ever enrolled in Medicaid during fiscal year 2013.

NOTES: Numbers may not add to totals because of rounding. Excludes data for Colorado, Idaho, and Rhode Island, and includes partial data for Kansas and North Carolina. Excludes enrollees ever enrolled in separate Title XXI Children's Health Insurance Program (CHIP).

SOURCES: CMS, Center for Medicaid and CHIP Services; U.S. Department of Commerce, Bureau of the Census.

Table I.19
Medicaid Beneficiaries/Part B State Buy-Ins for Medicare

	1975	1980	2000[1]	2015[1]
Type of Beneficiary		In thousands		
All buy-ins	2,846	2,954	5,549	9,518
Aged	2,483	2,449	3,632	5,513
Disabled	363	504	1,917	4,005
		Percent of Part B enrollees		
All buy-ins	12.0	10.9	14.9	18.4
Aged	11.4	10.0	11.1	12.7
Disabled	18.7	18.9	40.2	48.4

[1]Beneficiaries in person years.

NOTES: Represent beneficiaries for whom the State paid the Medicare Part B premium during the year. Numbers may not add to totals because of rounding. Includes outlying areas, foreign countries, and unknown.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Providers/Suppliers

Information about institutions, agencies, or professionals who provide health care services, and individuals or organizations who furnish health care equipment or supplies

These data are distributed by major provider/supplier categories, by geographic region, and by type of program participation. Utilization data organized by type of provider/supplier may be found in the Utilization section.

Table II.1
Inpatient Hospitals/Trends

	1990	2000	2010	2015
Total hospitals	6,522	5,985	6,169	6,140
Beds in thousands	1,105	991	928	932
Beds per 1,000 enrollees[1]	32.8	25.3	19.6	16.9
Short-stay	5,549	4,900	3,566	3,436
Beds in thousands	970	873	785	784
Beds per 1,000 enrollees[1]	28.8	22.3	16.6	14.2
Critical access hospitals	NA	NA	1,325	1,336
Beds in thousands	---	---	30	31
Beds per 1,000 enrollees[1]	---	---	0.6	0.6
Other non-short-stay	973	1,085	1,278	1,368
Beds in thousands	135	118	113	117
Beds per 1,000 enrollees[1]	4.0	3.0	2.4	2.1

[1]Based on number of total HI enrollees as of July 1 for years 1990, 2000, and 2010. Based on person-year HI enrollee count for 2015.

NOTES: Facility data are as of December 31 and essentially represent those facilities eligible to participate at the start of the next calendar year. Facilities certified for Medicare are deemed to meet Medicaid standards.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.2
Inpatient Hospitals/CMS Region

	Short-stay and CAH hospitals	Beds per 1,000 enrollees	Non Short-stay hospitals	Beds per 1,000 enrollees
All regions	4,772	14.7	1,368	2.1
Boston	175	11.5	65	3.5
New York	302	15.8	73	2.0
Philadelphia	358	13.0	133	2.4
Atlanta	878	15.1	251	1.7
Chicago	847	16.0	211	1.8
Dallas	758	17.4	362	3.8
Kansas City	453	18.4	64	1.8
Denver	314	15.6	50	2.5
San Francisco	477	12.9	132	1.5
Seattle	210	10.4	27	1.3

NOTES: Critical Access Hospitals have been grouped with short stay. Facility data as of December 31, 2015. Rates based on person-year hospital insurance enrollee count for 2015.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.3
Medicare Hospital and SNF/NF/ICF Facility Counts

Total participating hospitals	6,140
Short-term hospitals	3,436
Psychiatric units	1,118
Rehabilitation units	908
Swing bed units	488
Psychiatric	560
Long-term	426
Rehabilitation	266
Children's	100
Religious non-medical	16
Critical Access	1,336
Non-participating hospitals	782
Emergency	432
Federal	350
All SNFs/SNF-NFs/NFs only	15,640
All SNFs/SNF-NFs	15,236
Title 18-only SNF	750
Hospital-based	179
Free-standing	571
Title 18/19 SNF/NF	14,486
Hospital-based	564
Free-standing	13,922
Title 19-only NFs	404
Hospital-based	98
Free-standing	306
All ICF/IID facilities	6,202

NOTES: Data as of December 31, 2015. Numbers may differ from other reports and program memoranda.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.4
Long-Term Facilities/CMS Region

	Title XVIII and XVIII/XIX SNFs	Nursing Facilities	ICF/IIDs
All regions [1]	15,236	404	6,202
Boston	933	8	117
New York	995	2	508
Philadelphia	1,365	38	381
Atlanta	2,651	43	699
Chicago	3,391	68	1,375
Dallas	2,059	44	1,546
Kansas City	1,409	102	195
Denver	589	35	113
San Francisco	1,407	48	1,189
Seattle	437	16	79

[1] Includes outlying areas.

NOTE: Data as of December 2015.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.5
Other Medicare Providers and Suppliers/Trends

	1980	1990	2010	2015
Home health agencies	2,924	5,661	10,914	12,149
Independent and Clinical Lab Improvement Act Facilities	NA	4,828	224,679	252,044
End stage renal disease facilities	999	1,987	5,631	6,558
Outpatient physical therapy and/or speech pathology	419	1,144	2,536	2,130
Portable X-ray	216	435	561	499
Rural health clinics	391	517	3,845	4,104
Comprehensive outpatient rehabilitation facilities	NA	184	354	207
Ambulatory surgical centers	NA	1,165	5,316	5,470
Hospices	NA	772	3,509	4,302

NOTES: Facility data for 1980 are as of July 1. Facility data for 1990, 2010, and 2015 are as of December 31.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.6
Selected Facilities/Type of Control

	Short-stay hospitals	Skilled nursing facilities	Home health agencies
Total facilities	3,436	15,236	12,149
		Percent of total	
Non-profit	59.8	23.6	15.3
Proprietary	21.4	69.9	80.0
Government	18.8	6.5	4.7

NOTES: Data as of December 31, 2015. Facilities certified for Medicare are deemed to meet Medicaid standards.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.7
Periodic Interim Payment (PIP) Facilities/Trends

	1980	1990	2000	2010	2015
Hospitals					
Number of PIP	2,276	1,352	869	547	474
Percent of total participating	33.8	20.6	14.4	8.9	7.7
Skilled nursing facilities					
Number of PIP	203	774	1,236	381	320
Percent of total participating	3.9	7.3	8.3	2.5	2.0
Home health agencies					
Number of PIP	481	1,211	1,038	114	163
Percent of total participating	16.0	21.0	14.4	1.0	1.3

NOTES: These are facilities receiving Periodic Interim Payments (PIP) under Medicare. Effective for claims received on or after July 1, 1987, the Omnibus Budget Reconciliation Act of 1986 eliminates PIP for many PPS hospitals when the servicing Part A MAC meets specified processing time standards.

SOURCE: CMS, Center for Medicare.

Table II.8
Medicare Non-Institutional Providers by Specialty[1]

	Count
Total Providers	1,209,667
Primary Care	224,187
Surgical Specialties	108,784
Medical Specialties	144,942
Anesthesiology	40,993
Obstetrics/Gynecology	34,640
Radiology	37,038
Emergency Medicine	45,595
Non-Physician Practitioners	360,558
Limited Licensed Practitioners	104,681
All Other Providers	130,768

[1] Providers utilized by Original Medicare beneficiaries for all Part B non-institutional provider services. Providers may be counted in more than one specialty classification, but are reported as a single provider in the "Total Providers" count.

NOTE: Data for calendar year 2015, as reported on the Original Medicare claims.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table II.9
Medicare DMEPOS Providers by Specialty[1]

	Count
Total DMEPOS Providers	86,313
Pharmacy	50,124
Medical Supply Company	10,613
Optometry	5,871
Podiatry	5,380
Individual Certified Prosthetist/Orthotist	2,514
Optician	2,161
All Other DMEPOS Providers	9,951

[1] Providers utilized by Original Medicare beneficiaries for all Part B non-institutional DMEPOS services. Providers may be counted in more than one specialty classification, but are reported as a single provider in the "Total DMEPOS Providers" count.

NOTE: Data for calendar year 2015, as reported on the Original Medicare claims.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Expenditures

Information about spending for health care services by Medicare, Medicaid, CHIP, and for the Nation as a whole

Health care spending at the aggregate levels is distributed by source of funds, types of service, geographic area, and broad beneficiary or eligibility categories. Direct out-of-pocket, other private, and non-CMS-related expenditures are also covered in this section. Expenditures on a per-unit-of-service level are covered in the Utilization section.

Table III.1
CMS and Total Federal Outlays

	Fiscal year 2014	Fiscal year 2015
	$ in billions	
Gross domestic product (current dollars)	$17,244.0	$17,803.4
Total Federal outlays[1]	3,506.1	3,688.3
Percent of gross domestic product	20.3%	20.7%
Dept. of Health and Human Services[1]	936.0	1,027.5
Percent of Federal Budget	26.7%	27.9%
CMS Budget (Federal Outlays)		
Medicare benefit payments	591.3	615.6
SMI transfer to Medicaid[2]	0.7	0.7
Medicaid benefit payments	301.5	332.9
Medicaid State and local admin.	15.2	17.6
Medicaid offsets[3]	-0.7	-0.7
Children's Health Ins. Prog.	9.0	9.1
CMS program management	3.6	4.3
Other Medicare admin. expenses[4]	2.0	2.1
State Eligibility Determinations, for Part D	0.0	0.0
Quality Improvement Organizations[5]	0.5	0.6
Health Care Fraud and Abuse Control	1.4	1.6
State Grants and Demonstrations[6]	0.5	0.6
User Fees and Reimbursables	0.5	1.6
Total CMS outlays (unadjusted)	910.3	968.4
Offsetting receipts[7]	-94.5	-94.2
Total net CMS outlays	815.8	874.2
Percent of Federal budget	23.3%	23.7%

[1]Net of offsetting receipts.
[2]SMI transfers to Medicaid for Medicare Part B premium assistance ($688 million in FY 2014 and $749 million in FY 2015).
[3]SMI transfers for low-income premium assistance.
[4]Medicare administrative expenses of the Social Security Administration and other Federal agencies.
[5]Formerly peer review organizations (PROs).
[6]Includes grants and demonstrations for various free-standing programs, such as the Ticket to Work and Work Incentives Improvement Act (P.L. 106-170), emergency health services for undocumented aliens (P.L.108-173), and Medicaid's Money Follows the Person Rebalancing Demonstration (P.L. 109-171).
[7]Almost entirely Medicare premiums. Also includes offsetting collections for user fee and reimbursable activities, as well as refunds to the trust funds.

SOURCE: CMS, Office of Financial Management.

Table III.2
Program Expenditures/Trends

	Total	Medicare[1]	Medicaid[2]	CHIP[3]
		$ in billions		
Fiscal year				
1980	$60.8	$35.0	$25.8	--
1990	182.2	109.7	72.5	--
2000	428.7	219.0	208.0	$1.7
2010	940.9	525.6	403.9	11.4
2015	1,198.9	632.9	552.3	13.7

[1]Medicare amounts reflect gross outlays (i.e., not net of offsetting receipts). These amounts include: outlays for benefits, administration, Health Care Fraud and Abuse Control (HCFAC) activities, Quality Improvement Organizations (QIOs), the SMI transfer to Medicaid for Medicare Part B premium assistance for low-income Medicare beneficiaries and, since FY 2004, the administrative and benefit costs of the Transitional Assistance and Part D Drug benefits under the Medicare Modernization Act of 2003.

[2]The Medicaid amounts include total computable outlays (Federal and State shares) for benefits and administration, the Federal and State shares of the cost of Medicaid survey/certification and State Medicaid fraud control units, and outlays for the Vaccines for Children program. These amounts do not include the SMI transfer to Medicaid for Medicare Part B premium assistance for low-income beneficiaries, nor do they include the Medicare Part D compensation to States for low-income eligibility determinations in the Part D Drug program.

[3]The CHIP amounts reflect both Federal and State shares of Title XXI outlays. Please note that CHIP-related Medicaid began to be financed under Title XXI in 2001.

NOTE: Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Financial Management.

Table III.3
Annual Benefit Outlays by Program

	1967	1980	2010	2015
	Amounts in billions			
CMS program outlays	$5.1	$57.8	$915	$1,181
Federal outlays	NA	47.2	793	973
Medicare[1]	3.2	33.9	518	615
HI	2.5	23.8	250	275
SMI	0.7	10.1	209	265
Prescription (Part D)	NA	NA	59	75
Medicaid[2]	1.9	23.9	386	552
Federal share	NA	13.2	266	348
CHIP[3]	NA	NA	11	14
Federal share	NA	NA	8	10

[1]The Medicare benefit amounts reflect gross outlays (i.e., not net of offsetting premiums). These amounts exclude outlays for the SMI transfer to Medicaid for premium assistance and the Quality Improvement Organizations (QIOs).

[2]The Medicaid amounts include total computable outlays (Federal and State shares) for Medicaid benefits and outlays for the Vaccines for Children program.

[3]The CHIP amounts reflect both Federal and State shares of Title XXI outlays as reported by the States on line 4 of the CMS-21. Please note that CHIP-related Medicaid expansions began to be financed under CHIP (Title XXI) in FY 2001.

NOTES: Fiscal year data. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Financial Management.

Table III.4
Program Benefit Payments/CMS Region

	Fiscal Year 2014 Net Expenditures Reported[1]	
	Medicaid	
	Total Payments Computable for Federal funding	Federal Share
	In millions	
All regions	$470,269	$284,104
Boston	28,720	15,659
New York	66,189	35,900
Philadelphia	47,610	26,981
Atlanta	74,088	49,396
Chicago	75,970	47,353
Dallas	52,117	32,992
Kansas City	17,251	10,547
Denver	11,287	6,774
San Francisco	77,021	45,155
Seattle	20,016	13,347

[1]Data from Form CMS-64--Net Expenditures Reported by the States. Medical assistance payments only; excludes administrative expenses and Children's Health Insurance Program (CHIP). Unadjusted by CMS.
NOTE: Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table III.5
Medicare Benefit Outlays

	Fiscal Year		
	2014	2015	2016
	In billions		
Part A benefit payments	$261.8	$272.4	$284.7
Aged	216.8	225.9	237.2
Disabled	45.0	46.6	47.5
Part B benefit payments	256.6	271.5	294.4
Aged	207.9	220.6	240.3
Disabled	48.7	50.9	54.1
Part D	72.2	83.8	104.8

NOTES: Based on 2016 Trustees Report. Part A benefits include additional payments for HIT, CBC, IPAB, and Sequester. Part B benefits include additional payments for HIT, IPAB, and Sequester. Part D benefits include additional payments for IPAB. Aged/disabled split of Part D benefit outlays not available. Totals do not necessarily equal the sum of rounded components.

SOURCE: CMS, Office of the Actuary.

Table III.6
Medicare/Type of Benefit

	Fiscal Year 2016 Benefit Payments[1] in millions	Percent Distribution
Total Part A[2,3]	$284,748	100.0
Inpatient hospital	139,140	48.9
Skilled nursing facility	31,332	11.0
Home health agency[4]	6,787	2.4
Hospice	16,717	5.9
Managed care	90,772	31.9
Total Part B[3,5]	294,371	100.0
Physician/other suppliers[6]	70,516	24.0
DME	6,701	2.3
Other carrier	21,903	7.4
Outpatient hospital	45,446	15.4
Home health agency[4]	11,222	3.8
Other intermediary	20,305	6.9
Laboratory	9,054	3.1
Managed care	109,224	37.1
Total Part D[7]	104,786	100.0

[1]Includes the effects of regulatory items and recent legislation but not proposed law. [2]Includes HIT, CBC, IPAB, and Sequester expenditures. [3]Excludes QIO expenditures. [4]Distribution of home health benefits between the trust funds estimated based on outlays reported to date by the Treasury. [5]Includes HIT, IPAB, and Sequester expenditures. [6]Includes payments made for HIT. [7]Includes payments made for IPAB and Sequester.

NOTES: Based on 2016 Trustees Report. Benefits by type of service are estimated and are subject to change. Totals do not necessarily equal the sum of rounded components.

SOURCE: CMS, Office of the Actuary.

Table III.7
National Health Care/Trends

	Calendar Year		
	1990	2000	2014
National total in billions	$721.4	$1,369.7	$3,031.3
Percent of GDP	12.1	13.3	17.5
Per capita amount	$2,843	$4,857	$9,523
Sponsor		Percent of total	
Private Business	23.6	24.5	20.0
Household	36.2	32.4	27.8
Other Private Revenues	7.8	7.6	7.3
Governments	32.3	35.5	44.8
Federal government	17.2	19.0	27.8
State and local government	15.1	16.5	17.0

NOTE: Numbers may not add to totals because of rounding.

SOURCES: CMS, Office of the Actuary; U.S. Department of Commerce, Bureau of Economic Analysis; and U.S. Bureau of the Census.

Table III.8
Medicaid/Type of Service

	Fiscal Year		
	2012	2013	2014
	In billions		
Total medical assistance payments[1]	$408.8	$433.1	$470.3
	Percent of Total		
Inpatient services	14.5	14.5	12.1
General hospitals	13.7	13.7	11.6
Mental hospitals	0.8	0.8	0.5
Nursing facility services	12.3	11.7	10.6
ICF/IID services	3.3	2.8	2.2
Community-based long term care svs.[2]	13.5	13.0	11.9
Prescribed drugs[3]	2.1	1.5	1.7
Physician and other practitioner services	3.6	3.3	3.6
Dental services	1.1	0.9	0.8
Outpatient hospital services	3.8	3.9	3.4
Clinic services[4]	2.6	2.4	2.2
Laboratory and radiological services	0.4	0.4	0.4
Early and periodic screening	0.3	0.3	0.2
Case management services	0.7	0.7	0.6
Capitation payments (non-Medicare)	29.1	31.9	37.8
Medicare premiums	3.3	3.2	3.0
Disproportionate share hosp. payments	4.2	3.8	3.8
Other services	7.1	7.3	7.3
Collections[5]	-2.0	-1.6	-1.7

[1]Excludes payments under CHIP.

[2]Comprised of home health, home and community-based waivers, personal care and home and community-based services for functionally disabled elderly.

[3]Net of prescription drug rebates.

[4]Federally qualified health clinics, rural health clinics, and other clinics.

[5]Includes third party liability, probate, fraud and abuse, overpayments, and other collections.

NOTE: Numbers may not add to totals because of rounding.

SOURCES: CMS, CMCS, and OACT.

Table III.9
Medicare Savings Attributable to Secondary Payer Provisions by Type of Provision

	Fiscal Year		
	2013	2014	2015
	In millions		
Total	$8,925.8	$8,199.9	$8,490.8
Workers' Compensation[1]	1,888.5	1,711.7	2,148.2
Working Aged	3,838.4	3,545.8	3,426.8
ESRD	303.1	270.9	254.4
Auto	190.1	172.9	170.1
Disability	2,119.6	1,996.8	1,884.8
Liability	566.3	488.5	600.7
VA/Other	19.8	13.3	5.8

[1]Includes Workers' Compensation set-asides.

NOTES: Includes Liability savings of the global settlements recovered by CMS. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Financial Management.

Table III.10
Medicaid/Payments by Eligibility Status

	Fiscal Year 2014 Medical Assistance Payments[1]	Percent Distribution
	In billions	
Total[2]	$470.0	100.0
Age 65 years and over	81.7	17.4
Blind/disabled	192.1	40.9
Dependent children under 21 years of age	86.5	18.4
Adults	73.6	15.7
Expansion Adults	23.9	5.1
Disproportionate share hospital and other unallocated payments[3]	12.2	2.6

[1]Medicaid Total Computable Expenditures.

[2]Excludes payments under Children's Health Insurance Program (CHIP).

[3]Includes collections, prior period adjustments, and payments to territories.

SOURCE: CMS, Office of the Actuary.

Table III.11
Medicare/DME/POS[1]

BETOS Category	Allowed Charges[2]	
	2014	2015
	In thousands	
Total	$8,686,710	$9,222,185
Medical/surgical supplies	204,469	226,900
Hospital beds	119,600	110,304
Oxygen and supplies	1,429,545	1,427,220
Wheelchairs	617,261	616,072
Prosthetic/orthotic devices	2,363,720	2,495,475
Drugs admin. through DME[3]	827,574	874,702
Parenteral and enteral nutrition	512,214	499,397
Other DME	2,612,327	2,972,114

[1]Data are for calendar year. DME=durable medical equipment. POS=Prosthetic, orthotic, and supplies.

[2]The allowed charge is the Medicare approved payment reported on a line item on the physician/ supplier claim.

[3]Includes inhalation drugs administered through nebulizers only and does not include drugs administered through other DME such as infusion pumps.

NOTES: Over time, the composition of BETOS categories has changed with the reassignment of selected procedures, services, and supplies. Data for 2014 and 2015 as reported in the CMS Chronic Conditions Data Warehouse.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table III.12
National Health Care/Type of Expenditure

	National Total in billions	Per capita amount	Percent Paid		
			Total	Medicare	Medicaid
Total	$3,031.3	$9,523	36.8	20.4	16.4
Health Consumption Expenditures	2,877.4	9,040	38.7	21.5	17.2
Personal health care	2,563.6	8,054	40.1	22.7	17.4
Hospital care	971.8	3,053	43.1	25.8	17.3
Prof. services	801.6	2,518	29.8	19.8	10.0
Phys./clinical	603.7	1,896	33.5	22.9	10.6
Other Professional	84.4	265	30.6	23.2	7.4
Dental	113.5	357	9.3	0.4	8.9
Other Health Residential & Personal Care	150.4	472	59.2	3.4	55.8
Nursing Care Facilities & Continuing Care Retirement Communities	155.6	489	54.8	22.9	31.9
Home Health	83.2	261	77.3	41.7	35.6
Retail outlet sales	401.0	1,260	32.3	24.0	8.3
Admn., Net Cost, and public health	313.8	986	28.3	12.1	16.2
Investment	153.9	483	--	--	--

NOTE: Data are as of calendar year 2014.

SOURCE: CMS, Office of the Actuary.

Table III.13
Personal Health Care/Payment Source

	Calendar Year			
	1980	1990	2000	2014
	In billions			
Total	$217.0	$615.3	$1,162.0	$2,563.6
	Percent			
Total	100.0	100.0	100.0	100.0
Out of pocket	26.8	22.4	17.1	12.9
Health Insurance	60.9	65.5	72.6	78.0
Private Health Insurance	28.4	33.3	34.9	33.9
Medicare	16.7	17.4	18.6	22.7
Medicaid (Title XIX)	11.4	11.3	16.1	17.4
Total CHIP (Title XIX and Title XXI)	--	--	0.2	0.4
Department of Defense	1.8	1.7	1.1	1.5
Department of Veterans Affairs	2.6	1.8	1.6	2.2
Other Third Party Payers and Programs	12.3	12.1	10.2	9.1

NOTES: Excludes administrative expenses, the net cost of insurance, non-commercial medical research, investment in structures and equipment, and public health expenditures. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of the Actuary.

Utilization

Information about the use of health care services

Utilization information is organized by persons receiving services and alternately by services rendered. Measures of health care usage include: persons served, units of service (e.g., discharges, days of care, etc.), and dimensions of the services rendered (e.g., average length of stay, charge per person or per unit of service). These utilization measures are aggregated by program coverage categories, provider characteristics, type of service, and demographic and geographic variables.

Table IV.1
Medicare/Short-Stay Hospital Utilization

	2012	2013	2014	2015
Discharges				
Total in millions	10.5	10.1	9.8	9.8
Rate per 1,000 enrollees[1]	284	270	261	260
Days of care				
Total in millions	51	49	48	48
Rate per 1,000 enrollees[1]	1,382	1,323	1,284	1,275
Total payments per day	$2,152	$2,235	$2,280	$2,314

[1]The population base for the denominator is Part A Original Medicare enrollment. The enrollee counts are based on a person-year methodology.

NOTES: Data may reflect underreporting due to a variety of reasons, including: operational difficulties experienced by intermediaries; no-pay, at-risk managed care utilization; and no-pay Medicare secondary payer bills. Data are based on 100-percent Original Medicare claims data from the Chronic Conditions Data Warehouse (CCW). Data may differ from other sources or from the same source with a different update cycle.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.2
Medicare Long-Term Care/Trends

	Skilled Nursing Facilities		Home Health Agencies	
	Persons Served in thousands	Served per 1,000 enrollees	Persons Served in thousands	Served per 1,000 enrollees
Calendar year				
2010	1,844	52	3,424	95
2011	1,870	52	3,442	94
2012	1,847	50	3,440	93
2013	1,846	50	3,469	92
2014	1,832	49	3,415	91
2015	1,845	49	3,453	91

NOTE: Managed care enrollees excluded in determining rates.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.3
Medicare Average Length of Stay/Trends

	Calendar Year				
	2011	2012	2013	2014	2015
Total All Hospitals	6.0	6.0	6.1	6.1	6.0
Short-Stay	5.1	5.1	5.1	5.1	5.1
Critical Access	3.6	3.5	3.5	3.4	3.4
Long Term	30.1	30.1	30.5	30.5	31.4
Psychiatric	15.1	15.1	15.1	15.0	15.3
Rehabilitation	13.0	12.9	12.8	12.8	12.7
Religious Nonmedical	20.0	19.8	21.9	23.7	22.6
Childrens'	7.5	7.5	7.4	7.4	6.9
Other	6.4	6.7	6.8	6.9	6.9

NOTES: Calendar year data. Average length of stay is shown in days. Data are based on 100-percent Original Medicare claims data from the Chronic Conditions Data Warehouse. Data may differ from other sources or from the same source with a different update cycle.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.4
Medicare Persons Served/Trends

	Calendar Year				
	2011	2012	2013	2014	2015
Aged persons served per 1,000 enrollees					
HI and/or SMI	925	918	916	916	915
HI	223	216	210	204	205
SMI	1,004	1,003	1,004	1,006	1,007
Disabled persons served per 1,000 enrollees					
HI and/or SMI	869	872	877	885	891
HI	210	207	202	201	201
SMI	958	958	959	962	967

NOTES: Managed care enrollees excluded in determining rates. Persons served represent estimates of beneficiaries receiving services under Original Medicare during the calendar year. Data are based on 100-percent Original Medicare claims data from the Chronic Conditions Data Warehouse. Data may differ from other sources or from the same source with a different update cycle.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.5
Original Medicare Persons Served

	Year				
	2011	2012	2013	2014	2015
HI					
Aged					
Original Medicare Enrollees	29.5	30.1	30.5	30.7	31.0
Persons served	6.6	6.5	6.4	6.3	6.4
Rate per 1,000	223	216	210	204	205
Disabled					
Original Medicare Enrollees	6.7	6.7	6.7	6.6	6.5
Persons served	1.4	1.4	1.4	1.3	1.3
Rate per 1,000	210	207	202	201	201
SMI					
Aged					
Original Medicare Enrollees	27.0	27.4	27.6	27.8	28.0
Persons served	27.1	27.5	27.7	27.9	28.2
Rate per 1,000	1,004	1,003	1,004	1,006	1,007
Disabled					
Original Medicare Enrollees	6.0	6.1	6.1	6.0	5.9
Persons served	5.7	5.8	5.8	5.8	5.7
Rate per 1,000	958	958	959	962	967

NOTES: Medicare enrollment is based on a person-year methodology. Persons served represents counts of beneficiaries receiving reimbursed services under Original Medicare during the calendar year. Rate is the ratio of persons served during the calendar year to the number of Original Medicare enrollees. Counts are based on 100-percent Original Medicare claims data from the Chronic Conditions Data Warehouse (CCW). Data may differ from other sources or from the same source with a different update cycle.

Original Medicare enrollees and persons served counts are in millions.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.6
Medicare Persons Served/CMS Region

	Aged Persons Served in thousands	Served per 1,000 Enrollees	Disabled Persons Served in thousands	Served per 1,000 Enrollees
All Regions[1]	28,653	915	5,775	891
Boston	1,585	896	354	898
New York	2,592	867	481	818
Philadelphia	3,062	915	588	891
Atlanta	6,217	947	1,367	918
Chicago	4,914	998	1,065	932
Dallas	3,254	921	691	893
Kansas City	1,561	944	301	895
Denver	981	952	152	876
San Francisco	2,776	727	472	740
Seattle	1,127	881	213	856

[1]Includes utilization for residents of outlying territories, possessions, foreign countries, and unknown.

NOTES: Data are based on counts of beneficiaries receiving HI and/or SMI reimbursed services under Original Medicare during calendar year 2015. Numbers may not add to totals because of rounding.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.6a
Original Medicare Persons Served by Type of Service

	Total Persons Served in thousands	Aged Persons Served in thousands	Disabled Persons Served in thousands
Parts A and/or B	34,408	28,653	5,755
Part A	7,655	6,360	1,295
Inpatient hospital	6,630	5,394	1,235
Skilled nursing facility	1,845	1,676	169
Hospice	1,395	1,320	75
Home health agency	1,669	1,464	204
Part B	33,834	28,152	5,682
Physician/supplier	33,320	27,748	5,572
Outpatient	25,289	20,829	4,460
Home health agency	1,958	1,711	248

NOTES: Data are as of calendar year 2015. Persons served represents counts of beneficiaries receiving services under Original Medicare during the calendar year.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Table IV.7
Medicare End Stage Renal Disease (ESRD) by Treatment Modalities

	Medicare Entitled		
Year	Total	Dialysis Patients	Transplant Patients
1991	179,726	140,899	38,827
1999	317,965	247,446	70,519
2000	334,485	260,179	74,306
2004	394,465	303,848	90,617
2005	409,499	314,057	95,442
2006	426,249	325,777	100,472
2007	442,203	337,212	104,991
2008	459,037	349,622	109,415
2009	477,223	363,491	113,732
2010	495,294	377,117	118,177
2011	511,802	388,877	122,925
2012	528,661	401,776	126,885
2013	549,108	414,921	134,187
2014	568,255	426,574	141,681

SOURCES: United States Renal Data System. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

Table IV.8
Medicare End Stage Renal Disease (ESRD)
by Treatment Modalities and Demographics, 2013

	Medicare Entitled		
	Total	Dialysis Patients	Transplant Patients
Total--all patients	549,108	414,921	134,187
Age			
0-19 years	3,072	1,240	1,832
20-64 years	298,722	212,386	86,336
65-74 years	143,898	107,743	36,155
75 years and over	103,416	93,552	9,857
Sex			
Male	315,124	234,521	80,603
Female	233,984	180,400	53,574
Race			
White	335,879	241,045	94,834
Black	176,620	146,764	29,856
Native American	5,991	4,803	1,188
Asian/Pacific	27,952	21,077	6,875
Other/Unknown	2,666	1,232	1,434

SOURCES: United States Renal Data System. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases.

Table IV.9
Medicaid/Type of Service

	Fiscal year 2013 Medicaid Beneficiaries
	In thousands
Total eligibles	72,228
Number using service:	
Total beneficiaries, any service[1]	64,529
Inpatient services	
General hospitals	8,203
Mental hospitals	43
Nursing facility services[2]	1,446
ICF/IID services[3]	93
Physician services	45,213
Dental services	19,345
Other practitioner services	10,026
Outpatient hospital services	28,009
Clinic services	16,608
Laboratory and radiological services	29,644
Home health services	1,733
Prescribed drugs	39,933
Personal care support services	1,171
Sterilization services	280
PCCM capitation	7,882
HMO capitation	41,351
PHP capitation	19,838
Targeted case management	2,650
Other services, unspecified	16,058
Additional service categories[4]	14,239
Unknown	741

[1]Excludes summary records with unknown basis of eligibility, most of which are lump-sum payments not attributable to any one person. Counts are duplicated across types of services because a beneficiary may receive more than one type of service (e.g. physician and prescription drugs). [2]All nursing facility services. Unlike Medicare there is no distinction for SNFs. [3]Intermediate Care Facility for Individuals with Intellectual Disabilities (ICF-IID) services were previously known as Intermediate Care Facility for the Mentally Retarded (ICF-MR) services. [4]Additional services not shown separately sum to 7.6 million beneficiaries, not unduplicated.

NOTES: Data were derived from the MSIS State Summary Datamart. Beneficiary counts include Medicaid eligibles enrolled in Medicaid Managed Care Organizations. Excludes data for Colorado, Idaho, and Rhode Island and includes partial data for Kansas and North Carolina. Excludes CHIP.

SOURCE: CMS, Center for Medicaid and CHIP Services.

Table IV.10
Medicaid/Units of Service

	Fiscal Year 2013 Units of Service
	In thousands
Inpatient hospital	
Total discharges	7,799
Beneficiaries discharged	7,056
Total days of care	43,765
Nursing facility[1]	
Total days of care	286,312
ICF/IID[2]	
Total days of care	25,612

[1]All nursing facility services. Unlike Medicare, there is no distinction for skilled nursing facilities.

[2]ICF-IID indicates Intermediate Care Facility for Individuals with Intellectual Disabilities. This category is the same as what was previously labeled "Intermediate Care Facility for the Mentally Retarded."

NOTES: Data are derived from the MSIS Granular Database. Service counts produced using inpatient and long term care original fee-for-service and Medicaid managed care claims. Excludes enrollees ever enrolled in separate Title XXI CHIP program and beneficiaries that had claims but no matching Medicaid enrollment in 2013. Excludes data for Colorado, Idaho, and Rhode Island, and includes partial data for Kansas and North Carolina.

SOURCE: CMS, Center for Medicaid and CHIP Services.

Administrative/Operating

Information on activities and services related to oversight of the day-to-day operations of CMS programs

Included are data on Medicare contractors, contractor activities and performance, CMS and State agency administrative costs, quality control, and summaries of the operation of the Medicare trust funds.

Table V.1
Medicare Administrative Expenses/Trends

	Administrative Expenses	
Fiscal Year	Amount in millions	As a Percent of Benefit Payments
HI Trust Fund		
1967	$89	3.5
1970	149	3.1
1980	497	2.1
1990	774	1.2
1995	1,300	1.1
2000 [1]	2,350	1.8
2005 [1]	2,850	1.6
2010	3,328	1.4
2013	4,135	1.6
2014	4,332	1.7
2015	5,488	2.0
SMI Trust Fund[2]		
1967	135[3]	20.3
1970	217	11.0
1980	593	5.8
1990	1,524	3.7
1995	1,722	2.7
2000	1,780	2.0
2005	2,348	1.6
2010	3,513	1.3
2013	3,756	1.2
2014	4,297	1.3
2015	3,606	1.0

[1]Includes non-expenditure transfers for Health Care Fraud and Abuse Control.

[2]Starting in FY 2004, includes the transactions of the Part D account.

[3]Includes expenses paid in fiscal years 1966 and 1967.

SOURCE: CMS, Office of Actuary.

Table V.2
Medicare Administrative Contractors

	Number
A/B MACs	12
DME MACs	4

NOTE: Data as of January 2016.

SOURCE: CMS, Center for Medicare.

Table V.3
Medicare Redeterminations

	A/B MAC Redeterminations (Part A Cases Involved)	A/B MAC Redeterminations (Part B Cases Involved)	A/B MAC and DME MAC Redeterminations (Part B Cases Involved)
Number Processed	122,834	199,319	2,484,598
Percent Reversed (Includes Fully & Partially Reversed Cases)	20.1	47.4	38.5

NOTES: Data for fiscal year 2015. Data presented in cases.

SOURCE: CMS, Center for Medicare.

Table V.4
Medicare Physician/Supplier Claims Assignment Rates

	2005	2010	2012	2013	2014	2015
			In millions			
Claims total	951.6	972.7	1,003.2	994.6	990.4	997.7
Claims assigned	940.7	965.7	997.4	989.2	985.4	993.1
Claims unassigned	10.9	7.0	5.8	5.4	5.0	4.7
Percent assigned	98.9	99.3	99.4	99.5	99.5	99.5

NOTE: Calendar year data (Railroad Board, A/B MACs (B), DME MACs).

SOURCE: CMS, Center for Medicare.

Table V.5
Medicare Claims Processing

	Fiscal Year 2015
Part A claims processed in millions	213.3
Part B claims processed in millions[1]	1,009.2

[1]Includes replicate claims.

SOURCE: CMS, Center for Medicare.

Table V.6
Medicare Claims Received

	Claims received
A/B MAC (A) claims received in millions	214.1
	Percent of total
Inpatient hospital	7.0
Outpatient hospital	59.7
Home health agency	7.1
Skilled nursing facility	2.7
Other	23.5
A/B MAC (B) claims received in millions	997.7
	Percent of total
Assigned	99.5
Unassigned	0.5

NOTE: Data for calendar year 2015.

SOURCE: CMS, Center for Medicare.

Table V.7
Medicare Charge Reductions

	Assigned	Unassigned
Claims approved		
Number in millions	904.8	4.0
Percent reduced	96.4	83.5
Total covered charges		
Amount in millions	$371,731	$506
Percent reduced	64.2	23.0
Amount reduced per claim	$263.57	$29.05

NOTES: Data for calendar year 2015. As a result of report changes effective April 1, 1992, charge reductions include: reasonable charge, medical necessity, and global fee/rebundling reductions.

SOURCE: CMS, Center for Medicare.

Table V.8
Medicaid Administration

	Fiscal Year	
	2014	2015
	In millions	
Total payments computable for Federal funding[1]	$24,418	$25,603
Federal share[1]		
Family Planning	30	28
Design, development or installation of MMIS[2]	663	806
Skilled professional medical personnel	487	462
Operation of an approved MMIS[2]	1,569	1,783
All other	12,359	13,139
Mechanized systems not approved under MMIS[2]	85	153
Total Federal Share	$15,193	$16,371
Net adjusted Federal share[3]	$14,675	$15,954

[1]Source: Form CMS-64. (Net Expenditures Reported—Administration).

[2]Medicaid Management Information System.

[3]Includes CMS adjustments.

SOURCE: CMS, Office of Enterprise Data and Analytics.

Reference

Selected reference material including program financing, cost-sharing features of the Medicare program, and Medicaid Federal medical assistance percentages

Program Financing, Cost Sharing and Limitations

Medicare/Source of Income

Medicare Part A

Hospital Insurance trust fund:

1. Payroll taxes*
2. Income from taxation of Social Security benefits
3. Transfers from Railroad Retirement account
4. General revenue for uninsured persons and military wage credits
5. Premiums from voluntary enrollees
6. Interest on investments

*Contribution rate	2015	2016	2017
	Percent		
Employees and employers, each	1.45	1.45	1.45
Self-employed	2.90	2.90	2.90

Maximum taxable amount (CY 2017)	None[1]
Voluntary HI monthly premium[2]	$413.00

Part A (effective date)	**Amount**
Inpatient hospital deductible (1/1/17)	$1,316/benefit period
Regular coinsurance days (1/1/17)	$329/day for 61st through 90th day
Lifetime reserve days (1/1/17)	$658/day (60 non-renewable days)
SNF coinsurance days (1/1/17)	$164.50/day for 21st through 100th day
Blood deductible	first 3 pints/calendar year
Voluntary hospital insurance premium (1/1/17)[2]	$413/month; $227/mo. with 30-39 quarters of coverage
Limitations:	
Inpatient psychiatric hospitals	190 nonrenewable days

[1]The Omnibus Reconciliation Act of 1993 eliminated the Annual Maximum Taxable Earnings amounts for 1994 and later. For these years, the contribution rate is applied to all earnings in covered employment.

[2]Premium paid for voluntary participation of individuals aged 65 and over not otherwise entitled to hospital insurance and certain disabled individuals who have exhausted other entitlement. A reduced premium of $227 is available to individuals aged 65 and over who are not otherwise entitled to hospital insurance but who have, or whose spouse has or had, 30-39 quarters of coverage under Title II of the Social Security Act.

SOURCE: CMS, Office of the Actuary.

Program Financing, Cost Sharing and Limitations

Medicare Part B

Supplementary Medical Insurance trust fund:
1. Premiums paid by or on behalf of enrollees
2. General revenue
3. Interest on investments

Part B (effective date)	**Amount**
Deductible (1/1/17)	$183 in allowed charges/year
Blood deductible	first 3 pints/calendar year
Coinsurance[1]	20 percent of allowed charges
Monthly standard premium (1/1/17)	$134/month
Limitations:	
Outpatient treatment for mental illness	No limitations

[1]The Part B deductible and coinsurance applies to most services. Items and/or services not subject to either the deductible or coinsurance are clinical diagnostic lab tests subject to a fee schedule, home health services, items and services furnished in connection to obtaining a second or third opinion, and some preventive services.

SOURCE: CMS, Office of the Actuary.

Medicare Part B (continued)

Listed below are the 2017 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $107,000	Greater than $170,000 and less than or equal to $214,000	$53.50	$187.50
Greater than $107,000 and less than or equal to $160,000	Greater than $214,000 and less than or equal to $320,000	$133.90	$267.90
Greater than $160,000 and less than or equal to $214,000	Greater than $320,000 and less than or equal to $428,000	$214.30	$348.30
Greater than $214,000	Greater than $428,000	$294.60	$428.60

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse are listed below:

Married beneficiaries who lived with their spouse and filed a separate tax return:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$134.00
Greater than $85,000 and less than or equal to $129,000	$214.30	$348.30
Greater than $129,000	$294.60	$428.60

SOURCE: CMS, Office of the Actuary.

Medicare Part D Standard Benefits

Deductible (1/1/2017)	$400 in charges/year
Initial coverage limit (1/1/2017)	$3,700 in charges/year
Out-of-pocket threshold (1/1/2017)	$4,950 in charges/year
Base beneficiary premium (1/1/2017)[1]	$35.63/month

Medicaid Financing

1. Federal contributions (ranging from 50 to 75 percent for fiscal year 2017)
2. State contributions (ranging from 25 to 50 percent for fiscal year 2017)

[1]The base beneficiary premium was calculated based on a national average plan bid. The actual premium that a beneficiary pays varies according to the plan in which the beneficiary is enrolled.

NOTES: The beneficiaries who qualify for the low-income subsidy under Part D pay a reduced or zero premium. In addition, low-income beneficiaries are subject to only minimal copayment amounts in most instances.

SOURCE: CMS, Office of the Actuary.

Geographical Jurisdictions of CMS Regional Offices and Federal Medical Assistance Percentages (FMAP) Fiscal Year 2017

I. Boston	FMAP
Connecticut	50.00
Maine	64.38
Massachusetts	50.00
New Hampshire	50.00
Rhode Island	51.02
Vermont	54.46

III. Philadelphia	
Delaware	54.20
Dist. of Columbia	70.00
Maryland	50.00
Pennsylvania	51.78
Virginia	50.00
West Virginia	71.80

V. Chicago	
Illinois	51.30
Indiana	66.74
Michigan	65.15
Minnesota	50.00
Ohio	62.32
Wisconsin	58.51

VII. Kansas City	
Iowa	56.74
Kansas	56.21
Missouri	63.21
Nebraska	51.85

IX. San Francisco	
Arizona	69.24
California	50.00
Hawaii	54.93
Nevada	64.67
American Samoa	55.00
Guam	55.00
N. Mariana Islds	55.00

II. New York	FMAP
New Jersey	50.00
New York	50.00
Puerto Rico	55.00
Virgin Islands	55.00

IV. Atlanta	
Alabama	70.16
Florida	61.10
Georgia	67.89
Kentucky	70.46
Mississippi	74.63
North Carolina	66.88
South Carolina	71.30
Tennessee	64.96

VI. Dallas	
Arkansas	69.69
Louisiana	62.28
New Mexico	71.13
Oklahoma	59.94
Texas	56.18

VIII. Denver	
Colorado	50.02
Montana	65.56
North Dakota	50.00
South Dakota	54.94
Utah	69.90
Wyoming	50.00

X. Seattle	
Alaska	50.00
Idaho	71.51
Oregon	64.47
Washington	50.00

NOTE: FMAPs are used in determining the amount of Federal matching funds for State expenditures for assistance payments.

SOURCE: DHHS, Office of the Assistant Secretary for Planning and Evaluation.

U.S. Department of Health & Human Services
Centers for Medicare & Medicaid Services
Office of Enterprise Data and Analytics
CMS Pub. No. 03513 March 2017

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

HRSA
Health Resources and Services Administration

Table of Contents

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 (AACP) 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.

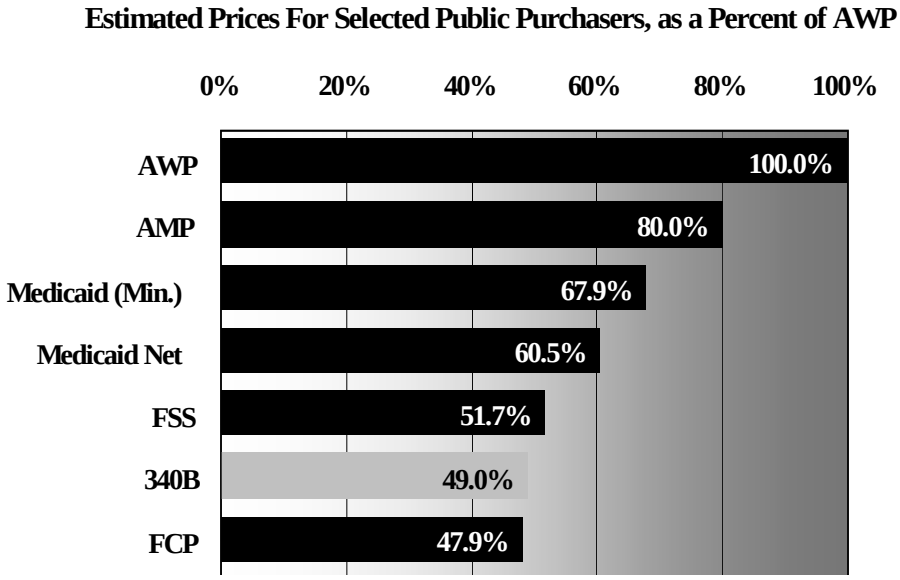
The guidelines in Appendix C cover the following topics:

- 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.



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 HTCs 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 confidentially 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, HTCs 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. HTCs in 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 superceded 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 HTCs do not provide funds for purchasing and dispensing FRP. This is an activity that many HTCs 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 HTCs. 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 l927 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 l927 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, l992. 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, l992) 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, l992, 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, l992, 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, l992, 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, l992, 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 propriety 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.]

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*,	)	
Plaintiffs,	)	
v.	)	No. 1:18-cv-02084-RC
ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services, *et al.*,	)	
Defendants.	)	

[PROPOSED] ORDER

The Court having considered Defendants' Motion to Dismiss, Plaintiffs' Motion for Preliminary Injunction, and the parties' submissions relating thereto, it is hereby

ORDERED that Defendants' Motion is GRANTED. It is further

ORDERED that Plaintiffs' Motion is DENIED. It is further

ORDERED that the Complaint is DISMISSED.

SO ORDERED.

_____
HON. RUDOLPH CONTRERAS
United States District Judge

DATED: