Good morning, Mr. Chairman. I am George M. Reeb, Assistant Inspector General for the Centers for Medicare and Medicaid Audits at the U.S. Department of Health and Human Services’ Office of Inspector General (OIG). Robert Vito, Regional Inspector General for Evaluation and Inspections in Philadelphia, accompanies me. We appreciate the opportunity to appear before you today to present information regarding Medicaid’s payments to pharmacies for prescription drugs.

In short, the Medicaid program continues to pay too much for prescription drugs. My testimony provides a brief overview of OIG’s body of work over the last several years related to Medicaid-covered drugs that provides the basis for our belief that Medicaid is paying too much for prescription drugs and offers suggestions for controlling Medicaid spending.

The testimony describes OIG’s findings regarding (1) pharmacy acquisition costs and average wholesale price, (2) the Federal upper limit program, (3) State variations in reimbursements for the same drugs, and (4) the Medicaid drug rebate program. I am also providing additional analytical information on pharmacy acquisition costs, highlights of Medicaid-related settlements with pharmaceutical manufacturers and chain drug stores, and a list of selected OIG reports and other guidance that are available on our Web site at http://www.oig.hhs.gov.

The Centers for Medicare & Medicaid Services estimated that calendar year 2003 Medicaid expenditures for prescription drugs totaled more than $31 billion, triple the $9.4 billion spent in 1994. Both the States and the Federal Government share these expenditures. Under Federal law, States have wide latitude in setting their reimbursement rates for prescription drugs. Federal regulations require that each State’s reimbursement for a drug not exceed, in the aggregate, the lower of estimated acquisition cost plus a reasonable dispensing fee or the
providers’ usual and customary charge to the public for the drug. For certain multiple-source (generic) drugs, Medicaid regulations set Federal upper limits that are contained on a list published by CMS. Within this general framework, the States use a variety of different pricing mechanisms when setting reimbursement amounts.

States must reasonably reimburse pharmacies for prescription drugs provided to Medicaid beneficiaries; yet, they lack access to pharmacies’ actual acquisition costs. Due to this lack of data, they rely on estimates to determine Medicaid reimbursement. These estimates include formulas for estimating pharmacy acquisition cost, pharmacies’ “usual and customary” charges, Federal upper limits, and State maximum allowable costs.

**Pharmacy Acquisition Costs and Average Wholesale Price**

Most States have used and continue to use the average wholesale price (AWP) to estimate pharmacies’ acquisition costs of drugs. For the most part, AWP’s (which are not clearly defined by law or regulation) are compiled in drug compendia such as Medical Economics’ *Red Book*. As our audit findings have demonstrated, the published AWPs that States use to establish their Medicaid drug reimbursements generally bear little resemblance to the prices incurred by retail pharmacies to purchase drugs.

Until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Medicare also used AWP as the basis for most drug reimbursements. Although the Congress recently took action to help lower excessive payment levels for Medicare, Medicaid’s reimbursement methodology continues to be based largely on the same inflated AWPs that had plagued Medicare.

To compare actual pharmacy acquisition costs to AWP, for calendar year 1999 we obtained from 217 pharmacies in 8 States pricing information that included thousands of invoice prices for both brand and generic drug products. We compared each invoice drug price to the AWP for that drug and calculated the percentage, if any, by which the invoice price was discounted.
below AWP. We estimated that pharmacy acquisition costs for brand name drugs in 1999 were an average of 21.8 percent below AWP and for generic drugs were an average of 65.9 percent below AWP. Both estimates were higher than our previous studies of 1994 data that showed 18.3 percent below AWP for brands and 42.4 percent below AWP for generics.

Our comparisons of pharmacy acquisition costs to AWP for 1999 did not adjust the invoice prices for the net effect of discounts available to most pharmacies, such as volume discounts, prompt pay discounts, and related rebates provided to pharmacies by manufacturers and/or wholesalers that would further lower the total pharmacy acquisition costs. For that one year, 1999, we estimated that the combined pharmacy invoice costs alone for brand name and generic drugs may have been as much as $1.5 billion lower than Medicaid would have paid for those drugs using the States’ national average discount from AWP of 10.3 percent. This $1.5 billion constitutes a spread from which States could have derived savings through better reimbursement methods. We used a single average discount in the calculation because, in 1999, most States used the same discount for brand name drugs as they did for the generics that did not have an upper limit.

In the audit of 1999 data, we did not attempt to assess the adequacy of dispensing fees paid by the States to pharmacies. Based on information available from CMS, it appears that States have significantly varying amounts of dispensing fees.

In 2002, in response to requests by the industry and the States’ interest in having more information on pharmacy purchase prices for additional categories of drugs, the OIG conducted an additional analysis of the 1999 data. That analysis provided a more comprehensive breakdown of percentages for a variety of drug categories. The analysis demonstrated a wide range of discounts from AWP for pharmacy purchases, depending on the category of drug that was being purchased. We concluded that the common method of reimbursing for brand name drugs and certain generic drugs using a single percentage discount does not adequately consider the large fluctuations in actual discounts between brands and generics. We recommended that, if States continue to use a reimbursement system based on AWP, they should consider adopting a four-tiered payment system. More information about
the additional analysis and the recommended four-tiered payment system is provided in Appendix A.

States continue to use a discounted AWP for estimating pharmacy acquisition costs. However, many have established separate discounts for brand name and generic drugs. CMS estimated that for the year 2003, for brand drugs, the States’ discounts from AWP ranged from 5 percent to 16 percent. For generic drugs, CMS estimated that the States’ discounts from AWP ranged from 5 percent to 50 percent. A small number of States use wholesale acquisition cost rather than AWP when estimating the acquisition cost.

One reason States continue to rely on AWP, despite its widely recognized deficiencies, is that States lack access to alternative, more accurate price information. One option that could be studied is the feasibility of developing a base payment methodology that uses actual pharmacy invoice prices adjusted, if necessary, for a profitability factor after netting post-invoice discounts and other considerations.

**Federal Upper Limits**

For multiple-source (generic) drugs, Medicaid limits reimbursement to Federal upper limit amounts if at least three generic equivalents are available and certain other requirements are met. The Federal upper limits restrict the amount that Medicaid can reimburse for drugs that have available generic equivalents (42 CFR § 447.332). Medicaid misses savings opportunities when qualified drugs are not placed on the Federal upper limit list in a timely manner.

To quantify the missed savings opportunities, we obtained a list of the top 200 multiple-source drugs based on retail sales for the year 2001 and determined whether the drugs were on CMS’s November 2001 Federal upper limit list. In a report issued in February 2004, we reported that 90 drugs were not included on the list despite meeting the established criteria. We estimated that Medicaid could have saved $123 million in 2001 if CMS had added just 55 of these 90
products to the Federal upper limit list. Four products alone accounted for 71 percent of the $123 million in potential savings. Subsequently, CMS added 9 of the 90 products to the Federal upper limit list. Seven of the nine products accounted for $94 million of the $123 million in savings we calculated for 2001.

As a follow-up to this report, your Committee requested that OIG conduct additional work to answer the following questions:

- Since 2001, how many generic drugs have met the criteria for inclusion on the Federal upper limit list?
- How many of these drugs have been included on the Federal upper limit list?
- How long, on average, did it take CMS to add newly qualified drugs to the list?
- How much does lag time between when a drug meets the criteria and its inclusion on the Federal upper limit list cost the Medicaid program?

Today, we are releasing the results of our work related to the Committee’s request. Again, we found that CMS does not consistently add qualified drugs to the Federal upper limit list in a timely manner. Of the 252 first-time generic drugs approved between 2001 and 2003, 109 products met the statutory and regulatory criteria for inclusion on the list. CMS had added only 25 of the 109 drugs to the list as of July 15, 2004 (date of analysis), and very few of these were included in a timely manner. It took CMS an average of 36 weeks to place these products on the list once they met the statutory and regulatory criteria for inclusion. Only 3 of the 25 drugs were included on the list when they first became qualified. The longest delay was for two versions of Metformin Hydrochloride, which were qualified for 102 weeks before being added in March 2004.

An additional 84 of the 109 drugs we reviewed had still not been added to the Federal upper limit list as of July 15, 2004. The delay in adding these 84 drugs averaged 55 weeks as of that date.
Delays in adding the reviewed drugs cost the Medicaid program an estimated $167 million between 2001 and 2003. A majority of the losses were attributable to delays in adding just eight drugs, which accounted for 85 percent ($143 million) of the estimated losses. The product with the highest losses for Medicaid, Fluoxetine 20 mg capsules (brand name Prozac), illustrates the potential effect of not adding drugs to the Federal upper limit list in a timely manner. Fluoxetine met all criteria for inclusion on the Federal upper limit list by April 1, 2002. However, CMS did not place Fluoxetine on the list until December 1, 2002. We estimate that this delay in adding the 20 mg dosage size of Fluoxetine capsules cost Medicaid an estimated $57 million dollars. The Federal share of the loss on Fluoxetine was approximately $32.6 million. The Federal share of the $167 million loss on all the drugs we reviewed was approximately $95.5 million.

Based on the findings of this report, we recommended that CMS establish an administrative procedure and schedule to govern the determination and publication of Federal upper limits. We also suggested that CMS focus its resources on ensuring that high-volume drugs that have recently come off patent are added to the list expeditiously. The report is available on OIG’s Web site today under “What's New,” and I have provided the report to the Committee.

State Variations in Reimbursements for the Same Drugs

As previously mentioned, States have wide latitude in setting their reimbursement amounts for prescription drugs. In September 2004, we issued a report of a study in which we assessed the extent to which States vary in their Medicaid reimbursement for the same drugs. We analyzed fiscal year 2001 State Medicaid prescription drug reimbursement data for a sample of 28 national drug codes. A national drug code is a numeric identifier issued by the Food and Drug Administration (FDA) for each drug. The code indicates the manufacturer of the drug, the product dosage amount, and the package size. Forty-two States agreed to participate in our review and provided us with their total ingredient reimbursement amount (excluding dispensing fees) and the total units reimbursed for each of the 28 national drug codes. Using the data supplied by States, we calculated an average unit price per drug and found substantial
variations in States’ payments for the same drugs. These variations translate into overspending by Medicaid.

Based on State data, we estimated that, overall, Medicaid could have saved as much as $86.7 million in fiscal year 2001 if all 42 States had reimbursed at the same price as the lowest paying State for each of the drugs reviewed. In fact, Medicaid could have cut its spending by more than half if all States had paid the same price as the lowest paying State for just 9 of the 28 drugs. These savings estimates derive from only 28 national drug codes that were randomly selected from 600 national drug codes for which there were substantial Medicaid outlays. Medicaid covers over 50,000 national drug codes, implying a potential for even greater program savings.

We believe savings could be achieved if CMS would: (1) share with the States the various types of price data it collects to help States develop better estimates of pharmacy acquisition costs, (2) conduct further research on the factors that affect States’ drug prices to be able to advise States more effectively on ways to set their reimbursement levels, and (3) annually review the States’ drug prices in order to share comparative State prices and methods to reduce costs.

**Medicaid Drug Rebate Program**

*State Accounting for Rebate Billings and Collections*

In addition to paying too much up front for Medicaid prescription drugs, States exacerbate their overspending of State and Federal funds by poor management of their rebate billings and collections. Pursuant to the Medicaid Drug Rebate Statute, States collect rebates from drug manufacturers for drug purchases made under the Medicaid program. The drug rebate program allows Medicaid to receive pricing benefits commensurate with its position as a high-volume purchaser of prescription drugs.
The statutory drug rebate program became effective in January 1991. After a start-up period, we audited the effectiveness of the new program in eight States. In June 1993, we reported that CMS had not ensured that States had established proper accountability and controls over the billing and collection of drug rebates. In addition, CMS could not develop a nationwide total of the uncollected portion of Medicaid drug rebates because States were only required to report the rebates that were collected. We replicated our review recently on a national scale, using 2002 information, and found that, while accountability had improved since our 1993 report, improvements are needed in most States. Weaknesses included the following:

- Rebate accounting systems were inadequate.
- Information submitted to CMS was unreliable, undermining CMS’s ability to oversee the program.
- Accounting for interest on late rebate payments was improper.
- The dispute resolution and collection processes were inadequate.

We are in the process of developing a national roll-up report. The individual final reports for each State and the District of Columbia are currently available on our Web site.

*Drug Rebate Calculations*

Additional Medicaid overspending occurs because of an inconsistency between the key values used for calculating rebates and reimbursements. Currently, Medicaid requires that rebates be based on a specifically designated value, average manufacturer price (AMP), while, at the same time, allowing reimbursements to be calculated using other values (usually a discounted AWP). This creates a situation whereby fluctuations in reimbursements do not result in a corresponding adjustment in the associated rebates. When a State increases its payments for a drug, it would not receive a correspondingly higher rebate on that drug purchase because there is currently no connection between the reimbursement and rebate calculations. Legislation is needed to establish a connection.
In a 1998 audit report, we recommended that CMS seek legislation requiring drug manufacturers to pay Medicaid drug rebates on the same basis that States determine reimbursements. The recommendation was supported by our review of data for calendar years 1994 through 1996 for 100 brand name drugs that had the greatest amount of Medicaid reimbursement in that period. We estimated that if rebates had been based on AWP (instead of on the statutorily required AMP) for that period, Medicaid would have achieved over $1 billion in added rebates. We used AWP to calculate the rebates for the period because most States were basing drug reimbursements on AWP minus a percentage discount. According to information States have reported to CMS, most States continue to use AWP in their reimbursement methodologies. Audit work in progress confirms that Medicaid continues to overspend because of the inconsistent bases used for reimbursement and rebates.

Manufacturers’ Calculation of AMP

AMP is supposed to represent the price at which the manufacturers sell their drugs to wholesalers for use in the retail class of trade. In addition to the situation described above, our work at selected manufacturers has shown they are making inconsistent interpretations as to what components are included in AMP. The inconsistencies have included how to treat Medicaid sales and accounting for sales and price concessions that flow through organizations that represent both retail and non-retail customers. It is important that all manufacturers report consistent and accurate information in order for the rebate process to work as intended. We therefore suggest that additional clarification of the definition of AMP be provided by CMS. This would both improve the rebate process and assist States that may consider the use of AMP data in estimating pharmacy acquisition costs for reimbursement purposes.

Conclusion

All States could reduce their spending on prescription drugs by adopting various strategies that other States have successfully used to contain costs. The savings could be even greater if states had better access to accurate pricing information. Reimbursement should reliably reflect the
actual costs of the drug to the pharmacy and be grounded in information that can be validated. There is an urgent need for the Medicaid policymaking community to assist States in strengthening their ability to make reasonable payments for the drugs they cover. This concludes my testimony, and I welcome your questions.
Appendix A

Additional Analysis of Pharmacy Acquisition Costs and Average Wholesale Price

OIG collected brand name and generic drug acquisition costs for calendar year 1999 and compared those costs to the average wholesale price (AWP) for each drug. After issuing separate reports on brand name and generic drugs, we conducted an additional analysis that provided a more comprehensive breakdown of percentages for a variety of drug categories. We found that:

- For single source innovator drugs, pharmacies purchased the drugs at an estimated discount of 17.2 percent below AWP.
- For all drugs without Federal upper limits (single source innovator, multiple source innovator, and multiple source non-innovator), pharmacies purchased the drugs at an estimated discount of 27.2 percent below AWP.
- For multiple source drugs without Federal upper limits, pharmacies purchased the drugs at an estimated discount of 44.2 percent below AWP. A further breakdown of these drugs showed the estimated discount for innovator multiple source drugs to be 24.4 percent and 54.2 percent for non-innovator multiple source drugs.
- For multiple source drugs with Federal upper limits, pharmacies purchased the drugs at an estimated discount of 72.1 percent below AWP.

These percentages do not consider discounts available to most pharmacies, such as volume discounts, prompt pay discounts, and related rebates that would further reduce acquisition costs.

The analysis shows that there is a wide range of discounts from AWP for pharmacy purchases depending on the category of drug that is being purchased. We concluded that, if States continue to use a reimbursement system based on AWP, CMS should encourage States to consider adopting a four-tiered payment system consisting of a percentage discount off AWP for:

1. single source brand name drugs;
2. innovator multiple-source drugs without a Federal upper limit; and
3. non-innovator multiple-source drugs without a Federal upper limit.
4. The fourth tier would be to pay the Federal upper limit price for qualified multiple source drugs.

As in the audits on which this additional analysis was based, we focused our efforts on evaluating the pharmacy’s acquisition costs for the drugs and offer no opinion on the adequacy of the dispensing fees being paid.
Appendix B

Medicaid-Related Prescription Drug Settlements

Settlements with Pharmaceutical Manufacturers

Recent Federal investigations of pharmaceutical manufacturers that led to settlements involving Medicaid prescription drug cases serve to illustrate weaknesses and vulnerabilities in the Medicaid drug reimbursement arena. Following are descriptions of some, but not all, relevant cases. Both the United States and individual States have negotiated other settlements that are not mentioned here.


Schering-Plough Corporation. Recently, Schering-Plough Corporation agreed to pay $345.5 million as part of a global settlement with the Government and entered a 5-year corporate integrity agreement (CIA) with the OIG. As part of the settlement, Schering-Plough agreed to pay $293 million to resolve its civil and administrative liabilities in connection with illegal and fraudulent pricing of its allergy drug Claritin under the Medicaid drug rebate program. The civil portion of the case focused on Schering-Plough’s alleged failure to include the value of certain incentives offered to two managed care organizations in Schering-Plough’s determination of the best price reported for purposes of the Medicaid drug rebate program. By failing to include the value of the incentives in its determination of best price, Schering-Plough allegedly underpaid rebates due to the States and overcharged entities (such as community health centers) that purchased drugs at ceiling prices that are based on Medicaid drug rebate prices. With regard to the criminal portion of the case, a subsidiary of Schering-Plough, the Schering Sales Corporation, pled guilty to a kickback charge and was sentenced to pay a $52.5 million criminal fine. Schering Sales Corporation was charged with paying a kickback of almost $2 million in order to keep Claritin on the formulary of a managed care organization.

Pfizer Inc. As part of a fiscal year 2004 global settlement of $430 million plus interest, Pfizer Inc. (Pfizer), Warner-Lambert Company LLC (Warner-Lambert), and the Parke-Davis Division agreed to pay $190 million in a civil False Claims Act settlement relating to Warner-Lambert’s promotion of the drug Neurontin. Pfizer acquired Warner-Lambert and its Parke-Davis Division in June 2000. Between July 1995 and June 2001, Neurontin was approved by FDA only for use in treating epilepsy, but Warner-Lambert allegedly engaged in a wide-ranging program to promote Neurontin for other uses. The Government alleges that these activities caused the submission of false and/or fraudulent claims to Medicaid. To resolve its criminal liability, Warner-Lambert pled guilty to violating the Federal Food, Drug and Cosmetic Act and agreed to pay a $240 million criminal fine. Pfizer entered a comprehensive 5-year corporate integrity agreement with OIG.
AstraZeneca Pharmaceuticals, LP and Zeneca Inc. In June 2003, the United States announced a global settlement with AstraZeneca. The company agreed to pay a total of almost $355 million and enter a 5-year CIA with OIG to resolve its criminal and civil liabilities relating to the marketing and pricing of its prostate cancer drug, Zoladex. AstraZeneca pled guilty to conspiracy to violate the Prescription Drug Marketing Act by causing the submission of reimbursement claims for Zoladex that had been provided free of charge as samples. The Government also alleged that AstraZeneca paid illegal remuneration (in various forms including grants, travel, and entertainment) to induce the purchase of Zoladex; that AstraZeneca created and marketed an average wholesale price (AWP) spread between the Medicare reimbursement for Zoladex and its cost; and that AstraZeneca misreported and underpaid Medicaid rebates for Zoladex. AstraZeneca also agreed to enter separate settlements with the States.

Bayer Corporation. In April 2003, Bayer Corporation agreed to pay $257.2 million in criminal fines and civil assessments to settle a False Claims Act case relating to the Medicaid drug rebate program. Bayer agreed to plead guilty to charges that it violated Federal law by failing to report certain information to FDA. The case focused on Bayer's failure to include certain sales to Kaiser Permanente Medical Care (an HMO) in its calculation of Best Price reported for purposes of the Medicaid drug rebate program. The Medicaid drug rebate program requires drug manufacturers to report their Best Prices to CMS and to pay rebates to the State Medicaid programs based on those reported prices.

GlaxoSmithKline. Also in April 2003, GlaxoSmithKline settled a Medicaid drug rebate case for almost $88 million, based on facts similar to the Bayer matter discussed above. In connection with the settlement, GlaxoSmithKline entered a 5-year CIA with OIG. GlaxoSmithKline also agreed to enter into separate settlement agreements with the States.

Pfizer, Inc. In October 2002, the United States settled a Medicaid drug rebate case with Pfizer, Inc., Warner-Lambert Company and the Parke-Davis Division. The Government alleged that Warner-Lambert failed to include the value of certain unrestricted educational grants in the best price reported for purposes of the Medicaid drug rebate program and, as a result, underpaid rebates due. The government alleged that Warner-Lambert paid the grants to a managed care organization in order to obtain unrestricted formulary status for the cholesterol-lowering drug, Lipitor. As part of the settlement, Pfizer paid $49 million and entered a five-year CIA with OIG.

TAP Pharmaceutical Products, Inc. In October 2001, the United States announced a major global health care fraud settlement with TAP Pharmaceutical Products Inc. TAP agreed to pay a total of $875 million to resolve its Medicare and Medicaid liability. TAP agreed to plead guilty to violating Federal law governing the use of drug samples. In addition, TAP allegedly set and reported AWPs for its prostate cancer drug, Lupron, at levels far higher than the actual acquisition cost of the majority of its customers (such as physicians) and caused those customers to receive excess reimbursement from Medicare and Medicaid. TAP also allegedly underpaid rebate amounts due to the States under the Medicaid drug rebate statute.

Bayer Corporation. In February 2001, the United States entered a $14 million settlement with Bayer Corporation in connection with Bayer’s AWP pricing and Medicaid drug rebate practices relating to six drugs. The Government alleged that Bayer set and reported AWPs for
the drugs at levels far higher than the actual acquisition costs of the products; that Bayer made misrepresentations to the Medicaid programs of certain States; and knowingly misreported and underpaid Medicaid rebates for the drugs. As part of the settlement, Bayer entered a five-year CIA with OIG.

**Settlements with Chain Drug Stores**

**Rite Aid Corporation.** In 2004, Rite Aid Corporation agreed to pay $7 million and enter a 4-year CIA to resolve its civil and administrative liability relating to the submission of claims to Medicaid and other Government health care programs for partially-filled prescriptions for drugs that were not delivered to the beneficiaries and, in some instances, were ultimately returned to stock. In addition to the settlement with the Federal Government, Rite Aid entered settlements with 28 States and the District of Columbia to resolve alleged liability to the States for the Medicaid damages.

**Wal-Mart Stores, Inc.** In 2004, Wal-Mart Stores, Inc., agreed to pay almost $2.87 million and enter a 4-year CIA to resolve alleged civil and administrative liabilities relating to the submission of claims for partially filled prescriptions between 1990 and 2000. The settlement resolved a False Claims Act *qui tam* suit alleging that Wal-Mart submitted false claims each time it dispensed only a portion of a prescription to a customer yet billed Medicaid, TRICARE, or the Federal Employee Health Benefits Program for the full amount of the prescription.

**Eckerd Corporation.** In May 2002, Eckerd Corporation entered a settlement with the United States and a group of States for $9 million. Eckerd also entered into a 5-year CIA with OIG. The Government alleged that Eckerd submitted false claims each time it dispensed only a portion of a prescription to the customers but billed for the full amount of the prescription. The claims at issue were submitted to Medicaid, TRICARE, and the Federal Employee Health Benefits Program between 1986 and 2000. Previously, ECK M.D., Inc., an affiliate of Eckerd, pled guilty to submitting false claims to Medicaid and to violating certain record-keeping requirements of the Controlled Substances Act.

**CVS Corporation.** In July 2001, the U.S. Department of Justice and the OIG, working jointly with representatives of the States, reached settlement in a *qui tam* action against CVS Corporation, involving allegations that the company submitted claims for partially filled prescriptions to Medicaid, TRICARE, and the Federal Employee Health Benefits Program. In addition to paying $4 million to the Government, CVS also agreed to a 4-year CIA.

**Walgreen Co.** In 1999, the Federal and State governments (through the Medicaid Fraud Control Units) entered the first settlement with a major retail pharmacy chain for conduct involving partially filled prescriptions billed to Medicaid and other Federal health care programs. Walgreen Co. paid $7.6 million and entered a 4-year CIA to resolve its liability.
### Appendix C

**Selected Medicaid Drug Reports Available on the OIG Web Site**

(https://www.oig.hhs.gov)

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