Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

REVIEW OF 340B PRICES

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EXECUTIVE SUMMARY

OBJECTIVE

To determine whether entities participating in the 340B Drug Pricing Program pay more than the statutorily defined 340B ceiling prices and, if so, the potential reasons for price discrepancies.

BACKGROUND

Section 340B of the Public Health Service Act (PHS Act) established the 340B Drug Pricing Program (340B Program), which requires pharmaceutical manufacturers to charge at or below statutorily defined prices, known as the 340B ceiling prices, to qualified entities (340B entities), including community health centers, public hospitals, and various Federal grantees. Since 340B ceiling prices are based on confidential pricing data, they are not disclosed to 340B entities, leaving the entities unable to determine if the prices they pay are higher than the 340B ceiling prices. The Health Resources and Services Administration (HRSA) is responsible for monitoring compliance with the 340B Program. Previous Office of Inspector General (OIG) studies have determined that HRSA does not systematically ensure that entities receive the prices to which they are entitled.

Our analysis compares the prices paid by 70 sampled 340B entities during a randomly selected month—June 2005—to 340B ceiling prices as calculated by HRSA and adjusted, where necessary, by OIG. These 70 340B entities made an estimated 229,796 total purchases during that month.

FINDINGS

In June 2005, 14 percent of total purchases made by 340B entities exceeded the 340B ceiling prices, resulting in total overpayments of $3.9 million. Fourteen percent, or one in seven, of the total projected 340B purchases made in June 2005 exceeded the 340B ceiling prices, resulting in a projected overpayment of $3.9 million for that month. Sixty-eight of the seventy sampled entities overpaid on at least one purchase. Overpayments made by these 68 entities were mostly modest, but there were a few exceptionally large overpayments.

The largest overpayments in our sample resulted from inappropriate handling of negative ceiling prices. The largest overpayments in our sample were due to prices that did not follow HRSA's "penny price" policy in situations to which applying the statutory 340B ceiling price

calculation yielded a negative number. In these cases, rather than paying a penny per unit, as directed by HRSA, entities paid anywhere from $1.65 to $1,931 per purchase over the ceiling price.

Patterns in our sample suggest that overpayments varied by the volume of 340B purchases or sales associated with entities, manufacturers, and wholesalers. In our sample, we found that most 340B entities, manufacturers, and wholesalers were involved in transactions that resulted in overpayments. However, when grouped by volume of purchases or sales, we found that low-volume entities, manufacturers, and wholesalers were associated with higher rates of overpayments.

Inaccuracies in HRSA's ceiling prices limit its ability to monitor 340B program compliance. Our analysis of the data HRSA used to calculate 340B ceiling prices for June 2005 revealed that some data on unit of measure and package size are inconsistent and, therefore, resulted in incorrect 340B ceiling prices for certain drugs in HRSA's pricing file. If HRSA were to conduct audits using these data to calculate ceiling prices, it would not be able to correctly identify or quantify overpayments.

RECOMMENDATIONS

HRSA should improve its oversight of the 340B Program to ensure that entities are charged at or below the 340B ceiling price. To ensure that entities do not pay more than the 340B ceiling prices, we continue to support our prior recommendations that HRSA improve its oversight of the 340B program by more closely monitoring the prices 340B entities are charged, by officially comparing its 340B ceiling prices to manufacturers' calculations to detect discrepancies, and by establishing penalties for PHS Act violations. HRSA could also work to ensure uniform and timely transmission of 340B ceiling prices by taking responsibility for disseminating a single verified list of its 340B ceiling prices to wholesalers.

HRSA should provide technical assistance regarding 340B Program implementation to all participating entities, manufacturers, and wholesalers. HRSA should provide 340B entities, manufacturers, and wholesalers with information about 340B Program requirements and policies to improve compliance among all participants. HRSA may also want to consider providing further assistance to specific entities, manufacturers, and wholesalers with low-volume purchases and sales.

Finally, as the marketplace continues to evolve, HRSA may want to consider formulating outreach programs to orient new entities, manufacturers, and wholesalers to the 340B Program.

HRSA should publish guidance regarding its penny price policy. HRSA should publish guidance alerting manufacturers to its current penny price policy, which instructs manufacturers to charge a penny multiplied by the drug's package size when faced with a negative 340B ceiling price. Since the largest identified overpayments were due to noncompliance with this policy, reinforcing the directive through publicly available guidance could have a significant impact on reducing overpayments with minimal effort.

To accurately calculate 340B ceiling prices, HRSA should obtain data on consistent unit of measure and package size. HRSA's ability to correctly calculate 340B ceiling prices depends on the consistency of the data related to unit of measure and package size. To ensure that these data are uniform, we suggest that HRSA work with the Centers for Medicare & Medicaid Services to identify incongruent data on unit of measure. HRSA must also develop protocol to identify and correct inaccurate package size data to ensure correct 340B ceiling prices.

AGENCY COMMENTS

HRSA concurred with each of our recommendations. The complete text of HRSA's comments can be found in Appendix D.

In response to our recommendation to improve oversight of the 340B Program, HRSA stated that it has taken steps to more closely monitor the prices paid by 340B entities. HRSA also agreed that, despite its limited resources, it will manage and coordinate the technical assistance efforts for the 340B Program, including special efforts to target new and smaller-volume purchasers of drugs. HRSA stated that it anticipates promulgating a penny price policy in conjunction with formalizing the instructions for the calculation of 340B ceiling prices. Finally, HRSA concurred with our final recommendation that it obtain consistent unit of measure and package size data.

OFFICE OF INSPECTOR GENERAL RESPONSE

We believe that the steps HRSA outlined in response to our recommendations will improve program oversight and the accuracy of 340B ceiling prices. We do, however, continue to encourage HRSA to

work toward a comprehensive comparison of its 340B ceiling prices to all manufacturers' data. We also maintain that HRSA should develop a systematic process to detect and resolve unit of measure and package size issues with its ceiling price data to ensure accurate 340B ceiling prices.

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INTRODUCTION

OBJECTIVE

To determine whether entities participating in the 340B Drug Pricing Program pay more than the statutorily defined 340B ceiling prices and, if so, the potential reasons for price discrepancies.

BACKGROUND

The 340B Drug Pricing Program (340B Program) resulted from the enactment of the Veterans Health Care Act of 1992 and is codified at section 340B of the Public Health Service Act (PHS Act).[1] The 340B Program requires manufacturers to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of the Department of Health and Human Services.[2] Under the 340B Program and in accordance with the PPA, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for sales to certain qualified entities.[3] The 340B entities spent an estimated $3.4 billion on covered outpatient drugs in calendar year 2003.[4] The Health Resources Services Administration (HRSA) oversees the 340B Program, which includes monitoring the PPA.

The 340B Drug Pricing Program

Section 340B(a)(4) of the PHS Act lists the types of entities eligible to participate in the 340B Program.[5] Eligible 340B entities include community health centers, Ryan White grantees, and disproportionate share hospitals, among others (for a complete list, see Appendix A). As of April 2006, more than 12,300 entities were enrolled in the 340B Program.[6]

Participation in the 340B Program is voluntary; eligible entities must notify HRSA of their intention to participate by completing appropriate registration forms.[7] Upon receipt and approval of the forms, HRSA adds the entity to its Covered Entity database, which is available on HRSA's Web site.[8] The 340B entity is responsible for alerting wholesalers and manufacturers of its participation and referring them to the database for confirmation so it can purchase covered outpatient drugs at or below the ceiling prices.[9] Manufacturers and wholesalers access this database to verify an entity's eligibility for the 340B Program and use the contact information for shipping and billing purposes. Once registration is completed and eligibility is approved, the entity can purchase covered outpatient drugs at or below 340B ceiling prices beginning the next calendar quarter.[10]

Pursuant to section 340B(a)(8) of the PHS Act,[11] HRSA established a prime vendor program to facilitate the delivery of covered drugs. HRSA's 340B Prime Vendor Program, managed by Healthcare Purchasing Partners International, serves its participants in three primary ways: negotiating discounts below 340B ceiling prices, establishing distribution solutions and networks that improve access to affordable medications, and providing other services designed to simplify participation in the 340B Program. Participation in the 340B Prime Vendor Program is voluntary and cost-free to entities. To date, nearly 2,400 340B entities participate in the program.[12]

Manufacturers are responsible for calculating 340B ceiling prices and ensuring that 340B entities are charged at or below 340B ceiling prices for their drug purchases, regardless of whether the 340B entity purchases drugs directly from the manufacturer or through a wholesaler. Section 340B(a)(10) of the PHS Act[13] provides that nothing shall prohibit a manufacturer from charging less than the ceiling price for a drug. If a manufacturer fails to abide by the 340B Program requirements, it may be required to reimburse the 340B entity for discounts withheld and can be terminated from the 340B Program. Further, a manufacturer that lacks a PPA will fail to meet the requirements of the Medicaid drug rebate program and its products will not be eligible for Federal Medicaid reimbursements.[14]

If a manufacturer's drugs are available to entities through wholesalers, the 340B discount must be made available through that avenue.[15] In other words, the wholesalers, acting on behalf of the manufacturers, must pass the 340B ceiling prices through to 340B entities. Currently, three large wholesalers, categorized as primary wholesalers, carry nearly all types of pharmaceutical products and handle approximately 90 percent of pharmaceutical product distribution in the United States.[16] The remaining 10 percent of drugs are delivered by secondary wholesalers, which serve smaller areas than primary wholesalers and may deliver a more limited line of pharmaceuticals. Both primary and secondary wholesalers must pass along 340B ceiling prices to the 340B entities, but are allowed to charge an administrative and/or distribution fee based on negotiations with the individual entities.

340B Ceiling Price Formula

The 340B ceiling prices are calculated according to a formula that is based on information generated in connection with the Medicaid drug rebate program. In that program, manufacturers are required to report

to the Centers for Medicare & Medicaid Services (CMS) each quarter the average manufacturer price (AMP) for each of their drugs.[17] CMS uses AMP and other data to calculate a unit rebate amount (URA) that serves as a basis for the rebate amounts paid by manufacturers.[18] The 340B ceiling price is based on these components and is essentially equal to the AMP reduced by the URA.[19]

The AMP and URA used in the 340B ceiling price formula are based on the smallest dispensable unit of each drug, such as a tablet, capsule, or milliliter. Therefore, taken literally, the ceiling price applies to each unit of the drug that the entity purchases—for example, $1 per pill.

To implement the 340B ceiling price requirement, the per-unit ceiling price must be multiplied by the drug package size in which entities purchase drugs—for example, a bottle of 100 tablets versus individual tablets. The 340B ceiling prices per package are calculated as follows:

[(AMP) - (URA)] * drug's package size

Occasionally, a drug's URA is greater than its AMP, resulting in a negative ceiling price.[20] Therefore, to convert negative prices to practical prices, HRSA developed the penny price policy, which advises manufacturers to charge entities one penny per unit in these situations.[21]

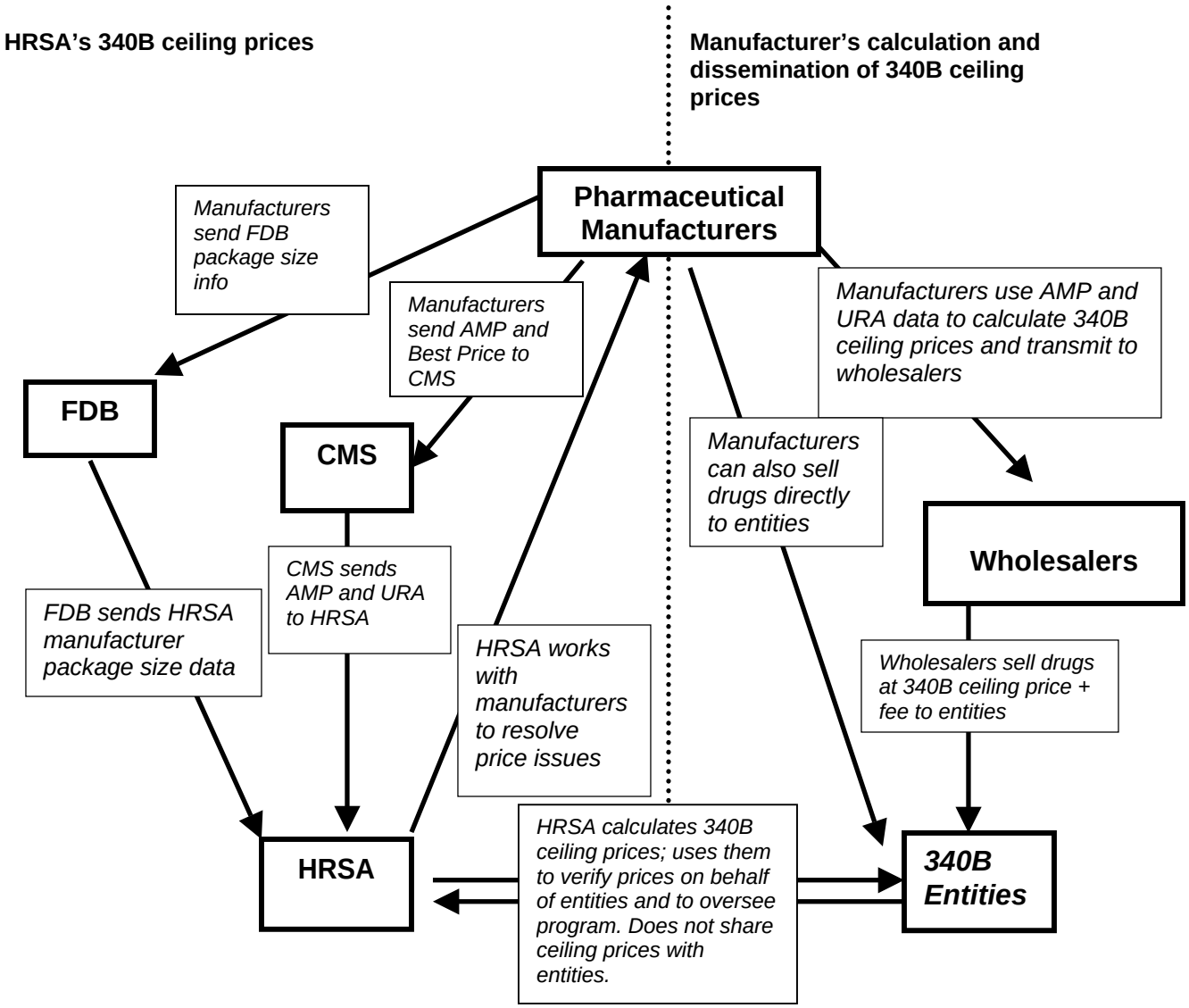
HRSA and Manufacturers' Use of 340B Ceiling Prices

Pharmaceutical manufacturers and HRSA calculate 340B ceiling prices every quarter. Pharmaceutical manufacturers use their calculated 340B ceiling prices in sales to 340B entities, but they are not required to report these prices to HRSA. Therefore, for oversight purposes, HRSA must calculate 340B ceiling prices as well.

To calculate 340B ceiling prices, HRSA receives the AMP and URA from CMS each quarter under the terms of an Intra-Agency Agreement. As explained above, CMS receives the manufacturers' pricing data for the Medicaid drug rebate program and calculates a URA. Under a separate contract, HRSA obtains the package size information needed to calculate 340B ceiling prices from First DataBank (FDB), a contracted provider of drug product information. HRSA assumed responsibility for calculating the 340B ceiling price in October 2005. Previous to this, CMS had calculated the 340B ceiling price and transmitted it to HRSA

each quarter. Chart 1 illustrates the calculation and use of 340B ceiling prices by HRSA and manufacturers.

CHART 1: 340B PRICING DATA AND PURCHASE FLOW



Confidentiality of 340B Ceiling Prices

The Medicaid drug rebate program statute, at Section 1927(b)(3)(D) of the Social Security Act, specifies that AMP and certain other pricing information "…shall not be disclosed by" the Department "in a form which discloses the identity of a specific manufacturer or wholesaler, [or] the prices charged for drugs" except as necessary to carry out the provisions of the Act or for certain other limited purposes. Due to this

provision, 340B entities have not had access to AMPs or to the calculated 340B ceiling prices, rendering them unable to check whether they paid more than the 340B ceiling prices. HRSA reports that it has, when requested, compared a sample of prices paid by entities to its 340B ceiling prices for a "market basket" of products, typically around 10 products, to check for discrepancies. Yet, since HRSA cannot disclose any information related to the ceiling prices, its response to the entity is limited to a discussion of how the entity's prices compared to the 340B ceiling price in the aggregate.

The Deficit Reduction Act of 2005 (DRA) requires certain disclosures of AMPs. Section 6001(b) of the DRA requires CMS to make AMPs available to State Medicaid programs monthly and to the public quarterly through its Web site beginning July 1, 2006. On May 22, 2006, however, CMS stated that it would not publicly release the current AMP figures, but instead would focus on developing a revised definition of AMP and AMP data based on the new definition for public disclosure.[22] It is unclear when this revised definition and data will be released or whether it will be useful for 340B entities in evaluating the appropriateness of the prices they are charged.

Related OIG Work

In June 2004, OIG issued "Deficiencies in the 340B Drug Pricing Program's Database" (OEI-05-02-00071), which reviewed the quality and timeliness of HRSA's database containing information on 340B participating entity enrollment. We found the enrollment database to be a poor source of contact and participation information for 340B entities and we recommended that HRSA develop a strategic plan for improved management of the 340B database. In response, HRSA has made significant improvements to its Covered Entity database, including the deletion of several nonparticipants and the recertification of more than 7,500 participating entities.

In October 2005, OIG issued "Deficiencies in Oversight of the 340B Drug Pricing Program" (OEI-05-05-00072), which assessed HRSA's oversight capacities. We found that due to systemic problems with the accuracy and reliability of HRSA's record of 340B ceiling prices, HRSA is unable to appropriately oversee the 340B Program. We also found that HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below 340B ceiling prices.

Based on these findings, we recommended that HRSA establish detailed standards for its calculation of 340B ceiling prices and institute

oversight mechanisms to validate its 340B ceiling prices and the prices charged to entities. We also recommended that CMS and HRSA work together to ensure the availability of accurate and timely pricing data for 340B ceiling prices. Finally, we recommended that HRSA seek legislative authority to establish penalties for PHS Act violations.

HRSA agreed with most of our recommendations and has already addressed many of the issues we raised. For example, HRSA is comparing its 340B ceiling prices to a subset of manufacturers' voluntarily submitted ceiling prices each quarter.

METHODOLOGY

To determine whether entities participating in the 340B Program pay more than the statutorily defined 340B ceiling prices, we compared the prices that a sample of 340B entities paid over a randomly selected month to the 340B ceiling price as calculated by HRSA and adjusted, where necessary, by OIG.

We randomly selected one month—June 2005—from the first 2 quarters of 2005, as these were the most recent data available. According to HRSA, pricing information is often delayed at the beginning of a new quarter as manufacturers update 340B prices; therefore, we excluded the first month of each quarter from selection. As such, our final conclusions apply only to the selected month, June 2005.

Below we provide an overview of our sampling, data collection, and analysis. For more details, see Appendix B.

Entity Sample Selection

To select our sample of entities, we accessed HRSA's Covered Entity database, available on its Web site. Although our 2003 report cited deficiencies in this database, it is the only official source from which to sample 340B entities. In addition, based on our recommendations, HRSA made some improvements to the database, as mentioned above. Finally, we did some additional verification of the data prior to selecting our sample. At the time we selected the sample, April 2005, the database included 11,947 entities.

Based on interviews with HRSA and several entity advocacy groups, we excluded certain entity types from our population.[23] We excluded 340B entities that regularly purchase drugs using other discount mechanisms, such as the discounts available via the Federal Supply Schedule or Title X. We also excluded 340B entities that purchase a

very low volume of drugs. These exclusions eliminated a total of 7,707 entities, giving us a population of 4,240 entities.

Because the 340B Program requires each location that receives 340B Program drug shipments to be registered individually in HRSA's Covered Entity database, the database includes multiple entity listings associated with the same organization. A 340B entity is often a grantee that has several satellite sites. The primary site purchases, pays for, and distributes drugs to be used in the satellite sites. We identified and linked related entities because we wanted our sampling units to be entities that purchase drugs either for themselves or on behalf of satellite sites. From the universe of 4,240 entities, our efforts to link related entities produced our final population of 1,708 primary sites, which we refer to as "purchasing agents".[24] For the purpose of this study, we refer to the purchasing agent and the satellite sites as a single 340B entity.

We next selected a stratified random sample of 98 entities. We stratified based on characteristics we believed might be related to price discrepancies: entity type and purchasing method. The resulting sample included five strata, described in Table 1.

Table 1. Stratification of 340B Entities

Strata	Entity Types Within Stratum	Reason for Stratum	Population Size	Sample Size
Direct Purchasers: Stratum 1	Disproportionate Share Hospitals	High pharmacy volume and sophisticated purchasing process	484	30
Direct Purchasers: Stratum 2	Consolidated Health Centers and Federally Qualified Health Centers	Diversity of products but at a lower volume than hospitals	620	30
Direct Purchasers: Stratum 3	Hemophilia Treatment Centers	Specific, expensive products, including anticlotting factor	43	8
Direct Purchasers: Stratum 4	Ryan White Title I, Ryan White Title II (ADAP Direct Purchasers), and Ryan White Title III	Slightly more diverse range of products than hemophilia treatment centers purchased for a specific population	137	10
Contracted Pharmacy Arrangement Purchasers: Stratum 5	All	Complicated distribution arrangements	424	20
		Total	**1,708**	**98**

Prior to data collection, we eliminated four entities in our sample that were located in Mississippi and Louisiana, because their operations may have been disrupted by Hurricane Katrina. This elimination reduced our sample of entities to 94. We contacted each of the 94 entities to verify contact information and to confirm participation, and found that only 73 of the 94 entities were actually participating in the 340B Program. In other words, 21 of the entities in our sample (which purchased on behalf of 32 individual entities) do not participate in 340B or were not participating in June 2005, even though they were included in HRSA's database of participants. The exclusion of these 21 entities reduced our number of eligible respondents from 94 to 73.

Data Collection

Entity invoice data. We requested that the 73 sampled 340B entities supply copies of invoices for purchases made over the sampled month and respond to an online survey regarding their purchasing process to provide context to the invoices. We informed sampled entities that we would need to capture information for our analysis based on the National Drug Code (NDC) from the Food and Drug Administration. The NDC is a three-segment universal product identifier that specifies the drug's manufacturer, product name, and package size. We received complete and usable submissions from 70 purchasing agents, which represented the purchases made on behalf of 165 individual sites listed in HRSA's database. Detailed information on response rate is included in Appendix B.

340B ceiling prices. To obtain the 340B ceiling prices used in June 2005, we requested and received the complete ceiling price file from HRSA for the relevant quarter.[25]

During our quality assurance review of HRSA's 340B ceiling prices, we discovered disparities between CMS and pharmaceutical industry standards for describing a drug's unit of measure and package size, which led to incorrect HRSA 340B ceiling prices for certain drugs. We reviewed 372 NDCs and adjusted the 340B ceiling prices on 164 NDCs. Therefore, for the purpose of our analysis, 340B ceiling prices reflect HRSA's submitted ceiling prices, with OIG adjustments for 164 NDCs. Further details on our process for detecting and resolving issues with HRSA's ceiling prices can be found in Appendix B.

Analysis

To conduct our analysis, we first calculated a unit difference amount by subtracting the 340B ceiling prices per unit from the unit prices paid by the entity, without accounting for quantity. In making this comparison, we considered the invoice price to be the same as the 340B ceiling price as long as it was within $0.01 of the ceiling price. This margin of error allowed us to disregard differences solely due to rounding. Per CMS guidelines, the AMP and URA calculations, and therefore the 340B ceiling prices as well, may be calculated to the fifth decimal place.[26] However, 340B entity prices reflect actual transactions, which are reported only to the second decimal place on the invoices.

In making our comparisons, we did not account for the addition or reduction of any wholesaler's fees or discounts since they were considered separate from the cost of the drug. Although it is reasonable to assume that the addition of a middleman would increase the entity's costs, of the 66 entities (out of 72 survey respondents) that provided us with information on wholesaler's fees, only 5 reported paying an administrative fee to the wholesaler which was considered separate from the cost of the drugs. More commonly, entities (23) reported receiving a volume-based discount from their wholesalers ranging from 1 to 3 percent below the ceiling price.

For the purpose of this study, we classified each of these unit comparisons as a single purchase. The term "purchase" reflects the single purchase of each package of product whether the entity purchased multiple quantities of the product at the same time or just a single package. For example, whether the entity purchased 10 packages of Drug A at 1 time or 1 package 10 separate times, both cases counted as 10 purchases. To compute the total financial impact of differences, we multiplied the unit price difference per purchase by the total quantity the entity reported ordering.

Our analysis only included line items for which the quantity shipped and the unit prices were greater than zero. It also excluded NDCs for which HRSA did not calculate a unit price because the AMP and/or URA was missing.[27]

We included 100 percent of purchases from 63 entities' invoices, as they were submitted electronically or were paper submissions that could reasonably be entered manually. Seven of the entities' paper submissions could not reasonably be manually entered, so we entered a simple random sample of their purchases. The number of purchases

entered into our database was 202,251. When the purchases reported by these 7 entities are appropriately weighted, our final conclusions relate to 229,796 purchases and 5,331 unique NDCs.

Pattern Analysis

To assess potential reasons for price discrepancies, we examined our sample to look for characteristics associated with overpayments. We considered whether overpayments occurred more often for transactions involving specific entities, manufacturers, or wholesalers. We also looked at whether specific drugs were associated more often with overpayments. We looked at volume of sales or purchases in light of the common business practice of manufacturers and wholesalers offering volume-based discounts to purchasers. To do this, we grouped entities, manufacturers, and wholesalers in clusters by volume, maintaining appropriate proportions given the range of each group's purchases or sales.

Projections

Due to issues with assigning appropriate strata,[28] as well as identifying 340B entities, we were prevented from projecting our findings by stratum. Our estimates of total 340B entity overpayments and total 340B entity spending are projected from our overall sample to the population of 1,708 purchasing agents that purchase on behalf of 4,240 entities listed in HRSA's database.

However, most of the analysis presented in this report relates only to our sample and is not projected to the population of 340B entities. We analyzed these data by purchase, by entity, and by NDC. We also analyzed the data by manufacturers and wholesalers who sold drugs to the 340B entities in our sample. The results from this analysis relate only to our sample and cannot be projected to the universe of manufacturers or wholesalers. Where appropriate, we tested differences we found in our sample for statistical significance.

Standards

This study was conducted in accordance with the "Quality Standards for Inspections" issued by the President's Council on Integrity and Efficiency and the Executive Council on Integrity and Efficiency.

In June 2005, 14 percent of total purchases made by 340B entities exceeded the ceiling price, resulting in total overpayments of $3.9 million

Fourteen percent, or one in seven, of the total projected 340B purchases in June 2005 exceeded 340B ceiling prices. Eighty-six percent of the purchases met the statutory requirement to be either at or below 340B ceiling prices. The 14-percent error rate corresponds to a total projected overpayment of $3.9 million (+/- $1.9 million at the 95-percent confidence level) for that month. We estimate that our population of 1,708 purchasing agents, representing 4,240 sites, spent an estimated $445 million on drugs during June 2005. Thus, the overpayments of $3.9 million represent slightly less than 1 percent of total spending.

Because 340B ceiling prices represent the maximum amount an entity should pay for drugs, any amounts over the ceiling prices are noncompliant with the requirements of the 340B Program. Congress intended the 340B Program to help "stretch Federal resources as far as possible, to reach more eligible patients and provide more comprehensive services."[29] The $3.9 million overpaid for this 1 month might instead have been used to lower the cost of acquiring additional drugs to serve indigent patients at low or no cost.

Overpayments by 340B entities may also result in financial loss to State Medicaid agencies. Because 340B entities may also serve patients covered by the Medicaid program, they can elect to charge the State at 340B prices for drugs dispensed to these beneficiaries if the State does not also collect Medicaid drug program rebates for the same drugs.[30] In fact, 37 of the sampled entities reported that they pass on the 340B price to the States instead of charging at the States' usual Medicaid rate.[31] Thus, when an entity pays in excess of the ceiling price, it may be unknowingly passing on an inflated price to the State.

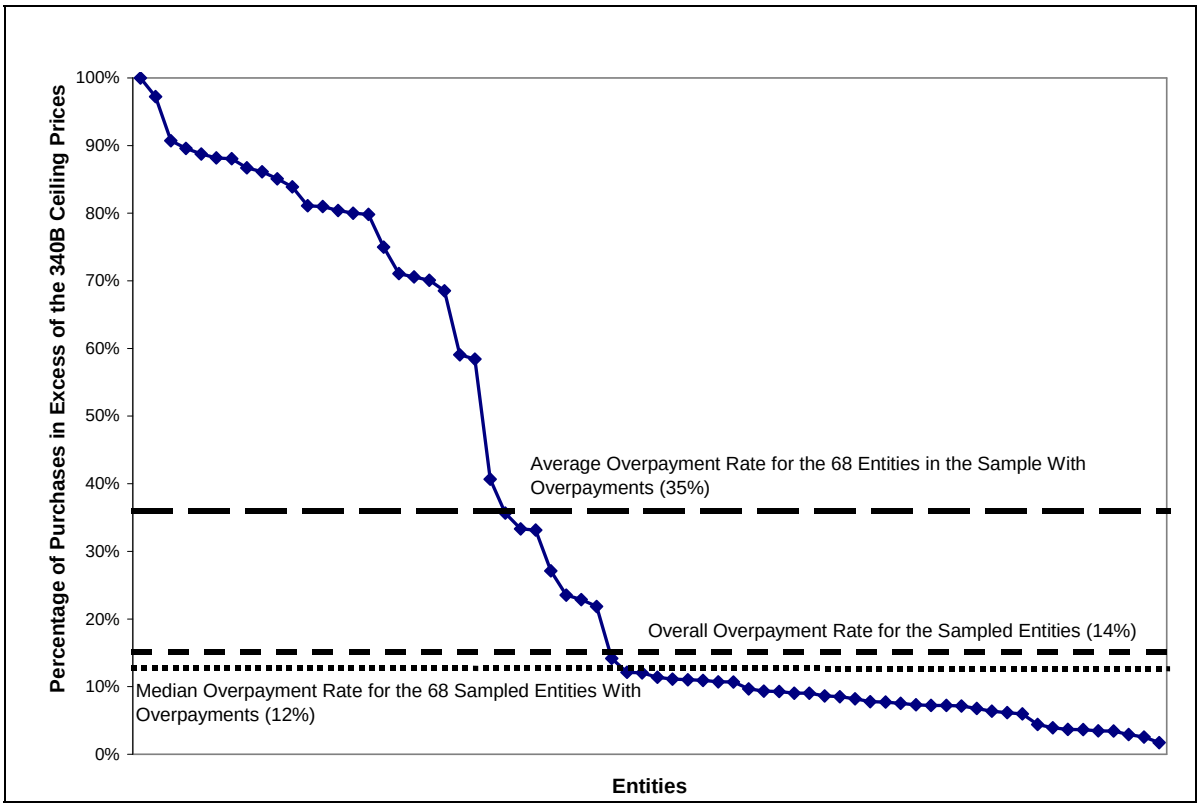
Sixty-eight of the seventy sampled entities overpaid on at least one purchase

Almost all 340B entities in our sample paid more than 340B ceiling prices at least once. Overall, 68 sampled entities paid more than the ceiling prices for between 2 and 100 percent of their total purchases. In terms of dollars, the total monthly overpayment range by entity ranged from $.51 to $36,730 over the ceiling prices. On average, 35 percent of

sampled entities' purchases in June 2005 exceeded the ceiling prices, with a median of 12 percent.

On the high end, however, 17 of the sampled entities paid above the 340B ceiling prices for 75 percent or more of their total purchases. One of these entities paid more than the ceiling prices on 100 percent of its purchases. The percentage of overpayments by entity is displayed in Chart 2.

CHART 2
Percentage of Purchases Overpaid for the 68 Sampled Entities With Overpayments



Source: Office of Inspector General analysis of sampled entities' invoices, 2006.

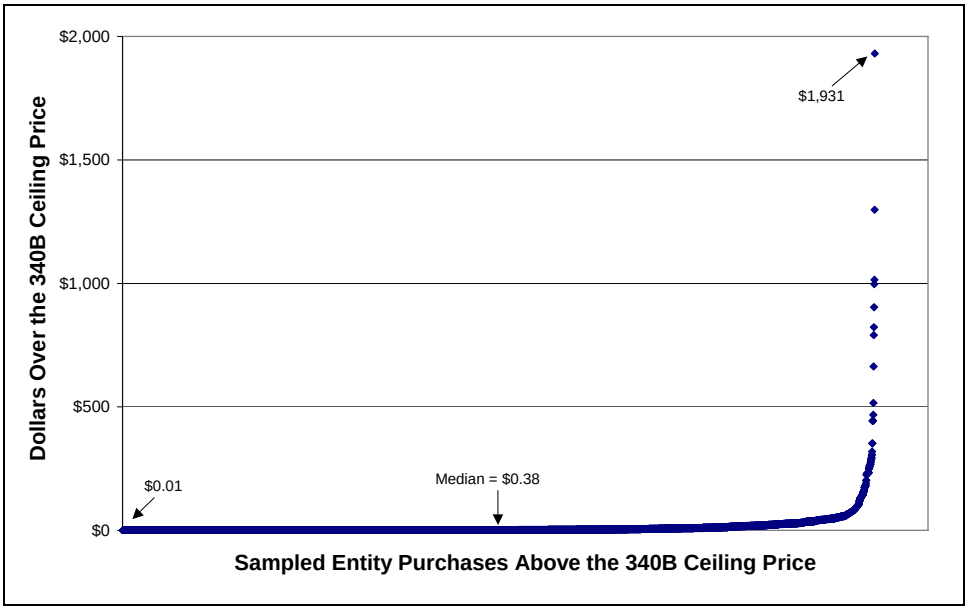
Overpayments by the sampled entities were mostly modest, with a few exceptionally large overpayments

Of the 32,201 purchases with associated overpayments, the extent to which they exceeded the 340B ceiling prices ranged broadly from less than 1 percent to 450,000 percent. However, the median overpayment was a modest 5 percent over the ceiling price. In fact, 72 percent of the overpayments in our sample exceeded the ceiling price by less than 25 percent.

In contrast, there were some large overpayments. Eighteen percent of the overpayments in our sample exceeded the 340B ceiling prices by more than 50 percent. For nearly 11 percent of overpayments, the purchase price exceeded the ceiling price by more than 100 percent. Finally, 3 percent of the entity overpayments exceeded the ceiling prices by more than 1,000 percent.

Overall, the dollar difference between the prices sampled entities paid per purchase and the respective ceiling prices ranged from $0.01 to almost $2,000. The median overpayment was $0.38. On the other hand, per-purchase overpayments in excess of $500 affected 27 purchases. Overpayments by sampled entities' purchases are displayed in Chart 3.

CHART 3
Dollars Paid Over the 340B Ceiling Prices for 229,796 Sampled Purchases



Source: Office of Inspector General analysis of sampled entities' invoices, 2006.

In our sample, the majority of purchases below the ceiling prices entailed modest discounts

Like the pattern of overpayments, entities' purchase prices that fell below the ceiling prices ranged widely. For the majority, the differences between purchase price and ceiling price were modest. In our sample, entities paid between less than 1 percent to almost 100 percent below 340B ceiling prices. However, the median discount off the ceiling prices was just 3 percent. In the aggregate, 75 percent of the payments below the ceiling price represented less than a 10-percent discount. On the

other hand, approximately 6 percent of the below-ceiling payments were more than 50 percent lower than the ceiling prices.

Overall, the dollar difference between the prices sampled entities paid and the respective ceiling prices ranged from $.01 below the ceiling prices per purchase to nearly $2,920 below per purchase. The median dollar difference between the entity price and the ceiling price was $1.54.

The largest overpayments in our sample resulted from inappropriate handling of negative ceiling prices

The largest overpayments within our sample were due to purchases for which the price did not reflect HRSA's "penny price" policy. In the 340B ceiling price calculation, occasionally the URA is greater than the AMP, resulting in a negative 340B ceiling price. This occurs when a manufacturer's reported AMP has increased faster than the rate of inflation, requiring it to pay an additional rebate amount. When the 340B calculation results in a negative price, HRSA has directed manufacturers to charge a penny per unit.

Of the 49 drugs in our sample for which the URA is greater than the AMP, the ceiling prices were not calculated according to HRSA's penny price policy for over half (27). In these cases, 340B entities paid anywhere from $1.65 to $1,931 per purchase over the 340B ceiling prices. These overpayments ranged from 1,790 to 450,000 percent over the 340B ceiling prices. It appears that instead of a price based on the penny price policy, entities were charged either at the retail price or at an approximation of the previous quarter's ceiling prices.

All purchase prices in excess of the ceiling prices by more than 100,000 percent were the result of noncompliance with the penny price policy. The discrepancies account for 7 percent of the sample's total overpayment of approximately $259,000. If purchases of the 27 drugs not in compliance were corrected to follow HRSA's penny price policy, the savings would equal $18,553 for the month for the sampled entities.

Although HRSA's penny price policy is not stated in statute or regulation, HRSA says that it has been verbally communicated to manufacturers and has been a routine practice since the program started. For slightly less than half of the drugs, penny prices were

correctly charged, indicating that some manufacturers and wholesalers are aware of and follow this policy.

Patterns in our sample suggest that overpayments varied by the volume of 340B purchases or sales associated with entities, manufacturers, and wholesalers

In our sample, we found that most entities, manufacturers, and wholesalers were associated with transactions resulting in overpayments. We also found that an overpayment by one entity for a particular drug did not mean that all entities overpaid for that drug. In fact, a drug sold to one entity at a price above the 340B ceiling price is often sold below the ceiling price to a different entity. Over 40 percent of the unique drugs in our sample that were sold at least once at a price above the 340B ceiling price were also sold at prices equal to or below the ceiling price.

Upon further examination of the sample, we identified patterns that may offer insights into some overpayments. When entities, manufacturers, and wholesalers were grouped by volume of purchases or sales, we saw consistent patterns associated with overpayments. In particular, the sampled data suggest that overpayments occurred more often in transactions involving entities, manufacturers, and wholesalers with lower volume of 340B sales or purchases. Although we expected higher-volume purchasers to negotiate larger volume-based discounts below the ceiling price and lower-volume entities to pay prices closer to the ceiling price, we did not anticipate that lower-volume entities would have more overpayments. It is possible that the low-volume entities, manufacturers, and wholesalers with limited involvement with the 340B Program may be less familiar with its requirements and policies, resulting in noncompliance.

Sampled entities with fewer 340B purchases paid more than the ceiling price for a higher percentage of purchases

In our sample, entities with fewer purchases for the month had a significantly higher percentage of purchases above 340B ceiling prices than entities that made a greater number of purchases. When grouped by purchase volume, distinct differences exist among the three categories of purchasers, as seen in Table 2 on the following page. These differences are statistically significant within our sample.

Table 2. Percentage of Purchases Over the 340B Ceiling Price by Volume of Entity Purchases

Number of Purchases	Percentage Over
Less than 500 (28 entities)	43%
500 to 1,500 (17 entities)	27%
Greater than 1,500 (23 entities)	12%

Source: Office of Inspector General analysis of sampled entities' invoices, 2006.

This pattern results in overpayments having a more pronounced financial impact on entities with lower 340B drug expenditures. For the 26 entities that purchased more than $100,000 of drugs during June 2005, overpayments accounted for less than 5 percent of their total spending. Conversely, for the sampled entities that spent under $100,000 on 340B purchases for the month, 13 had overpayments that accounted for more than 5 percent of total expenditures made during June 2005. The 3 entities with the highest percentages of overpayments (15, 17, and 35 percent) spent less than $11,000 on 340B drugs for the month.

In our sample, the manufacturers with the lowest volume of sales had the greatest percentage of sales that resulted in overpayments

Similar to the entity pattern, when we grouped manufacturers by volume of total 340B sales in our sample, we found that a relationship between total sales and percentage of sales with overpayments became clear.[32] These differences are illustrated in Table 3 below and are statistically significant within our sample.

Table 3. Percentage of Sales Resulting in Overpayments by Volume of Manufacturer Sales

Number of Sales	Percentage Over
Less than 100 (112 manufacturers)	46%
100 to 1,000 (51 manufacturers)	28%
Greater than 1,000 (49 manufacturers)	13%

Source: Office of Inspector General analysis of sampled entities' invoices, 2006.

In our sample, overpayments occurred more frequently for products sold through secondary wholesalers than through primary wholesalers

A statistically significant relationship between lower sales volume and more frequent overpayments also holds true for the wholesalers in our sample. When we examined the differences between the rates of overpayments associated with the two groups of wholesalers, primary and secondary, we found that 14 percent of the products sold through primary wholesalers were sold at prices above the ceiling prices, whereas 68 percent of the products sold by secondary wholesalers were sold at prices above the ceiling prices. The three primary wholesalers in our sample accounted for significantly greater volume of sales than the 13 secondary wholesalers. In fact, the primary wholesalers represented 178 times the total sales volume of secondary wholesalers in our sample.

Inaccuracies in HRSA's ceiling prices limit its ability to detect price discrepancies and oversee the 340B program

Our analysis of the data HRSA used to calculate 340B ceiling prices for June 2005 revealed that data regarding unit of measure and package size are inconsistent and, therefore, result in incorrect HRSA 340B ceiling prices for certain drugs. If HRSA were to conduct audits using these data to calculate ceiling prices, it would not be able to correctly identify overpayments.

Inconsistent drug pricing data produce incorrect HRSA 340B ceiling prices

Some of HRSA's 340B ceiling prices for June 2005 were incorrect due to problems related to unit of measure and package size data, which are necessary to calculate 340B ceiling prices from AMPs. Section I(a) of the Medicaid drug rebate program agreement entered into by drug manufacturers defines the AMP to be a manufacturer's average unit sales price to wholesalers for drugs distributed to the retail pharmacy class of trade (e.g., per pill, milliliter, or tube). However, manufacturers set prices for the sale and distribution of drugs in various package sizes (e.g., per bottle, vial, or kit). Pharmacies purchase drugs by the package and 340B ceiling prices are set at this package level. As previously explained, in the 340B ceiling price formula, the AMP (discounted by the URA) must be multiplied by package size in order to correspond with market practices.

To calculate 340B ceiling prices, HRSA obtains AMP and URA data from CMS and contracts with FDB to receive industry package size

information. FDB package size information conforms to standards established by the National Council for Prescription Drug Programs (NCPDP)[33] to facilitate use of uniform billing units in all transactions.[34] For the most part, CMS and FDB use the same standards; however, when the standards vary, calculating 340B ceiling prices using data adhering to two different standards yields inaccurate results.

To accurately calculate a 340B ceiling price from the AMP, it is necessary to consistently apply the unit of measure across all pricing data. We identified instances in which the definition of a unit of measure differed between CMS and FDB. For instance, manufacturers report the AMP to CMS for a particular drug–Drug A–based on a milliliter unit of measure; however, FDB lists the unit of measure for Drug A as "each."[35] Drug A is sold to pharmacies as a powder for infusion in a vial with a unit of measure of "each." Medicaid rebates are based on how Drug A was dispensed, as a reconstituted liquid dose (milliliter). Although both descriptions of the unit of measure (each and milliliter) are correct for their respective purposes, the combination of the data results in incorrect ceiling prices. In this situation, the HRSA computed 340B ceiling price was 10 times too low.

Beyond issues with defining a unit of measure, OIG also uncovered instances in which the information on units per package size reported by manufacturers to CMS differed from the package size they reported to FDB. These differences led to incorrect 340B ceiling prices because the AMP was multiplied by the inappropriate package size. For further details on these issues, see Appendix C.

HRSA's ability to monitor the appropriateness of prices that 340B entities pay is significantly limited by flawed ceiling price data

Based on the problems outlined above, OIG had to adjust the ceiling prices for 164 unique NDCs, which affected 4,332 entity purchases. In some cases, the comparison of 340B entity prices to the revised ceiling prices changed the original determination of whether a price was above, at, or below the 340B ceiling price. In other cases, it affected the size of the difference between ceiling prices and entity prices.

We found that 1,673 of the sampled entity purchases went from an overpayment when compared to HRSA's 340B prices to at or below the ceiling prices when compared to the OIG-adjusted prices. Using HRSA's 340B ceiling prices to project to the population would result in an estimate that entities overpaid $12.6 million in June 2005—nearly $9 million more than the estimate based on OIG-adjusted prices.

We also found that certain purchases went from at or below the ceiling prices when compared to HRSA's calculated ceiling prices to an overpayment based on the OIG-adjusted prices. Using HRSA's 340B prices would have missed 380 purchases that exceeded the ceiling prices for the month reviewed.

Finally, we identified purchases for which comparing 340B entity prices to HRSA's calculated 340B prices would have accurately identified the direction of price discrepancies, but would not have accurately identified the extent of the discrepancies. For these 2,279 purchases, comparing entity prices to OIG-adjusted prices (as opposed to HRSA's calculated prices) did not change whether a price discrepancy was above or below the ceiling price. Rather, it changed the extent of the discrepancy.

If HRSA had used its ceiling prices to assess the appropriateness of prices paid by 340B entities, it would have erroneously identified overpayments as transactions that were actually at or below the ceiling price, which could have led to inappropriate enforcement actions. It is also possible that use of HRSA's prices might result in attempts to recoup incorrect amounts where overpayments are identified but the amount is incorrect. In addition, use of inaccurate data could also interfere with the ability to detect actual overpayments.

RECOMMENDATIONS

Despite the requirements of the 340B Program, 14 percent of purchases made by 340B entities exceeded the 340B ceiling price, resulting in $3.9 million in projected overpayments for the month reviewed.

Previous OIG work found that HRSA is unable to appropriately oversee the 340B Program.[36] In particular, we found that HRSA lacked the mechanisms and authority to ensure that 340B entities pay at or below 340B ceiling prices. This report quantifies the potential impact that a lack of oversight has on the 340B Program. Furthermore, we found, as in our previous report, that HRSA's calculated ceiling prices can be inaccurate, which causes further concern related to HRSA's ability to monitor the 340B Program.

This review also explores potential reasons for the price discrepancies we uncovered in our sample of 70 purchasing agents, which made 229,796 purchases on behalf of 165 eligible sites in June 2005. We discovered that noncompliance with HRSA's penny price policy accounts for some of the largest overpayments in our sample. We also found that manufacturers, wholesalers, and entities in our sample that sell or purchase drugs using the 340B Program less frequently tend to be associated with more overpayments, suggesting that at least some overpayments stem from lack of experience with the complex 340B system.

The following recommendations reiterate and build upon our previous recommendations to HRSA to improve its oversight of the 340B Program to ensure that entities pay at or below the mandated ceiling price.

HRSA Should Improve Its Oversight of the 340B Program to Ensure That Entities Are Charged at or Below the 340B Ceiling Price

To ensure that entities are charged at or below the 340B ceiling price, we continue to support our prior recommendation that HRSA increase its oversight of the 340B Program. Increased monitoring could include HRSA's comparing its 340B ceiling prices to the manufacturers' ceiling prices each quarter to detect and resolve discrepancies. HRSA could also conduct spot-checks of entity invoices to ensure that entities are charged at or below 340B ceiling prices. Finally, as previously proposed, we believe it is important that HRSA have sufficient penalty authority

in case its current informal approach toward dispute resolution is insufficient.

HRSA has made steps toward improving 340B Program oversight based on these prior OIG recommendations. In December 2005, HRSA requested manufacturers to voluntarily submit their 340B ceiling prices to HRSA for comparative purposes and received responses from more than 130 manufacturers, from which it has run comparisons on a subset of 50. HRSA is currently working on an automated program to compare the 340B ceiling prices to prices within the 340B market. Finally, HRSA reported that it included a request for funds in its 2007 appropriation to support efforts to resolve pricing discrepancies when they are detected. We support these efforts and encourage HRSA to formalize the process of comparing all of the more than 700 participating manufacturers' ceiling prices to its 340B ceiling prices under a prescribed protocol to ensure a thorough and consistent verification process.

In addition to these efforts to ensure the accuracy of the 340B ceiling prices, HRSA could assist the uniform and timely transmission of 340B ceiling prices by taking responsibility for disseminating a single verified list of 340B ceiling prices to wholesalers. To do this, HRSA could receive ceiling prices from all manufacturers for comparison to its 340B ceiling prices, flag differences, follow up on the discrepancies, and create a single verified list of 340B ceiling prices. This action would streamline the process significantly as wholesalers would receive one 340B pricing file from HRSA instead of the current process whereby wholesalers exchange data with more than 700 participating manufacturers each quarter. To implement this process, HRSA might consider its Prime Vendor as a possible conduit of this data, since the Prime Vendor has links to the wholesalers.

Finally, we recommend that HRSA monitor the way in which the AMP disclosure provisions required in Section 6001(b) of the DRA are implemented. The revised definition of the AMP, when made available, could potentially be useful to 340B entities in approximating whether they are paying more than 340B ceiling prices.

HRSA Should Provide Technical Assistance Regarding 340B Program Requirements to All Participating Entities, Manufacturers and Wholesalers

HRSA should increase its efforts to provide entities, manufacturers, and wholesalers with information about 340B Program requirements and policies with the goal of improved compliance among all participants.

Though we are unable to project, the patterns detected in our sample suggest a potential link between infrequent interactions with the 340B program and overpayments. We found that low-volume purchasers were disproportionately affected by overpayments. HRSA may want to consider providing further assistance to specific entities, manufacturers, and wholesalers with low-volume purchases and sales.

HRSA might increase the 340B Program's visibility to entities through further promotion of its Pharmacy Services Support Center (PSSC), a pharmacy technical assistance resource established in 2002 to provide information, education, and policy analysis to help eligible entities optimize the value of the 340B Program.[37] One valuable tool offered through PSSC that merits increased attention is the HRSA technical initiative called "PharmTA." This program provides 340B entities with an opportunity to request and receive 340B and pharmacy technical assistance via a team of HRSA-trained consultants by phone, by e-mail, or in person.

For manufacturers and wholesalers, HRSA could further its education efforts geared toward increasing industry compliance with the 340B Program. HRSA has participated in several industry conferences designed to specifically educate manufacturers and wholesalers, and we believe continuing to actively pursue opportunities for training will assist the success of the 340B Program. HRSA could also, like CMS, publish letters on its Web site addressed to all manufacturers and wholesalers, for example, to direct 340B pricing or distribution practices or to clarify policies.

HRSA may also want to form a work group with members representing the entities, manufacturers, and wholesalers to identify and resolve ongoing issues related to the 340B Program. HRSA has enjoyed success with this informal approach in addressing issues with its Covered Entity database and interaction with Medicaid.

Finally, as the marketplace continues to evolve, HRSA may want to consider creating and conducting outreach programs to orient new entities, manufacturers, and wholesalers to the 340B Program.

HRSA Should Publish Guidance Regarding Its Penny Price Policy

HRSA should publish guidance that will serve as an explicit confirmation of its currently unofficial penny price policy. A formal, publicly available statement of this policy would help ensure that manufacturers consistently charge a penny (multiplied by the drug's package size) when a negative ceiling price is calculated. Since the

inappropriate handling of negative ceiling prices results in significant overpayments, accounting for 7 percent of the total overpayments in our sample, reinforcing the penny price policy with official guidance could have a significant impact on reducing the amount entities overpaid with minimum effort.

HRSA has already committed to publish detailed instructions for the calculation of the 340B ceiling price on its Web site, and we encourage it to include guidance related to the penny price in these policies.[38] If, however, HRSA finds that this guidance is insufficient to ensure compliance, the agency may want to pursue promulgating regulations about the policy. HRSA may want to also create an exceptions process to the policy to address instances in which adherence to this policy results in a higher price than the previous quarter's ceiling prices.

To Accurately Calculate 340B Ceiling Prices, HRSA Should Obtain Consistent Data on Unit of Measure and Package Size

HRSA's ability to monitor the 340B Program depends on having accurate 340B ceiling prices. Though HRSA's current package size data from FDB yield a correct ceiling price for most drugs, the prices are incorrect for certain products for which CMS and NCPDP have divergent standards for defining a unit or package. Until these unit of measure and package size issues are resolved, HRSA will continue to incorrectly calculate the 340B ceiling price for certain drugs.

HRSA has recently recognized the potential for discrepancies stemming from different unit of measure or package size conventions, and reports that it is working toward a more systematic process to detect and resolve these differences. We recommend as part of these efforts that HRSA develop protocol that compares CMS and FDB unit of measure definitions to detect discrepancies. This comparison requires a fairly simple data match. We also suggest that HRSA work directly with CMS to identify NDCs for which the unit of measure is captured differently by CMS and FDB. The agencies should also exchange information on instances in which CMS has exceptions to its unit of measure standards, as this information could isolate where standards diverge. HRSA and CMS have already engaged in discussions regarding accurate and timely drug pricing data, so they could add unit of measure issues to the agencies' collaborative efforts.

To address the package size issues, we offer two suggestions to improve the integrity of HRSA's 340B ceiling price calculations. First, because most unit of measure differences also require adjustments to the

package size data, HRSA could systematically review the package size data associated with unit of measure discrepancies. Second, HRSA could request that manufacturers submit the package size information they use directly to the Agency to be used as its official package size source or as a source of comparison. This information would not necessarily be the same package size information reported to either FDB or CMS, but would assist in calculating correct 340B ceiling prices.

AGENCY COMMENTS

HRSA concurred with each of our recommendations. The complete text of HRSA's comments can be found in Appendix D.

In response to our recommendation to improve oversight of the 340B Program, HRSA stated that it has taken steps to more closely monitor the prices paid by 340B entities. Specifically, HRSA has requested that manufacturers voluntarily submit their prices for comparison to the agency's ceiling prices. HRSA stated that it already receives ceiling price information on a voluntary basis from more than 50 manufacturers and expects that many more manufacturers will voluntarily submit data. HRSA also stated that it will continue to work toward dissemination of verified ceiling prices to wholesalers. Further, HRSA intends to explore ways to provide ceiling prices to wholesalers and entities, while protecting the confidentiality of the pricing data. Additionally, HRSA stated that it will explore the possibility of seeking the authority and resources needed to impose fines and civil penalties for violations of the PHS Act.

In response to our other recommendations, HRSA agreed that, despite its limited resources, it will manage and coordinate the technical assistance efforts for the 340B Program, including special efforts to target new and smaller-volume purchasers of 340B drugs. HRSA also stated that it anticipates promulgating a penny price policy in conjunction with formalizing the instructions for the calculation of 340B ceiling prices, which OIG recommended in a previous report. Finally, HRSA concurred with our recommendation that it should obtain consistent unit of measure and package size data.

OFFICE OF INSPECTOR GENERAL RESPONSE

We believe that the steps HRSA outlined in response to our recommendations will improve its program oversight and the accuracy of 340B ceiling prices. We do, however, continue to encourage HRSA to

work toward a comprehensive comparison of its 340B ceiling prices to all manufacturers' data. We also maintain that HRSA should develop a systematic process to detect and resolve unit of measure and package size issues with its ceiling price data to ensure accurate 340B ceiling prices.

ENDNOTES

[1] 42 U.S.C. § 256b.

[2] 42 U.S.C. § 256b(a)(1).

[3] Ibid.

[4] This estimate of total purchases is the most recent available from the Office of Pharmacy Affairs, Health Resources and Services Administration.

[5] 42 U.S.C. § 256b(a)(4).

[6] The total number of entities listed on HRSA's Covered Entity Database is 12,334. Available online at http://opanet.hrsa.gov/opa/Login/MainMenu.aspx. Accessed on May 24, 2006.

[7] The 340B Program registration form may be found on HRSA's Web site at www.hrsa.gov/opa/introduction.htm.

[8] http://opanet.hrsa.gov/opa/Login/MainMenu.aspx; select "Covered Entity" to search for participating entities.

[9] The statement from HRSA requiring entities to notify manufacturers of their participation is available online at http://www.hrsa.gov/opa/introduction.htm. Accessed on May 31, 2006.

[10] "Introduction to 340B Drug Pricing Program," available online at http://www.hrsa.gov/opa/introduction.htm. Accessed on July 11, 2006.

[11] 42 U.S.C. § 256b(a)(8).

[12] Prime Vendor Program's Power Point presentation of 340B Participation numbers. Available online at http://www.340bpvp.com/faq/default.asp. Accessed on May 22, 2006.

[13] 42 U.S.C. § 256b(a)(10).

[14] Sections 1927(a)(1) and (a)(5)(A) of the Social Security Act.

[15] Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, Section (10) Dealing Direct or Through a Wholesaler, 59 FR 25113, May 13, 1994.

[16] Forbes Magazine, "Healthcare: Cardinal Health," available at www.forbes.com/global/2002/0415/072.html, and Eban, Katherine, "Dangerous Doses," May 2006.

[17] Section 1927(b)(3) of the Social Security Act.

[18] Section 1927(c) of the Social Security Act outlines the manner in which rebate amounts are determined.

[19] Sections 340B(a)(1-2) of the PHS Act; 42 U.S.C. § § 256b(a)(1-2).

[20] Under the Medicaid drug rebate program, CMS indexes quarterly AMPs to the rate of inflation. Section 1927(c)(2)(A) provides that if the AMP increases at a rate faster than inflation, the manufacturer pays an additional rebate amount which is reflected in an increased URA. Thus, Section 1927(c)(2)(A) could increase the rebate amount manufacturers must pay to the States, but could also result in negative 340B prices.

[21] Though this policy is not officially stated in regulation or guidance, HRSA staff have discussed this expectation in several interviews with OIG and publicly stated the expectation at several 340B conferences and meeting. HRSA staff says that this policy has been expressed since the start of the program.

[22] Remarks of CMS Administrator Dr. Mark B. McClellan as delivered to the National Community Pharmacists Association, May 22, 2006.

[23] We interviewed several member organizations of the 340B Coalition, which represents the thousands of safety net providers and programs participating in the Public Health Service's 340B Program. Members interviewed included the Public Hospital Pharmacy Coalition, Hemophilia Alliance, Inc., National Association of Community Health Centers, and National Alliance of State and Territorial AIDS Directors.

[24] Technically, our efforts to link related entities resulted in a final population of 1,727 entity networks, but we eliminated 20 entities and added 1 previously dropped entity, bringing our reported total to 1,708. We eliminated 20 hospitals due to ongoing OIG investigations and included 1 Ryan White Title IV grantee (previously excluded from the sample because of its very low volume of products purchased) after discovering it had a contract pharmacy arrangement.

[25] We requested the 340B ceiling prices for second quarter of 2005, which HRSA calculated using AMPs and URAs from the fourth quarter of 2004.

[26] Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Operational Guide, p. H2.

[27] If a manufacturer does not submit AMP to CMS, CMS is unable to calculate a URA and, therefore, cannot supply HRSA with either the AMP or URA needed to compute 340B ceiling prices.

[28] During our review, we discovered that HRSA's database had the incorrect entity type listed for six of the sampled entities—e.g, the entity was categorized as a Ryan White grantee, but reported that it was actually a Consolidated Health Center. Since our stratification was based on entity type, these inaccuracies meant we had placed them in incorrect strata.

[29] H.R. Rpt. 102-384, 102nd Cong., 2nd session, pt. 2 at 12 (1992).

[30] Entity Guidelines, 58 FR 68922,68923, December 29, 1993. Entities may instead opt to bill the State for Medicaid beneficiaries at the State's usual acquisition cost plus a fee. Entities using this option must purchase a separate inventory at a non-340B contract price for Medicaid patients.

[31] Of the 73 eligible entities in our sample, 72 responded to the Web-based survey, of which 69 responded to this question on passing on the 340B discount or billing States at the Medicaid rate.

[32] As a quality control check, we also analyzed the relationship between the volume of sales associated with the unique labeler codes of each of the 306 sampled manufacturers and overpayments. We found that, when

categorized in the same three groups, the relationship between low-volume manufacturers and higher overpayments was still evident and statistically significant. In this analysis, the high-volume manufacturers had a 12 percent overpayment rate; medium-volume, 22 percent; and low-volume, 39 percent.

[33] The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit standards development organization consisting of more than 1,300 members representing virtually every sector of the pharmacy services industry.

[34] NCPDP Billing Unit Standard Implementation Guide Version 2.0.

[35] According to the NCPDP Billing Unit Standard, "each" is one of the three appropriate billing units other than milliliter or gram. The term "each" may refer to a tablet, a capsule, a suppository, or a transdermal patch. NCPDP Billing Unit Standard Implementation Guide Version 2.0.

[36] "Deficiencies in Oversight of the 340B Drug Pricing Program," OEI-05-02-00072, October 2005.

[37] The Pharmacy Services Support Center operates under a contract between the American Pharmacists Association and HRSA.

[38] Agency comments section, "Deficiencies in the Oversight of the 340B Drug Pricing Program," OEI-05-02-00072, October 2005.

APPENDIX ~ A

Types of Entities Eligible to Participate in the 340B Program:

Black lung clinics

Community health centers

Disproportionate share hospitals

Family planning clinics

Federally qualified health center lookalikes

Federally qualified health centers funded by the Office of Tribal Programs

Healthcare for the homeless centers

Hemophilia treatment centers

Migrant health clinics

Native Hawaiian Health Care Program

Public housing clinics

Ryan White Title I

Ryan White Title II

Ryan White Title II (AIDS Drug Assistance Program direct purchase)

Ryan White Title II (AIDS Drug Assistance Program rebate option)

Ryan White Title III

Ryan White Title IV

School-based programs

Sexually transmitted disease clinics

Special Projects of National Significance

Tuberculosis

Urban Indian Clinics

DETAILED METHODOLOGY

Entity Sample Selection

Based on interviews with the Health Resources and Services Administration (HRSA) and other 340B interest groups, we excluded certain entity types from our population. We excluded entities that regularly purchase drugs using other discount mechanisms, such as the reductions available via the Federal Supply Schedule or Title X. We also excluded entities that purchase a very low volume of drugs. These exclusions eliminated a total of 7,707 entities, giving us a population of 4,240 entities. Table 1 lists the excluded entities.

Table 1. Entities Excluded From Sample

Entity Type	Number of Entity Listings Excluded	Reason for Exclusion
Federally Qualified Health Centers Funded by the Office of Tribal Programs	102	Indian Health Service grantees may receive pharmaceutical discounts under multiple Federal programs, not just 340B
Urban Indian Organizations	17	Special relationship with Indian Health Service
Ryan White Title II Rebate Option	47	Do not purchase drugs using the 340B ceiling price
Family Planning Clinics	5,118	Routinely receive nominal prices or samples and rarely order products
Sexually Transmitted Disease Clinics	1,344	Purchase drugs using Title X discounts
Tuberculosis Clinics	1,024	Majority of products that sampled entities reported on invoices during previous 340B work were vaccines, which are not covered under the 340B Program
Black Lung Clinics	10	Very low volume of products purchased
Native Hawaiian Clinics	5	
Ryan White Title IV	7	
Special Projects of National Significance	8	

Purchasing Agents

At the time we selected the sample, HRSA's database did not include a link demonstrating the relationship between the purchasing agent and its affiliates. Therefore, we used the HRSA-assigned unique 340B identification number to group entities. This identification number typically consists of three segments: first, an alpha-prefix that indicates the entity type; second, numbers assigned at HRSA's discretion, which sometimes consists of the site's Zip code; and third, if a site is related to another site, a terminal alpha-suffix. An example of the unique identification number would be DSH1234A. Using this number, we

grouped entities together if their HRSA identification number differed only by their alpha-suffix or alpha-prefix, and counted each grouping as one purchasing agent. In attempting, for example, to link DHS1234A to other entities, we would have grouped it with DSH1234B and DSH1234C. In addition, entities were grouped together if they had an identical address and contact information. Each group of entities was counted as one purchasing agent. Entities with no listed affiliates were also counted as one purchasing agent. To further confirm linkages among just the Consolidated Health Centers, we relied on the data listed on HRSA's Bureau of Primary Health Care Web site, which contains information on these grantees' service delivery sites. For each center, the Web site lists the main site and its supported sites. We also used the information on this Web site to update the centers' contact information. Our efforts to link related entities resulted in a population of 1,727 purchasing agents, referred to in the report as 340B entities for simplicity. Table 2 summarizes our efforts to link related entities and identify the purchasing agent for our sample.

Table 2. Identifying 340B Purchasing Agents

Entity Type	Number Listed in Covered Entity Database	Overall Number of Purchasing Agents Identified by OIG
Disproportionate Share Hospital	1,153	498
Consolidated Health Center	2,500	841
Federally Qualified Health Center	162	84
Hemophilia Treatment Centers	74	73
Ryan White Title I	89	54
Ryan White Title II	79	65
Ryan White Title III	183	92
Total	**4,240**	**1,727**

Sample Selection

Prior to selecting our sample, we eliminated 20 disproportionate share hospitals from Stratum 1 due to ongoing OIG investigations. We also included a Ryan While Title IV network in Stratum 5 after discovering that it differed from the rest of its category in that it had a contract pharmacy arrangement. These adjustments resulted in a final

population of 1,708 purchasing agents from which the sample was selected and projections were made.

We selected a stratified random sample of 98 purchasing agents based on entity type and purchasing method. The resulting sample included five strata representing disproportionate share hospitals, Consolidated Health Centers, hemophilia treatment centers, Ryan White grantees, and any entity type with contract pharmacy arrangements.

We stratified our sample based on characteristics we believed might influence price discrepancies. Based on potential administrative or operational differences, we stratified purchasing agents as either direct purchasers or entities with contract pharmacy arrangements. Additionally, with regard to the direct purchasing agents, we further stratified our sample, selecting a stratified random sample from four strata of entity types determined by characteristics of 340B participating entities, namely pharmacy volume, sophistication of purchasing, diversity of products, and proportional impact on the 340B program. Table 3 displays the stratification results including the population size and sample size by stratum.

Table 3. Stratification of 340B Entities

Stratum	Entity Types Within Stratum	Reason for Stratum	Population Size	Sample Size
Direct Purchasers: Stratum 1	Disproportionate Share Hospitals	High pharmacy volume and sophisticated purchasing process	484	30
Direct Purchasers: Stratum 2	Consolidated Health Centers and Federally Qualified Health Centers	Diversity of products but at a lower volume than hospitals	620	30
Direct Purchasers: Stratum 3	Hemophilia Treatment Centers	Specific, expensive products, including anticlotting factor	43	8
Direct Purchasers: Stratum 4	Ryan White Title I, Ryan White Title II (ADAP Direct Purchasers), and Ryan White Title III	Slightly more diverse range of products than hemophilia treatment centers purchased for a specific population	137	10
Contracted Pharmacy Arrangement Purchasers: Stratum 5	All	Complicated distribution arrangements	424	20
		Total	**1,708**	**98**

Sample Verification

After we made our sample selection, Hurricane Katrina hit the Gulf Coast. As a result, we dropped four purchasing agents located in

Louisiana or Mississippi to avoid imposing a burden on health care providers in the region. Calls to each of the remaining 94 purchasing agents to confirm participation status and address information revealed that 21 of the purchasing agents did not participate the 340B Program and, therefore, were not eligible for this study. In total, of the 98 purchasing agents originally sampled, only 73 were included in our study. Table 4 provides a breakdown of the responses of the ineligible entities.

Table 4. Description of Ineligibles

Reason Not Eligible	Number
Does not participate in 340B at all or does not purchase drugs	10
Enrolled in 340B, but has not yet used the program	4
Enrolled in 340B, but did not purchase drugs in June 2005	3
Dropped from study because of Hurricane Katrina (entities in hurricane-affected areas of Louisiana and Mississippi)	4
Does not qualify to participate in 340B	1
Center does not exist or we were unable to locate it	2
Other	1
Total	**25**

Data Collection

To obtain information on the prices from the 73 purchasing agents in our sample, we requested invoices for purchases made under 340B contracts during the sampled month. We requested that the purchasing agent only submit invoices relating to purchases made under their 340B contract and exclude any inpatient or group purchasing organization prices negotiated under a separate contract. We also requested that the purchasing agent provide additional information we deemed necessary to ascertain that the invoice data supplied were correct, including contract and purchase order numbers.

Of the 73 eligible purchasing agents, only 1 did not respond to our request for 340B invoices for June 2005. An additional two purchasing agents responded, but we were unable to use their invoice submissions. For one purchasing agent, paper drug invoices did not include NDC codes. For another purchasing agent, information about prescriptions and not invoice purchases was supplied. Therefore, our final number of sampled respondents was 70. These 70 purchasing agents purchase on

behalf of a total of 165 entities. Table 5 provides a breakdown of sample responses by stratum.

Table 5. Response Rate by Stratum

Stratum Description	Sample Size	Eligible for Study	Responses
Direct Purchasers: Disproportionate Share Hospitals	30	24	24
Direct Purchasers: Consolidated Health Center Programs and Federally Qualified Health Centers	30	19	18
Direct Purchasers: Hemophilia Treatment Centers	8	6	6
Direct Purchasers: Ryan White Title I, Ryan White Title II, and Ryan White Title III	10	5	5
Contracted Pharmacy Arrangement Purchasers	20	19	17
Total	98	73	70

Sampling Invoice Line Items

We requested that the sampled purchasing agents supply invoice information electronically if possible. Of the 70 purchasing agents that submitted usable invoice data, 32 submitted invoices electronically and 38 submitted paper invoices. We imported all line items, after we verified accuracy and reliability, for any invoices received electronically. Of the 38 purchasing agents that submitted reasonable paper invoice data, we entered all line items for 31 purchasing agents. For the remaining 7 purchasing agents whose paper invoice submissions were too extensive to reasonably enter manually in our timeframe (e.g., the total number of line items reported exceeded 500), we took a second-stage, simple random sample of the line items. To do this, we determined the number of line items we would sample based on the total number of line items on the invoices. Specifically, if the total number of line items was under 30, we took them all. If the total number of line items was over 30, we calculated the sample size based on the following formula: ((number of line items *60) /(number of line items + 60)). We rounded up to the next integer and took that number in the sample. If the number of line items exceeded 600, we took 60 transactions at a minimum.

We input the NDC, the price paid, and the quantity purchased for each outpatient drug purchased within the sample month.

When possible, we excluded any transactions associated with products that had been returned, as indicated on the invoice, and only included the entity's net sales. We recognize that the nature of the 340B market

includes the potential for returns and, since two quarters had passed between the initial purchase and data request, some electronic invoice data included these returns.

Projections and Confidence Intervals

For our projection to the population of entities, we did not include the six purchasing agents that were assigned to an incorrect stratum. Even though we did not make projections to the stratum level, we excluded the six purchasing agents that were assigned to the wrong stratum from the overall population for projections to reduce bias in our estimate. Table 6 below contains the results: the total projected overpayments and total amount spent on 340B drugs as well as overpayment rates for the population of 340B entities during June 2005.

Table 6. Projected Spending and Overpayments for Population of 340B Entities

Statistic	Point Estimate	95-Percent Confidence Interval
Dollars Paid in Excess of the 340B Ceiling Price Using OIG-Adjusted 340B Ceiling Prices	$3,865,718	$2,024,514 - $5,706,922
Total Dollars Spent	$445,318,538	$182,795,807 - $707,841,269
Rate of Purchases Above the 340B Ceiling Price	14.4%	8.2% - 20.6%
Rate of Purchases at or Below the 340B Ceiling Price	85.6%	79.4% - 91.8%
Dollars Paid in Excess of the 340B Ceiling Price Using HRSA Calculated 340B Ceiling Prices	$12,617,290	$6,656,187 - $18,578,393

To analyze our sample, we accounted for the seven purchasing agents from which we took a sample of line items. To do this, we projected overpayment dollars, total spending, and overpayment rates for the seven purchasing agents. For the remaining 63 purchasing agents, we did not sample line items and therefore did not need to make projections. Additionally, we included the six purchasing agents that were assigned to an incorrect stratum since analysis of our sample was not weighted by stratum. Table 7, on the next page, contains the results for overpayment dollars and overpayment rates for the sample.

Table 7. Projected Spending and Overpayments for Our Sample of 70 Entities

Statistic	Point Estimate	95-Percent Confidence Interval
Dollars Paid in Excess of the 340B Ceiling Price	$258,556	$253,717 - $263,395
Total Dollars Spent	$32,192,304	$31,323,532 - $33,061,076
Rate of Purchases Above the 340B Ceiling Price	14.0%	13.2% - 14.8%
Proportion of Dollars Paid in Excess of the 340B Ceiling Price Due to Noncompliance With HRSA's Penny Price Policy	7.2%	6.9% - 7.4%

Office of Inspector General Review of HRSA's 340B Ceiling Prices

To correct for the discrepancies in unit of measure and package size information, we compared drug data for 372 National Drug Codes (NDCs) and adjusted unit and package size data as needed based on research on how each drug is supplied. We primarily relied on manufacturers' package insert information by drug, which is typically available on the manufacturer's Web site.

To ensure a proper ceiling price calculation for NDCs with unit of measure and/or package size discrepancies, we identified NDCs for which the Centers for Medicare & Medicaid Services unit of measure or package size differed from First DataBank's unit of measure. Then, using the Internet to research manufacturers' Web sites and the Food and Drug Administration Web site, we made adjustments to the ceiling price when needed.

In total, we identified 372 out of 5,331 unique NDCs in our sample for which the unit of measure or package size descriptions did not correspond and potentially resulted in an incorrect ceiling price. Of those, we made adjustments to 164 of HRSA's ceiling prices for which the disparities proved problematic.

Specifically, for our unit of measure discrepancy analysis, we reviewed 182 unique NDCs. Of those, we adjusted the ceiling price for 52. This affected 289 line items and 1,872 purchases in our sample. In our package size discrepancy analysis, we reviewed 190 unique NDCs. Of those, we adjusted the ceiling price for 112. This affected 340 line items and 1,742 purchases in our sample.

Pattern Analysis

To look at patterns among entities, we divided the entities into three groups: entities with more than 1,500 purchases, between 500 and

1,500 purchases, and fewer than 500 purchases for the month. By "purchase," we mean the single purchase of each package of product whether the entity purchased multiple quantities of the product at the same time or just a single package. We chose these cutoffs because they fit the scale of the range of sales. We also divided entities by total dollars spent, using $100,000 as the dividing point.

For the manufacturer analysis, we grouped manufacturer sales into three groups: high (more than 1,000 sales), medium (between 100 and 1,000 sales) and low (below 100 sales). Similar to our definition of "purchase," a single sale reflects the individual sale of each package of product. The range of manufacturers' sales was from 1 to 15,885 sales, with an average of 751. We selected these three classifications because they also fit the scale of the range of sales.

To conduct our analysis by manufacturers, we first identified and grouped all related subsidiaries, acquired companies, various divisions, or divisions located outside the mainland United States and treated the grouping as a single manufacturer. All of our price comparisons were conducted at the NDC level, of which the first 5 digits represent the "labeler code," or manufacturer, of the drug. We identified and linked related labeler codes into a "manufacturer" because, much like our identification of the entity purchasing agents, we wanted our unit of pattern analysis to be based on the "network" of businesses that make up the single "manufacturer." Further, because some of our conclusions reference the manufacturers' level of interaction with the 340B Program, our groupings treat related companies as having the same level of interaction with the program.

Since there is no single source for linking labeler codes of affiliated manufacturers, we identified related manufacturers using a combination of sources. For instance, some manufacturers voluntarily submit a single 340B ceiling price file to HRSA that contains the prices for all affiliated labeler codes. We requested this file from HRSA and were able to link several related manufacturers. Of the 306 total unique labeler codes in our sample, our efforts to group related codes resulted in a universe of 212 "manufacturers." We also researched company Web sites and drug data Web sites to collect information on related manufacturers.

For the pattern analysis of wholesalers, we grouped wholesalers into two groups: primary and secondary wholesalers. As previously mentioned, secondary wholesalers are associated with lower-volume

business than primary wholesalers, who account for 90 percent of drug distribution. We identified which wholesalers were associated with each entity's sales using entity survey responses and submitted invoices.

We identified a total of 16 wholesalers in our sample. The "primary wholesalers" category is composed of the Big 3, as they are known in the industry; namely, Amerisource Bergen, Cardinal, and McKesson. Included in our category of secondary wholesalers are 13 regional wholesalers, repackagers, and pharmacy benefit managers. We excluded contract pharmacies from our analysis of wholesalers because we could not tell which wholesaler they purchased through. We also excluded any manufacturer-direct sales, as no wholesaler was used.

Finally, we classified NDCs into three groups: high (more than 1,000 sales), medium (between 100 and 1,000 sales) and low (below 100 sales). We wanted to keep the NDC and the manufacturer grouping similar, so that both high-volume groupings had about 10 times the purchases and or sales totals as the low-volume group.

INCONSISTENCIES IN PACKAGE SIZE DATA USED TO CALCULATE 340B PRICES

OIG uncovered three issues that resulted in discrepancies in package size information between CMS and FDB, and ultimately led to inaccurate 340B ceiling prices.

Discrete package size. First, discrepancies in package sizes may occur when package size data related to discrete (inner) packages and outer package size are not consistently reported. Complete package size consists of two parts, the inner package size and the outer package size. The outer package size reflects the number of discrete (inner) packages that must be sold together. We discovered instances in which FDB captured the complete package size (inner x outer package size), while CMS listed the package size in relation to the inner package size only. It appears that the case had been "broken" and 340B entities were buying bottles individually and not in the designated case pack as reported to FDB. For example, FDB captures the full case pack information for a particular drug as 12 bottles of 100 tablets. However, CMS lists the package size for this drug as 100 (e.g., 1 bottle of 100 tablets). Using FDB package size information to calculate the 340B ceiling price resulted in a price that was 12 times too high.

Metric conversion. Both the NCPDP standards used by FDB and the CMS guidelines for the Medicaid drug rebate program require that drugs be billed in metric units. However, drugs are not always sold in metric units, and therefore must be converted for billing purposes. For example, cough syrup is typically sold in 12 fluid ounce bottles, but an ounce is not an accepted unit of measure and must, in this case, be converted to milliliters for billing purposes. In making metric conversions of this nature, manufacturers have the discretion to report either the actual metric quantity, in this case 355 milliliters, or use NCPDP metric conversion standards, which are based on traditional pharmacy standards, resulting in 360 milliliters. This discretion allows for the possibility that manufacturers will report different metric amounts to CMS and FDB, creating a discrepancy in package size.

Rounding. Finally, package sizes can differ between CMS and FDB due to differences related to rounding. CMS does not use decimal places in its package size field, but FDB occasionally does use decimal package sizes. Thus, when CMS rounds decimals to a whole number, there is a potential for discrepancy between CMS and FDB package sizes.

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, Maryland 20857

JUL 10 2006

TO: Daniel R. Levinson
Inspector General

FROM: Administrator

SUBJECT: Comments on Draft Report: "Review of 340B Prices"
(Code # OEI-05-02-00073)

Thank you for the opportunity to provide comments on the above subject draft report. Attached please find our comments.

Questions may be referred to Gail Lipton in HRSA's Office of Federal Assistance Management (OFAM) at (301) 443-6509.

Betty James Duke

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General DRAFT Report: "Review of 340B Prices", OEI-05-02-00073

The Health Resources and Services Administration is pleased to respond to the June 2006 draft report from the Office of the Inspector General (OIG) *Review of 340B Prices* (OEI-05-02-00073).

OIG RECOMMENDATION

HRSA Should Improve Its Oversight of the 340B Program to Ensure That Entities Are Charged at or Below the 340B Ceiling Price

HRSA should:

- **More closely monitor prices paid by 340B entities**
- **Compare government-calculated 340B ceiling prices with manufacturer-calculated prices to detect discrepancies**
- **Establish penalties for PHS Act violations**
- **Disseminate a single verified ceiling price list to wholesalers**

HRSA RESPONSE

HRSA generally concurs with these recommendations and is more closely monitoring prices paid by 340B entities by taking the following actions:

1. Manufacturers have been requested to voluntarily submit their calculated prices for comparison with government calculated prices. More than 50 manufacturers are currently submitting price files, in an easy to use digital format, and many more are expected to do so.
2. HRSA will continue to explore the possibility of seeking authority and resources necessary to impose fines and civil penalties for violation of Sec. 340B of the PHS Act. We note that there is congressional interest in establishing these authorities.
3. HRSA will work within the confines of the existing law that protects the confidentiality of manufacturer pricing data while exploring ways to provide ceiling prices to wholesalers and buyers of 340B drugs.

HRSA will continue to work with drug manufacturers, wholesalers, and the 340B Prime Vendor and CMS to explore possible mechanisms for the dissemination of verified ceiling prices lists to wholesalers.

OIG RECOMMENDATION

HRSA should provide technical assistance regarding 340B Program implementation to all participating entities, manufacturers, and wholesalers.

HRSA should:

- **Provide 340B entities, manufacturers, and wholesalers with information about Program requirements and policies in order to increase compliance**
- **Provide further assistance to entities, manufacturers, and wholesalers with low-volume purchases and sales.**
- **Formulate outreach programs to orient new entities, manufacturers, and wholesalers to the 340B Program.**

HRSA RESPONSE

HRSA concurs with these recommendations. Within the constraints imposed by limited resources, HRSA will manage and coordinate the technical assistance efforts (PharmTA) for the 340B Program. HRSA is exploring ways to extend the reach of technical assistance to all stakeholders. Special efforts will be undertaken to reach manufacturers, wholesalers and entities new to the 340B Program, particularly those with small purchase volume of 340B drugs.

The HRSA Administrator is also taking action to require that all grants project officers and employees with program review responsibilities receive training in the 340B Program that will enable them to better assist grantees to maximize the use and value of the Program and pharmacy technical assistance.

OIG RECOMMENDATION

HRSA should publish guidance regarding its penny price policy.

HRSA RESPONSE

HRSA concurs with this recommendation and anticipates promulgating the penny price policy in conjunction with formalizing the instructions for the calculation of 340B ceiling prices. HRSA has gained experience with 340B ceiling price calculations since assuming that responsibility in October 2005 from the Centers for Medicare and Medicaid Services (CMS).

OIG RECOMMENDATION

2

To accurately calculate 340B ceiling prices, HRSA should obtain data on consistent unit of measure and package size.

HRSA RESPONSE

HRSA concurs with this recommendation. HRSA currently computes 340B ceiling prices using Average Manufacturer's Price (AMP) and Unit Rebate Amount (URA) data from CMS at the 9-digit National Drug Code (NDC) level and purchases 11-digit NDC package size data from a third-party vendor.

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ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Tom Komaniecki, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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