Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

DEFICIENCIES IN THE OVERSIGHT OF THE 340B DRUG PRICING PROGRAM

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EXECUTIVE SUMMARY

OBJECTIVE

To assess the ability of the Health Resources and Services Administration (HRSA) to ensure that entities participating in the 340B Drug Pricing Program are able to purchase products at or below a statutorily established ceiling price.

BACKGROUND

In 1992, Congress amended section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. 2566, to establish the 340B Drug Pricing Program (340B Program). Pursuant to the PHS Act, manufacturers agree to charge certain covered entities at or below a specified maximum price for outpatient drug purchases, known as the 340B ceiling price. Covered entities include public hospitals, AIDS Drug Assistance Programs, and community health centers, which serve some of the country's most vulnerable populations. HRSA oversees the 340B Program, managing the pricing arrangements among the 702 participating manufacturers and nearly 12,000 entities. Participating entities spent an estimated $3.4 billion on outpatient drugs in calendar year 2003.

The Government and pharmaceutical manufacturers separately calculate a 340B ceiling price each quarter. The Government's calculation is intended to be used in program oversight, while the manufacturers' calculation is the price used in sales to participating entities. The 340B price is based on required sales data that manufacturers must report to the Government for the purposes of the Medicaid Drug Rebate program. Manufacturers and the Government use the same pricing data and formula to calculate 340B ceiling prices. Due to provisions and policies protecting the manufacturers' pricing data, neither the Government's nor the manufacturers' ceiling prices are disclosed to the covered entities.

In June 2004, the Office of Inspector General (OIG) issued a report entitled "Appropriateness of 340B Drug Prices" (OEI-05-02-00070), which evaluated whether participants in the 340B Program received the prices to which they are entitled by law. During follow-up work on the report, we uncovered a number of problems with the data used to develop the report's findings. Therefore, we withdrew this report on October 21, 2004, and conducted a focused review of the Government's 340B ceiling prices.

For this review on the deficiencies in the oversight of the 340B Program, we thoroughly analyzed the data previously collected for "Appropriateness of 340B Drug Prices," which included a sample of entity invoices and the Centers for Medicare & Medicaid Services (CMS) ceiling price calculations for the third quarter of 2002. We also reviewed and further evaluated CMS's reported analysis on the completeness of 340B ceiling prices effective in the first quarter of 2005. We interviewed both CMS and HRSA staff about the 340B ceiling price calculation and oversight of the 340B Program.

FINDINGS

Due to systemic problems with the accuracy and reliability of the Government's record of 340B ceiling prices, HRSA is unable to appropriately oversee the 340B Program. HRSA needs an accurate record of 340B ceiling prices to verify that entities receive the discount to which they are entitled by law. A review of CMS's analysis of the first quarter 2005 340B ceiling prices revealed significant problems with the underlying data used in its calculation. In particular, the Government's record was missing 28 percent of the 340B ceiling prices. Further, 8 percent of its prices did not include the 340B discount, producing inaccurate ceiling prices. Finally, HRSA received a substantial amount of information that was not relevant to the 340B program, but upon which it inappropriately relied in conducting analyses and performing its oversight role.

HRSA's oversight of the program is further hindered by the lack of detailed, written procedures for calculating 340B ceiling prices. Consequently, the 340B ceiling prices calculated by CMS used incomplete package size information, which yielded incorrect ceiling prices. HRSA also has no procedure to convert ceiling prices with negative values into practical ceiling prices.

HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price. Until September 2005, HRSA relied on CMS to calculate 340B ceiling prices and, while HRSA anticipates calculating the price now, it has yet to establish a system to perform the calculations itself. In line with this new responsibility, HRSA does not systematically compare its record of 340B ceiling prices to the ceiling prices calculated by pharmaceutical manufacturers to identify any discrepancies. HRSA also does not

perform program monitoring designed to ensure that 340B participants receive the 340B ceiling price.

Confidentiality provisions related to disclosure of 340B ceiling prices further hamper HRSA's ability to effectively implement its prime vendor program which, besides offering distribution services through a network of wholesalers, is intended to negotiate subceiling discounts for participating entities. Finally, HRSA does not have the authority to enforce compliance with either the PHS Act or the Pharmaceutical Pricing Agreement, which is the formal agreement between HRSA and manufacturers participating in the 340B Program.

Participating entities cannot independently verify that they receive the correct 340B discount due to confidentiality provisions. Entities participating in the 340B Program do not have access to 340B ceiling prices. Therefore, entities are unable to determine the prices to which they are entitled under the 340B statute and whether they receive them.

RECOMMENDATIONS

CMS and HRSA should work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices. CMS and HRSA have already engaged in discussions about calculating the 340B ceiling price. On September 19, 2005, CMS and HRSA signed a new Intra-Agency Agreement, retroactively effective for Fiscal Year 2005, which states that HRSA will continue to receive pricing data from CMS, but will itself calculate the government's 340B ceiling price. We encourage HRSA and CMS to continue to work together to improve the accuracy and timeliness of the pricing data CMS has agreed to provide HRSA.

HRSA should establish detailed standards for its calculation of 340B ceiling prices. To prevent the types of errors we discovered in CMS's calculation of the 340B ceiling price, we suggest that HRSA take action to ensure the accuracy of its calculations. In particular, HRSA needs to develop specific policies around correctly calculating the 340B ceiling prices. HRSA's standards should include specifics on the use of correct package sizes and a conversion factor for negative ceiling prices.

HRSA should institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities. We suggest these mechanisms include:

- Comparing the Government's official 340B ceiling prices to the manufacturers' ceiling prices each quarter to detect discrepancies;
- Spot-checking covered entity invoices against ceiling price data to ensure that entities are charged at or below 340B ceiling prices; and
- Selectively auditing manufacturers, wholesalers, and covered entities to ensure the integrity of the discount program.

HRSA should seek authority to establish penalties for PHS Act violations. HRSA should propose a legislative package that might include a variety of sanctions, such as fines and civil monetary penalties, for manufacturer or wholesaler violations of the 340B Program requirements. We recommend that HRSA consider as a model CMS's statutory authority to enforce the Medicaid rebate program, pursuant to § 1927(b)(3)(C)(i) of the Social Security Act, and seek similar authorities with respect to enforcement of the 340B Program.

HRSA should provide participating entities with secure access to certain pricing data to help approximate 340B ceiling prices. We suggest that HRSA develop a price verification system by which entities can submit prices to determine whether they comply with the 340B discount requirements, while protecting the confidentiality of protected data. We additionally suggest that HRSA reinstate the publication of its 340B prime vendor program's selling prices on the agency Web site so covered entities can validate the prices they are charged.

AGENCY COMMENTS

HRSA and CMS concur with most of our recommendations. The complete text of the comments can be found in Appendix B.

Based on the issues raised and recommendations offered in our withdrawn report, HRSA and CMS have already engaged in numerous technical discussions about calculating the 340B ceiling price. As a result of these discussions, HRSA will continue to receive pricing data from CMS, but will itself calculate the Government's 340B ceiling price. To improve the quality and timeliness of the data sent to HRSA, CMS has agreed to reiterate the 30-day pricing data submission requirement for manufacturers and will consider referring appropriate cases of late submission to OIG to levy penalties. HRSA commented that it will work with CMS to maximize the acquisition of manufacturers' data as well as resolve problems related to missing data. HRSA also agreed to

publish detailed standards for the calculation of 340B ceiling prices to its Web site.

In response to our recommended steps for instituting oversight to improve the integrity of 340B ceiling prices, HRSA stated its intent to review the data that manufacturers and entities voluntarily submit, to the extent that resources permit. For more intensive audits of the 340B Program, HRSA deferred to its reliance upon OIG audits and evaluations.

HRSA does not support our recommendation to seek legislation to establish penalties for violations of the PHS Act, preferring to first acquire experience with its planned changes. Finally, HRSA does not concur with our recommendation that it reinstate the publication of HRSA's 340B prime vendor program's selling price on the agency Web site.

OFFICE OF INSPECTOR GENERAL RESPONSE

We are encouraged that CMS and HRSA concur with most of our recommendations and have already taken steps to improve the calculation of the 340B ceiling price. We also support HRSA's stated intention to compare the manufacturers' data currently received voluntarily to the ceiling price and review the prices charged to entities; however, we do not believe this represents an adequate approach to oversight of the program. While this level of review might prove helpful in some instances, it will only cover the number of limited manufacturers and entities who choose to supply drug pricing data.

We are concerned about the limited nature of HRSA's own plans for oversight of the 340B Program. While OIG is committed to ensuring the integrity of the HHS programs, we believe that routine oversight is an agency's responsibility. Therefore, we maintain that HRSA itself needs to develop a comprehensive auditing program.

We also do not agree with HRSA that it is best to wait to seek authority to establish penalties for violations of the PHS Act. Rather, we believe that the ability to impose fines and civil penalties is essential in ensuring that entities receive the full 340B discount.

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INTRODUCTION

OBJECTIVE

To assess the ability of the Health Resources and Services Administration (HRSA) to ensure that entities participating in the 340B Drug Pricing Program are able to purchase products at or below a statutorily established ceiling price.

BACKGROUND

In June 2004 the Office of Inspector General (OIG) issued a report entitled "Appropriateness of 340B Drug Prices" (OEI-05-02-00070), which evaluated whether participants in HRSA's 340B Drug Pricing Program (340B Program) were able to purchase their products at or below established ceiling prices as specified in the Public Health Service Act (PHS Act). Because the formula for 340B ceiling prices contains protected manufacturer pricing information, the entities cannot access the ceiling price to verify the accuracy of their charges, nor can HRSA precisely identify potential overcharges. Therefore, we analyzed whether 340B entities were being charged at or below the ceiling prices.

For the June 2004 report, we applied quality assurance standards to ensure the sufficiency, competency, and relevancy of the Government's record of the 340B ceiling price data per Government Auditing Standards.[1] Following our integrity checks, we presumed the Government's 340B ceiling price data to be reliable.

After the publication of the report, however, we discovered a number of problems with the underlying data used to support the first of the report's four findings. A comparison of the Government's ceiling prices to industry pricing data, along with interviews with CMS staff, led us to conclude that CMS provided us with 340B ceiling prices for the wrong timeframe. Based on our data concerns, we withdrew the report on October 21, 2004.

After receiving the data for the correct timeframe, our review revealed other, more subtle, embedded issues that caused us to further question the validity of the data. Thus, we determined that we would not use that data to report whether 340B entities receive drugs at or below the statutory discount. The report that follows describes the various data problems that need to be addressed prior to drawing such conclusions.

This report restates the findings related to HRSA's limited oversight as previously noted in "Appropriateness of 340B Drug Prices" and

introduces new concerns regarding the data used to provide appropriate oversight. Once we are assured that the data issues have been resolved, we intend to begin work on a new study to examine if and to what extent entities pay at or below 340B ceiling prices.

The 340B Drug Discount Program

In 1992, Congress amended section 340B of the PHS Act, "Limitations on Prices of Drugs Purchased by Covered Entities," to create the 340B Program. Under the 340B Pharmaceutical Pricing Agreement (the agreement), a manufacturer agrees to sell covered drugs at or below a specified ceiling price to certain PHS and Government-supported facilities, called covered entities, which serve some of the country's most vulnerable patient populations. These entities include community health centers, Ryan White grantees, and disproportionate share hospitals, among others (for a complete list, see Appendix A). Through the 340B Program, outpatient prescription drug costs are reduced by an estimated 20 to 50 percent.[2] Participating entities spent an estimated $3.4 billion on outpatient drugs in calendar year 2003.[3] HRSA is responsible for interpreting, implementing, and overseeing compliance with section 340B on behalf of the estimated 12,000 participating entities.

HRSA also maintains the electronic database of participating covered entities. Entities must notify HRSA of their intention to participate by completing and submitting appropriate registration forms. Upon receipt, HRSA adds the entity to the participating database and the entity is eligible to receive pharmaceuticals at the 340B discounted price beginning the next calendar quarter. Manufacturers rely on this list to verify an entity's eligibility for the 340B discount and use the contact information for shipping and billing purposes.

Section 340B(a)(8) of the PHS Act requires the Government to establish a prime vendor program to facilitate the delivery of covered outpatient drugs. HRSA's prime vendor serves its participants in three primary roles: negotiating prices below the 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 prime vendor program is voluntary.

Calculation of 340B Ceiling Prices

The drug discount that manufacturers must provide to participating entities is calculated according to a formula tied to the calculation of the

Medicaid drug rebate amount and to manufacturers' figures for a drug's average manufacturer price (AMP) and its best price offered during a quarter. Specifically, the 340B discount is equal to the AMP reduced by Medicaid's unit rebate amount (URA), which CMS calculates based on a formula stipulated in the Omnibus Budget Reconciliation Act of 1990 (OBRA '90).[4]

Pursuant to the PHS Act, inputs to the 340B discount formula are based on the smallest dispensable unit of each drug, such as a tablet, capsule, or milliliter. Therefore, taken literally, the discount yields a price that applies to each unit of the product that the entity purchases—for example, $1 per pill. Though it is not explicitly stated in law, the per-unit result of the ceiling price calculation must be multiplied by the drug package size to practically apply the discount to the way in which entities, such as hospitals, purchase products—for example, a bottle of 100 tablets versus an individual tablet.

Manufacturers report the product package size when applying for a National Drug Code (NDC) from the Food and Drug Administration (FDA). The NDC is a three-segment universal product identifier for drugs. FDA assigns the first segment of the code, which identifies the manufacturer. Manufacturers determine the second and third segments—the product code and package size code—and report this information to the FDA. Manufacturers report this same information to third-party contracted providers of prescription drug information, such as First Databank and Medispan, which sell the information to States, insurance companies, and CMS.

Pharmaceutical manufacturers and the Government each calculate 340B ceiling prices each quarter. Pharmaceutical manufacturers' calculated 340B ceiling prices are used in sales to covered entities. Manufacturers are not required to share their 340B ceiling prices with the Government. However, manufacturers are required to submit sales data to CMS for the Medicaid drug rebate program. In the past, CMS used this manufacturer-reported data to calculate the Government's official 340B ceiling prices on behalf of HRSA. On September 19, 2005, HRSA and CMS agreed that HRSA would be responsible for calculating 340B ceiling prices.

HRSA needs official Government 340B ceiling prices to "verify that the selling price to covered entities does not exceed the statutory ceiling price and for research, analysis, audit and dispute resolution purposes."[5] HRSA receives information on 340B selling prices from

manufacturers that elect to send their 340B prices to HRSA and from covered entities that have questions or concerns on the accuracy of the prices they pay.

Manufacturers' calculation of 340B ceiling prices. Under the PHS Act, manufacturers agree to charge covered entities at or below a maximum price calculated using specific sales and pricing data defined under the Social Security Act (the SSA Act) and used to calculate the Medicaid Drug Rebate amount. Section 340B(10) states that nothing shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price calculated using the specified formula.

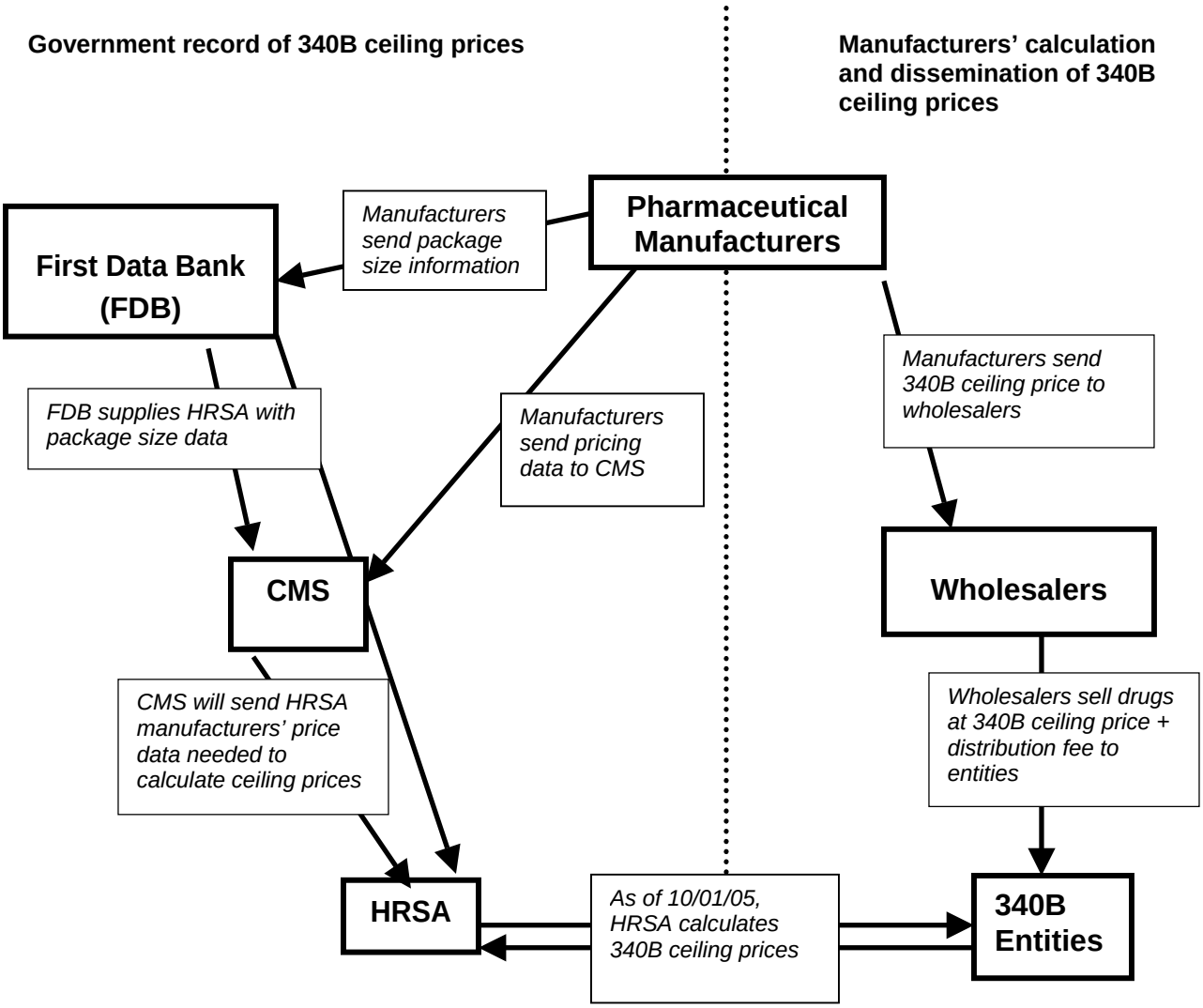
Manufacturers are responsible for ensuring that the 340B discount is passed on to the covered entity, regardless of whether the entity purchases drugs from a wholesaler or directly from the manufacturer.[6] HRSA staff stated that it is acceptable for wholesalers to charge covered entities 340B ceiling prices plus a distribution fee, which varies based on standard business practice. If a manufacturer fails to sell covered drugs at or below the ceiling price, it may be required to reimburse for discounts withheld and can be terminated from both the 340B and Medicaid Drug Rebate programs.

Government's official calculation of 340B ceiling prices. HRSA and CMS negotiated a new Intra-Agency Agreement and Data Use Agreement on September 19, 2005. Under the Agreement, HRSA will receive pricing data from CMS effective during Fiscal Year (FY) 2005, but will itself calculate the Government's 340B ceiling price. Prior to this agreement and covering the period of this report, CMS calculated the 340B ceiling prices on behalf of HRSA each quarter. Although CMS and HRSA have yet to negotiate an Agreement for FY 2006, OIG understands that HRSA will continue to be responsible for calculating 340B ceiling price.

Pursuant to the Intra-Agency Agreement, CMS provides HRSA with an electronic file containing the pricing data components needed to calculate 340B ceiling prices. These elements include the manufacturer's reported AMP and CMS's calculation of the URA for each NDC, which CMS sends HRSA approximately 45 days after a quarter's end. HRSA stated that it intends to use package size data from First Databank, a contractor that provides prescription drug information reported by manufacturers.

Chart 1 illustrates the two ways in which CMS and pharmaceutical manufacturers calculate 340B ceiling prices.

CHART 1: 340B PRICING DATA AND PURCHASE FLOW



Confidentiality of Ceiling Price Information

OBRA '90 stipulates that information disclosed by manufacturers, including AMP and Best Price ". . . shall not be disclosed by the Secretary . . . in a form which discloses the identity of the manufacturer, or the prices charged by the manufacturer, except as necessary to carry out the provisions of the Act."[7] Because of this provision, the 340B covered entities are not given access to the AMP, Best Price, or the calculated ceiling price. However, language in the Pharmaceutical Pricing Agreement states that the confidentiality protections only extend to the 340B ceiling price, not to the 340B selling price, to which

entities have access through their wholesaler price lists. The Pharmaceutical Pricing Agreement states:

> Section 340B requires the manufacturers to charge a price for covered outpatient drugs that will not exceed the amount determined under a statutory formula. This charged price, termed the 340B "Selling Price," is provided to wholesalers and covered entities by manufacturers and is available in the marketplace for the buying and selling of drugs by covered entities and is considered separate from the ceiling price as generated by the MDRI [CMS's Medicaid Drug Rebate Initiative] data elements.[8]

Related OIG Work

In June 2004, OIG also issued "Deficiencies in the 340B Drug Discount Program's Database" (OEI-05-02-00071), which reviewed the quality and timeliness of HRSA's database containing information on 340B entity enrollment. The PHS Act requires HRSA to maintain an electronic listing of all the entities enrolled in the 340B Program. Pharmaceutical manufacturers refer to the listing to verify entities' eligibility for the ceiling price and to ensure that their drugs are shipped to legitimate sites.

We found the enrollment database to be a poor source of information on participating 340B entities. Thirty-eight percent of our sampled entities were listed as enrolled, but do not actually participate in the 340B Program. The database had incorrect addresses for 43 percent of sampled entities and did not provide essential information on the entities' billing and shipping arrangements. According to interviews with nine major pharmaceutical corporations, the extent of incorrect addresses listed in the database hinders their ability to effectively identify entities eligible for the discount program.

We recommended that HRSA develop a strategic plan for improved management of the 340B database and HRSA is currently taking steps to address this recommendation.

METHODOLOGY

The findings in this report rely on data from two points in time. First, we used ceiling prices from the quarter effective during September 2002, which includes July, August, and September. These are the data originally collected for the now-withdrawn "Appropriateness of 340B Drug Prices." Second, to provide further information on the accuracy of the Government's 340B ceiling prices, we examined an analysis

conducted by CMS on pricing data used to calculate the 340B ceiling prices effective during the first quarter (January to March) of calendar year 2005.

Government's Official Record of the 340B ceiling price

CMS 2002 ceiling prices. For "Appropriateness of 340B Drug Prices," we requested CMS's confidential data used to calculate 340B ceiling prices for the quarter effective during September 2002, which includes July, August, and September. We requested invoices from a sample of participating entities for purchases made during the same month.

Upon receipt of the data, we applied quality assurance standards to ensure the sufficiency, competency, and relevancy of the Government's record of the 340B ceiling price data per Government Auditing Standards. Following our integrity checks, we presumed the Government's 340B ceiling price data to be reliable.

Following the publication of the report, however, we discovered a number of problems with the underlying data used to support the first of the report's four findings. A comparison of the Government's ceiling prices to industry pricing data, along with followup with CMS staff, led us to conclude that CMS had provided us with 340B ceiling prices for the wrong timeframe. Therefore, we requested that CMS extract the ceiling prices for the appropriate timeframe and received the correct data in November 2004.

Our analysis of the ceiling price data for the correct timeframe revealed serious data issues that caused us to further question the validity of the data. During our followup on "Appropriateness of 340B Drug Prices," we discovered issues with the Government's package size data. Therefore, we reassessed the package size data CMS used in the calculation of the 340B ceiling price.

To compile an accurate and verified list of package sizes, we compared the package size information listed in CMS's 2002 third-quarter ceiling prices against the package size information maintained by First Databank. CMS reported that it relied on First Databank for the 340B package size information. For those drug products for which there was a discrepancy between CMS and First Databank's information, we replaced CMS's package size with First Databank's package size. For the 10 drug products for which First Databank did not have information, we compared CMS's package size data to data maintained by FDA and replaced CMS's package size where applicable.

We also analyzed the 2002 data in great detail to uncover other, less-obvious data issues.

CMS 2005 ceiling prices. In addition to our analysis of the 2002 340B ceiling price data, we also examined an analysis that CMS conducted on ceiling prices effective for the first quarter of calendar year 2005. CMS conducted this analysis to assess the completeness of the data and to identify causes for missing data or instances in which ceiling prices were equal to zero. This initial analysis provided descriptive statistics on which data elements were missing—for example, AMP, Best Price, and package size—which could then result in missing 340B ceiling prices. Given that CMS staff had the ability to analyze data used for the Medicaid program more thoroughly than we could for the purposes of this report, we felt it was important to include the findings of their analysis. Additionally, the analysis CMS conducted covers 2005—much more recent than our 2002 analysis—showing that the concerns with the 340B data persist.

We verified the accuracy and reliability of the analysis conducted by CMS by duplicating the analysis where possible and by meeting with CMS analysts to review the methods used in the analysis.

We also used the data CMS provided to create two categories from which to assess the data: those NDCs that should have ceiling prices and those NDCs that should not have ceiling prices. This approach differs from CMS's analysis of the data, which evaluates the overall completeness of the categories combined. Because we felt inclusion of NDCs that should not have ceiling prices would skew the results of our analysis, we did not include them in our overall estimations. Consequently, our results and basis for findings differ from what CMS originally reported.

Interviews and Document Review

To assess the adequacy of 340B Program oversight, we reviewed relevant statutes, the Pharmaceutical Pricing Agreement, and HRSA program memoranda. We also interviewed officials from CMS and HRSA. We requested documentation of the Government's process for calculating the 340B ceiling price, but neither CMS nor HRSA could provide such information.

Limitations

We did not review CMS's oversight of manufacturer-reported prices required by OBRA '90. We did not audit the accuracy of manufacturers' reported prices. We relied on CMS's analysis of 340B ceiling prices for

the first quarter of 2005, verifying and testing its conclusions where possible. Lastly, we did not assess whether price discrepancies or overcharges are occurring.

Our results describe challenges related to the Government's ceiling prices as calculated by CMS. With the 2005 Intra-Agency Agreement, HRSA, rather than CMS, will be calculating the 340B prices.

Despite this change, HRSA will rely on the same pricing data and will continue to face the same challenges CMS faced in ensuring that the 340B ceiling prices are accurate.

Standards

We conducted our review in accordance with the Quality Standards for Inspections issued by the President's Council on Integrity and Efficiency.

Due to systemic problems with the accuracy and reliability of the Government's record of the 340B ceiling price, HRSA is unable to appropriately oversee the 340B Program

As the administrator of the 340B Program, HRSA's responsibilities extend to overseeing the validity of the ceiling price data used to monitor the program. HRSA needs the quarterly 340B ceiling price to verify that the 340B covered entities receive the discount to which they are entitled by law. Based on reviews of the data collected, we found the 340B ceiling prices HRSA received from CMS to be so problematic that they are of little use to the agency's oversight of the 340B Program.

The official 340B price record was missing 28 percent of the ceiling prices

The 340B ceiling price file for the first quarter of 2005 was missing 28 percent of the prices needed for appropriate program oversight. For 49 percent of these missing ceiling prices, the file did not contain the AMP. For 29 percent, the products were missing package size data. For the remaining 21 percent, the products had neither the AMP nor the package size.[9]

Missing AMP data are most likely the result of manufacturers not reporting or delaying submission of AMP data to CMS. Manufacturers are required to report their drugs' AMP and the single best price within 30 days after a quarter's end so that CMS can calculate the drug's URA. If the data are late, the Secretary may impose a civil monetary penalty for failure to provide timely information on AMP or the best price.[10] Instead of seeking penalties, CMS staff typically notify the manufacturers of the missing data and request prompt submission. Manufacturers typically include previously missing data with their next quarter's submission.

While late submission of pricing data may delay, rather than prevent, State Medicaid agencies' rebate collections, it has a more immediate impact on the 340B Program because HRSA will be unable to calculate ceiling prices at the time they are needed for the 340B Program. Further, although CMS will supply HRSA with a separate file of previously missing pricing data along with the quarterly updates, HRSA does not have a policy in place to use the file to update the official ceiling prices. Therefore, any missing ceiling prices will remain missing.

Eight percent of the Government's 340B ceiling prices were inaccurate because the calculation did not include the 340B discount

To correctly calculate a 340B ceiling price, HRSA will need the drug's AMP, URA, and package size. Based on our analysis of the 37,067 official CMS-calculated 340B ceiling prices for the first quarter of 2005, 8 percent were inaccurate because the price did not include the URA. The URAs were not included because CMS's validity test for a manufacturer's AMP submission, known as the "50/50" edit,[11] rejected the AMP. Without an AMP, CMS does not calculate a URA, so the ceiling price submitted to HRSA was equal to AMP-0. Thus, HRSA received ceiling prices that appeared to be complete, but did not include the 340B discount.

For 90 percent of the records with no URA, package size information is available. However, the 340B ceiling price was overstated because the ceiling price is equal to (AMP-0) multiplied by the package size, which did not include the discount.

For the remaining 10 percent of the records, HRSA's file was missing both the URA and package size. Again, HRSA received data that appeared complete, but in reality were incorrect and dramatically understated the real ceiling price. This is because the ceiling price was the equivalent of the unit (AMP-0) multiplied by a blank field (a result of no package size data), therefore generating a price that did not represent the price for the full product purchased and which did not include the discount.

According to CMS staff, when CMS received a manufacturer's corrected pricing information at a later date in response to its 50/50 request, the revised AMPs and URAs were sent to HRSA in a separate file; however, HRSA did not have a policy to make adjustments to the official ceiling prices, so the prices remain inaccurate.

The Government's record of 340B ceiling prices included a substantial amount of information that is unnecessary to the discount program and upon which HRSA inappropriately relied on in its oversight role

According to CMS's analysis, the Government's official record of the 340B ceiling prices included information about 95,928 NDCs, which is nearly 50,000 more than the number of active NDCs listed in CMS's Medicaid Drug Rebate database for the same timeframe. Thus, 46 percent of the records that HRSA had received from CMS were irrelevant to the 340B Program. To further complicate this matter,

HRSA inappropriately relied on some of this irrelevant information in its limited program oversight efforts.

Based on CMS's analysis, the 340B ceiling price file generated each quarter included all products with a termination date after November 30, 1993; products with future market dates; and terminated manufacturers. CMS staff were unable to explain why the file contained this extraneous information. They stated that that was how the file was set up in the early 1990s. HRSA also could not explain why the information was included and had no documentation as to why it is included. Neither CMS nor HRSA was aware of the unnecessary information because neither agency had reviewed or questioned the data or the resulting 340B ceiling price since the program was established.

None of the information pertaining to terminated manufacturers or terminated products should be used for 340B ceiling price purposes. However, in November 2004, HRSA reported the results of its analysis on the completeness of CMS's ceiling price file and included these expired NDCs in the universe. Because HRSA's universe was overstated, it concluded that 60 percent of the ceiling price data were missing and requested a response from CMS. When the irrelevant data are excluded, however, the actual error rate is 28 percent.

The lack of established technical procedures for calculating the Government's record of 340B ceiling prices resulted in unreliable data

According to CMS and HRSA staff, no established written procedures exist for calculating the 340B ceiling price. Neither CMS nor HRSA has a 340B ceiling price operations guide or manual that explicitly states policies for calculating the ceiling prices. The staff at both agencies do not know who set up the initial Intra-Agency Agreement or how the calculation was originally determined. Instead, as CMS staff explained, the policies for calculating the ceiling prices have been orally passed down since the early 1990s. CMS officials have never questioned the policies for calculating the ceiling price because HRSA never raised any issues with the outcomes.

A general lack of detailed procedures for calculating the 340B ceiling price results in unreliable data with which to oversee the 340B Program and could lead to inappropriate enforcement actions. For example, if HRSA had conducted a review of the appropriateness of entities' prices using the data CMS generated, the improper 340B ceiling prices would have produced faulty results and potentially misleading information.

Due to the absence of established procedures, the 340B ceiling price was calculated using incorrect package size information. CMS was using incomplete information on a product's package size, thereby calculating and supplying HRSA with incorrect 340B ceiling prices. Based on our analysis of the ceiling prices from 2002, we estimate that incorrect package size data significantly affected 6 percent of the 3,000 prices we reviewed. HRSA had never examined the completeness of package size information or specified to CMS the type or source for package size data needed to calculate 340B ceiling prices.

To correctly compute 340B ceiling prices, it is necessary to multiply the Medicaid unit price by the product's total package size. To define a product's package size, it is necessary to multiply the number of units in a bottle or vial by the number of bottles or vials that are packaged and sold together. This is typically expressed in a "unit X amount" notation. For example, 100 pills sold in a bottle would have a total package size of 100 X 1=100.

In our analysis of package size data, we found that the ceiling prices calculated by CMS included only units in calculating the 340B ceiling price, rather than correctly multiplying units X amount to determine the total package size. When CMS used the package size information from First Databank, it only captured the field containing units, not the second field listing the amount.

Package size problems are rarely found in drug products delivered as pills. For these products, it is easy to identify the unit as a pill and the amount as the bottle that contains them. Using the example from above, 100 pills sold in a bottle would have a total package size of 100 X 1. In these cases, since the amount, or multiplier, is one, the information on units previously captured by CMS and the total package size necessary to correctly calculate the 340B ceiling price are the same.

However, for products measured by liquid volume or weight, such as inhalers, ointments, or products sold in vials, incomplete package size information does present a problem. In these cases, it can be difficult to determine what constitutes a unit and what constitutes the amount. In many of these cases, the manufacturer specifies the amount as a number greater than one.

For example, the manufacturer may report the total package size for a liquid prescription drug as "3 mL X 5," equal to 3 milliliters of product in each of 5 vials. In this case, it is necessary to multiply the unit X amount, or the number of milliliters (3) by the number of vials (5),

which results in a total package size of 15. Using only the units, the calculated 340B ceiling price would underestimate the actual 340B ceiling price by a factor of 5.

As this example illustrates, the miscalculation of the ceiling price due to incomplete package size information may significantly understate the price. In our review of CMS's listed package sizes, we discovered cases in which the ceiling price was 50 percent lower than the actual ceiling price calculated using the correct package size.

Our review of FDA and First Databank package size data, which are both reported by manufacturers, yielded marked discrepancies that raise questions about potential problems with the general consistency and reliability of manufacturers' package size reporting. Manufacturers are not held to any specific standards when reporting the package size, so determining the correct amount for the purposes of calculating the 340B ceiling price is complicated and affects the entire pharmaceutical industry.

HRSA has no procedure for converting negative ceiling price values received from CMS into practical ceiling prices. HRSA does not have an official policy regarding how to convert negative prices to reflect positive, and therefore practical, ceiling prices. HRSA has never communicated with CMS about the incidence of negative ceiling prices, nor did it perform the necessary conversions for its record of 340B ceiling prices. Our review of CMS's 3rd quarter 2002 data found 117 products with negative prices.

Because the 340B ceiling price formula is essentially AMP minus URA, negative ceiling prices occur when the discount, the drug's URA, is greater than the base price, the AMP. This situation creates a negative price that is meaningless in the marketplace. HRSA recommends to manufacturers that if the ceiling price calculation yields a negative number, it expects the manufacturer to charge the entity a penny. However, HRSA has not provided official guidance on this issue or updated its records to reflect this expectation.

If HRSA uses data containing negative ceiling prices to determine if entities paid at or below 340B ceiling prices, the results will be skewed. Mathematically, subtracting a negative number is the same as adding a positive; therefore, the presence of negative figures in the Government's official record would seriously distort any assessment of price discrepancies. For example, if the covered entity actually paid $0.01 for a product, but HRSA's uncorrected data had a ceiling price of -$2.50, the

subtraction of $0.01 minus (-$2.50) would result in a positive $2.51 overcharge. In reality the manufacturer may have charged the entity a penny, which is the amount it should have charged per HRSA's recommendation; however, the comparison of these two prices would show an overcharge. These false positives might cause HRSA to draw invalid conclusions about compliance with the discount requirements.

HRSA lacks the oversight mechanisms and authority to ensure that 340B entities pay at or below the 340B ceiling price

Even if HRSA's record of the ceiling price were completely and accurately calculated, HRSA does not use the information to oversee the 340B Program because it lacks the necessary mechanisms and authorities. HRSA has no process for ensuring that participating entities receive the price to which they are entitled. HRSA also does not have the statutory authority to enforce compliance with the PHS Act or the the Pharmaceutical Pricing Agreement, or to effectively implement its prime vendor program.

While manufacturers have a vested interest in complying with the terms of the PHS Act and the Pharmaceutical Pricing Agreement, HRSA has not pursued increased authority or developed a plan designed to ensure the integrity of the 340B Program.

HRSA has no system for ensuring that entities participating in the 340B Drug Discount Program receive the statutory discount

According to interviews with HRSA officials, the agency has no reliable way to document that entities purchasing drugs under the 340B discount are actually receiving the discount to which they are entitled.[12] Because confidentiality provisions of OBRA '90 prevent the disclosure of 340B pricing data to the entities, HRSA has the primary responsibility of ensuring that the program's participants do not pay more than the 340B ceiling price. However, we found that HRSA does not conduct audits or spot checks of entities' or manufacturers' prices, citing insufficient authority.

HRSA does not compare the 340B ceiling prices calculated by CMS to pharmaceutical manufacturers' 340B ceiling prices

HRSA does not verify the official Government 340B ceiling prices against manufacturers' 340B ceiling prices to detect discrepancies. Manufacturers must calculate their ceiling prices to participate in the 340B Program, but they are not required to report their final ceiling prices to HRSA. However, manufacturers sign the Pharmaceutical Pricing Agreement, which states they must charge entities at or below

the ceiling price and can face consequences for violating the terms of the agreement. Theoretically, the Government and the manufacturers should calculate the same ceiling price because they use the same numbers. However, HRSA does not check and thus is unable to detect whether manufacturers perform the calculation properly and whether entities are paying at the correct ceiling price.

HRSA has no statutory authority to enforce compliance with the PHS Act or the Pharmaceutical Pricing Agreement, or to effectively implement its prime vendor program

HRSA does not have the necessary legislative, regulatory, or contractual authority to effectively oversee the 340B Program. Unlike the Medicaid Rebate Program statute, the PHS Act does not impose civil penalties for noncompliance with the 340B Program requirements. Instead, the PHS Act, in accordance with its predecessor, the SSA Act, states that manufacturers must comply with the terms of the 340B Program or be terminated from participation in the Medicaid and 340B Programs.[13] Currently, HRSA has guidance on a voluntary process for resolving disputes between manufacturers and entities,[14] but, according to interviews with HRSA staff, pharamaceutical manufacturers, entities, and other industry experts, no one has engaged in the dispute resolution process.

HRSA's only statutory authority to enforce 340B Program requirements may be too extreme to actually use; in addition, other authorities mentioned in program guidance are ambiguous. According to 340B Program guidelines, if HRSA determines that a manufacturer has violated the provisions of section 340B of the PHS Act, the manufacturer's Pharmaceutical Pricing Agreement could be terminated or "other actions taken, as deemed appropriate."[15] However, terminating a manufacturer's participation is an extremely severe sanction, given the effect terminating a manufacturer would have on access to medications for the millions of Medicaid and 340B beneficiaries. Further, it is unclear what "other actions" HRSA can take.

Because HRSA's informal dispute resolution process is voluntary, covered entities or manufacturers are not required to participate. If a covered entity believes that a manufacturer is charging a price for a covered drug that exceeds the ceiling price, it can submit a written request for a review of the dispute, but this does not guarantee the resolution of such dispute. If the manufacturer does not cooperate with

the resolution process because there is no requirement to do so, HRSA cannot enforce the consequences for violations as stated in HRSA's Pharmaceutical Pricing Agreement.

Pursuant to this Agreement, if a manufacturer is noncompliant, the HHS Secretary "may require the manufacturer to reimburse the entity for discounts withheld."[16] However, the directive to reimburse overcharges is only found in the agreement, which does not have the same force as a contract and is not reinforced by the PHS Act.

Even when HRSA attempts action against violators of the 340B Program, its lack of legal authority makes it challenging to enforce its guidelines. For example, in 2003, OIG issued a report citing five manufacturers with charging 340B providers $6.1 million more than they should have under the law.[17] In September 2004, HRSA issued letters to each of the drug companies identified in the audit requesting that they develop action plans that include refunding covered entities for overcharges. According to HRSA, the companies have responded to the letters, but refunds have yet to be recovered.

To further illustrate the ineffectiveness of HRSA's current authorities, in 2001, HRSA itself discovered overcharges based on entities' invoices, but did not pursue the issue further, citing insufficient authority. The Public Hospital Pharmacy Coalition, an organization that represents the interests of public hospitals participating in the 340B Program, submitted six hospitals' sales data to HRSA for price verification. HRSA analysts found that 37 of the 50 drug prices exceeded the ceiling price, but could not provide specific information on the extent of the overcharges. Instead, HRSA informed the coalition that the differences ranged from 10 to 100 percent over the 340B ceiling price. Despite the evidence, HRSA did not initiate the dispute resolution process or take other action to resolve this issue.

Insufficient legal authority also hampers HRSA's ability to effectively implement its prime vendor program. Section 340B(8) of the PHS Act requires HRSA to establish a prime vendor program that negotiates discounts below the ceiling price based on the buying power of the participating entities. However, HRSA does not have the specified authority to disclose the 340B ceiling prices to its prime vendor for the stated purpose of negotiation. As a result, the prime vendor's ability to perform its assigned role is challenged by the lack of information.

Participating entities cannot independently verify that they receive the correct 340B price due to confidentiality provisions

Pursuant to the confidentiality provisions in OBRA '90 regarding manufacturers' pricing information, covered entities do not have access to confidential drug pricing information used to calculate the 340B discount—AMP, best price, and URA. Therefore, HRSA cannot share 340B ceiling prices with the entities.

HRSA's 340B Program guidance states that "confidential drug pricing information includes both 'best price' and 'average manufacturer price.' The quoted price and actual price given by the manufacturer to the covered entity is not confidential."[18] The selling price that manufacturers provide to wholesalers and entities is considered public information because it is not data reported to the Government for the purpose of the Medicaid program or the 340B Program. Also, since the 340B discount is a ceiling price, a variety of selling prices can exist under the ceiling.

In a 2004 survey of 340B participants, commissioned by HRSA and conducted by Mathematica Policy Research, 23 percent of respondents complained about the lack of price transparency. Entities may submit written requests to HRSA for 340B price approximations, but survey respondents viewed this process as cumbersome and inefficient.[19] HRSA staff confirmed that they are only able to review price requests limited to 10 products at a time due to staffing limitations. Further, due to the confidentiality provisions, HRSA can only provide a general indication to the entity on whether the price is over the ceiling. In other words, if an entity's reported price exceeds the ceiling price, HRSA can inform the entity of the overcharge, but not the extent of the overcharge.

In October 2000, HRSA attempted to provide entities with a tool to verify prices but was ultimately unsuccessful. HRSA posted the selling prices of 207 commonly prescribed drugs (negotiated by and purchased through its prime vendor) on its Web site to demonstrate the prices entities could receive if they signed up for the prime vendor program. However, due to industry complaints that the publication violated the confidentiality provisions stated in the Medicaid statute, HRSA removed the list in January 2001.[20] This action removed the only tool entities had to verify discounts. HRSA does not currently post any information related to price on its Web site or elsewhere.

Since HRSA cannot share the protected data and is faced with industry opposition to supplying sales data, entities are unable to determine or approximate whether their purchases are at or below the 340B ceiling price. Absent such data, entities either assume that the manufacturer's reported price is compliant with the law or expend significant resources to obtain drug pricing information from secondary sources (including wholesalers, consultants, and other purchasers).

RECOMMENDATIONS

Our findings point to systemic problems with HRSA's oversight of the 340B Program and with the data used in the calculation of 340B ceiling prices. HRSA's 340B ceiling price has not historically been based on accurate pricing information and we have concerns about the continued problems posed by inaccurate and incomplete data. Even if HRSA did possess accurate ceiling prices, we believe that it does not have appropriate mechanisms in place to ensure that entities are charged at or below the appropriate ceiling price. HRSA also does not have the authority to enforce the terms of the PHS Act. Finally, confidentiality provisions prevent HRSA from sharing the 340B ceiling price data with covered entities so they can verify that they are receiving the price to which they are entitled. As a result, it is nearly impossible for HRSA to assess whether the 340B Program is being implemented as intended to "stretch Federal resources as far as possible, to reach more eligible patients and provide more comprehensive services."[21]

HRSA's ability to protect the integrity of the 340B Program is not only crucial to the thousands of Federal grantees and public hospitals whose patients currently benefit from the discount, but is also important to the growing number of future beneficiaries. Due to a change enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, rural and urban hospitals with fewer than 100 beds now meet the eligibility criteria to enroll in the 340B Program.[22] State Medicaid Directors are also seeking ways to cover the pharmaceutical needs of some Medicaid beneficiaries using the 340B discount price, which is typically lower than the Medicaid rebate. Finally, the President's proposed budget for fiscal year 2006 completes the Administration's 5-year commitment to create 1,200 new or expanded health center sites serving an estimated additional 6.1 million people.[23] Each new site will be eligible for the 340B Program. These beneficiaries depend on receiving discounted prescription drugs through the 340B Program; therefore, it is essential that the program receive appropriate oversight.

The following recommendations focus on improving HRSA's oversight of the 340B Program as it relates to the integrity of its ceiling prices, as well as its ability to ensure that entities pay no more than the appropriate price.

CMS and HRSA should work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices

CMS and HRSA have already engaged in discussions about calculating the 340B ceiling price. On September 19, 2005, CMS and HRSA signed a new Intra-Agency Agreement, which states that HRSA will receive pricing data effective during FY 2005 from CMS, but will itself calculate the Government's 340B ceiling price. We encourage CMS and HRSA to continue to work together to improve the accuracy and timeliness of the pricing data CMS has agreed to provide HRSA. Additionally, because no Agreement has been signed for FY 2006, we anticipate the need for continued cooperation to ensure that there is no interruption in the calculation of the 340B ceiling prices used to monitor the program. To improve the data contained in the 340B ceiling price file, CMS and HRSA should:

- Restate the need for manufacturers to provide complete and timely pricing data, as required by OBRA '90; if manufacturers' pricing data submissions do not comply with the 30-day requirements, CMS should consider making referrals to OIG to levy penalties for late data in appropriate cases;
- Determine a solution for updating missing prices so HRSA's record is complete; and
- Eliminate data that are not relevant to the 340B Program, such as terminated products and labelers, as well as products with future market dates.

HRSA should establish detailed standards for the calculation of 340B ceiling prices

To prevent the types of errors we discovered in CMS's calculation of the 340B ceiling price, we suggest that HRSA take action to ensure the accuracy of its calculations. In particular, HRSA needs to develop specific policies around correctly calculating 340B ceiling prices. HRSA's standards should include specifics on the use of correct package sizes and a conversion of negative ceiling prices.

HRSA should institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities

We suggest that this oversight protocol include:

- Comparing the Government's official 340B ceiling prices to the manufacturers' ceiling prices each quarter to detect discrepancies. HRSA could accomplish this by requesting that manufacturers

submit either a sample of 340B prices or send all 340B prices directly to HRSA each quarter.

- Spot-checking entity invoices to ensure that entities are charged at or below 340B ceiling prices.
- Selectively auditing manufacturers, wholesalers, and covered entities to ensure the integrity of the 340B Program.

HRSA should seek authority to establish penalties for violations of the PHS Act

Other than exclusion from participation in the Medicaid drug rebate and 340B programs, HRSA has no effective penalties to use for violations of the PHS Act or the Pharmaceutical Pricing Agreement. HRSA should propose a legislative package that might include a variety of sanctions, such as fines and civil monetary penalties. We recommend that HRSA consider as a model CMS's statutory authority to enforce the Medicaid rebate program, pursuant to § 1927(b)(3)(C)(i) of the Social Security Act, and seek similar authorities with respect to enforcement of the 340B Program.

HRSA should provide covered entities with secured access to certain pricing data to help approximate 340B ceiling prices

To optimize 340B savings and maximize the efficiency of the covered entities' role in the program, we suggest two methods to help entities detect differences between the price they pay and the price they are entitled to under the law:

1. <u>HRSA could design a mechanism that allows participating entities to assess whether prices exceed the ceiling price.</u> Because OBRA '90 requires the HHS Secretary to keep components of the 340B ceiling price—AMP and Best Price—confidential, HRSA may not disclose the 340B ceiling price to the entities. Presently, HRSA can informally review a limited number of prices on behalf of the entities and inform them if their prices exceed the ceiling price. However, to protect confidential data, it cannot reveal the extent of any overcharge.

   We suggest that HRSA develop a price verification system that informs entities if they are paying above the ceiling price. Entities should have enough information to, at the very least, submit prices to determine whether they comply with the 340B discount requirements. Through this system, entities should be able to identify potential vulnerabilities and pursue further communication

with HRSA or the manufacturer. One suggestion is to institute a password-protected, Web-based query function to allow entities to check the prices they paid against 340B ceiling prices, while still protecting the confidentiality of the manufacturers' data. For example, entities could enter the price they paid for a drug and receive a response if it exceeds the ceiling price within a specified percentage (for example, within 5 percent). Alternatively, entities could submit the prices paid for a market basket of products to obtain information about the appropriateness of the charges in the aggregate.

2. HRSA could reinstate the publication of its 340B prime vendor program's selling price list on the agency Web site so covered entities could estimate the potential savings available to them. Pursuant to HRSA's entity guidelines, confidential pricing information includes both the best price and the AMP; however, the quoted price and the actual price given by the manufacturer to the entity are not confidential.[24]

   Because the absence of an offical 340B price list presents a major challenge to participation in the 340B Program, we suggest that HRSA maximize the use of its prime vendor to provide nonconfidential pricing information to covered entities. HRSA's posting of the agency's prime vendor program's prices in 2000 did not reveal information protected by OBRA '90; rather, HRSA's information included quoted and/or actual wholesaler prices that are widely available in the marketplace. The reinstatement of this list would provide entities with a tool to compare the prices they pay to a source that is overseen by the prime vendor.

AGENCY COMMENTS

HRSA and CMS concurred with most of our recommendations. The complete text of the comments can be found in Appendix B.

Based on the issues raised and recommedations offered in our withdrawn report, HRSA and CMS have already engaged in numerous technical discussions about calculating the 340B ceiling price. As a result of these discussions, HRSA and CMS negotiated a new Intra-Agency Agreement and Data Use Agreement. Under this Agreement, HRSA will receive pricing data from CMS effective during FY 2005, but will itself calculate the Government's 340B ceiling price. To improve the quality and timeliness of the data sent to HRSA, CMS has agreed to

reiterate the 30-day pricing data submission requirement for manufacturers and will consider referring appropriate cases of late submission to OIG to levy penalties. HRSA commented that it will work with CMS to maximize the acquisition of manufacturer's data as well as resolve problems related to missing data. HRSA also agreed to publish detailed standards for the calculation of 340B ceiling prices on its Web site.

In response to our recommended steps for instituting oversight to improve the integrity of 340B ceiling prices, HRSA stated its intent to review the data that manufacturers and entities voluntarily submit, to the extent that resources permit. HRSA stated that it further intends to compare manufacturers' pricing data, provided through wholesalers to its Prime Vendor Program, to its 340B ceiling prices. For more intensive audits of the 340B Program, HRSA deferred to its reliance upon OIG audits and evaluations.

HRSA does not support our recommendation to seek legislation to establish penalties for violations of the PHS Act, preferring to first acquire experience with its planned changes. Finally, HRSA does not concur with our recommendation that it reinstate the publication of HRSA's 340B prime vendor program's selling price on the agency Web site. HRSA stated that it is exploring other options.

OFFICE OF INSPECTOR GENERAL RESPONSE

We are encouraged that CMS and HRSA concur with most of our recommendations and have already taken steps to improve the calculation of the 340B ceiling price. In addition, we support HRSA's intention to publish detailed standards for the calculation of the 340B price. However, HRSA did not indicate an approximate timeline for posting this information or provide details on what we should expect of the standards.

We also support HRSA's stated intention to compare the manufacturers' data currently received on a voluntary basis to the ceiling price and review the prices charged to entities; however, we do not believe this represents an adequate approach toward oversight of the program. While this level of review might prove helpful in some instances, it will only cover the number of limited manufacturers and entities who choose to voluntarily supply drug pricing data. Comparing manufacturers' selling prices to the official Government 340B prices represents a positive step toward comprehensive oversight.

We are concerned about the limited nature of HRSA's own plans for oversight of the 340B Program. While OIG is committed to ensuring the integrity of the HHS programs, we believe that routine oversight is an agency's responsibility. Therefore, we maintain that HRSA itself needs to develop a comprehensive auditing program.

We also do not agree with HRSA that it is best to wait to seek authority to establish penalties for violations of the PHS Act. Rather, we believe that the ability to impose fines and civil penalities is essential in ensuring that entities receive the full 340B discount.

ENDNOTES

[1] OIG quality assurance standards are based on the Government Auditing Standards, 2004.

[2] Total purchase estimates from the Office of Pharmacy Affairs, 2003.

[3] 340B entity expenditures are based on estimates from the Director of HRSA's Office of Pharmacy Affairs in a presentation to the 340B Coalition on July 14, 2003. This is the most recent estimate available.

[4] Section 1927 of the Social Security Act, 42 U.S.C. 1396s, defines the sales information drug manufacturers must provide to CMS, including the AMP and Best Price for the total sales of each covered outpatient drug over a quarter's time.

[5] Intra-Agency Agreement signed between CMS and HRSA, 2004.

[6] Guidance Regarding Section 602 of the Veterans Health Care Act of 1992 Limitation on Prices of Drugs Purchased by Covered Entities, 58 FR 27291, December 29, 1993.

[7] Section 1927(b)(3)(D)(i) of the Social Security Act, 42 U.S.C. 1396r-8(b)(3)(D)(i).

[8] Intra-Agency Agreement signed between CMS and HRSA, 2004.

[9] Totals do not equal 100 due to rounding.

[10] The amount of the penalty, as set forth in section 1927(b)(3)(C)(i) of the Act, is $10,000 for each day in which such information has not been provided. The Secretary has delegated the responsibility of imposing such penalties to OIG when CMS identifies instances in which manufacturers are in violation of the 30-day submission requirement.

[11] The 50/50 edit was designed to reject an AMP when it is either 50 percent higher or lower than the manufacturer's submission from the previous quarter. When the 50/50 edit detects faulty AMP values, CMS sends a report to the manufacturer requesting corrected information.

[12] OIG interview with HRSA's Office of Pharmacy Affairs, June 2003.

[13] 42 U.S.C. 1396r-8(b)(4)(B).

[14] 59 FR 30023, May 13, 1994.

[15] 61 FR 65413, December 12, 1996.

[16] Pharmaceutical Pricing Agreement, section IV, Dispute Resolution, subsection (c).

[17] Office of Inspector General, "Pharmaceutical Manufacturers Overcharged 340B Entities," A-06-01-00060, March 10, 2003.

[18] 58 FR 68922, December 29, 1993.

[19] Mathematica Policy Research, Inc., August 30, 2004, "The PHS 340B Drug Discount Program: Results of a Survey of Eligible Entities."

[20] Pharmaceutical Researchers and Manufacturers of America letter to HRSA, January 16, 2001.

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

[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, section 402, increased the Medicare Disproportionate Share Hospital cap from 5.25 percent to 12 percent. (SSA 1886(d)(5)(F)(xiv)

[23] President's Budget FY 2006, "Advancing the Health, Safety, and Well-Being of Our People," pp. 3-4.

[24] 59 FR 25110, May 13, 1994.

APPENDIX ~ A

Programs Eligible to Participate in 340B:

Community health centers

Tuberculosis clinics

Sexually transmitted disease clinics

Disproportionate share hospitals

Migrant health clinics

Healthcare for the homeless centers

Federally qualified health center look-alikes

Hemophilia treatment centers

Ryan White Title I

Ryan White Title II (direct purchase)

Ryan White Title II (rebate option)

Ryan White Title III

Public housing clinics

School-based programs

Special Projects of National Significance

Black lung clinics

Urban Indian organizations

Federally qualified health centers funded by the Office of Tribal Programs

Family planning clinics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville MD 20857

SEP 28 2005

TO: Daniel R. Levinson
Inspector General

FROM: Administrator

SUBJECT: Office of the Inspector General (OIG) Draft Report: "Deficiencies in the Oversight of the 340B Drug Pricing Program" OEI-05-02-00072

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

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

Betty James Duke

Attachment

Health Resources and Services Administration's Comments on the Office of Inspector General's Draft Report "Deficiencies in the Oversight of the 340B Drug Pricing Program: OEI-05-02-00072

OIG RECOMMENDATION

CMS and HRSA should work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices. CMS and HRSA have already engaged in discussions about the challenges of calculating 340B ceiling prices and deciding on the conditions of the most recent Intra-Agency Agreement. We encourage them to continue to work together to resolve these issues. In addition, CMS and HRSA should focus on improving the quality of the data contained in the 340B ceiling price file. We believe that to improve the data contained in the 340B ceiling price file, CMS and HRSA should:

- **Restate the need for manufacturers to provide complete and timely pricing data, as required by OBRA '90; if manufacturers' pricing data submissions do not comply with the 30-day requirements, CMS should consider referrals to the OIG to levy penalties for late data in appropriate cases;**
- **Determine a solution for updating missing prices so HRSA's record is complete, and;**
- **Eliminate data that are not relevant to the 340B Program.**

HRSA Response:

HRSA concurs with this recommendation. HRSA will continue to work with CMS to maximize their acquisition of current manufacturers' data as well as resolve problems with missing data.

OIG RECOMMENDATION

HRSA should establish detailed standards for the calculation of 340B ceiling prices. To maintain accurate records for their oversight of the program, HRSA should clearly specify how to calculate 340B prices, particularly in relation to package size and negative ceiling prices.

- **To ensure that the correct package size data are used to calculate 340B ceiling prices, HRSA could clearly specify to CMS the source and type of package size data needed for the calculation in the Intra-Agency Agreement. HRSA should also continue to obtain the pricing information from CMS, but calculate the ceiling prices itself or through a contractor using the complete package size information collected from one of the drug price data vendors or from the manufacturers.**

HRSA Response:

The Intra-Agency Agreement negotiated between HRSA and CMS contains the provisions that CMS will continue to provide the quarterly 340B pricing data to HRSA. HRSA will calculate the ceiling prices itself. HRSA has identified a source for the package size data that will permit it to compute accurate ceiling prices.

- **HRSA needs to establish a formal policy regarding the conversion of negative ceiling prices into practical ceiling prices and needs to perform the conversions in the 340B database.**

HRSA Response:

HRSA has had a long practice of recommending to pharmaceutical manufacturers that they charge $0.01 to convert a negative price to a positive one. HRSA will work with CMS to develop a mechanism to convert negative 340B prices to positive prices that equate to $0.01 per unit. HRSA anticipates publishing detailed standards for the calculation of 340B ceiling prices to HRSA's Office of Pharmacy Affairs (OPA) Web site.

OIG RECOMMENDATION

HRSA should institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities. We suggest this oversight protocol include:

- **Comparing the Government's official 340B ceiling prices to the manufacturers' ceiling prices each quarter to detect discrepancies. HRSA could accomplish this by requesting that manufacturers submit either a sample of 340B prices or send all 340B prices directly to HRSA each quarter.**

HRSA Response:

Some manufacturers currently provide to HRSA's OPA their quarterly pricing data. HRSA will validate this data with the Government's official 340B prices. HRSA also plans to compare manufacturers' pricing data (that is provided by major wholesaler distributors through its Prime Vendor (PV) Program) with official 340B pricing data computed by the Government. Discrepancies in these comparisons will be promptly investigated and resolved, to the extent that resources permit.

- **Spot-checking entity invoices to ensure that entities are charged at or below 340B ceiling prices.**

HRSA Response:

HRSA concurs with the utility of such an exercise in improving the integrity of 340B prices being paid by participating covered entities. However, this particular program lacks the authority to require covered entities (grantees and non-grantees) to submit their invoices for review by the Government. To the extent that resources permit, HRSA will request voluntary

submission of samples of invoices for spot check comparison with official Government ceiling prices.

- **Selectively auditing of manufacturers, wholesalers, and covered entities to ensure the integrity of the 340B Program.**

HRSA Response:

There are levels of audits that are necessary to ensure the integrity of the 340B program. HRSA currently relies on the referral of fraud, waste and abuse issues to the OIG. These issues may result in OIG audits. HRSA proposes to continue this practice. HRSA has also discussed with the OIG the possibility of an intra-agency agreement (with the OIG) that would permit HRSA to utilize the OIG audit contractors to carry out additional audits that may not be considered to be within the OIG's priority, but may be of interest to HRSA. This action would be contingent on the concurrence of the OIG and the availability of HRSA resources to perform the audits. HRSA will continue to discuss this intra-agency agreement with the OIG. HRSA also notes that legislation has been introduced in the Congress that would provide increased authority and funding to carry out periodic third party audits of covered entities and manufacturers.

OIG RECOMMENDATION

HRSA should seek authority to establish penalties for violations of the PHS Act.

HRSA Response:

HRSA should acquire experience with the changes that it plans to make with the administration of the 340B program before legislation is proposed. However, we note that a bill has been introduced in the Congress that would authorize HRSA to provide audits of the 340B program.

OIG RECOMMENDATION

HRSA should provide covered entities with secured access to certain pricing data to help approximate 340B ceiling prices. To optimize 340B savings and maximize the efficiency of the covered entities' role in the program, we suggest two methods to help entities detect differences between the price they pay and the price they are entitled to under the law:

- **HRSA could design a mechanism that allows participating entities to assess whether prices exceed the ceiling price.**

HRSA Response:

HRSA concurs that this is a reasonable idea and will explore it for policy options. As a first step we are proposing to enter into a demonstration project with a large drug manufacturer to test these ideas.

- **Reinstate the publication of HRSA's 340B prime vendor program's selling price list on the agency Web site so covered entities can estimate the potential savings available to them.**

HRSA Response:

HRSA does not concur. We are exploring other options.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

SEP 15 2005

Administrator
Washington, DC 20201

TO: Daniel R. Levinson
Inspector General
Office of Inspector General

FROM: Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services

RECEIVED
2005 SEP 16 PM 12:49
OFFICE OF INSPECTOR GENERAL

SUBJECT: Office of Inspector General (OIG) Draft Report: "Deficiencies in the Oversight of the 340B Drug Pricing Program" (OEI-05-02-00072)

Thank you for the opportunity to review and comment on the above OIG draft report. The purpose of this OIG report is to assess the ability of the Health Resources and Services Administration (HRSA) to ensure that entities participating in the 340B Drug Pricing Program are able to purchase products at or below a statutorily established ceiling price. The Centers for Medicare & Medicaid Services (CMS) has supported HRSA's oversight of the 340B program since the program's inception by providing pricing information to HRSA via an Intra Agency Agreement. CMS comments primarily reflect technical concerns with the report. The following CMS responses and technical comments are reflected below:

OIG Recommendation

CMS and HRSA should work together to ensure accurate and timely pricing data for the government's official record of 340B ceiling prices.

CMS and HRSA have already engaged in discussions about the challenges of calculating the 340B ceiling price. We encourage the continuation of these discussions to resolve the data issues identified in this report. In addition, CMS and HRSA should focus on improving the quality of the data used to calculate the 340B ceiling price. We believe that to improve the data contained in the 340B ceiling price file, CMS and HRSA should:

- Restate the need for manufacturers to provide complete and timely pricing data, as required by Omnibus Budget Reconciliation (OBRA) '90; if manufacturers' pricing data submissions do not comply with the 30-day requirements, CMS should consider making referrals to OIG to levy penalties for late data in appropriate cases;
- Determine a solution for updating missing prices so HRSA's record is complete; and
- Eliminate data that are not relevant to the 340B program, such as terminated products and labelers, as well as products with future market dates.

CMS Response

We concur with the first bulleted recommendation. Although the 30-day pricing data submission requirement is currently stated within the terms of the rebate agreement, CMS will reiterate this requirement. CMS is also willing to explore OIG's proposal that CMS consider referring appropriate cases to the OIG to levy penalties.

Regarding the second bulleted recommendation, CMS has historically transmitted a separate file to HRSA with the regular quarterly pricing file that contains a list of prices that were modified from prior quarters. This file is where CMS transmits any prices missing from earlier quarters.

With regard to the second and third bulleted recommendations, we have engaged in numerous technical discussions to resolve the data issues identified in the report. We are in the final stages of negotiating a revised Intra Agency Agreement and Data Use Agreement with HRSA. Under these agreements, CMS expects that it will no longer be calculating the 340B ceiling price on behalf of HRSA. CMS expects to send quarterly pricing data to HRSA, as well as supporting data fields, so that HRSA can calculate the 340B ceiling price. HRSA will use the pricing data it receives from CMS, combine that data with package size information, and calculate the government's 340B ceiling price.

OIG Recommendation

HRSA should establish detailed standards for the calculation of 340B ceiling prices.
To maintain accurate records for its oversight of the program, HRSA should clearly specify how to calculate 340B prices, particularly in relation to package size and negative ceiling prices.

- To ensure that the correct package size data are used to calculate 340B ceiling prices, HRSA could clearly specify to CMS the source and type of package size data needed for the calculation in the Intra Agency Agreement. HRSA could also continue to obtain the pricing information from CMS, but calculate the ceiling prices iteself or through a contractor using the complete package size information collected from one of the drug price data vendors or from the manufacturers.
- HRSA needs to establish a formal policy regarding the conversion of negative ceiling prices into practical ceiling prices and needs to perform the conversions in the 340B database.

CMS Response

We note that there will not be a need for HRSA to specify to CMS the source and type of package size data needed for calculation of the 340B ceiling prices because, as noted earlier, CMS will no longer be calculating the 340B prices. We have no comment on the remainder of this recommendation.

Attachment

Technical Comments

Page Three, Third Paragraph

This section states that manufacturers report product and package size information "to third-party contracted providers of prescription drug information, such as First Data Bank and Medi-Span, which sell the information to states, insurance companies and to CMS so that CMS can calculate drug prices." This is an inaccurate statement because CMS does not calculate drug prices. CMS receives product, package size, and pricing information from drug pricing compendia (i.e., First Data Bank and Medi-Span) only to assist in the calculation of the Federal Upper Limit prices.

ACKNOWLEDGMENTS

This report was prepared under the direction of William C. Moran, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Ann T. Maxwell, Assistant Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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