

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**DEFICIENCIES IN THE 340B DRUG
DISCOUNT PROGRAM'S DATABASE**



Inspector General

**June 2004
OEI-05-02-00071**

Office of Inspector General

<http://oig.hhs.gov>

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JUN 14 2004

TO: Elizabeth M. Duke, Ph.D.
Administrator, Health Resources and Services Administration

FROM: George Grob *George Grob*
Assistant Deputy Inspector General
for Evaluation and Inspections

SUBJECT: OIG Final Reports: "Appropriateness of 340B Drug Prices,"
OEI-05-02-00070
"Deficiencies in the 340B Drug Discount Program's Database,"
OEI-05-02-00071

The attached final inspection reports focus on the administration of the 340B Drug Discount Program. We conducted these inspections because of concerns about the appropriateness of prices that 340B covered entities are paying for outpatient drugs and the efficiency of the program's administration.

Appropriateness of 340B Drug Prices (OEI-05-02-00070) reveals that entities participating in the 340B Drug Discount Program did not receive the correct discount for 31 percent of sampled drug purchases made in September 2002. Based on this sample, we estimate that 340B entities spent \$41.1 million more that month on prescription drugs. The Health Resources and Services Administration (HRSA) does not have a process for ensuring that entities enrolled in the program receive the appropriate discount. Moreover, entities do not have information needed to verify that they pay the statutory price. Lastly, there is no match of HRSA's 340B ceiling price data to the manufacturers' data to detect and resolve discrepancies upfront.

To improve the integrity of the 340B program, HRSA should spot check entity-level transactions. HRSA should also seek legislative authority to establish penalties for violations of the Public Health Service Act (PHS Act). We also recommend that HRSA provide entities with data to approximate their discount. Finally, HRSA should verify their 340B prices against the manufacturers' prices.

In the agency response, HRSA agreed with the objectives of our recommendations. HRSA stated it is considering a number of activities in an effort to achieve systematic monitoring of manufacturer compliance with the pricing formula in the 340B statute. We look forward to receiving the results of these efforts. HRSA does not support our final recommendation to develop a legislative proposal to establish penalties for violations of the 340B statute at this time, and prefers to evaluate the impact of the ultimate action plan before taking legislative action. We understand

this approach, but believe that the ability to impose fines and civil penalties is essential in ensuring that entities receive the full 340B discount.

Deficiencies in the 340B Drug Discount Program's Database (OEI-05-02-00071) found that the poor quality of the Pharmacy Affairs Branch's database interferes with the successful administration of the 340B Drug Discount Program. The database's quality is deficient in three ways. First, 38 percent of our sampled entities were listed as enrolled in the 340B database, but reported not participating in the program. Second, the addresses for 43 percent of sampled entities from the 340B database were incorrect. Third, the 340B database also excludes essential billing and shipping information needed to verify a shipment's destination. According to interviews with nine major pharmaceutical corporations, incorrect information contained in the database undermines their efforts to prevent illegal sales of discounted products to ineligible entities.

To improve the integrity of the database, HRSA should develop a strategic plan to better manage the 340B program data. We suggest HRSA's plan include: (1) a revalidation of all current information in the database; (2) an annual recertification process for entities participating in the discount program; (3) a separate listing of newly added or deleted entities; (4) a standard reporting format for entities' addresses; and (5) an additional field to designate entities with contracted pharmacy arrangement.

HRSA's comments describe the action already taken to improve the integrity of the 340B database, but mention the impact budgetary limitations have on the agency's ability to commit to a timetable for full implementation. We encourage HRSA to optimize its Pharmacy Services Support Center contract as a means to move toward complete action. Concurrently, we anticipate that HRSA will determine if a Federal Register notice to announce a new annual certification requirement is necessary.

Please send us your final management decision, including any action plan, as appropriate, within 60 days. If you have any questions, please do not hesitate to call me or one of your staff may contact Elise Stein, Director, Public Health and Human Services Branch, at 202-619-2686 or through e-mail [Elise.Stein@oig.hhs.gov]. To facilitate identification, please refer to report numbers OEI-05-02-00070 and OEI-05-02-00071 in all correspondence.

2 Attachments

Final Report - "Appropriateness of 340B Drug Prices," OEI-05-02-00070

Final Report - "Deficiencies in the 340B Drug Discount Program's Database,"
OEI-05-02-00071

Section 340B of the Public Health Service Act (the PHS Act) created the 340B Drug Discount Program to lower drug prices for over 10,500 entities, including community health centers, public hospitals, and various Federal grantees. The Health Resources and Services Administration's (HRSA's) Pharmacy Affairs Branch (PAB) administers the program for the 10,500 enrolled entities, estimated to spend \$3.4 billion on drugs in 2003.

The PHS Act required PAB to maintain an electronic listing of all the entities enrolled in the 340B discount. Pharmaceutical manufacturers refer to the listing to verify entities' eligibility for the discount and to ensure that their drugs are only shipped to legitimate sites. Due to the importance of the database, we reviewed the quality and timeliness of its information.

We found that the poor quality of the Pharmacy Affairs Branch's (PAB) database interferes with the successful administration of the 340B Drug Discount Program. Thirty-eight percent of our sampled entities were listed as enrolled in the 340B database, but reported not participating in the program. The database also had incorrect addresses for 43 percent of sampled entities. We also found that the database does 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 recommend that HRSA develop a strategic plan for improved management of the 340B database. We suggest this plan include: (1) a revalidation of all current information in the database (2) an annual recertification process for entities participating in the discount program (3) a separate listing of newly added or deleted entities (4) a standard reporting format for entities' addresses and (5) an additional field to designate entities with contracted pharmacy arrangement.

OBJECTIVE

To assess the accuracy of information contained in the Pharmacy Affairs Branch (PAB) 340B Drug Discount Program's database.

BACKGROUND

The PAB in the Health Resources and Services Administration (HRSA) is required to maintain a complete listing of all entities participating in the 340B Drug Discount Program for pharmaceutical manufacturers and wholesalers to use in verifying an entity's eligibility to receive the discount. It is crucial that the roster contain exact information on the identity of the entities because it is the source wholesalers and manufacturers consult to verify the entity's participation in the program, as well as its address. This inspection stems from complications faced while attempting to extract a sample of providers from the database for the inspection entitled "*Appropriateness of 340B Prices*" (OEI-05-02-00070). Given the importance of the database, we examined the integrity of the database and assessed the effects that errors had on our work, as well as other end users.

FINDINGS

Thirty-eight percent of sampled entities are incorrectly listed in the 340B database as participating in the 340B Drug Discount Program. Despite being listed in the 340B database as "participating" in the 340B Drug Discount Program, 38 percent of our sample reported "not participating." Manufacturers reported that the correctness of an entity's eligibility status in the 340B database interferes with an entity's ability to purchase drugs at the 340B price.

The 340B database had incorrect address information for 43 percent of sampled entities. Forty-three percent of the entities sampled from the 340B database were listed with incorrect addresses. Incorrect information in the database hinders pharmaceutical manufacturer's ability to verify entity enrollment and increases the risks for diversion.

The 340B database does not provide essential information on entities' billing and shipping arrangements. Manufacturers reported that the absence of fields in the database that list both an entity's billing and a shipping address hinders their ability to verify that their

discounted products are going to eligible sites. The current design of the database only lists one address, but because of complex drug delivery and contracted pharmacy arrangements, the address listed may not be where the bill is sent or where the product is shipped.

RECOMMENDATIONS

To ensure accurate information on entities' participation and location status, HRSA should develop a strategic plan for managing 340B program data that:

- ❑ revalidates all of the current information in the database
- ❑ requires all enrolled entities to resubmit their 340B registration forms to PAB annually
- ❑ creates a separate listing of entities newly added or deleted from the roster each quarter to facilitate the efficient transmission of information to the manufacturers
- ❑ establishes a standard format for reporting entities' addresses, which clearly identifies the appropriate “ship to/bill to” arrangements and does not include post office boxes
- ❑ creates a field that designates entities with a contracted pharmacy arrangement

AGENCY COMMENTS

HRSA's comments describe the action already taken to improve the integrity of the 340B database, but mention the impact budgetary limitations have on the agency's ability to commit to a timetable for full implementation. We encourage HRSA to optimize its Pharmacy Services Support Center contract as a means to move toward complete action. Concurrently, we anticipate that HRSA will determine if a Federal Register notice to announce a new annual certification requirement is necessary.



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OBJECTIVE

To assess the accuracy of information contained in the Pharmacy Affairs Branch 340B Drug Discount Program's database.

BACKGROUND

This report stems from complications faced while attempting to use the 340B Drug Discount Program database of participants for the inspection entitled "Appropriateness of 340B Prices" (OEI-05-02-00070). Efforts to conduct a review of Health Resources and Services Administration's (HRSA's) management of the 340B program were compromised by the poor quality of the database. Because the success of the 340B program depends on the accuracy of the information contained in the database, we evaluated the overall condition of the database. This report demonstrates the effects that deficient data has on the ability of the 340B Drug Discount Program to operate efficiently.

The 340B Drug Discount Program

In 1992, Congress enacted Section 340B of the Public Health Service Act (the PHS Act), establishing the 340B Drug Discount Program. This Federal discount program requires pharmaceutical manufacturers to lower outpatient drug prices for over 10,500 qualified Federal grantees, including community health centers and public hospitals. To calculate the 340B price, manufacturers adhere to a formula stipulated in the PHS Act. The 340B price is a ceiling price, meaning it represents the highest price the entity may be charged for that product, but does not limit sales below the calculated price.

HRSA's Pharmacy Affairs Branch (PAB) administers the 340B Drug Discount Program. The 340B participating entities are estimated to spend \$3.4 billion for outpatient drugs in 2003.

The 340B Participant Database

Section 340B requires PAB to "maintain accessible data on the identity of participating entities." In 1993, PAB created an electronic bulletin board representing the registration and certification of eligibility. Although an entity may be eligible to participate in 340B by virtue of the grant it receives, it must notify PAB of its intention to participate in the discount program by completing and submitting the "340B Program Registration Form for Covered Entities." Eligible entities must also commit to avoiding duplicate discounts or rebates, preventing drug diversion and providing the Health and Human Services' (HHS) Secretary and

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manufacturer access to its records related to its compliance with 340B requirements.

Once PAB receives, verifies, and processes the registration form, the entity is listed in the electronic database and is eligible to purchase drugs at the 340B price. The PAB Web site stresses the importance of entities supplying the agency with accurate and up-to-date information, particularly the exact name and street address. PAB states that, “It is the responsibility of each covered entity to contact the PAB with any changes.”

The 340B Drug Discount Program’s database is intended to serve as a centralized source of contact information for those entities registered to participate in the discount program. The database lists the facility name, address, type of entity, date added to the database, and date terminated from participation.

It is crucial that the roster contain exact information on the identity of the entities because it is the source wholesalers and manufacturers consult to verify the entity's participation in the program, as well as its address. Manufacturers need to confirm that the entity's reported address matches that in the 340B database before shipping the discounted drugs. Furthermore, an accurate database helps prevent potential diversion of drug products.

Any incorrect information in the database compromises both the participants and the manufacturers. If the contact information on an eligible entity is wrong, a manufacturer may have to delay shipping the product until it can verify the correct information. If an entity is eligible for the discount, but is not listed, they could be overcharged because manufacturers do not have to offer the 340B discount.

Conversely, manufacturers may face other consequences if their products are sold to ineligible clinics at the 340B price. The integrity of the 340B program is weakened if prohibited transactions occur. For example, if a manufacturer discovers sales to entities not eligible for the 340B discount or to entities that are eligible to enroll but have yet to do so, the 340B contract is violated, damaging the reputation of the program.

In addition, if a manufacturer sells a drug at the 340B price to a non-eligible entity, it may accidentally set a “best price” (BP), which is part of the formula used to calculate a manufacturer's rebate owed to the State Medicaid agencies. Manufacturers must report their lowest selling price, or BP, each quarter to the Centers for Medicare & Medicaid Services

(CMS) for the purpose of the Medicaid Drug Rebate Program. Sales to 340B entities are exempt from this calculation.

PAB estimates that participation in the 340B discount program is growing at an annual rate of 12 percent. The program's rapid growth is partially due to the HHS's pharmacy demonstration projects that allow entities to develop new ways to purchase drugs and serve patients. In addition, the President's Community Health Center expansion initiative, which plans to add 1,200 new and expanded health center sites eligible for the 340B discount, will significantly impact the number of eligible participants, giving added importance to the need for an accurate database.

METHODOLOGY

As part of our data collection effort in the report, *Appropriateness of 340B Prices* (OEI-05-02-00070), we selected a random sample of 75 plus 10 spare 340B entities out of 4,246 using the information contained in the PAB database. To ensure the delivery of our data requests, we attempted to verify the addresses and participation of the selected entities through telephone calls and Internet searches. Ultimately, we requested data from 76 entities, accessing one of the spares.

In addition, we interviewed nine pharmaceutical manufacturers about their role in the 340B Drug Discount Program. These manufacturers were selected, based on geographic convenience, but are all major, billion-dollar corporations and comprise over 40 percent of the total prescription sales market.¹ During those interviews, much of the conversation focused on the issues that manufacturers face using the 340B database. We did not independently verify the nine manufacturers' reported difficulties; however, the comparable responses among the nine were consistent with our experience in attempting to use the data for our own analysis.

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

► FINDINGS

Thirty-eight percent of sampled entities are incorrectly listed in the 340B database as participating in the 340B Drug Discount Program.

Twenty-nine of the 76 sampled entities, or 38 percent, were listed in the database as participants, but reported not using the 340B discount. These entities may have enrolled in the program at some point since its

start in 1992, but reported that they no longer participate. Therefore, these providers are registered in the database as covered entities, but are not actually purchasing drugs at the 340B discount. This also indicates that entities are either not providing a drug benefit or purchasing their drugs at regular market prices. Table 1 illustrates the entities' reported reasons for ineligibility.

Table 1- Entities with Inaccurate 340B Participation Listing in the Database	
Number of Entities with Incorrect Status (29)	Reported Reasons for Non-participation
16	Entities reported purchasing pharmaceuticals, but not through the 340B Drug Discount Program
1	Receive drugs from a larger 340B participant, but do not purchase drugs themselves
12	Entities offer no pharmacy services

Failure to fully participate in the 340B discount program reduces the scope of the entities' health care services and makes inefficient use of HRSA grant funds. According to PAB, the database's information on an entity's address and participation status is only as good as the information they receive.² PAB enters an entity's information when it registers for the 340B discount, but then relies on the entity to voluntarily provide any changes. If the health care provider has had leadership or pharmacy staff turnover, it might not be aware of the benefits the 340B discount program offers.

From the pharmaceutical manufacturers' perspective, accurate information on an entity's participation status in the 340B database is important for two reasons. First, if the entity is eligible to purchase at the 340B price, but is excluded from the 340B database, the

manufacturer risks charging that entity more than the 340B ceiling price. Second, sales to ineligible entities place manufacturers in a vulnerable position for fraud and diversion.

The 340B database had incorrect address information for 43 percent of sampled entities.

During data collection for our inspection, *Appropriateness of*

340B Prices (OEI-05-02-00070), we found that of our sample of 85 entities (75 plus 10 spares), 37 entities, or 43 percent, of the addresses listed in the 340B database were incorrect. According to interviews with pharmaceutical manufacturers, the database’s incorrect entity contact and address information hinders their ability to efficiently manage 340B contracts.

The 340B database needs to have correct address information to confirm that only participating facilities and their patients have access to drugs purchased at the 340B price. While manufacturers maintain their own listing of their 340B contracts, they use the 340B database as the official source to compare and update their information each quarter. If an entity’s contact and address information does not match the manufacturer’s listing, the manufacturer has to take additional time to obtain accurate information. According to the manufacturers, this extra effort creates product delivery delays for the 340B entities.

According to the manufacturers, because the 340B database is a cumulative list that does not separate those entities newly added to or deleted from the previous quarter, to locate new participants or detect deletions, they must sort through the entire list of 10,500 entities each quarter.

The 340B database does not provide essential information on entities’ billing and shipping arrangements.

The 340B database does not include complete entity address information, which is necessary to identify the eligibility of the

entity, as well as confirm that the address is legitimate prior to shipping product.

HRSA permits entities to have arrangements with affiliated retail pharmacies or hospitals, as long as those arrangements are documented in writing to PAB. However, the complexity of the drug distribution

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system is not reflected in the design of the 340B database and confuses manufacturers.

The “entity address” field lists the address submitted on the entity’s grant application, but, due to the variety of drug delivery arrangements among 340B entities, the listed address may not be where the bill is sent or where the product is shipped. An eligible entity may order pharmaceuticals, but have them shipped to a retail pharmacy that distributes the drugs to the entity’s patients. Alternatively, a hospital may order products on behalf of its affiliated entities. Frequently, the address listed on the Web site is actually the grantee’s administrative office or a post office box where bills are sent, but not products.

HRSA allows for 340B qualified entities without on-site pharmacies to contract out their pharmacy services. In this arrangement, the entity is billed for the drugs, but the pharmacy receives the shipment and dispenses the prescriptions to the entity’s patients. Covered entities contracting with a retail pharmacy are required to supply PAB with a signed self-certification, documenting their agreement so drug manufacturers and wholesalers recognize the arrangements. However, the 340B database does not include a field that clearly identifies those entities with a contracted pharmacy arrangement. As a result, manufacturers have to search PAB’s separate “Contract Pharmacy” database to ensure that their products are both appropriately procured by an eligible entity and then sent to the appropriate address. Only after identifying the entities with contract pharmacy arrangements can the manufacturer return to the entity database to verify that the arrangement exists.

The database also does not define or link related entities with purchasing associations, such as a large public hospital and its smaller satellite clinics, making it difficult to discern which entity is billed and which receives the shipment. When a hospital orders and pays for drugs, but has them shipped to other eligible sites, manufacturers need to be aware of this arrangement so they can verify that the other sites are eligible.

RECOMMENDATION

To ensure accurate and timely information on the entities' locations and participation status, HRSA should develop a strategic plan for managing the 340B program's data that:

- ❑ revalidates all of the information currently in the 340B database
- ❑ requires all participating entities to resubmit their 340B registration forms to PAB annually to ensure continued accuracy
- ❑ creates a separate listing of entities newly added or deleted from the roster each quarter to facilitate the efficient transition of information to the manufacturers
- ❑ establishes a standard format for reporting entities' addresses, which clearly identifies the appropriate “ship to/bill to” arrangements and does not include post office boxes
- ❑ creates a field that designates entities with a contracted pharmacy arrangement

AGENCY COMMENTS

HRSA's comments on the draft report concur with all but one of the findings and all of the recommendations. The complete text of the comments is in Appendix A. HRSA also provided technical comments on the reports.

HRSA has already taken action in response to two of our recommendations. First, HRSA is updating the Web site's entity contact information and participation status in real time as opposed to the former, once-quarterly update. Second, HRSA linked the covered entities and contract pharmacy databases to clearly delineate the contractual relationships. We commend HRSA for its actions to strengthen the integrity of the database, as well as the administration of the 340B Drug Discount Program.

HRSA expressed the desire to implement our recommendation to annually recertify entities enrolled in the discount program, but cited the need to first identify resources and protocol required to achieve this. During this consideration, we propose that HRSA consider its Pharmacy Support Services Contract that HRSA awarded to the American Pharmacists Association in September 2002 as a potential resource for accomplishing this task. Since HRSA also stated that it might be necessary to publish a Federal Register notice to announce a new annual certification requirement, we hope they will concurrently determine whether this action is necessary.

HRSA disagreed with part of one finding that states manufacturers could inadvertently set a lower than intended price if they offered a 340B discount to an excluded entity. According to HRSA, as long as the entity received a grant or met other eligibility criteria the manufacturer would not set a new best price. We agreed with this clarification and made the appropriate changes to the report.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services
Administration

Rockville MD 20857

APR -6 2004

TO: Dara A. Corrigan
Acting Principal Inspector General
Office of the Inspector General

FROM: Administrator

SUBJECT: Office of Inspector General's Draft Report: "Deficiencies in the 340B
Drug Discount Program Database" (OEI-05-02-00071)

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

Questions may be referred to Ms. Gail Lipton in HRSA's Office of Financial Policy and
Oversight at (301) 443-6509.


Betty James Duke

Attachment

**Health Resources and Services Administration's Comments
on the Office of the Inspector General's Draft Report:
*Deficiencies in the 340B Drug Discount Program's Database (OEI-05-02-00071)***

Background

The draft report, *Deficiencies in the 340B Drug Discount Program's Database*, is based on the difficulties that OIG staff encountered in the survey of prices paid by covered entities that resulted in the draft report, *Appropriateness of 340B Drug Prices*. Initially, OIG staff drew a sample of 76 covered entities for the survey of drug prices. Due to problems with the database, only 37 entities were accessible and able to provide invoices for 340B drug purchases. In addition to problems with entity addresses and pharmacy staff, 29 entities in the initial sample either did not provide pharmacy services or were purchasing all of their drugs outside the 340B program. They also experienced difficulties in tracking contract pharmacies used by the covered entities.

OIG Recommendation(s)

Based on these findings, the draft report makes the following recommendations:

To ensure accurate information on entities' participation and location status, HRSA should develop a strategic plan for managing 340B program data that:

- Revalidates all of the current information in the database.
- Requires all enrolled entities to resubmit their 340B registration forms annually.
- Creates a separate listing of entities newly added or deleted from the roster each quarter to facilitate the efficient transmission of information to the manufacturers.
- Establishes a standard format for reporting entities' addresses, which clearly identifies the appropriate "ship to/bill to" arrangements and does not include post office boxes.
- Creates a field that designates entities with a contracted pharmacy arrangement.

HRSA's Response

Health Resources and Services Administration (HRSA) concurs with these recommendations and has already taken some steps to execute them. However, budgetary limitations make it impossible for HRSA to commit to a timetable for their full implementation. To date, HRSA has added updated entity information to the Pharmacy Affairs Web site as it comes in so that manufacturers and wholesalers can access it without waiting for the quarterly update of the full

database. In addition, HRSA has added a link between the covered entity and contract pharmacy databases so that the contractual relationship is clearly accessible.

HRSA is particularly concerned about providers that registered as covered entities who are not actually purchasing 340B drugs. This indicates that the entities are either not providing a drug benefit or purchasing their drugs at regular market prices. Non-participation may be the consequence of turnover in pharmacy staff or the entity leadership. In any case, failure to fully participate in 340B reduces the scope of the entities' health care services and makes inefficient use of HRSA grant funds. HRSA requests the OIG to provide a list of the entities dropped from the sample so that our staff can contact them to obtain more information about why they are not participating and, if necessary, provide technical assistance to help them take advantage of the 340B program.

To improve the quality of data contained in HRSA's 340B database, we would like to be able to implement the IG recommendation to do an annual recertification of the covered entities that have registered for the 340B program. This process would enable HRSA to capture more current information on the names, addresses and other necessary data and purge obsolete data and alert current grantee management to the fact that the entity is authorized to purchase outpatient drugs at 340B prices. Entities that no longer provide a drug benefit would be dropped from the database. In addition to identifying the budgetary resources needed to accomplish this, it may also be necessary to publish a Federal Register notice announcing the new requirement.

HRSA disagrees with one of the findings on pages 4 & 5 of the draft report which states that manufacturers could inadvertently be exposed to a lower than intended best price if they sold a 340B priced drug to one of the excluded entities. This would be the case only if the entities did not receive the grant or meet other eligibility criteria in the 340B law. Nothing in the draft report indicates that they are not eligible to participate. The problem is that they registered as covered entities but were not taking advantage of the 340B discounts.

APPENDIX A 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 Natalie Coen, Deputy Regional Inspector General. Other principal Office of Evaluation and Inspections staff who contributed include:

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¹*Prescription Drug Trends-A Chartbook Update*, Kaiser Family Foundation, November 2001

² OIG interview with Pharmacy Affairs Branch, June 2003