MEDICAID PRESCRIPTION DRUGS: EXAMINING OPTIONS FOR PAYMENT REFORM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JUNE 22, 2005

Serial No. 109–25

Printed for the use of the Committee on Energy and Commerce

Available via the World Wide Web: http://www.access.gpo.gov/congress/house

U.S. GOVERNMENT PRINTING OFFICE

★22–985PDF WASHINGTON : 2005

For sale by the Superintendent of Documents, U.S. Government Printing Office
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MEDICAID PRESCRIPTION DRUGS: EXAMINING OPTIONS FOR PAYMENT REFORM

WEDNESDAY, JUNE 22, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to other business, at 3:04 p.m., in room 2123 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Bilirakis, Norwood, Cubin, Shimkus, Shadegg, Buyer, Bono, Ferguson, Myrick, Burgess, Brown, Waxman, Green, Capps, Allen, Baldwin, and Dingell (ex officio).

Also present: Representative Wilson.

Staff present: Jeanne Haggerty, majority professional staff; Chuck Clapton, chief health counsel; David Rosenfeld, majority counsel; Brandon Clark, health policy coordinator; Eugenia Edwards, legislative clerk; Bridgett Taylor, minority professional staff; Amy Hall, minority professional staff; and Jessica McNiece, minority research assistant.

Mr. DEAL. This meeting will come to order. The Chair recognizes himself for an opening statement.

I certainly want to welcome everyone to this hearing today and our distinguished panel members. We have two panels that you are going to hear from, and they will give various perspectives on this issue of Medicaid prescription drugs and various payment options—and certainly this is an issue that everybody, I suppose, has their own point of view on—Medicaid: a system that only a healthcare plan could love, one where generic drugs definitely keep Medicaid costs artificially high. Generic drugs—and lower costs, but under Medicaid's rules, the system has been turned on its head.

According to a recent CBO report, the largest, single factor contributing to the rapid increase in markups on prescription drugs under Medicaid was the use of new or generic drugs. What is truly outrageous is that these prices are rising above—prices of prescription drugs based upon manufacturer reporting average wholesale prices, or AWPs. As my former colleague has noted several years ago, AWP, which also stands for "ain't what's paid." In many instances, AWP bears little or no resemblance to what pharmacists really pay for drugs. This is especially true for generic drugs.

In a recent report, CBO estimated the average markup between what Medicaid pays the pharmacy for each prescription and what

the pharmacy or wholesaler actually pays for the drug has dramatically increased. They estimated that between 1997 and 2002, an average markup on generic drugs increased by nearly 79 percent per prescription. Generic drugs have a critical role to play in containing soaring drug costs. My concern, however, is that the cost of AWP, Medicaid is missing out on a large portion of these cost savings. I want to increase Medicaid's use of generic drugs but not at the expense of rapidly increasing drug costs. Pharmacies gain substantial Medicaid margins on many generic drugs, but the purpose of this hearing is not to vilify pharmacists. Pharmacists believe that the current overpayments for prescription drugs are necessary to offset Medicaid dispensing fees, which they assert do not cover the true cost of the services that they provide to Medicaid beneficiaries.

I believe that any effort to reform Medicaid drug reimbursement must reflect three basic principles: transparency, accuracy, and fairness. Payments for drugs must be transparent to the purchaser without hidden payments that undermine competition. Payments must also accurately reflect the costs pharmacists pay for the drugs. Finally, Medicaid reimbursements for both drugs and dispensing fees should fairly pay pharmacies for all of the costs of treating Medicaid beneficiaries. Fairness is essential so that Medicaid beneficiaries continue to get access to community pharmacy services.

Both the Administration and the National Governors Association have included changes to prescription drug pricing in their Medicaid reform proposals. I hope that this is an issue where we can find bipartisan consensus and work together to solve the problem.

I want to thank all of the witnesses, both on this panel and the one that will follow, for today's hearing for taking time to attend the hearing. It is an important and worthy issue of this committee's attention, and I hope the hearing will help us in our efforts to reform the system that I believe is obviously in need of change.

Mr. Brown, I recognize you for an opening statement.

Mr. BROWN. Thank you, Mr. Chairman. And welcome, Dr. Holtz-Eakin, for joining us and other distinguished witnesses on the other panel.

I appreciate your decision, Mr. Chairman, to focus on pharmaceutical payment reform under Medicaid. I have actually heard rumors that the intent is to focus solely on the pharmacists—and from the chairman's opening statements on generics—but I am sure that wouldn't be the case. CBO just completed a study on drug rebates. I am sure neither side of the aisle is going to ignore that analysis in a hearing entitled "Examining Options", with an "s", "for Payment Reform." It would make no sense to focus on one small piece of the cost puzzle and ignore the bigger ones.

And the Medicaid debates raise the most notorious cost issue of all: drug prices. Prescription drug spending is the fastest growing component of health care spending inside and outside government programs. Tax dollars are a scarce commodity. They should be used wisely. And drug companies should be made to charge the government a fair price. That is what the rebate program is all about; so while business dollars also are a scarce commodity, they should be used wisely, too, and drug companies should be made to charge

businesses a fair price. And American family dollars are scarce, too. Drug companies should be made to charge every American a fair price. While we do nothing, more and more Americans purchase their medicines from Canada, because they can't afford medicines in this country, and that is not good for our drug stores, frankly.

The prescription drug industry issue isn't a Medicaid issue. It is a health care issue affecting every individual and business in our country. So the question is: Will taking action to reduce drug prices in Medicaid stifle innovation? Will taking steps to reduce drug prices outside Medicaid stifle innovation?

There has been talk recently about weak profitability in the drug industry, so we checked on that. According to the most recent listing of 2005 profitability, drug makers earn nearly 4 times, 400 percent, the median for Fortune 500 industries, and government analysts, including S&P industry watcher, Herman Saphlis, think the outlook for the drug industry is bright. In a recent interview, Mr. Saphlis highlighted the drug industry's capacity for, get this, repatriating foreign earnings. How could the drug industry have ample foreign earnings if the price controls that they always talk about in foreign markets are so draconian?

According to a recent study by Donald Light of Columbia University in New York that is, in this country, price controls in Canada, Britain, and other countries are not too low to sustain a brisk pace of R&D. In fact, prices in these countries are more than sufficient to cover operating and R&D costs and to provide for healthy profits. That is why drug makers sell their products in those countries. That is not to say price controls can't have a dampening effect on R&D; it is to say they don't need to have a dampening effect. With careful effort, the U.S. can secure lower drug prices and spur increased R&D. The drug companies can earn astronomical profits, after all, on a single blockbuster product. Maybe they will be prompted to reduce their emphasis on those blockbuster drugs and further diversify R&D efforts.

Based on his testimony, Mr. Calfee, our witness from the American Enterprise Institute, is not a big fan of price controls. Clearly, he is an advocate of free market competition. We all are. And he is right that price controls distort free market competition. However, no one who understands the concept would confuse the prescription drug market for a competitive free market. In a free market, you would have a large number of small producers, each of which charges similar prices reflecting consumer demand. In a free market, the government doesn't hinder competition by granting patent extensions. Rather than a large number of small producers, the drug market is characterized by a small number of large producers, each of which has a patent monopoly bestowed on them by the much-despised government over the products that they make. As a result, drug makers have infinite market power, not only to decide how much to charge for medicine, but as a practical matter, frankly, in many cases, who lives and who dies.

Indulging the fantasy that the drug market bears any resemblance to the idealized college textbook free market is a waste of time and money that the American people don't have. Of course, we should require the drug industry to charge fair prices. That can be our first step, but it shouldn't be our only one. We ought to re-

quire the drug industry to charge fair prices to every American. Medical innovation loses value with every person who doesn't have access to it.

Thank you, Mr. Chairman.

Mr. DEAL. I thank the gentleman.

Ms. WILSON. Mr. Chairman?

Mr. DEAL. I recognize Ms. Wilson.

Ms. WILSON. Thank you, Mr. Chairman.

I would ask unanimous consent to participate and listen to the witnesses and ask questions of witnesses.

Mr. DEAL. Is there any objection? Hearing none, so ordered.

Mr. Bilirakis for an opening statement.

Mr. BILIRAKIS. Thank you, Mr. Chairman.

I am pleased that you have called this hearing to examine options for improving the way prescription drugs are paid for in the Medicaid program. We are here today to examine possible solutions to problems with Medicaid's system of reimbursement for prescription drugs, which the Energy and Commerce Committee's ONI Subcommittee reviewed extensively last December.

For the past few years, this committee has been examining the appropriateness of using the average wholesale price, or AWP as we refer to it, payment methodology for reimbursement of prescription drugs. We found it to be inaccurate and inefficient to Medicare, which ultimately led to the inclusion of provisions in the Medicare Prescription Drug Law, which are expected to save $15 billion over the next 10 years. The ONI Subcommittee's hearing last year was to determine whether the Federal Government pays too much for prescription drugs under the Medicaid program. The CBO subsequently reported that Medicaid's reimbursement system has allowed a growing disparity between what States pay for prescription drugs and what it actually costs pharmacies to obtain them. These efforts have shown definitively that Medicaid pays too much for prescription drugs. These overpayments have resulted from a flawed payment policy that makes it difficult, if not impossible, to determine the actual cost that retailers pay to manufacturers to obtain the drugs that they provide.

The current use of AWP, or the list price of a drug that few purchasers actually pay to calculate these costs, falls far short of the standard we should demand. It is clear to me that the use of AWP-based reimbursement as a payment benchmark under Medicaid is fatally flawed. The potential remedies for this flawed payment policy are varied and certainly complex. What is clear, however, is that States and the Federal Government simply cannot continue to pay more than they should for prescription drugs under Medicaid. Allowing this inefficient practice to continue is costing Medicaid millions and millions of dollars that otherwise could be used to help those who rely on Medicaid to meet their basic health care needs.

So I am hopeful, Mr. Chairman, under your tutelage, that this committee can craft a fair and efficient policy for the reimbursement of prescription drugs under Medicaid, which must be part of any comprehensive effort to modernize this valuable program. I commend you for focusing our attention on this issue and look forward to learning how today's witnesses believe we can improve Medicaid's reimbursement of prescription drugs.

Thank you, Mr. Chairman. I yield back.

Mr. DEAL. I thank the gentleman.

Ranking Member Dingell, is recognized for an opening statement.

Mr. DINGELL. Mr. Chairman, I thank you for holding this hearing. It is an important one. I believe that it is clear that we can help both beneficiaries and taxpayers by making sensible changes to the payment system for Medicaid prescription drugs. Currently, drug companies are being overpaid. Generic drugs are being underutilized. The taxpayers and the beneficiaries of the program are being hurt. But as we examine the various options for reforms, I caution my colleague the changes that would have the effect of shifting more of the cost burden to beneficiaries and providers could be dangerous and counterproductive.

We will hear a good deal today about payments to pharmacists. Improvements to their payments could down right benefit both the pharmacies and save money for the government, but the Medicaid policy is multifaceted, and there are many other options for reforms to prescription drug policy that we should not ignore. As we hear from the Congressional Budget Office, the drug companies, too, have something to offer.

Medicaid has generally been doing a good job with getting rebates from manufacturers. The Medicaid program accounts for 15 percent of U.S. spending on prescription drugs. With that level of purchasing power, Medicaid shouldn't merely get a good discount. They should get the best, and I will repeat that. They should get the best.

As the Government Accountability Office will testify, there is certainly also need for greater accountability, particularly on the part of Centers for Medicaid and Medicare Services, CMS, and their administration of the rebate program. CMS has been lax in issuing guidelines on how manufacturers should calculate the rebates, so that the Inspector General, because of this laxity, has been unable to conduct appropriate audits, and that is a matter into which we should go today. This, too, could save money for the States and the Federal Government, and it would not harm the beneficiaries of the program.

We should also explore ways to increase the use of generic medicines, an opportunity to save money for the program without compromising beneficiary access to good care. Some States, such as Arizona, have done an outstanding job of increasing the use of generic drugs. This saves Medicaid and its programs significant funds. Other States have not moved far along that path. We must see to it that they begin that process.

But as we consider these changes, we must protect the access to medicines for more than 50 million Americans who depend on Medicaid for their care. Already one in four adult Medicaid patients cannot afford to fill a needed prescription. This burden falls disproportionately on the sick in Medicaid where more than 40 percent of the patients with two or more chronic conditions could not obtain needed medicines because of the cost. In States that have implemented multiple cost controls, such as prior authorization and preferred drug lists, the danger of precluding access is even greater. Given that Medicaid was designed to ensure access to medical

care for the poorest and sickest Americans, what we should be addressing now is how to expand rather than to restrict access to needed health care by those who are most vulnerable in our society.

Again I commend you, Mr. Chairman, for holding this hearing. I hope we will consider all of the options for improving Medicaid prescription drug programs, not just the narrow issue of payments to the pharmacists. At the same time, we must keep in mind when a benefit is unaffordable for those in need; it does nothing for us. Clearly, an unaffordable benefit is no benefit at all. Payment reform should not mean that those who need care under Medicaid cannot get it.

I thank you, Mr. Chairman, for the recognition.

Mr. DEAL. I thank the gentleman.

Dr. Norwood is recognized for an opening statement.

Mr. NORWOOD. Thank you, Mr. Chairman.

You know, I would like to start out by saying and recognizing the very good that has been done by prescription medicines in this country in reducing health care costs, prolonging life, and quality of life.

That said, the Medicaid program has experienced a rapid increase in spending for prescription drugs. A combination of factors is driving this growth, including increases in beneficiaries' drug utilization and drug prices. Nearly half of Medicaid drug costs are for low-income seniors who are dually eligible for Medicare and Medicaid. That is important to note as dual-eligibles are transferred to part D.

In recent years, most all States have worked to implement pharmacy cost containment measures, but Congress has a responsibility to make sure that every dollar under the program goes to those citizens who deserve it and need it. We also have an obligation to closely guard the taxpayers' dollar.

Unfortunately, the current reimbursement system doesn't always match these goals. States are required and should reasonably reimburse pharmacies, yet they lack access to actual costs. Because of this, Medicaid reimbursement, based on average wholesale price, does not match the price incurred by retail pharmacies to purchase the very drugs.

So I think most can agree that AWP isn't where we need to be. Although it was a government idea, it is still not where we need to be. But where do we go? It is average sales price. Is that it? Well, while ASP does not reflect the retail pharmacy's acquisition cost, ASP is likely a better starting point for estimating cost. But do we want to simply do better? Ultimately, the benefit to States of ASP would depend on how well CMS calculates and reports ASP prices. I don't feel that should be overlooked. But ASP is an outdated price. It doesn't take into account different classes of trade pricing and leaves pharmacies at a loss when brand manufacturers raise their prices. If ASP had been in effect this year for Medicaid when many brand name increased its prices over 6 percent, pharmacies would have been significantly affected. This is something to note before we risk impacting pharmacies, especially in areas where access is already an issue, especially since pharmacies in rural areas often take a large amount of Medicaid prescriptions.

I want to be clear that price competition is a very good thing. Generic drugs have a critical role to play. My concern is that under AWP or ASP retail pharmacies are not given incentives to dispense generics. Pharmacies would still make more money under an ASP-plus-six system for brands than they would for generics. CMS should share with the States the price data it collects to develop better estimates of acquisition costs.

I am also interested to hear from our witnesses on how cost savings can be found by addressing the disconnect between the formula that is used to calculate the rebates and reimbursements. I also think States can do a better job managing rebate billings and collections. At the end of the day, we simply can't go looking to the pharmacies to fix all of our problems.

I will put the rest of it in the record, Mr. Chairman, but say we should undertake this hearing with a goal of comprehensive reform that works with Governors to reduce Medicaid costs for prescription drugs through a multi-pronged approach.

Mr. DEAL. I thank the gentleman.

Mr. Waxman for an opening statement.

Mr. WAXMAN. Mr. Chairman, I am pleased the subcommittee is holding this hearing today. Reform in the Medicaid payment policies for prescription drugs is one of the legitimate areas where we potentially can achieve program savings without harming beneficiaries or undermining basic protections in this program. In my view, however, the savings we achieve in this area should be reinvested in Medicaid to help make necessary changes in the program to better serve beneficiaries and to help States meet the fiscal demands of the program.

Having said that, let me make just a few points that I hope will guide us as we look into appropriate drug payment policy reforms.

First, we need to be sensitive to the impact of the changes we make of the access of beneficiaries to needed drugs. To the extent we are overpaying for drugs, as in some cases we clearly are, we need to fix that. But I am concerned that the proposal included in the Administration budget does not accurately reflect the acquisition costs for pharmacies, and could in some cases result in a loss of access for recipients.

Second, we need to recognize that increased utilization of generics is one of the most effective ways to reduce drug expenditures. We must be sure that the reforms we undertake do not have the unintended effect of undermining the use of generics where they are available. Basing the payment to the pharmacist on a percent of the cost of the drug raises some serious concerns in this regard.

Third, we need to remember that most of our drug expenditures are for brand name drugs that don't have generic versions available. This is where the dollars are, and we certainly should ask the brand name companies to contribute to the savings we seek in this area. Increasing the rebate should be the first option on the table, in my view.

Fourth, transparency in drug prices would provide significant help to the States and hospitals and other members of the so-called 340 B Coalition that use the Medicaid discount system. If States had access to the best price information, for example, I believe they

would have in place systems that would not result in the overpayments we see with systems based on the average wholesale price, which we know is easily manipulated.

And finally, CMS needs to do a better job of administering the best price and rebate system so that we are basing our payments on accurate information. The study GAO did at my request indicated lack of clarity on the policy and little real monitoring by CMS, all of which resulted in inaccurate information on which the payments were based. This situation allows manipulation of prices by the companies. Further, it fails to capture the effect of discounts that PBMs receive. We need to change that. Whatever reforms we put into place will only be as effective as the accuracy of the information on which they are based.

I look forward to hearing from our witnesses today.

Mr. DEAL. I thank the gentleman.

It appears we do have a series of at least two votes. If we have other opening statements, though, we may try to get one or two more in, if they are short. Anyone on the Majority side wish to make an opening statement? Dr. Burgess, do you wish to make an opening statement?

Mr. BURGESS. Yes, Mr. Chairman. I——

Mr. DEAL. You are recognized for that purpose.

Mr. BURGESS. I was going to submit my opening statement for the record, and I will still do that, but I just can't help myself after listening to some of the comments that I have heard here this morning.

In the year 2000, when I was away from thinking about running for Congress, Congress passed a copyright extension for Mickey Mouse for an additional 50 years. I presume that the research and development costs on Mickey Mouse had been recouped back in the 1930's, but for whatever reason, we have extended it to well on into this century. Our patent protection in this country for pharmaceuticals runs for 10 years. And we can argue whether that is an appropriate time or not. Maybe it needs to be a little bit longer, and maybe drug prices could come down. But the fact remains that it is the regulation in the pharmaceutical environment, in my opinion, that is the cause for a great deal of the price inflation that we see in our pharmaceuticals in this country. Remember Paul Irlich in Germany at the turn of the century was trying to find the silver bullet to cure syphilis. Alexander Fleming actually found the silver bullet in what he thought was a spoiled Petri dish. But it was the Pfizer Corporation that developed the commercial production of penicillin that saved lives on the battlefield in World War II with newborns in the nursery and the Staphylococcus epidemics of the 1950's. And let us not forget that those are uniquely American companies. Syntax Corporation that discovered the precursor for estrogen in a cactus out in west Texas made the commercial production of estrogen in compounds available in this country.

Now Mr. Chairman, I have lived under a system of price controls in my previous life, my whole professional career. It is called medicine, and we lived under Medicaid and Medicare price controls. I don't think Federal price controls are the way for us to go, and I would urge this committee to not go down that path. Differential pricing and lack of transparency in pharmaceuticals have been a

big problem in this country, certainly in all of my professional career. That has been a battle that I have fought. I was grateful 2 years ago or last year, actually, when the Medicare Prescription Drug Act was passed and we have the discount card that allowed for some transparency in drug pricing in the Medicare system, which I think allowed drug prices to come down. And I think we could work a lot harder in that regard in bringing some transparency and some common sense to the marketplace. But I don't think Federal price controls, and I don't think punishing pharmaceutical companies, are the correct ways to go about that.

I will submit my formal statement for the record.

Mr. DEAL. I thank the gentleman.

I believe we will suspend on opening statements and come back after the votes, but before we do so, Mr. Shadegg, who has got a conflict and will not probably be here for the second panel, I would recognize him at this time to introduce one of our second panel members.

Mr. SHADEGG. Thank you, Mr. Chairman. I will include that in my opening remarks.

I want to thank you for holding this hearing and continuing the dialog on Medicaid reform. I also want to thank our witness on this panel and our witnesses on the remaining panels. I think this is an important discussion, and I applaud you for proceeding in this direction.

I particularly want to thank Anthony Rodgers, who will appear on the second panel. He is the Director of the Arizona Health Care Cost Containment System, which is Arizona's Medicaid program. As the ranking member of the full committee already indicated, that program has been widely recognized across the country as being a model for reform of the access program. Mr. Rodgers is a veteran of the health care industry. He has worked both for hospitals and health plans. He was the general manager of State sponsored programs for Wellpoint Health Networks and was also the CEO of one of California's largest health plans, LA Healthcare Plan.

Today, he successfully directs Arizona's access program, as I indicated, which provides coverage to more than 1 million Arizonians and I think does it right. Indeed, it has had great success in holding down the cost of prescription drugs within the program, and it is some of the best. Arizona has been, I believe, a pioneer in this area, for more than 20 years ago, we embraced the waiver process to create a viable alternative to traditional Medicaid. It is a managed care alternative. And since that time, access has been nationally recognized for its success in containing costs while providing beneficiaries access to very high quality care.

I do want to thank the chairman for this opportunity and mention that savings in the prescription drug program alone have been outstanding. A 2003 study found that access had the lowest pharmacy cost in the entire Medicaid program nationally. Not only did the program as a whole cost less, but the per-member-per-month cost was the lowest in the Nation.

Again, I welcome Mr. Rodgers to testify here and encourage the committee to continue to look carefully at the access model.

Mr. DEAL. I thank the gentleman.

The committee will stand in recess pending completion of the votes on the floor.

[Brief recess.]

Mr. DEAL. The committee will come back to order.

We will proceed with our opening statements as members continue to come back in. And, well, Mr. Allen has come in. Mr. Allen, I will recognize you for an opening statement.

Mr. ALLEN. Thank you, Mr. Chairman, for calling this hearing on examining options for controlling rising drug costs in the Medicaid program. We need to examine a wide range of options rather than place an undue burden on beneficiaries by cutting benefits or raising cost sharing. There needs to be sound evidence that any proposed solution will actually achieve savings and will not further drive pharmacies from the Medicaid program. It seems premature to recommend moving to average sales price "plus some factor." What would this factor be and how would this be determined? States have been squeezing pharmacy-dispensing fees in the last few years, so pharmacies in some States, including Maine, are gravely concerned by the impact this would have in their ability to serve their customers. Fourteen pharmacies have closed in Maine since September of 2003.

I believe that we must increase investment in evidence-based research on prescription drugs. Last Congress, I introduced a bipartisan bill, H.R. 2356, the Prescription Drug Comparative Effectiveness Act. It authorized $50 million in funding to NIH and $25 million in funding to the Agency for Health Care Research and Quality. The bill directed these agencies to examine existing research and, if necessary, conduct new research, including head-to-head clinical trials in order to develop balanced scientific evidence regarding the comparative effectiveness, the cost effectiveness, and comparative safety relative to other drugs and treatments for the same disease or condition.

My bill would essentially provide a consumer reports for prescription drugs, giving doctors and their patients valid, evidence-based information on how drugs that treat a particular condition compare to one another. Section 1013 of the Medicare law makes initial investments in evidence-based research, authorizing the Agency for Healthcare Research and Quality to conduct outcomes research on prescription drugs and other treatments. This provision was not funded at the full $50 million level but rather at $15 million in fiscal year 2005 and 2006.

Facing rapidly rising drug expenditures in large budget shortfalls, States have been examining various measures to reign in drug spending, including utilizing evidence-based reviews of the clinical effectiveness of drugs in the same therapeutic class. In 2003, a group of States joined to form the Drug Effectiveness Review Project, which funds systematic reviews of drug classes. This information can be utilized to help State pharmaceutical and therapeutics committees make informed coverage decisions for their Medicaid preferred drug list. The Drug Effectiveness Review Project, which now has 13 member States, has completed studies on 15 classes of drugs and has 9 more currently scheduled for review. This approach would yield, I believe, lower costs and higher quality for our prescription drug services under Medicaid.

So I think we need to build on these State efforts in determining comparative effectiveness research, and I certainly look forward to hearing from our distinguished panels.

Thank you, Mr. Chairman.

Mr. DEAL. I thank the gentleman.

Mr. Ferguson is recognized for an opening statement.

Mr. FERGUSON. Thank you, Mr. Chairman. Thank you for holding this hearing, which is one of a series of hearings the committee has held on the problems associated with AWP. The President's budget, and recently the National Governors Association, stated what this committee has discussed in a hearing last December, which studied a widely inappropriate number to use as a reimbursement mechanism for Federal programs. I think everyone here can agree on that.

I look forward to hearing from our panelists today to help the committee craft a plan that will most accurately reflect the costs involved in procuring and dispensing drugs to the Medicaid population without overcharging the system, as AWP has done. I want to stress, however, that it is imperative that we choose real reforms that will slow the growth curve of this program and not simply increase price controls or impose de facto taxes on sectors of the Medicaid program that have become the very small share of Medicaid spending in 2006.

I am encouraged that our committee will be looking into how we can save taxpayers' money by updating how States pay for prescription drugs. Currently, States are using AWP, which is unfortunate, because that is costing our taxpayers a lot of money in overpayments. We need to remember, however, that we are not talking about how to increase existing burdens on specific to Medicaid providers simply to raise money into a broken program. As we found in every hearing that we have had on this issue, Medicaid is broken, and we have to fix it. We have to enact real reform. I am confident that what we will ultimately develop is a fair mechanism to pay pharmacists adequately so they can secure products to dispense to Medicaid beneficiaries.

Thank you, Mr. Chairman. I yield back.

Mr. DEAL. I thank the gentleman.

Ms. Baldwin is recognized for an opening statement.

Ms. BALDWIN. Thank you, Mr. Chairman, and thank you to the witnesses who will be testifying before us shortly.

Almost everybody is feeling the effects of rising health care costs, including the State Medicaid programs. Just yesterday, the Center for Studying Health System Change released a study that found that growth in medical costs far outpace the gross of wages for the eighth straight year. In fact, in 2004, the growth in medical costs was four times the growth in wages. And the implications of these rising costs are clear: more and more Americans will be unable to afford insurance, more and more Americans will either join the ranks of the 45 million who are uninsured, or join the ranks of those 50 million who rely on Medicaid, the safety net, for their health care.

In 2003, gross Medicaid drug expenditures were close to $30 billion, and States received about $5.6 billion in rebates. These are obviously significant amounts of money. If savings can be gained

through changes in the Medicaid Drug Reimbursement System and we conclude that these changes do not negatively affect beneficiaries, this is certainly an area that we must explore. It seems abundantly clear to me that some of the key ingredients prerequisite to reform include accurate information and greatly increased transparency from all transaction participants.

I look forward to today's discussion.

Mr. DEAL. I thank the gentlelady.

Mr. Buyer, do you have an opening statement?

Mr. BUYER. Mr. Chairman, I want to thank you for this hearing.

This whole idea of how we calculate the average wholesale price has always fascinated me and how that is really done and how it also can easily be manipulated I think is of a strong interest to me.

I also would like to say that I am very proud of the men and women who work in the drug industry. I am proud of them, because we have an enterprise whereby we recruit great talent all over the world to come here to again press the bounds of science, great discoveries that improve the quality of life are people. The problem is that everybody then demands it, and the social systems of the world think that they are "entitled to it." And they then really press us in what I would call real trade issues and penalize our companies, parent companies of America who also then become multi-national companies.

So I was a little concerned when I heard this slam when we, in the last year, did this initiative to allow these companies to repatriate those dollars back to America. I think that was a pretty good thing. It was a great move. But now to somehow slam that as if saying to these drug companies, "Oh, I didn't think you were making any profits overseas." That is one of the shallowest things I have ever heard, because a multi-national corporation, in order to do business in any country, they have to create an entity to do business. So that is why they call it multi-national.

So when you are a big company, if you want to do business in another country, you create a what? Subsidiary. And then of that subsidiary, whether you want to sell your product in that country, you have got to create that entity. So you might be in 100 countries all over the world and you have got 100 entities out there. And of those entities, whether it is by sale, you might have warehousing. You might do manufacturing. You might do some marketing. Everywhere you create an entity, you, then, have a government. You have a taxing authority. And those taxing authorities, they have an expectancy that they get an allocation of a percentage of the profits based on the business enterprise in the life cycle.

I am just dumbfounded that we have really smart people love to just make some simple little attack. That is ridiculous.

So I am going to end where I finish. I am proud of the men and women who work in the drug industry that benefit our society and benefit the world, based on their discoveries. And I am pleased that they were able to bring back a percentage of those profits to America, so we can continue in our new discoveries. Our challenge is as we look toward our own "social systems" that we have in our own quasi-free market system of America and how we can make improvements.

I yield back.

Mr. DEAL. I thank the gentleman.

Ms. Myrick, do you have an opening statement?

Ms. MYRICK. No, I will waive my statement, for questions.

Mr. DEAL. Ms. Cubin, do you have an opening statement?

Ms. CUBIN. I don't have an opening statement.

Mr. DEAL. Mr. Bilirakis, I think we have already recognized you for an opening statement. It was so long ago, I can't remember.

Ms. Wilson, you are recognized for an opening statement.

Ms. WILSON. Thank you, Mr. Chairman. I will waive and for the questions.

Mr. DEAL. All right. Dr. Holtz-Eakin, we appreciate your patience. He told me, though, that if we were working on the legislative branch appropriations bill, for us just to take just as long as we needed on the floor, and he wasn't making any complaints. So that is, in fact, what the rule was that we just voted on.

We are, indeed, pleased to have you here. As most of the members of this committee know, he is a frequent person to testify, and we have always appreciated his candor. He is the Director of the Congressional Budget Office, and I am pleased to recognize you now for your testimony. Your written testimony, of course, is a part of the record.

STATEMENT OF DOUGLAS HOLTZ-EAKIN, DIRECTOR, CONGRESSIONAL BUDGET OFFICE

Mr. HOLTZ-EAKIN. Thank you, Mr. Chairman, Mr. Brown, and members of the committee.

The CBO is very pleased to be here today to testify on this important topic. We have submitted for the record two reports that we have done recently on payments for prescription drugs in Federal programs in general, Medicaid in particular. And I thought I would devote my time at the outset to an overview of the payment system and the places where those reports address payments and the findings of those reports. And to do so, I thought I would walk through this diagram that we have got on the screen and which I hope is in front of you for easy viewing. And the basic notion is to review the kinds of payment flows that are in the Medicaid system.

[Slide.]

So the blue arrows are the easy ones. They are the traffic that takes prescription drugs from the drug manufacturer through a wholesale and pharmacy chain and to a Medicare beneficiary. That is the delivery of the healthcare itself. The remainder of the discussion is about the smaller green arrows, which is the set of transactions, financial transactions that support the delivery of the pharmaceuticals. And there is one small caveat that I will offer at the outset, which is that this is a stylized depiction of many different State systems, and it will fit no individual State exactly. For details on individual States, we would be happy to work with you. This is a broad overview.

In terms of the financial payments, a small footnote from the point of view of where testimony today is the fact that beneficiaries may be responsible for a minor co-payment and the pharmacy might collect that from that. I will leave that to the side and instead focus on the triangle of payments that connects the program pharmacies and the drug manufacturer.

Now in the conduct of this business, pharmacies and wholesalers negotiate with drug manufacturers for the price at which they will acquire the drugs to deliver to beneficiaries. And those market-based prices are the foundation of the business transaction by which they acquire these drugs.

In turn, they get a tiny bit of money from the co-payment, as I mentioned, and a reimbursement from the Medicaid program itself to cover the cost of acquiring these drugs for beneficiaries.

The formula differs by State, but really has two components. One component is a dispensing fee, usually a fixed amount of $3 to $5 meant to cover the cost of storage and consultation and dispensing. And the remainder is an attempt to compensate, through some proxy, for typical market price at which the pharmacy might acquire those drugs. As has been widely noted in the opening statements, the proxy is currently the AWP, the average wholesale price, and that is a list price, a sticker price that does not correspond to any particular transaction. And in recognition of the fact that it is higher than typical market transactions, a typical reimbursement will be 15 or 20 percent, say, below the AWP. Those monies are sent from the Medicaid program to the pharmacy in compensation for acquisition of the drugs. That is one part of this chain.

The second part is the negotiation with the drug manufacturer. And then the third part is the fact that everyone in this system recognizes that on the whole, these transactions are above yet what it really costs the entire system to deliver these drugs. And so there is a requirement that manufacturers, in order to have the drugs considered, provide rebates to the Medicaid program as a whole. And that is the third part of the triangle, payments from drug manufacturers back to the Medicaid program.

Now as with all of the considerations today, there are differences between those drugs which are brand name drugs and those drugs which are generics. In the payment from Medicaid programs to pharmacies, the list price for brand name drugs tracks pretty well on a closed basis to the kinds of things that might on in the market, whereas the list prices, the AWPs for generics, does not. And in recognition of this, there have been a series of payment limits put on, the FULs at the Federal level, or a maximum price that will be compensated by the States. Again, in the rebates from drug manufacturers back to the program as a whole, there will be a distinction between rebates on brand name drugs, which average about 30 percent, and rebates on generics, which average about 11 percent.

That set of transactions is the heart of the CBO report, and the second two slides summarize the two key findings that we have. The first is to compare payments that go out from the Medicaid program to the pharmacies with payments that actually come into the drug manufacturer. The payment coming into the drug manufacturer is what I will call the acquisition price. The payment going out would be the total payment to pharmacies. And everything in between is, by definition, called the markup. This covers all parts of the distribution chain, including wholesalers, where appropriate.

[Slide.]

So if we go to the second slide, you can see that in 2002, an overall average for all drugs in the system, Medicaid paid $60, almost $61, per prescription. That can be broken into these two pieces. Money is actually flowing into the manufacturer, $47, and monies which are to cover markups by pharmacies, about $14.

Now there is a big difference that you can see between the generic drugs and the brand name patented drugs. Brand name drugs are much more expensive on the whole, $97 on average; new generics, those which have just been introduced, $46; older ones, about $14. And there is a big difference in the pieces of those overall prices as well. For the brand name drugs, the acquisition costs, payment to manufacturers, the bulk of the cost, the markup, a much smaller percentage. In contrast, for new generics, the acquisition cost is relatively low, and the markup is $32, a much higher piece of the overall price.

Now one of the things to note in this in thinking about the incentives involved is that because of this high markup, there is a clear incentive to, where possible, steer beneficiaries to a new generic drug. And from the point of view of the system as a whole, this may be desirable because the total cost is much lower. And those incentives should be an important part of the thinking in any reforms that the committee might want to consider.

[Slide.]

And then I will close with the final slide, which shows the second piece of the CBO analysis, which is after consideration of rebates, how much does the manufacturer actually reap from delivering prescription drugs to different types of Federal buyers. Here, you can see a diversity of bottom line results, which are detailed in our report. I will highlight just one item that is of interest when thinking about reforms and that is, for example, the fact that while the Medicaid net manufacturer price is a bit higher than the VA average price, this is reflective of the ability of an entity like the VA to control its formulary to deliver not just to beneficiaries but also doctors in training and provide a variety of incentives for manufacturers to give them a better deal. Thinking about those private sector incentives in reforming the Medicaid system as a whole is also an important part of the debate.

There is a lot of material in the reports. That was a pretty high-speed overview. We are happy to be here today. I look forward to your questions.

[The prepared statement of Douglas Holtz-Eakin follows:]

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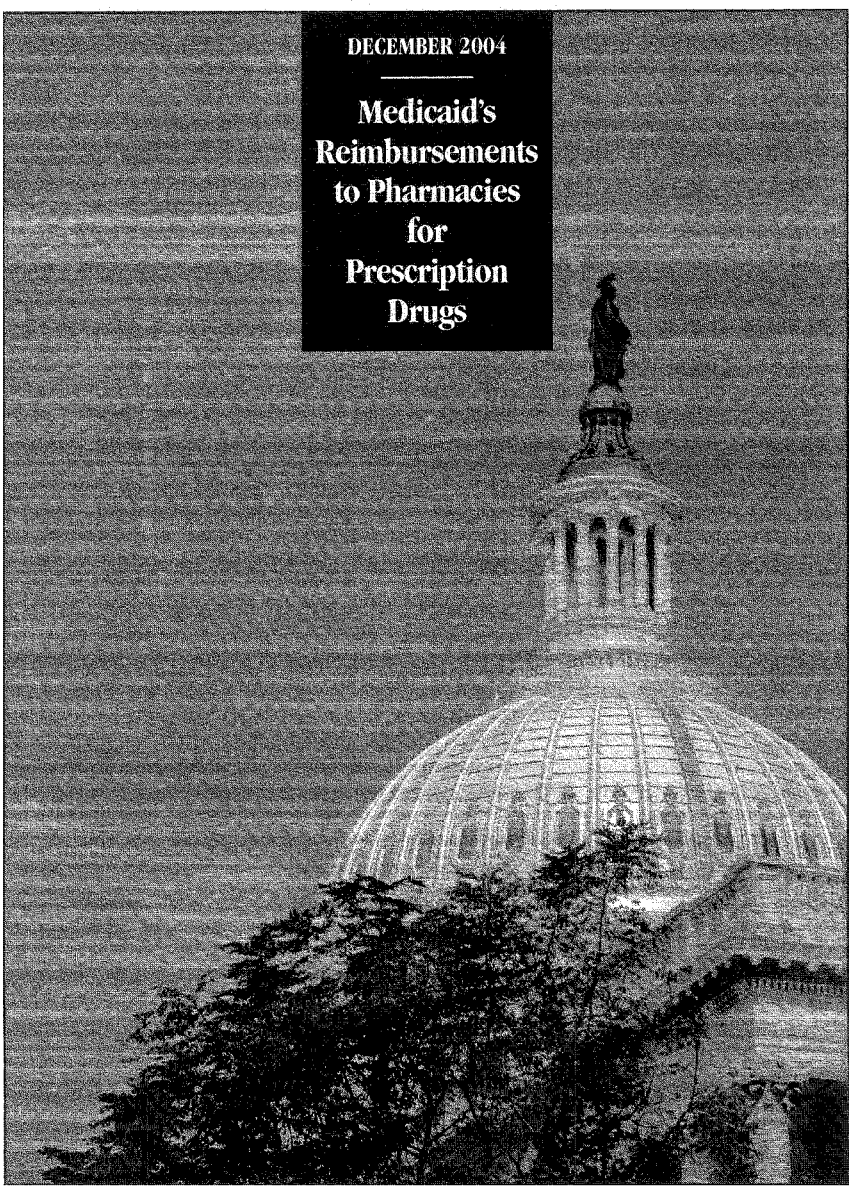

DECEMBER 2004

Medicaid's Reimbursements to Pharmacies for Prescription Drugs

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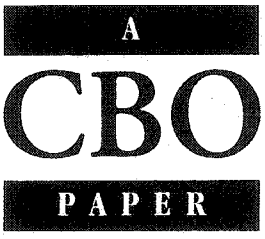

Medicaid's Reimbursements to Pharmacies for Prescription Drugs

December 2004

The Congress of the United States ■ Congressional Budget Office

Note

Numbers in the text and tables may not add up to totals because of rounding.

Preface

Between fiscal years 1997 and 2002, Medicaid's expenditures on prescription drugs in the fee-for-service part of the program increased from $10.2 billion to $23.4 billion. About one-quarter of those amounts went to wholesalers and pharmacies to compensate them for distributing and dispensing the drugs.

Prepared at the request of the House Committee on Energy and Commerce, this paper examines recent trends in that "markup"—or the difference between the total amount that state Medicaid agencies paid to pharmacies and the amount that pharmacies and wholesalers paid to purchase the drugs from manufacturers. In keeping with the Congressional Budget Office's (CBO's) mandate to provide objective, impartial analysis, the paper makes no recommendations.

Todd Anderson, Anna Cook, and Judy Wagner of CBO's Health and Human Resources Division wrote the paper under the supervision of Steve Lieberman, Bruce Vavrichek, and James Baumgardner. (Steve Lieberman and Judy Wagner have since left CBO.) Perry Beider made helpful suggestions on early drafts, and Samuel Kina provided research assistance. Richard Frank of Harvard University provided a valuable review. (The assistance of an external reviewer implies no responsibility for the final product, which rests solely with CBO.)

John Skeen edited the paper, and Leah Mazade proofread it. Judith Cromwell produced drafts of the manuscript. Maureen Costantino formatted the document for publication, Lenny Skutnik produced the printed copies, and Simone Thomas formatted the electronic versions for CBO's Web site (www.cbo.gov).

Douglas Holtz-Eakin
Director

December 2004

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Medicaid's Reimbursements to Pharmacies for Prescription Drugs

Summary and Introduction

In recent years, the Medicaid program has experienced a rapid increase in spending for prescription drugs. Between fiscal years 1997 and 2002, Medicaid's expenditures on them in the fee-for-service part of the program increased at an average annual rate of 18 percent, growing from $10.2 billion to $23.4 billion.[1] Consequently, policymakers at both the federal and state levels are considering ways to moderate that growth. Some states have already taken action by adopting lists of preferred drugs (to encourage beneficiaries to use less expensive drugs) or increasing the rebates that drug manufacturers pay to Medicaid.

One important component of Medicaid's spending on prescription drugs is the amount that the program pays for wholesalers and retail pharmacies to distribute and dispense the drugs to beneficiaries. On the basis of data from the Centers for Medicare and Medicaid Services (CMS), the Congressional Budget Office (CBO) estimates that the amount paid for distributing and dispensing those drugs accounts for approximately 23 percent of Medicaid's reimbursement to pharmacies. That percentage is roughly in line with the industry average for the entire outpatient pharmaceutical sector.[2] However, Medicaid's payments for those services have increased markedly in recent years, adding significantly to the overall cost of the program.

For each prescription that a pharmacy fills under the program, Medicaid pays the pharmacy an amount meant to cover both the cost of acquiring the drug from the manufacturer and the cost of distributing and dispensing it. That "markup" that Medicaid pays is defined in this paper as the dollar difference between the total amount that Medicaid pays the pharmacy for each prescription and the amount that the pharmacy or wholesaler pays the manufacturer for the drug.[3] Between 1997 and 2002, by CBO's estimates, the average markup increased by nearly 60 percent—rising from $8.70 to $13.80 per prescription, or by about 9.7 percent per year (see Table 1).[4] Those are national estimates; the experiences of individual states and individual pharmacies can differ greatly from them.

Much of the increase in the average markup was attributable to the use of relatively new generic drugs. For generic drugs that came on the market between 1997 and 2002, Medicaid reimbursed pharmacies an average of about $46 per prescription in 2002, of which only about $14 went for the purchase of the drug itself. Pharmacies and wholesalers retained the remainder, or markup, of about $32 per prescription.

1. Those expenditures are net of rebates that prescription drug manufacturers pay to Medicaid on drugs purchased by the program. In 2002, for example (the most recent year for which data were available when CBO began its review), Medicaid received $5.9 billion in rebates from manufacturers, reducing Medicaid's drug expenditures from $29.3 billion to $23.4 billion. Both the federal government and the states pay for the drug benefit, with the federal share averaging 57 percent nationwide.

2. The National Association of Chain Drug Stores estimates that of the average retail prescription cost of $53.10 in 2002, the wholesaler received 3 percent, and the pharmacy, 21 percent. See www.nacds.org/wmspage.cfm?parm1=507 (figures obtained on May 9, 2003).

3. Pharmacies can sometimes collect a small copayment from the Medicaid beneficiary (usually $1 to $3). Those copayments are not included in this analysis.

4. Those estimates represent averages based on data for 40 states and the District of Columbia (see the appendix).

Table 1.

Summary of Medicaid's Average Reimbursements, Wholesalers' and Pharmacies' Acquisition Costs, and Markups for Prescription Drugs, 1997 and 2002

(Dollars per prescription)

	Medicaid's Reimbursements to Pharmacies		Acquisition Costs[a]		Markups	
	1997	2002	1997	2002	1997	2002
All Drugs	37.00	60.90	28.30	47.10	8.70	13.80
Generic Drugs						
Newer	*	45.70	*	13.60	*	32.10
Older	11.90	14.20	4.30	4.40	7.60	9.90
Brand-Name Drugs	61.90	97.30	52.20	83.40	9.80	13.80

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services (CMS).

Note: * = not estimated, because most such drugs were not available in 1997.

a. To estimate acquisition costs, CBO used the average price that manufacturers earned on sales of outpatient drugs to wholesalers and pharmacies, as reported to CMS under Medicaid's rebate program (see the appendix).

That markup significantly exceeded the average markup that Medicaid paid for older generic drugs in 2002 ($10 per prescription) as well as for brand-name drugs ($14 per prescription). Although the Medicaid program saved money overall from the substitution of newer generic drugs for brand-name drugs, spending was not reduced to nearly the extent it might have been if the markups on newer generic drugs had more closely approximated those on the other classes of drugs.

One of the main factors behind high markups for some types of drugs was Medicaid's reimbursement system. That system relies on the published list prices of drugs (which are largely set by manufacturers) to determine pharmacies' reimbursements, instead of using the actual cost of the drugs to the pharmacies. States reimburse pharmacies using formulas that are typically based on the average wholesale price (AWP) of a drug, which (like the sticker price on a car) is a published list price that few purchasers actually pay. For example, a state might reimburse a pharmacy 85 percent to 90 percent of the average wholesale price of a drug plus a fixed dollar amount of $3 to $5 (as a dispensing fee) to cover the pharmacy's other costs. By relying on list prices, Medicaid's reimbursement formulas lead to large markups on drugs that have large differences between their list price and the price that the pharmacy actually pays. Within that system, then, the use of new generic and new brand-name drugs, for which that price spread tends to be larger, contributed to the recent increase in average markups.

Especially in the case of a newer generic drug, manufacturers have an incentive to set a high list price but to make the drug available to pharmacies at a significantly lower price. A relatively high markup on a generic drug gives a pharmacist an incentive to substitute that drug for another generic or brand-name drug. When a new generic drug becomes available, manufacturers can compete for the pharmacy's business partly by setting a high list price and a low actual price for the pharmacy. Over time, manufacturers continue to compete on the prices they charge pharmacies, but eventually their incentive to maintain high list prices diminishes for most generic drugs, in part because Medicaid's reimbursement rates to pharmacies for those drugs usually become subject to federal upper limits (FULs) that are based on the lowest-priced versions available.

State Medicaid programs have not shifted to using actual rather than list prices of drugs in part because those actual prices are not readily available to them. (For this analysis, CBO estimated actual prices on the basis of data reported by manufacturers directly to the Centers for Medicare and Medicaid Services as part of Medicaid's rebate program.) Nonetheless, many states have recently taken actions to reduce Medicaid's reimbursement rates to phar-

macies. Those actions have included setting state-specific upper limits on the reimbursement for drugs available in both generic and brand-name versions (limits that are frequently lower than the federal upper limits) and lowering the estimated acquisition costs used as a basis for the reimbursement for brand-name drugs. Perhaps partly as a result of those state actions, the average annual growth rate in markups slowed from 11 percent over the 1997-2000 period to 8 percent over the 2000-2002 period.

Measuring Markups

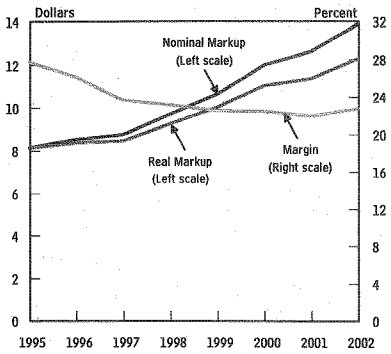
In addition to dollar terms, the difference between the amount that Medicaid pays pharmacies for prescription drugs and the amount that manufacturers charge pharmacies for the drugs can be expressed in percentage terms as a margin (or gross margin)—that is, the difference between what Medicaid pays a pharmacy and the cost of acquiring the drug from the manufacturer, divided by Medicaid's payment.

The two measures—the markup and the margin—yield very different pictures. For example, the percentage margin retained by pharmacies and wholesalers has been about the same in recent years for both newer and older generic drugs, but because Medicaid's reimbursements for newer generic drugs have been higher, the dollar markup on them has been more than three times that on older generic drugs.

Because pharmacies' cost of filling a prescription is largely unrelated to the cost of acquiring its ingredients or the size of the prescription, the dollar markup is a better indicator of the size or adequacy of Medicaid's reimbursements to pharmacies than is the percentage margin. The time a pharmacist spends filling a prescription is generally unrelated to the drug's cost and is only marginally greater for larger prescriptions than for smaller ones. Moreover, the shelf space required to store a $5 pill is no different from that required for a $1 pill. If ingredient costs increase, pharmacies' cost of invested capital tied up in inventories will increase, as drugs are held on the shelves and pharmacies are waiting for payment from Medicaid. By CBO's estimates, however, on a per-prescription basis, those costs account for only a small share of the increase in markups over the period.[5]

Figure 1.

Markups per Prescription and Margins Under Medicaid, 1995 to 2002



Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

Note: The real (inflation-adjusted) markup is calculated using the chain-weighted gross national product price index.

Factors Contributing to Rising Markups

After rising slowly between 1995 and 1997, the average dollar markup for all Medicaid prescriptions increased between 1997 and 2002, as described, by 59 percent, rising from $8.70 to $13.80, or about 9.7 percent annually (see Figure 1). In comparison, pharmacists' wages—a key component of dispensing costs—increased by 5.3 percent

5. Over the 1997-2002 period, the average acquisition cost per prescription increased by 66 percent, from $28.30 to $47.10. Assuming a cost of capital for pharmacies of 8 percent per year and an average shelf life of two months would put the associated rise in capital costs at about 25 cents per prescription. Adding in the cost of waiting for a final payment from Medicaid would probably no more than double that amount. Sales taxes (another type of cost that could increase with the price of a prescription) currently are imposed by only one state (Illinois, at 1 percent). See an analysis by the Federation of Tax Administrators at www.taxadmin.org/fta/rate/sales.html.

Table 2.

Medicaid's Reimbursements, Wholesalers' and Pharmacies' Acquisition Costs, and Markups for Brand-Name and Generic Drugs, 1997 to 2002

(Dollars per prescription)

	Medicaid's Reimbursements to Pharmacies			Acquisition Costs			Markups		
	All	Brand-Name Drugs	Generic Drugs	All	Brand-Name Drugs	Generic Drugs	All	Brand-Name Drugs	Generic Drugs
1997	37.00	61.90	12.00	28.30	52.20	4.30	8.70	9.80	7.70
1998	41.80	69.30	13.20	32.20	58.80	4.50	9.70	10.50	8.80
1999	47.20	76.80	14.10	36.60	65.50	4.20	10.60	11.30	9.90
2000	53.30	83.30	16.10	41.30	71.30	4.20	12.00	11.90	12.00
2001	57.40	89.60	18.30	44.80	77.00	5.70	12.60	12.60	12.60
2002	60.90	97.30	19.90	47.10	83.40	6.00	13.80	13.80	13.80

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

per year during that same period, and the overall inflation rate was less than 2 percent per year.[6] If the rate of increase of markups had matched the rate of increase of pharmacists' wages for that period, the markups under Medicaid would have cost about $1 billion less in 2002 than they actually did.[7]

Overall, the largest single factor contributing to the rapid increase in markups was the use of newer generic drugs, with their high markups. Another factor was the use of newer single-source brand-name drugs, which had somewhat higher average markups than did older brand-name drugs.

Markups on Generic and Brand-Name Drugs

Even as they produce savings for the Medicaid program as a whole, generic drugs are an important source of pharmacies' revenue from markups. Although generic drugs account for close to half of all prescriptions dispensed in the fee-for-service portion of Medicaid, because of their lower cost they account for only 14 percent to 16 percent of the program's reimbursements to pharmacies. Yet since the average markup on generic drugs is close to that on brand-name drugs, reimbursements for generic drugs provided an estimated 47 percent of total revenue from markups on Medicaid drugs in 2002.

In recent years, the average dollar markup on generic drugs has grown closer to that on brand-name drugs. In 1997, the average markup on generic drugs was about $2 less than that on a brand-name drugs—at $7.70 compared with $9.80 (see Table 2). But by 2002, the average markup on brand-name drugs had increased by 41 percent, while that on generic drugs had increased by 79 percent. Thus, by 2002 the average markup on generic drugs was about the same as that on brand-name drugs—at $13.80.

The growth in both acquisition costs and Medicaid's reimbursements for brand-name drugs has slowed in recent years, falling from over 12 percent annually during the 1995-1997 period to less than 8 percent between 2000 and 2002 (see Figure 2). At the same time, the growth rate of markups on brand-name drugs has increased. During the 2000-2002 period, all three measures grew at roughly the same rate—and the growth rate in markups was at its highest level.

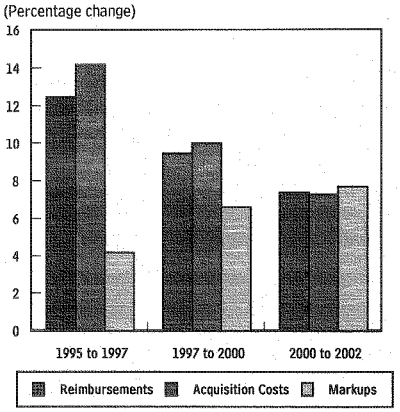
While the relationship between acquisition costs and Medicaid's reimbursements has been stable for brand-name drugs, it has been more variable for generic drugs. Throughout the 1997-2002 period, the acquisition costs for brand-name drugs averaged about 85 percent of Medicaid's reimbursements. For generic drugs, the acquisition

6. Inflation is calculated using the chain-weighted gross national product price index.

7. The estimated changes in markups presented here do not measure changes in pharmacies' profits from Medicaid-related sales. While CBO has data on the cost of the ingredients used in filling Medicaid prescriptions, it has few comparable data on the level of, or changes in, the cost of distributing drugs and operating the pharmacies that serve Medicaid patients.

Figure 2.

Average Annual Change in Reimbursements, Acquisition Costs, and Markups for Brand-Name Drugs Under Medicaid



Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

costs averaged 36 percent of reimbursements in 1997, fell to 26 percent in 2000, and then climbed back up to 30 percent in 2002. In fact, for generic drugs, the average reimbursement continued to rise even as the average acquisition cost changed little: between 1997 and 2000, the average acquisition cost per prescription fell slightly (from $4.30 to $4.20), while the average reimbursement increased by about $4, from $12.00 to $16.10.

Markups by Type of Brand-Name or Generic Drug

A more detailed analysis of markups shows that new generic drugs and new brand-name drugs had predominant roles in the increase in markups from 1997 to 2002. For this analysis, CBO placed drugs into three groups—single-source brand-name drugs (brand-name drugs that had no generic substitutes, in the same dosage form and strength, on the market), multiple-source brand-name drugs (brand-name drugs that had generic competitors), and generic drugs—and then accounted for the "newness" of the drugs and any change in their status (for example, from being a single-source brand-name drug to becoming a multiple-source brand-name drug).

Single-source brand-name drugs were designated as follows:

- Continuing single-source drugs—single-source brand-name drugs that were introduced by the first quarter of 1997 and remained single-source throughout the 1997-2002 period;
- New single-source drugs introduced by 2000—single-source brand-name drugs that were introduced between the second quarter of 1997 and the end of 2000; and
- New single-source drugs introduced by 2002—single-source brand-name drugs that were introduced between the beginning of 2001 and the end of 2002.

Multiple-source brand-name drugs, as follows:

- Continuing multiple-source drugs—brand-name drugs that already faced competition from generic drugs by the first quarter of 1997;
- New multiple-source drugs introduced by 2000—brand-name drugs that were single-source drugs in the first quarter of 1997 but that faced competition from generic drugs by the end of 2000; and
- New multiple-source drugs introduced by 2002—brand-name drugs that were single-source drugs from 1997 through the end of 2000 but that faced competition from generic drugs by 2002.

And generic drugs, as follows:

- Continuing generic drugs—generic drugs that were introduced by the first quarter of 1997;
- New generic drugs introduced by 2000—generic drugs that were introduced between the second quarter of 1997 and the end of 2000; and
- New generic drugs introduced by 2002—generic drugs that were introduced between the beginning of 2001 and the end of 2002.

Table 3.

Distribution of Medicaid Prescriptions, by Drug Type, 1997, 2000, and 2002

Drug Type	Status of Drug by Year			Percentage of Medicaid Prescriptions Dispensed		
	1997	2000	2002	1997	2000	2002
All Brand-Name Drugs				**50.0**	**55.4**	**53.0**
Continuing single-source	Single-source	Single-source	Single-source	21.5	26.8	25.8
New single-source introduced by 2000	n.a.	Single-source	Single-source	0.1	8.7	14.1
New single-source introduced by 2002	n.a.	n.a.	Single-source	0	0	3.7
Continuing multiple-source	Multiple-source	Multiple-source	Multiple-source	5.5	3.0	2.4
New multiple-source by 2000	Single-source	Multiple-source	Multiple-source	9.6	3.8	1.1
New multiple-source by 2002	Single-source	Single-source	Multiple-source	8.2	10.0	3.9
Unclassified because of lack of data[a]				2.1	0.7	0.5
Unclassified because of conflicting classification[b]				3.1	2.4	1.5
All Generic Drugs				**50.0**	**44.6**	**47.0**
Continuing generic drugs	Multiple-source	Multiple-source	Multiple-source	49.8	42.0	38.5
New generic drugs introduced by 2000	n.a.	Multiple-source	Multiple-source	0.2	2.7	4.7
New generic drugs introduced by 2002	n.a.	n.a.	Multiple-source	0	0	3.7
Total, All Drugs				100.0	100.0	100.0
Alternative Breakouts						
Multiple-source brand-name	Multiple-source	Multiple-source	Multiple-source	5.5	6.8	7.4
Single-source brand-name	Single-source	Single-source	Single-source	39.2	45.5	43.7
Unclassified (for either reason)	n.a.	n.a.	n.a.	5.2	3.1	1.9

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services (CMS).

Note: n.a. = not applicable.

a. Brand-name drugs for which CBO lacked sufficient data to determine whether they were single-source or multiple-source drugs.

b. Drugs that were classified in CMS's data as brand-name in one year and generic in a different year.

Medicaid's Reimbursements by Drug Type. Single-source brand-name drugs accounted for 75 percent to 77 percent of Medicaid's reimbursements in 1997, 2000, and 2002. Generic drugs accounted for 14 percent to 16 percent, and multiple-source brand-name drugs constituted the remainder.

In terms of the number of Medicaid prescriptions dispensed, in 2002, generic drugs introduced in 2001 or later constituted 3.7 percent of the total, and those introduced over the four-year period from 1997 through 2000 accounted for only slightly more, at 4.7 percent of the total (see Table 3). The market share of affected brand-name drugs fell quickly after generic drugs entered the market. Brand-name drugs that were single-source drugs at the beginning of 1997 but that faced competition from generic drugs by the end of 2000 constituted almost 10 percent of the market in 1997 but only about 1 percent by 2002. Similarly, brand-name drugs that became available as generic drugs as well in 2001 and 2002 saw their market share decline from 10 percent in 2000 to about 4 percent in 2002.

Markups by Drug Type. Among the markups for the groups of drugs considered here, those for new generic drugs stand out. Generic drugs first marketed between 1997 and 2000 had an average markup of $35.20 in 2000 (see Table 4)—which was about two-and-one-half times their average acquisition cost of $13.60. Between 2000 and 2002, that markup fell somewhat, to $29.20. Thus, markups on those new generic drugs in 2002 re-

Table 4.

Medicaid's Reimbursements, Wholesalers' and Pharmacies' Acquisition Costs, and Markups, by Type of Brand-Name or Generic Drug, 1997, 2000, and 2002

(Dollars per prescription)

Drug Type	Medicaid's Reimbursement to Pharmacies			Acquisition Costs			Markups			Percentage Change in Markups, 1997-2002
	1997	2000	2002	1997	2000	2002	1997	2000	2002	
All Brand-Name Drugs	**61.90**	**83.30**	**97.30**	**52.20**	**71.30**	**83.40**	**9.80**	**11.90**	**13.80**	**40.8**
Continuing single-source	79.40	91.70	98.20	68.90	80.10	85.50	10.50	11.60	12.70	21.0
New single-source introduced by 2000	n.a.	102.40	113.20	n.a.	89.40	98.20	n.a.	12.90	15.00	n.a.
New single-source introduced by 2002	n.a.	n.a.	110.70	n.a.	n.a.	97.20	n.a.	n.a.	13.60	n.a.
Continuing multiple-source	28.40	30.30	29.40	20.60	18.80	17.80	7.80	11.40	11.60	48.7
New multiple-source by 2000	59.00	65.10	64.30	49.70	52.70	48.90	9.30	12.40	15.40	65.6
New multiple-source by 2002	63.20	77.00	83.30	53.30	65.90	67.40	9.90	11.10	15.90	60.6
Unclassified[a]	28.60	50.00	71.70	19.00	35.20	52.80	9.60	14.80	18.90	96.9
All Generic Drugs	**12.00**	**16.10**	**19.90**	**4.30**	**4.20**	**6.00**	**7.70**	**12.00**	**13.80**	**79.2**
Continuing generic drugs	11.90	14.00	14.20	4.30	3.50	4.40	7.60	10.50	9.90	30.3
New generic drugs introduced by 2000	n.a.	48.80	42.50	n.a.	13.60	13.30	n.a.	35.20	29.20	n.a.
New generic drugs introduced by 2002	n.a.	n.a.	49.80	n.a.	n.a.	13.90	n.a.	n.a.	35.80	n.a.
Average	**37.00**	**53.30**	**60.90**	**28.30**	**41.30**	**47.10**	**8.70**	**12.00**	**13.80**	**58.6**

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services (CMS).

Note: n.a. = not applicable.

a. Brand-name drugs for which CBO lacked sufficient data to determine whether they were single-source or multiple-source drugs and drugs that were classified in CMS's data as brand-name in one year and generic in a different year.

mained high even though most had been on the market for at least three years. Generic drugs first marketed in 2001 and 2002 also had a high markup, of $35.80, in 2002.

The ratio of acquisition cost to reimbursement per prescription was roughly the same for new generic drugs and older generic drugs in 2002, at about 30 percent. Therefore, their percentage margins were similar, at roughly 70 percent. But because newer generic drugs were much more expensive (the average reimbursement on the newest ones was nearly $50 in 2002), that constant percentage led to particularly high dollar markups for them.

Single-source brand-name drugs introduced between 1997 and 2000 had markups that exceeded those of continuing single-source drugs by $1.30 in 2000 ($12.90 versus $11.60). Markups for those new single-source drugs continued to rise, reaching $15.00 by 2002. Single-source drugs introduced between 2001 and 2002 also had markups that were almost $1 more than those on continuing single-source drugs in 2002 ($13.60 compared with $12.70).

The ratio of acquisition cost to reimbursement was roughly the same for newer single-source drugs as it was for older single-source drugs (between 87 percent and 88 percent). But because the new single-source drugs were more expensive on average (at over $110 per prescription

in 2002), their average dollar markups were higher than those for older single-source brand-name drugs.

Besides newer generic drugs, those with the highest markups in 2002 were new multiple-source drugs—that is, brand-name drugs that were newly available from multiple sources in that they first faced competition from generic drugs during the 1997-2002 period. Typically, such drugs were brand-name drugs that lost patent protection. Markups for new multiple-source drugs were over $15.00 in 2002, and the percentage change in markups from 1997 to 2002 was relatively high, at over 60 percent.

The lowest markups in 2002 were on older generic drugs—that is, those introduced prior to 1997—at $9.90, followed by those for older multiple-source brand-name drugs at $11.60 and then older single-source drugs at $12.70. While markups on older generic drugs grew faster than inflation between 1997 and 2000, those markups actually declined between 2000 and 2002 as the average acquisition cost for those drugs rose more quickly than Medicaid's average reimbursement for them did.

The Relative Contribution of Generic and Brand-Name Drugs to Rising Markups

Of the total increase in average markups of $5.10 between 1997 and 2002, just over one-half was attributable to generic drugs and one-third to brand-name drugs (see Table 5). (The remainder of the increase came largely from shifts in utilization between 1997 and 2002 that were not fully captured in CBO's analysis.)[8] Although new generic drugs constituted only 8.4 percent of the prescriptions dispensed in 2002, they accounted for 37 percent of the increase in average markups since 1997.[9] Conversely, while older generic drugs accounted for nearly 40 percent of the prescriptions dispensed in 2002, their relative contribution to increasing markups was less than half as large—at 17 percent.

Single-source drugs introduced after the first quarter of 1997 accounted for 18 percent of the prescriptions dispensed in 2002 and 15 percent of the total increase in markups between 1997 and 2002.[10] Older single-source brand-name drugs constituted about one-fourth of the prescriptions dispensed in 2002, yet they accounted for only 11 percent of the total increase in markups between 1997 and 2002.

Medicaid's Reimbursement Policies That May Have Contributed to Increasing Markups

Following federal guidelines, states typically reimburse pharmacies for a prescription on the basis of an estimate of the cost of acquiring the drug from the manufacturer plus a dispensing fee—both of which vary among the states.[11] Costs for brand-name drugs that have no generic substitutes (or single-source drugs) are typically reimbursed at a rate equal to the average wholesale price minus roughly 10 percent to 15 percent plus a dispensing fee of $3 to $5.[12] The AWP is a published list price that is based on information provided by the manufacturers. Like the sticker price on a car, it is a price that few purchasers actually pay.

For many multiple-source drugs, which include generic drugs and their brand-name counterparts, the reimbursement formula is more complicated. For such drugs that are sold by at least two or three different manufacturers, state Medicaid reimbursements are subject to a federal upper limit of 150 percent of the lowest-priced therapeutically and biologically equivalent drug (which is usually a generic drug). CMS sets that limit on the basis of its

8. In order to attribute the change in markups over time to different types of drugs, CBO assigned a weight to each type based on its share of total Medicaid prescriptions in a single year, 2002. Consequently, part of the effect on markups of shifts in utilization between 1997 and 2002 is not captured by the fractions presented here (but appears in "other factors" in Table 5).

9. The contribution of new generic drugs to the total increase in markups is calculated by multiplying their share of prescriptions in 2002 by the difference between their markups in 2002 and those of their brand-name counterparts (new multiple-source drugs) in 1997.

10. The contribution of new brand-name drugs to the total increase in markups is calculated by multiplying their share of prescriptions in 2002 by the difference between their markups in 2002 and those of single-source brand-name drugs in 1997.

11. In addition, Medicaid's payments cannot exceed pharmacies' "usual and customary charges" (42 C.F.R. 447.331).

12. Some states use the published wholesale acquisition cost, which is another type of published price that more closely approximates pharmacies' acquisition costs but is less widely available. Typically, states using the wholesale cost add on (rather than subtract) a percentage to approximate pharmacies' acquisition costs. See National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, Va.: National Pharmaceutical Council, Inc., 2003), p. 4-41.

Table 5.

Distribution of Increasing Markups Among Types of Brand-Name and Generic Drugs, 1997 to 2002

(Dollars per prescription)

Drug Type	Markups 1997	Markups 2002	Markups Increase	Share of Medicaid Prescriptions Dispensed in 2002 (Percent)	Contribution to Increase in Markup, 1997 to 2002	Share of Total Increase in Markup (Percent)
Continuing Single-Source Brand-Name	10.50	12.70	2.20	25.8	0.57	11.1
New Single-Source Brand-Name	n.a.	14.70	4.20 [a]	17.9	0.75	14.7
Continuing Multiple-Source Brand-Name	7.80	11.60	3.80	2.4	0.09	1.8
New Multiple-Source Brand-Name	9.60	15.80	6.20	5.0	0.31	6.1
Continuing Generic Drugs	7.60	9.90	2.30	38.5	0.89	17.4
New Generic Drugs	n.a.	32.10	22.50 [b]	8.4	1.90	37.2
Unclassified[c]	9.60	18.90	9.30	1.9	0.18	3.5
Other Factors[d]					0.42	8.2
All Drugs	8.70	13.80	5.10	100.0	5.10	100.0

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services (CMS).

Note: n.a. = not applicable.

a. Because new single-source drugs were not available in 1997, the change in markup is calculated relative to the average markup (of $10.50) on continuing single-source drugs in 1997.

b. Because new generic drugs were not available in 1997, the change in markup is calculated relative to the average markup (of $9.60) for their brand-name counterparts in 1997.

c. Brand-name drugs for which CBO lacked sufficient data to determine whether they were single-source or multiple-source drugs and drugs that were classified in CMS's data as brand-name in one year and generic in a different year.

d. In order to attribute the change in markups over time to different types of drugs, CBO assigned a weight to each type based on its share of total Medicaid prescriptions in a single year, 2002. Consequently, part of the effect on markups of shifts in utilization between 1997 and 2002 is not captured for the particular types of drugs but is included as an overall figure here.

analysis of list prices.[13] If, in the aggregate, a state's Medicaid reimbursement for multiple-source drugs exceeds the federal upper limit, the state does not receive federal matching funds on the excess amount. One recent study found that generic drugs with a FUL accounted for 65 percent of the total sales of generic drugs nationwide in 2001.[14]

States also have the latitude to set an upper bound on a reimbursement, referred to as the maximum allowable cost (MAC), that is different from the FUL, as well as to set a MAC for a multiple-source drug that does not yet have a federal limit. Because of that flexibility and a desire to contain Medicaid costs, some states have MAC programs that include more drugs than are on the federal list, and some states are also more aggressive in setting price limits (by setting maximum allowable costs that are lower

13. See www.cms.hhs.gov/medicaid/drugs/drug10.asp. If there is only one manufacturer of a generic drug and the Food and Drug Administration (FDA) has classified it as therapeutically equivalent (with an A rating) to the brand-name product, then CMS may establish a FUL for that drug. If there are multiple generic versions, then FDA must have classified at least two of the versions as equivalent in order for CMS to establish a FUL.

14. Richard G. Abramson and others, "Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC [maximum allowable cost] Programs," *Health Care Financing Review*, vol. 25, no. 3 (Spring 2004), pp. 25-34.

than the federal upper limits).[15] By 2003, about 40 states had a MAC program in place.[16]

Under Medicaid's system for paying for drugs, reimbursement for new generic drugs may be based on their list price if an upper limit has not yet been set by CMS or the state. Only a handful of states have set a separate reimbursement formula for generic drugs that are not yet subject to a federal upper limit.[17] The remaining states provide reimbursement for such generic drugs by using the same reimbursement formula as for brand-name drugs (usually the AWP minus 10 percent to 15 percent plus a dispensing fee).

On the one hand, a relatively high markup on new generic drugs gives pharmacists an incentive to substitute them for brand-name drugs, even before an upper limit has been placed on Medicaid's reimbursement that could make the brand-name drug unprofitable to dispense.[18] Such substitution of new generic drugs for their brand-name counterparts helps to reduce Medicaid spending. On the other hand, whether markups that are over three times those of brand-name drugs are necessary to accomplish that outcome is unclear.

Manufacturers may have an incentive to increase the gap between their list prices and the prices that they charge pharmacies when they compete for pharmacies' business. That situation occurs for generic drugs because pharmacies frequently have the choice of acquiring what is essentially the same drug from several manufacturers.[19] Pharmacists have an incentive to stock the generic drug with the lowest acquisition cost relative to its list price. The incentive for a manufacturer of a generic drug to maintain a high list price may be greatest before the FUL pricing formula takes effect because once it does, the list price becomes irrelevant to reimbursement under Medicaid unless that price is the lowest available.[20] However, the incentive to compete for pharmacies' business by selling the drug at a low price remains.

Manufacturers of multiple-source brand-name drugs may also have a similar incentive to increase the gap between the list prices and acquisition costs. Once the patent for a drug expires (and before the FUL is in effect), increasing that gap would help to make the brand-name drug more profitable for pharmacies to dispense relative to its generic competitors. Indeed, the data that CBO analyzed show that average markups tended to be higher for multiple-source brand-name drugs that had recently lost patent protection than for older single-source brand-name drugs.[21] Although markups were relatively high for brand-name drugs that had recently faced competition from generic drugs compared with those for other brand-name drugs, however, they were not nearly as high as those for new generic drugs.

Recent research has also shown that the percentage difference between list prices and acquisition costs generally is much larger for generic drugs than for brand-name drugs. And, perhaps more important, the relationship between list prices and acquisition costs is much more variable for generic drugs. The larger percentage gap for generic drugs enables the markups on them to be comparable with those on brand-name drugs on average and thus provides an incentive for pharmacies to dispense generic drugs. However, the more variable relationship between list prices and acquisition costs for generic drugs means that states may not be able to accurately estimate the size of the markups on those drugs. States do not have access to the average prices that manufacturers report to CMS (and that are used in this paper) and therefore may find assess-

15. Ibid.

16. National Pharmaceutical Council, *Pharmaceutical Benefits* (2003).

17. For example, Illinois reimburses such generic drugs at the AWP minus 20 percent.

18. In most states, the substitution of generic drugs is encouraged through an upper limit on reimbursements that applies to both the brand-name and generic versions. When the upper limit is in effect, pharmacists will usually lose money by dispensing the brand-name drug. There is sometimes a delay before CMS establishes a federal upper limit. Of 200 top-selling multiple-source drugs in 2001, 90 did not have a federal upper limit, although they met the established criteria. See Department of Health and Human Services, Office of Inspector General, *Omission of Drugs from the Federal Upper Limit List in 2001*, OEI-03-02-00670 (February 2004).

19. Provided all generic drugs have received an A rating from FDA on their therapeutic equivalence to the brand-name drug, patients and physicians are generally indifferent about the manufacturer of the generic drugs.

20. The incentive to set a high list price is also affected by how pharmacies are reimbursed by payers other than Medicaid.

21. For example, in 2002, the markup on new multiple-source brand-name drugs exceeded $15 while that on continuing single-source drugs averaged about $13 (see Table 4).

ing the appropriateness of reimbursement rates for generic drugs difficult.

According to a September 2002 report by the Office of Inspector General within the Department of Health and Human Services (HHS), the acquisition costs of brand-name drugs with no generic substitutes averaged 17 percent below the AWP, with relatively little variation around that level.[22] For multiple-source brand-name drugs not yet subject to a FUL, the difference was somewhat greater, with acquisition costs 24 percent below the AWP. For generic drugs not yet subject to a FUL, acquisition costs averaged 54 percent below the AWP. And for multiple-source drugs subject to a FUL (brand-name and generic drugs combined), acquisition costs averaged 72 percent below the AWP.[23] Consequently, HHS's Inspector General recommended that CMS work with states to reexamine their reimbursement formulas, particularly for multiple-source drugs.

Recent Changes in States' Policies for Reimbursing Pharmacies

Although markups increased over the 1997-2000 period, states' Medicaid reimbursement formulas themselves remained relatively unchanged. More recently, however, many states have taken actions to reduce their reimbursement rates, which probably helped slow down the average annual growth rate in markups, from 11 percent between 1997 and 2000 to 8 percent between 2000 and 2002.

According to a study by HHS's Office of Inspector General, 17 of 43 states responding to a 2003 survey had recently reduced their Medicaid reimbursement formulas for prescription drugs.[24] In addition, drawing on the National Pharmaceutical Council's semiannual surveys of states' Medicaid reimbursement policies, CBO found that more than 10 states had lowered the estimated acquisition cost that they used as a basis to reimburse pharmacies for brand-name drugs between 2000 and 2002.[25] By 2003, about 40 states had a MAC list in place. Also, five states had begun to set separate reimbursement formulas for generic drugs that were not subject to a FUL or on a state MAC list.[26] Changes to dispensing fees were generally more modest: nationally, only 10 states significantly changed their dispensing fees—five of those states slightly lowered their fees, and five states slightly raised them.[27]

By 2002, 31 of the 41 states examined in CBO's analysis had taken steps to hold down reimbursements for multiple-source drugs by adopting a MAC list. States that have adopted such a list tend to have lower average markups than states that have not. For states with a MAC list in effect by 2002, the average markup was $13.30—roughly $2 less than the average of $15.50 among states without that list (see Table 6). The growth rate in markups over the 2000-2002 period was also much lower in states that had adopted a MAC list—at 6.2 percent, compared with 10.9 percent for the other states. Perhaps states that had a list in place were more active than other states in monitoring reimbursement rates overall, so the differences

22. For over 90 percent of brand-name drugs dispensed to Medicaid patients in 1999, pharmacies' acquisition prices were between 82 percent and 84 percent of the AWP. See Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy: Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041 (September 12, 2002), p. 5.

23. About 600 of the 5,575 products examined had acquisition costs that ranged from 15 percent to 20 percent below the list price. Those were probably the brand-name multiple-source drugs within the group of drugs subject to a FUL.

24. Department of Health and Human Services, Office of Inspector General, *State Strategies to Contain Medicaid Drug Costs*, OEI-05-02-00680 (October 2003).

25. National Pharmaceutical Council, *Pharmaceutical Benefits* (2000 and 2002).

26. The states were Arkansas, Colorado, Illinois, Indiana, and Kansas. The formulas varied for generic drugs, from the AWP minus 20 percent to the AWP minus 35 percent. See National Pharmaceutical Council, *Pharmaceutical Benefits* (2003).

27. See National Pharmaceutical Council, *Pharmaceutical Benefits* (2000 and 2002).

Table 6.

Average Markups in States With and Without a Maximum Allowable Cost List, 1997 to 2002

(Dollars per prescription)

	Average Markups						Average Annual Growth Rate in Markups (Percent)	
	1997	1998	1999	2000	2001	2002	1997 to 2002	2000 to 2002
States With a MAC List in 2002	8.50	9.50	10.40	11.80	12.30	13.30	9.4	6.2
States Without a MAC List in 2002	9.30	10.30	11.20	12.60	13.50	15.50	10.8	10.9

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

Notes: MAC = maximum allowable cost.

The designation of states with and without a MAC list comes from National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs* (Reston, Va.: National Pharmaceutical Council, Inc., 2002).

Table 7.

Distribution of Average Markup Levels Among States, 1997, 2000, and 2002

Markup Intervals (Dollars)	1997		2000		2002	
	Number of States	Percentage of States	Number of States	Percentage of States	Number of States	Percentage of States
5.00 to 5.99	2	4.9			1	2.4
6.00 to 6.99	3	7.3			1	2.4
7.00 to 7.99	8	19.5	2	4.9		
8.00 to 8.99	14	34.1			1	2.4
9.00 to 9.99	10	24.4	5	12.2		
10.00 to 10.99	3	7.3	9	22.0	2	4.9
11.00 to 11.99			9	22.0	8	19.5
12.00 to 12.99	1	2.4	7	17.1	8	19.5
13.00 to 13.99			7	17.1	5	12.2
14.00 to 14.99					7	17.1
15.00 to 15.99			2	4.9	2	4.9
16.00 to 16.99					4	9.8
Over 17.00					2	4.9
Total	41	100.0	41	100.0	41	100.0

Source: Congressional Budget Office based on data from the Centers for Medicare and Medicaid Services.

cannot be attributed to MAC policies alone. Still, the differences suggest that state MAC lists have contributed to lower markups.

Given the variation that now exists in reimbursement formulas among states, the level of markups also varies considerably. In 1997, the weighted average markup in 41 states was $8.70, and markups ranged between $7.00 and $10.00 for 78 percent of those states (see Table 7). By 2002, the weighted average markup was $13.80 and the range spanned from $11.00 to $17.00 for 83 percent of those states.

Data and Methods

To estimate pharmacies' revenues from dispensing drugs to Medicaid patients, the Congressional Budget Office's (CBO's) analysis relies on quarterly data published by the Centers for Medicare and Medicaid Services (CMS). The data cover prescriptions and units (for example, tablets) dispensed to Medicaid recipients and reimbursements to pharmacies by state Medicaid agencies from 1995 to 2002 for each drug covered by Medicaid. CMS receives those data from the states, and reporting lapses occur. Data were unavailable for some states in some quarters. CBO's analysis included data reported by 40 states and the District of Columbia when those data were available in at least three quarters of four benchmark years: 1995, 1997, 2000, and 2002.[1]

To estimate the cost of acquiring drugs, CBO used the per-unit average manufacturer price (AMP) reported to CMS by manufacturers as part of the Medicaid rebate program. The AMP is the average price at which the manufacturer sells a unit in the retail class of trade, including sales to wholesalers, who distribute to pharmacies; direct sales to pharmacies; and sales to mail-order pharmacies. Because rebates from manufacturers to Medicaid are calculated on the basis of the AMP, their value could be scrutinized by government auditors. Retail pharmacies that buy through wholesalers may pay more than the AMP, but the wholesale markup constitutes a very small proportion (estimated at about 3 percent by the National Association of Chain Drug Stores) of the total retail price.

Medicaid's drug purchases in a fee-for-service setting, to which this analysis applies, accounted for about 14 percent of total nationwide outpatient drug expenditures, net of rebates, in 2002.[2] CBO's analysis excluded drugs that were sold over the counter and was limited to oral solid dosage forms (that is, tablets and capsules), which accounted for about 73 percent of prescriptions filled and 77 percent of reimbursements by Medicaid agencies in the fee-for-service sector of the program in 2002.[3] After CBO further limited the analysis to 41 states, the reimbursements covered in this paper accounted for 58 percent to 66 percent of total Medicaid reimbursements over the 1997-2002 period.

1. Reimbursement data were drawn from CMS's Web site on June 27, 2002; see www.hcfa.gov/medicaid/drugs/drug5.htm.

2. CMS estimated that total outpatient drug spending, net of manufacturers' discounts and rebates, was $162 billion in 2002; see www.cms.hhs.gov/statistics/nhe/historical/t2.asp. Medicaid's fee-for-service spending came to $23.4 billion in 2002—constituting 14.4 percent of the outpatient market. Some states reimburse HMOs (health maintenance organizations) on a capitated basis to cover drug expenditures for Medicaid beneficiaries; others "carve out" the drug benefit so that it remains in the fee-for-service system (and states continue to collect the rebates from manufacturers). CBO's analysis does not apply to Medicaid's drug spending that falls outside Medicaid's fee-for-service reimbursement system.

3. CBO used the number of units of the drug dispensed per prescription in combination with the average manufacturer price per unit (reported under Medicaid's rebate program) to estimate the acquisition cost of the drugs dispensed. Because the unit variable (number of units) is more reliable for drugs that come in tablets and capsules, CBO limited its analysis to drugs in those forms.

Mr. DEAL. Thank you, Doctor, and I will begin the questions.

As I understand it, according to your report and other reports, Medicaid pays the pharmacies based on the average wholesale price——

Mr. HOLTZ-EAKIN. Yes.

Mr. DEAL. [continuing] but the rebates are calculated on the average manufacturers price.

Mr. HOLTZ-EAKIN. Yes.

Mr. DEAL. Obviously when we use different scales to judge things, it gets more complicated for everybody to understand. Is there any advantage, if any, for going to using one price to calculate both the rebates and the payment to pharmacists? And what are the pros and cons of that?

Mr. HOLTZ-EAKIN. If one thinks about the AWP, the intent, one can broadly say, would be to have some sort of price index, AWP or AMP or some of the other of the alphabet soup that is out there. And it is meant to indicate the typical price of a market transaction that Medicaid can then use as a proxy for reimbursement. In moving to some other index, instead of AWP, which is convenient, because it is a list price and out there, easily accessible, there are probably three different things to consider.

The first is the degree to which it is readily available. One of the advantages of AWP is it is always available. It is updated by the manufacturers. It is available in a timely fashion. So would the proxy be available in a regular fashion?

The second is the degree to which that would be the correct comparison group for whomever you are trying to reimburse. Who are the correct comparisons for pharmacies, for example? Is it the VA? Is it hospitals? Or is it closer to the kinds of retail pharmacy transactions that you see in the private market?

And then the third would be the impact that going to a new index would have on private sector bargaining. If you went to a different index and manufacturers new that that was going to affect reimbursements, it might change the way they cut the deal with their other customers.

So those three things will come up regardless of whether you go to AMP or an average sales price or whatever it may be.

Mr. DEAL. The testimony that we heard from the National Governors Association last week reiterated something that I think many committee members have said, both publicly and privately, and that is that we do not want to make changes that are going to adversely affect the pharmacists, because many of those really are the point of contact for health consultations within small rural communities, in particular.

The current structure, which as you outlined, I think, on your second chart, indicates that the markup for newer brand name generics is the highest category of markup, which, I presume the pharmacist gets to keep that markup. Is that right?

Mr. HOLTZ-EAKIN. The pharmacist and whoever else might be in that chain. The wholesalers get some.

Mr. DEAL. Okay. But it would still be more profitable in this scenario for a pharmacist to be able to fill a prescription with a new generic. Is that right?

Mr. HOLTZ-EAKIN. Yes.

Mr. DEAL. Is that an appropriate incentive, in your opinion?

Mr. HOLTZ-EAKIN. It is clear that if you look at the total cost of the system, the new generic is a cheaper total cost to the system than is a brand name drug. If they are therapeutically equivalent, that would seem to be the kind of incentives you want to embed in the system. Whether it has to be that big, I think, is the question of the hour.

Mr. DEAL. Right. Okay. In your December-of-last-year report, you highlighted that some of the largest markups happen in the new single source generics, and that is one of the areas that you focused on. Could you go through how the average markups on each of these various levels are arrived at? And how does this discrepancy happen in those variations?

Mr. HOLTZ-EAKIN. Well, the computations are the same in each case. You will take the list price, the AWP, and take 15 or 20 percent of it, and that will be the appropriate reimbursement. The real action is in the degree to which the actual transaction between a pharmacist and a manufacturer differs greatly below that list price. And there is a far greater aggressive negotiation on the part of the new generic entry, the single source generic drug, where their list price might be up here, they are willing to discount to get it into the market, and that provides a clear incentive for adoption by the pharmacists. And as a result, you get this disparity between those single source generics and then, say, older ones that are in the table where you don't see a big discount from the list.

Mr. DEAL. But even in spite of that, as your chart indicates, there is still significant savings to the system to go that route?

Mr. HOLTZ-EAKIN. Yes. Yes.

Mr. DEAL. All right. Well, thank you.

Mr. Brown, you are recognized for questions.

Mr. BROWN. Thank you, Mr. Chairman.

It is my understanding, Dr. Holtz-Eakin, that it is unclear whether authorized generics are included with generic drugs or brand name drugs in the data base you use for the markup study. For those unfamiliar with the term, authorized generics refer to brand name drugs repackaged by their manufacturer as a generic and priced just below, in a shadow sort of way, the brand price. It is a way for brand companies to undermine the incentive for true generic competitors into the market. So if you include them with the brand names, it skews it down, if you will, the average price. If you put them with generics, it skews up the average generic price so that, either way, the drug industry wins. Am I correct about that?

Mr. HOLTZ-EAKIN. I, to be honest, don't know how we class that, but certainly to the extent this is an issue, and we will get back to you with a clear answer about how the computations were done for our study, one thing that we will do is check the sensitivity of the results to classifying them one way or another. It is a very straightforward thing to check. And the second is to just provide the overall caveat that is true in this area, which is our results are for particular years and for the rules that were in place in those years. And results are going to differ as new drugs——

Mr. BROWN. But could one——

Mr. HOLTZ-EAKIN. We can check on that in detail.

Mr. BROWN. Okay. Because I mean it is hard for me to think it doesn't skew the results depending on which one you classified it with. It is just mathematics, and it would skew the results.

Mr. HOLTZ-EAKIN. Oh, it will matter, there is no question, but the matter of magnitude, I don't know.

Mr. BROWN. Okay. Let me shift to something else.

Many individuals don't realize there are two distinct areas in Medicaid drug payments for Congress to achieve savings. The first deals with the payments by States to pharmacists, which we will discuss at some length. The second deals with the rebates or mandatory discount given to States by drug manufacturers, as we have discussed, because they are such large purchasers of drugs. I would like you to tell me how much money could be saved increasing the rebate paid from the statutory 15.1 to say 20 percent. And I ask that, and before you answer, and that will be my last question, it is pretty clear from what we have seen with the profitability of the drug industry, as I pointed out in my opening statement, the 400 percent profit is larger than other companies in other industries, and the fact that, as Mr. Buyer so politely pointed out, that drug companies are repatriating profits, profits that they always seem to disclaim because they say that those price controlled prices in Europe and around the world, they can't make any money from that. So tell me, one, what you think of moving it from 15.1 to 20 percent, if you are willing to do that, but maybe more importantly, tell me what kind of money it would save by increasing the rebate.

Mr. HOLTZ-EAKIN. Well, the basic rebate being moved from 15 to 20 percent would save about $600 million in 2006 and a bit over $3 billion over the 5-year budget window. So those are the magnitudes of the monies involved. The rebate structure has two pieces: the basic rebate and then an additional rebate for those drug prices that rise more rapidly than inflation. And I think it is best to think about the sort of desirability of modifying the rebate structure and thinking about all of the pieces and not just one in isolation. Those are the monies that would be involved in any proposal that you might go in that direction.

Mr. BROWN. Can the drug industry continue its research and development, and can you comment on that?

Mr. HOLTZ-EAKIN. I——

Mr. BROWN. Would this mean less research and development for the drug industry?

Mr. HOLTZ-EAKIN. One of the central questions in this area for the past several years has been the tradeoff between the sort of any year reduction in prices, given the production costs are actually a small fraction of things, and then the incentives over time for the development of new chemical entities, new drugs that will be beneficial. And this is something about which we have been deeply interested in, and which we are actually working on at this time. I won't prejudge the outcome of our looking at that, but we are working on the links between retail pricing and R&D, and it is something that we will continue to work with years after.

Mr. BROWN. Do they spend more on marketing or do they spend more on research?

Mr. HOLTZ-EAKIN. I don't know the exact numbers off the top of my head, but it is, again, something that as we finish, I would be happy to——

Mr. BROWN. I am not looking for exact numbers. I just said do they spend more on marketing or on research? It is hard to think the CBO doesn't know the answer to that question.

Mr. HOLTZ-EAKIN. Well, the question is which data source you go to, sir. And——

Mr. BROWN. Do you think accurate data, data not coming from the drug industry, might be a start?

Mr. HOLTZ-EAKIN. Why don't we get back to you?

Mr. BROWN. Okay. Thank you.

Mr. DEAL. Mr. Bilirakis is recognized for questions.

Mr. BILIRAKIS. Doctor, again, our apologies for making you wait so long, as we usually do at these hearings while you have to listen to our rhetoric up here.

We have AWP. We have AMP. We have ASP. We have rebates. We have markups. We have measuring of markups. I could just go on and on and on here. All of these years, we have never been able to simplify this process or get a handle on it. So I would have maybe one question to you in three or four parts.

States, as I understand it, can currently negotiate pharmacy reimbursement rates. So one question is why does Medicaid continue, then, to overpay for drugs if the States already have the ability to negotiate lower prices? Continuing on, can't we make this process more simple? We are going to hear from the next panel how Arizona relies on health plans to negotiate drug prices for Medicaid beneficiaries, and they reportedly get some of the lowest prices in the market. So I guess could we have more States follow the Arizona model and have health plans handle these negotiations? And I guess does having the government handle these negotiations just unnecessarily complicate the process?

So if you are able to kind of get a handle on all of those questions, I am talking about simplicity here. We have got more darn acronyms up here than you could shake a stick at and complications in trying to solve AWP and all of that stuff. But is it really truly necessary in order to be able to get the best price for the drugs?

Mr. HOLTZ-EAKIN. Well, first of all, I want to share my sympathy with all of the acronyms. I am new to this area, and I found it absolutely frightening.

I think that it is useful to think about it in really three steps. Step No. 1 is do the private entities, and in my simple diagram, pharmacies versus drug manufacturers, do the private entities have sufficient incentives and abilities to negotiate hard for low prices? And that is a question about whether you are happy with the power of the pharmacies and the wholesalers relative to the drug companies in cutting a good deal. And if those incentives and tools are in place, that should be sufficient in a market economy. If not, then you might want to bring the government in with extra leverage.

Second, can you see those transactions? Are they transparent, reported to CMS, or even reported publicly? And if so, how will that influence the level of negotiation and the satisfaction of the people

of the price that is received? And then given the ability to see them, it is very easy to reimburse.

And so there are really three different steps there. No. 1 is power from the negotiation. Step two, who gets to see the negotiation? And then step three, having been able to see it directly or have to approximate it, the problem with the AWP is it is a bad approximation to the market deal, how do you do the reimbursement? With the wide diversity of experience in the States, I think that is a great laboratory to really look and see where it seems to be the most successful. And the Arizona model is one that certainly stands out. It doesn't look like most of the other Medicaid programs, and accounting for all of the differences, the heavy reliance on managed care, for example, is something that we would be interested in working with you on.

Mr. BILIRAKIS. Well, why aren't the States taking a good look at the Arizona model, or are they? And what do you think, is coming down the pike? Florida, for instance, my Governor is concerned about this problem. Is he familiar with it, do you know? I suppose I should ask him.

Mr. HOLTZ-EAKIN. I don't know.

Mr. BILIRAKIS. And is he trying to put that into effect in Florida or take a look at it, or maybe some sort of a pilot project? You don't know the answers, though?

Mr. HOLTZ-EAKIN. I don't know the answer to that one.

Mr. BILIRAKIS. Okay. Is it right, on newer generic drugs, that there be approximately a 70 percent markup?

Mr. HOLTZ-EAKIN. It is a clear outcome of the reimbursement formula and the incentives of the manufacturers and the pharmacists. There is no way around it.

Mr. BILIRAKIS. And the States can't do a better job in negotiating the——

Mr. HOLTZ-EAKIN. Change the reimbursement formula and, as a result, alter the scale of that markup, but given the nature of reimbursement based on AWP, incentives for entry into the market by new generics——

Mr. BILIRAKIS. Well, why are we fooling around? I mean, my time is up, but again, here we go. AWP and ASP. You know, we have got a free market in this country. We take pride in it, and yet we are not really letting it work, I don't think.

Okay. My time is up. Thanks, Mr. Chairman. Thank you, Doctor.

Mr. DEAL. Thank you.

Mr. Allen.

Mr. ALLEN. Thank you, Doctor, for being here.

I wanted to ask you a couple questions, but to start with an issue related to the dual-eligibles, those people who qualify for both Medicare and Medicaid. The Medicare Modernization Act includes a provision by which the States must pay back to the Federal Government a portion of the savings that they receive from the transition of low-income Medicare beneficiaries, who get their prescription drugs from Medicaid, over to the Medicare drug benefit. Under that law, the base year for determining the payments is 2003. And my State, among others, has taken significant steps to save prescription drug costs under Medicaid in the interim. In Maine, what we have done is we have used prior authorization and we have

used prior authorization requirements, so essentially what would happen, those States like Maine would not get credit for those savings, and we would be overpaying the Federal Government for the so-called savings that we would have. And I wonder if the CBO has examined this issue and whether or not, if you have given any thought to the cost implications if Congress were to move the base year from 2003 to 2004?

Mr. HOLTZ-EAKIN. We have looked at this a little bit. The key issue is the way it is calculated starts with a spending per beneficiary, and then you find out how many beneficiaries and what fraction the State pays, and then there is a percentage of phaseout. So the starting point is the key, spending per beneficiary. And if one were to move the base year from 2003 to 2004 for that number, it would actually not make it easier for the States. In fact, it would go the other direction. But it will differ by State. And so I don't know the particular experience with Maine, but for the system as a whole, that wouldn't be the case.

Mr. ALLEN. Well, obviously my constituents care a lot about what happens to Maine. I raise it as an issue, a real challenge, I think.

And one other quick issue I just want to mention, and I don't expect you to deal with this, but I am very concerned about the transition under the new Medicare law of the dual-eligibles. In 6 weeks, starting January 1, 2006, we are expected to move 6 million Americans, who now get their prescription drugs through Medicaid, to Medicare plans, which they don't know about yet, we don't know about yet, we don't know if their drugs are going to be covered. I would just suggest that that is an area both Jay Rockefeller and I have legislation to deal with it, but it is a very serious potential problem.

But let me come back to one more point. The CBO report on Medicaid reimbursements to pharmacies, as you have indicated, indicates this dramatic difference, and maybe it would be worthwhile putting up your second chart again, if we could have that. The pharmacies' profit margin has been increasing significantly, as you pointed out, on newer generic drugs. And in response to Mr. Bilirakis' question, you referred to incentives of the manufacturers. And I wanted to have you elaborate, if you could, a little bit on the incentives of the manufacturers. I mean, my information is that the inflation of the list price to the pharmacies is driven, in part, by the manufacturers' desire to expand their market share. And they know the pharmacies will make more if they keep their list prices higher. Could you confirm that, deny it, comment on it?

Mr. HOLTZ-EAKIN. I think you have characterized the calculation and the incentive very clearly. I mean, there is a computation that delivers what we have labeled the markup to a pharmacy. That computation is between what you actually sell it and what the list price is. So the manufacturer who wishes to have lots of beneficiaries use their drug has a clear incentive to make that gap as large as possible to give the pharmacists an incentive to use that generic drug. And that is an outcome of basic economic incentives and the way the reimbursements are structured.

Mr. ALLEN. I mention it because on this chart, which is on the screen, it shows the markup for newer generic drugs to be $32.10 and the markup for older generics to be $9.90. And you know,

when we think there is a markup, when we talk about a markup, generally, we would think it is the pharmacists who are doing the markup, but in this case, there is a profound and strong incentive for the manufacturer to have a higher list price for the reason you indicated.

I see my time has run out. I thank you and yield back.

Mr. DEAL. I thank the gentleman.

Ms. Cubin.

Ms. CUBIN. Thank you, Mr. Chairman.

The more I listen to this, the more ridiculous this system sounds, and I think it probably is. If we can't do better than this, then we all need to have our heads examined. This is just one of the worst examples of government gone awry that I think I have ever seen.

Now I want to ask you a question, Doctor. In theory, the AWP is the price that the drug manufacturers suggest that the wholesalers charge retail pharmacists, right?

Mr. HOLTZ-EAKIN. Yes.

Ms. CUBIN. But you testified that that varies greatly. Has the CBO uncovered any information as to AWP variance related to the socioeconomic makeup of a region? In other words, is there any regional connection between what that price might be?

Mr. HOLTZ-EAKIN. I am unaware of anything like that. We haven't looked for that, specifically. These are national list prices.

Ms. CUBIN. Okay. I am interested in understanding further the relationship between pharmacy reimbursement rates and Medicaid beneficiaries' access to pharmacies, particularly in rural areas, because rural areas have the least opportunity to have a choice in where they go to get their drugs and so on. Can you please discuss what the implications would be on beneficiary access by moving to a pharmacy reimbursement payment based on ASP?

Mr. HOLTZ-EAKIN. I think it will depend exactly what is meant by ASP. ASP, at the moment, exists only under Medicare part B, and whether that particular calculation is the one that you would want to use for reimbursement of pharmacies when it is really not completely comparable to the kinds of transactions that the pharmacies are going to make under Medicaid. So you might want to have a different measure of sales, a different set of retail sales put into that index. And so that would be, probably, the first thing that would be important. And the second of the issues that I mentioned earlier——

Ms. CUBIN. The three issues, yeah.

Mr. HOLTZ-EAKIN. [continuing] how quickly will this be available? Can you do this? And how will the use of these transaction prices change the kinds of transactions that are actually done and reported?

Ms. CUBIN. Yes. It just seems to me that doing something simpler could outweigh those three things, because I just think this is so unnecessarily complicated. And maybe when I understand the issue better I won't feel that way about it.

You have discussed a number of potential methods for cutting Medicaid prescription drug costs, each of which essentially put the onus of cost savings on pharmacies or drug manufacturers. I would like to hear your thoughts on the matter of increased co-payment

system. Has CBO studied the feasibility of a sliding scale system based on somebody's means?

Mr. HOLTZ-EAKIN. We have looked, not just in this area, at the issue of cost sharing with beneficiaries in the health programs, and you run into the fact that additional cost sharing provides incentives for not undertaking unnecessary care, or in this case, purchases, looking for the lower cost source of necessary care. And the flip side of that is the concern that people will skip care which is desirable and necessary, and as a result, has bad either financial or worse health consequences. And we are trying to investigate, in all areas of our work, what we can learn about those tradeoffs. And I don't think there is anything definitive we have to offer at this moment, but it is a very important issue.

Ms. CUBIN. And I appreciate your observations. I just think it has to be weighed with the fact that people have to be responsible for their own health and that they have to play a responsible part in what they do and how they spend their money.

Mr. Chairman, I yield back. Thank you so much.

Mr. DEAL. I thank the gentlelady.

Ms. Baldwin, questions.

Ms. BALDWIN. Thank you, Mr. Chairman.

Dr. Holtz-Eakin, I am looking at the table on page four and five of your report, the June 2005 report, on the prices for brand name drugs under selected Federal programs. This chart is very informative, and one thing I would note is that we do not yet have a box on that chart for the prices paid by Medicare. As we all know, Medicare will begin its prescription drug benefit in 6 months. And I am wondering whether the Congressional Budget Office plans to update this chart to reflect the discounts off average wholesale price received by Medicare.

Mr. HOLTZ-EAKIN. We will certainly work with the Congress and provide them anything that is requested. We don't have a specific plan to do that at the moment, and we did feel it was appropriate to leave that issue out of this report. Given the transition at the moment, it would be impossible to do a fair job on that. But that is something we would be happy to continue to work with this committee on, if it becomes important.

Ms. BALDWIN. I think it is going to be vital for Congress to understand where Medicare will fall in the spectrum of Federal programs that purchase drugs. I am wondering what sort of information the Congressional Budget Office will need in order to provide such an analysis. And as a follow-up, you can tackle both at the same time, whether you are sufficiently able to get that information from CMS, or whether you require any legislative change to derive the information that you will need to inform us in this regard.

Mr. HOLTZ-EAKIN. We were able to do the report that we have with the cooperation of CMS, and we thank them for that. And to the best of my understanding, CMS will require drug plans under the Medicare program to make public the prices they negotiate. And that will be an important element in being able to analyze it. There are some details about the delivery of that information that may not make it possible to do it in a way that is exactly comparable to this, but we will work with CMS and see if we can't get

the information necessary to do that. But I think, from what we know right now, there is every indication that the data will be public. It may not be calculated in exactly the same, and we will work with them.

Ms. BALDWIN. Thank you.

I yield back.

Mr. DEAL. I thank the gentlelady.

Ms. Myrick.

Ms. MYRICK. Thank you, Mr. Chairman.

I am new to the committee, so I am digesting all of this, and I actually agree with Barbara that it sure is convoluted the way all of this is put together. So I hope this process will help to simplify some of that.

But I do have a question I wanted to ask you, because I keep hearing from people who come into my office and talk to me about people who are involved in Medicaid one way or the other. And they say that moving to an ASP system would really come at the expense of the retail pharmacists. And I wanted to ask you, and again it follows a little bit on what she was talking about, but is ASP plus 6 percent really unfair to retail pharmacists?

Mr. HOLTZ-EAKIN. Let us talk about the ASP and the plus 6 separately.

Ms. MYRICK. Okay.

Mr. HOLTZ-EAKIN. The ASP, as it is currently configured, the concern is that those folks who are using the ASP in the Medicare program, have a greater ability to negotiate with the manufacturers and get lower prices than would retail pharmacies who have to provide a wide array of drugs. They can't limit the formulary. They have to provide the drugs that beneficiaries are prescribed when they walk in.

Ms. MYRICK. Okay.

Mr. HOLTZ-EAKIN. And so there may be a differential ability to negotiate. So that is sort of piece one on whether the ASP is a good comparison as it is currently configured. The plus 6 changes incentives, as well, because there 6 percent of a brand name drug could be a potentially large number, if you look at our charts, whereas 6 percent of a generic drug would be much smaller. And incentives will come into play, and the question would be is it desirable to shift incentives in that way and move people toward brand name drugs, which might be more expensive from the system, as a whole.

Ms. MYRICK. Right. The other thing is, and again, I am just trying to understand this, the difference between a pharmacy's ability to negotiate prices for drugs from manufacturers compared to physicians and hospitals, et cetera, can you just briefly——

Mr. HOLTZ-EAKIN. You can think of the mechanics of these negotiations. You go to the manufacturer and say, "Look, if you give me a good deal, all of my guys are going to use your drug and your drug only, and I have got lots."

Ms. MYRICK. Like 600 people or whatever.

Mr. HOLTZ-EAKIN. And so it is an ideal chance for a good deal. Lots of quantity and "exclusive" use of that manufacturer's drug. If you have got an obligation to provide whatever drug is on the prescription when someone walks in the door, you can't make that

same promise. You may not be in the same position when the bargaining takes place, and it will be a different outcome as a result.

Ms. MYRICK. Thank you.

Mr. DEAL. I thank the gentlelady.

Ms. Capps.

Ms. CAPPS. Thank you, Mr. Chairman. And thank you for your testimony, Dr. Holtz-Eakin.

The topic I wish to discuss is one that is proposed by the President, which is to move from a system where States pay pharmacists based on average wholesale price, essentially the manufacturer's list price for a drug, to a system where States pay pharmacists based off the average sales price, an average of prices paid by certain purchasers. I have heard concerns, which I would like to hear you address, that average sales price is not representative of the price that pharmacies actually are able to purchase medicines for, because the ASP includes prices from hospitals and other organizations that get deeper discounts than pharmacies get. Could you address this concern?

Mr. HOLTZ-EAKIN. This is the issue that Ms. Myrick just raised. It isn't, obviously, a fair, at all, apples to apples comparison, as the ASP is currently configured, that——

Ms. CAPPS. The pharmacist isn't at a disadvantage based on the large quantities that hospitals——

Mr. HOLTZ-EAKIN. May be at a disadvantage. It would not be the same for the pharmacist in a large hospital. The hospital would have a better negotiating position and would be able to strike a better deal.

Ms. CAPPS. So why is this an advantage for pharmacies, then, to be enthused about——

Mr. HOLTZ-EAKIN. A disadvantage.

Ms. CAPPS. It is a——

Mr. HOLTZ-EAKIN. Yes.

Ms. CAPPS. It is a disadvantage? So the way that is structured, that is——

Mr. HOLTZ-EAKIN. Other things equal, yeah.

Ms. CAPPS. The President is proposing something that might not resonate too well with one segment of the drug dispensing industry that is very central to Medicaid and Medicare, too.

Okay. I will move to another concern of the President's average sale price based proposal, and that is that it would pay asp plus 6 percent and that 6 percent would be intended to fully or partially compensate pharmacies for dispensing, stocking, counseling patients, and other activities. However, 6 percent of a $100 drug is much more than 6 percent of a $10 drug, and so on. And as best as I can tell, that flat 6 percent has no relationship to what the pharmacist is actually doing or what the pharmacy's actual overhead costs may be. And I am concerned that such a concept would provide perverse incentives, for example, for pharmacies to actually dispense the more expensive prescriptions, medicines, not the least expensive ones, because it would be in their interest to do so, which would drive prices up all of the way around. Do you have comments to say on this?

Mr. HOLTZ-EAKIN. I think the first point I would like to emphasize is that the question whether the 6 percent or a fixed dis-

pensing fee covers the pharmacists' costs. That is something that we were unable to address in our report. I want to be clear about that. We don't have a comprehensive measure of their cost of dispensing a prescription. We tried to get some proxies for growth in their costs by looking at the wages of the kinds of people who would be in the pharmacies. But we couldn't, in any scientific way, say that number is big enough to cover their costs. The second piece of the——

Ms. CAPPS. Excuse me, but do you know what it was based on?

Mr. HOLTZ-EAKIN. The 6 percent?

Ms. CAPPS. Yes.

Mr. HOLTZ-EAKIN. I do not. It is the President's proposal. And then, I think you have summarized the incentives we have heard discussed earlier, 6 percent of a more expensive drug is more than 6 percent of a cheaper drug. And again, other things being the same, the incentive to get a larger reimbursement would push you toward the more expensive drug.

Ms. CAPPS. Yes. We have heard discussed today some of the concerns about attempts now with the proposals, the roll-outs of proposals, that there are efforts to restrict cost, and that, as a couple of my colleagues have said on the other side, certain populations, for example in rural areas, might be really unduly restricted by, or at least have no choice, when it comes down to the actual medications that they need, for example, the national Medicaid buying pool, which attempts to bring a large number of Medicaid populations in several States, in order to negotiate deeper discounts, and some of this might result in hampering beneficiaries from receiving the medications that they need, and we are not talking about frivolous medications. Many times, we are talking about lifesaving medications. This is a situation that I would like to hear you comment on. I am really concerned that we now are finding a situation, not just with Medicaid patients, but one in two uninsured, for example, one in three publicly insured, and one in six privately insured working age adults, with at least one chronic condition, have reported not purchasing all of their prescription drugs because of cost concerns. And this reporting is increased from 16.1 percent in 2001 to 18.3 percent. So the number of people reporting these kinds of concerns is not diminishing. Is there any way of seeing the end result of what is being proposed as addressing this at all?

Mr. HOLTZ-EAKIN. Not from what we have in front of us today. The studies that we put together are national studies. They used national prices. They are typical outcomes across States, which do have differences, and they will differ both in urban and regional dimensions. But they do reflect the basic notion that the pharmaceutical market is a national market and that the ability to manufacture and distribute it is not a regional phenomenon, that that is a national phenomenon. So we think these are sensible studies to do. If there are important regional differences that you would like to pursue, we would be happy to work with you on that.

Ms. CAPPS. Okay. Thank you very much.

Mr. DEAL. I thank the gentlelady.

Dr. Burgess is recognized for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

Thank you, Doctor, for being here and staying with us so long.

Just to go back for a minute to the average wholesale price and then the average manufacturers' price: included in the average manufacturer's price, do we include the cost for research and development, or is that simply the cost for the active ingredient and the vehicle and then the gelatin capsule?

Mr. HOLTZ-EAKIN. The average wholesale price is the list price.

Mr. BURGESS. Yes.

Mr. HOLTZ-EAKIN. The average manufacturing price is a transaction price and reflects just the outcome of the negotiation and the transaction of the pharmaceutical itself.

Mr. BURGESS. So the nomenclature of the use of the word "manufacture" in there is, in fact, not erroneous, but it is actually a negotiated price, so it wouldn't necessarily reflect just the cost of manufacturing the pill?

Mr. HOLTZ-EAKIN. Right. It is the manufacturer's sale price, and presumably they are going to not sell in a way which makes them unable to cover their full costs and recover those costs.

Mr. BURGESS. So research and development would be included in that on something that was still covered under patent and presumably not included on something that had left the coverage from the patent protection?

Mr. HOLTZ-EAKIN. From the manufacturer's point of view, you have a clear incentive to cover all of your costs, research and development, manufacturing, distribution, marketing, whatever they may be. The flip side of that is, of course, the other side of the negotiation who wants the low prices. And this is the outcome, but it is hard to imagine that there wouldn't be a price that didn't recover costs, if at all possible.

Mr. BURGESS. But is it your opinion that drugs that are now off of the protection from the patent, are they always sold at just about the cost of manufacture or are there healthy profit margins built in?

Mr. HOLTZ-EAKIN. We haven't done a particular analysis of profit margins. What one sees is the not terribly surprising result that with the loss of patent protection, the entry of generic competition, retail prices tend to come down from single-source, patent protected drugs. But how that price is relative to production costs and the margins as a result is something that is not covered here.

Mr. BURGESS. On the bar graph that you showed us, you ran through very quickly the difference between the Federal supply schedule price and the VA average price, and you referenced that the VA has a tighter control of its formulary. Could you just run through that again for us?

Mr. HOLTZ-EAKIN. I was trying to spare the committee a bar-by-bar description, and I will do that again. But you just saw the Medicaid bars——

Mr. BURGESS. Spare us nothing.

Mr. HOLTZ-EAKIN. Be careful what you wish for.

If one just looks at the Medicaid bar and looks at the VA bar and they are not the same, and you raise the question, "Gee, why wouldn't they be? They are both government programs. Why don't we get the same price?" And the answer is the VA carries with it into its negotiation some clout that the Medicaid program cannot,

because it has the ability to pick a formulary and deliver that formulary to the veterans and, as a result, negotiate strongly with the manufacturers to have their drug included in the formulary. It is a training ground for doctors, and so they can go to the manufacturer and say, "We can expose these young physicians to your products," and that is an advantage to manufacturers. So those dimensions to the negotiation matter, and that is one reason why you might see those bars be different, because the programs, while they are both Federal programs on the face, differ in their substance.

Mr. BURGESS. I thank you for explaining that so clearly.

Do you have an opinion—as you have heard from several of us up here today—that this is not the system that any one of us would hope to construct if we were setting up today to build the system? Do you have an opinion as to what type of system that Congress ought to aspire to?

Mr. HOLTZ-EAKIN. I think that the consensus of the committee that I have heard today is that when the system was designed to use a sticker price to proxy the actual market transactions between pharmacies, wholesalers, and manufacturers, it failed to do so, and that the rough justice adjustments that came after the fact, discounts from AWP rebates, fail to capture the actual cost of transactions. The harder question, to which I think there is no single answer, is how to better reimburse based on market transactions, get closer to what it actually costs, and do that in a way that does not destroy the incentives for the pharmaceutical market as a whole to negotiate hard and have low prices. If you just say, "We are only going to reimburse for the lowest price ever found in the United States," that is a clear incentive to not drive down too hard in other transactions, and all prices will drift up. That is the tradeoff you face.

Mr. BURGESS. All right. I see my time is up. Thank you very much.

Mr. DEAL. I thank the gentleman.

I recognize Mr. Waxman for questions.

Mr. WAXMAN. Thank you, Mr. Chairman.

Dr. Holtz-Eakin, the 2005 CBO budget options book says that allowing States to increase cost sharing from $3 for adults and $0 for children to $5 and $3 respectively will result in $1.9 billion savings over 5 years. The budget option book also states that a potential drawback of this proposal is that a "reduction in the use of appropriate healthcare services could also result." For instance, previous research has shown that poorer individuals facing higher co-payments displayed worse health on some measures. Another example of the introduction of a co-payment for prescription drugs in several State Medicaid programs was found to lead to many beneficiaries going without their medications. Is it the case that some portion of the $1.9 billion that is saved is a result of Medicaid beneficiaries foregoing necessary and appropriate medical care and services, including prescription drugs, due to the higher co-payment?

Mr. HOLTZ-EAKIN. It is certainly the concern. There is evidence that it happens as part of the reaction to higher co-pays. What fraction that would be passing up desirable medical treatment, we don't know, but it is an element of the behavioral response.

Mr. WAXMAN. And so therefore, a portion of that savings is really people foregoing needed medical care?

Mr. HOLTZ-EAKIN. Yes. This is the ultimate attention in everything the CBO produces, which is the programs are there for the benefits. We measure the costs and exclusive reliance in the costs misses the flipside of the program's desirability.

Mr. WAXMAN. And you don't think CBO can factor in how much is coming from that respect?

Mr. HOLTZ-EAKIN. It is not currently feasible for us to draw a line between those parts of the cost reduction, which are just better shopping and skipping luxuries from those parts of the cost reduction which are skipping things you shouldn't.

Mr. WAXMAN. Well, we appreciate the work that you have done on this issue and hope you will continue to look at it.

Dr. Holtz-Eakin, many of us are concerned about the transition of the dual-eligibles, those individuals who are enrolled in both Medicare and Medicaid, to the new Medicare prescription drug benefit in 2006. In particular, many dual-eligibles have chronic illnesses and take multiple prescription drugs. Those living with mental illness, for example, are already stabilized on a particular drug regime, and an abrupt change in their medication could cause great harm. They could no longer get their medicines through Medicaid. They will have to go through Medicare's drug plan. Medicare's prescription drug plan may not include all medicine that that individual needs under formulary. There are some individuals who get involved in these plans without any consideration to what the medicine may be or the cost they will be paying out of pocket may be may insurmountable to may of these individual. A number of us are interested in exploring ways to use fluid continuity of treatment for these elderly and disabled individuals. And example of one option might be to require Medicaid drug plan to cover all medicine an individual was taking prior to the transition to Medicare for a certain period of time, so that you can change to a more appropriate plan or find another way to continue taking their medicines if unable to switch to another product. Has the CBO examined this issue? Do you have any sense of the magnitude of costs or even potential savings associated with such a beneficiary protection?

Mr. HOLTZ-EAKIN. We have looked at this to the extent that we have tried to understand the transition to the new drug benefit in our baseline, and there are aspects of the transition that have features like the ones you mentioned where, for certain classes of drugs, the formulary requires that all of the drugs be available, that the dual-eligibles can switch plans as necessary, perhaps, because they don't have the drug they have been stabilized on. There is an appeals process. So there are aspects of this transition, which are in the current CBO baseline, because that is the current CMS procedure. We have not done anything beyond that to look at the cost or the impact of more expansive guarantees during the transition period.

Mr. WAXMAN. It doesn't sound like it would be all that much different than what you have already looked at if you are suggesting that they have some of these drugs available to people.

Mr. HOLTZ-EAKIN. In some cases the anti-psychotics and things, it doesn't sound like it would be very different at all, but there may be examples where it is different and we just haven't run across those yet. So if there are some particulars that you want to bring to our attention, we would be happy to take a look.

Mr. WAXMAN. Well, if, perhaps, you could look at this kind of option if we spelled it out to see how much an additional savings we might find.

Mr. HOLTZ-EAKIN. Okay.

Mr. WAXMAN. But this might be a way to help those people who would be affected by an abrupt cutoff in the drugs that they are already conditioned to using and won't be able to afford otherwise.

Mr. HOLTZ-EAKIN. There is also another feature of this. There is a provision for advanced refills and extended supplies to literally take the current Medicaid program and use it as the bridge to the new drug plan, and to the extent that that helps it, that is already built in. But that may not cover the entire universe, and if there are more that you would like us to look at, we would be happy to do it.

Mr. WAXMAN. Okay. Thank you.

Mr. DEAL. The gentleman's time has expired.

Mr. Ferguson, you are recognized for questions.

Mr. FERGUSON. Thank you, Mr. Chairman.

Dr. Holtz-Eakin, we certainly appreciate you being here, and thank you for your candid answers to so many of our questions.

Just before my questions, some have suggested, and some on this committee have suggested, that some of the drug manufacturers actually spend more in advertising than they do in research and development. That, of course, is absurd. The drug companies spend enormous amounts of capital and make enormous investments in research and development. Perhaps sometimes the television advertisements that people see on TV are a little bit more obvious than the countless people in labs and scientists and researchers and clinicians and others who make up the investments that go into finding the new cures and the new treatments and the new drugs, but just to clear the air and to clear the record, it is absurd to suggest that companies spend more on advertising than they do for research and development of these drugs.

My question—and some have suggested that raising the rebate from 15.1 to 20 percent as a way to raise more money—is there a policy rationale for that? In my estimation, that is not reform; that is simply changing some of the numbers of the system as it is currently in place, to try and raise additional revenue. But if we are talking about reforming the system, trying to fix some of the problems that we face, in your estimation with CBO, is there any policy rationale, reform rationale, for raising the rebate to 20 percent?

Mr. HOLTZ-EAKIN. We didn't originate the proposal. You would have to talk to those who are interested in doing this for their rationale. The economics, I think, set up an incentive system where the rebate is a lower net received by the manufacturer. That is what that does. It lowers the price they get. But they still have the opportunity to access a large client pool by entering the Medicaid program. And so it is the tradeoff of being in versus being out

versus getting a higher or lower price once you are in. And that is the tradeoff underneath all of these kinds of policies.

Mr. FERGUSON. Doesn't it amount to a tax on the manufacturer?

Mr. HOLTZ-EAKIN. You could label this anything. It is a lower price to the manufacturer.

Mr. FERGUSON. I could think of a lot of things to label it, but I am just trying to be accurate.

Mr. HOLTZ-EAKIN. I am a sufficiently good economist that I could call it a negative subsidy. I could call it a tax. It is a lower price to the manufacturer.

Mr. FERGUSON. But there is no, as far as you can see, reform-minded rationale, policy rationale for this; it is simply looking for money in a system which isn't producing enough money?

Mr. HOLTZ-EAKIN. The proposers would be best positioned to answer that question.

Mr. FERGUSON. Fair enough. The prescription drug component of Medicaid amounts to about 15 percent of the program. Is that correct?

Mr. HOLTZ-EAKIN. We will check the number and get the exact number back to you.

Mr. FERGUSON. More or less? I am not asking for a specific decimal point. The estimates that I have seen have said that after the drug benefit for Medicare goes into effect, because of dual-eligibles, obviously, and other things, that the prescription drug component for Medicaid will drop much lower than that.

Mr. HOLTZ-EAKIN. Yes.

Mr. FERGUSON. Perhaps by two-thirds down to maybe 6 percent. Does this seem like, to you, from a budget standpoint, talking about raising the rebate now to 20 percent, if we are going to try and raise the rebate on a shrinking portion of the Medicaid program, isn't it rational to think that that the amount that that raises is going to continue to fall if more dual-eligibles and others are going to be covered by the Medicare program?

Mr. HOLTZ-EAKIN. Well, the estimates that we provided for this proposal would recognize the transition, and so it would be built off a base that recognized the duals heading into the Medicare program and out of Medicaid. So the numbers you have got are consistent with that. The more general point is that with the shifting, the population mix impacts in the Medicaid program that spill over to private sector outcomes, prices negotiated, and things like that, will be smaller in the future than they have been in the past, and that will be something we will have to think about in looking at the response of manufacturers, pharmacies, beneficiaries to different incentives that come up in the payment system.

Mr. FERGUSON. But as you have acknowledged and as you have said your study included, it is a much smaller portion, and it is a shrinking portion——

Mr. HOLTZ-EAKIN. Going forward.

Mr. FERGUSON. [continuing] of the Medicaid program going forward.

Mr. HOLTZ-EAKIN. Yes.

Mr. FERGUSON. I think of that as squeezing water from a rock, a shrinking rock, perhaps.

Mr. DEAL. The gentleman's time has expired.

Mr. FERGUSON. Thank you, Mr. Chairman.

Mr. DEAL. Mr. Shimkus, you are recognized for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I will try to be really brief. I know you have been here for a long time, and I appreciate the second panel we still have to listen to.

Your report states that there is currently an incentive for pharmacists to dispense generics because of the markup. Since we already have this incentive to dispense generics, how do we increase generic utilization by changing from average wholesale price to another reimbursement model?

Mr. HOLTZ-EAKIN. Ask the question again. I am not sure I understood. How do you increase it?

Mr. SHIMKUS. Right. I mean, the intent has been to increase generic utilization, but I mean, your report says the markup does that.

Mr. HOLTZ-EAKIN. Yes. Other things equaled. There is a clear incentive to supply the newer generic drugs.

Mr. SHIMKUS. But if we move to another model, will there still be that incentive?

Mr. HOLTZ-EAKIN. That is far from obvious. I guess one of the examples that came up was providing ASP plus 6 where you would have to worry about undermining the incentive for generics and moving the balance back toward incentives to provide brand name drugs, so I think that that is an important thing to keep your eye on if you go forward with changing the payments mechanism.

Mr. SHIMKUS. Based on the current incentives, shouldn't we already have high rates of utilization when generics are available?

Mr. HOLTZ-EAKIN. The ultimate utilization is going to depend on, first and foremost, the medicine and whether it is the right medicine and then second the relative prices and the incentives to deliver it. And so without knowing what the nature of the underlying prescription necessarily is, you can't really answer that.

Mr. SHIMKUS. Okay. Great.

Thank you, Mr. Chairman. I yield back.

Mr. DEAL. I thank the gentleman.

And Mr. Brown suggested we lock the doors before any other members come in and want to ask any more questions. We are not going to do that; but Dr. Holtz-Eakin, we do appreciate your patience to bet with us today and for your testimony, as always. And we will let you get back to doing some of the scoring that some of us are interested in on some other issues as well. But thank you. As always, a great witness.

Mr. HOLTZ-EAKIN. I appreciate it. Thank you.

Mr. DEAL. And we will ask the second panel if they will come forward.

Once again, I thank this panel for your patience as well. A very distinguished group, and I will make a very brief introduction so we can hear your testimony as quickly as possible.

Our first witness is Mr. Anthony Rodgers. We already heard a rather in-depth introduction from Mr. Shadegg. He, of course, is the Director of the Arizona Health Care Cost Containment System. Mr. Craig Fuller is President and Chief Executive Officer of the National Association of Chain Drug Stores. Ms. Kathy King is the Director of Health Care at the U.S. Government Accountability Of-

fice. And Ms. Kathy D. Gifford is Principal of the Health Management Associates of Indianapolis, Indiana. And Mr. Jack Calfee is the Resident Scholar of the American Enterprise Institute. A very distinguished panel, and we will start with you, Mr. Rodgers.

I would add that all of your written testimony is a part of the record.

STATEMENTS OF ANTHONY D. RODGERS, DIRECTOR, ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM; CRAIG L. FULLER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL ASSOCIATION OF CHAIN DRUG STORES; KATHY KING, DIRECTOR, HEALTH CARE, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; KATHY D. GIFFORD, PRINCIPAL, HEALTH MANAGEMENT ASSOCIATES; AND JOHN CALFEE, RESIDENT SCHOLAR, AMERICAN ENTERPRISE INSTITUTE

Mr. RODGERS. Thank you, Mr. Chairman.

I will be talking about the Arizona model, especially the results that we have been able to achieve related to our pharmacy benefit.

[Slide.]

What you have on our slides, and go to the next slide, shows a little bit about how we started. We started as a Medicaid waiver back in 1982, 23 years ago. We still are a waiver program. The waiver does allow us to operate a Statewide, mandatory, Medicaid managed care program that requires the members to enroll in a contracted health plan. The members receive their Medicaid services, including pharmacy benefits, through their health plan. Now access reviews the actuarial models for each health plan, and we set our rates and establish a PMPM capitation. And what is important about this is that this is the nature of aligning the financial incentives for the health plans, because they compete against each other on quality and on service, but they also compete in a way that relates to their capitation. If one health plan is out of alignment in capitation, we can see this. And those health plans are able to play off of that and keep our costs down. So the managed competition model works very well for Arizona.

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[Slide.]

Our model is a full risk model. It creates a strong motivator on the part of plans to operate cost-effectively to come up with innovative ways to control costs and prescription drug benefits. That is one area that our plan has been very innovative. Our plans also are in competition for the members, and they compete by their networks, the networks they offer the members, and they compete by a reputation, whether they get a reputation as a good plan. And oftentimes, that is dependent on how the physicians as well as other members describe a plan. So a lot of our plan growth is due to choice, and there is a lot of loyalty to plans.

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We have no single State Medicaid formulary. The State contracts with the plans. They establish a formulary. And this allows the plans to negotiate very good prices. Each plan develops a specific formulary, and there is always concern, "Well, will the plans develop an appropriate formulary?" Well, they are at risk for the

whole medical cost. And so what they are managing is not just a formulary, but what happens to that member if they don't get access to their medication. And I think that is going to be reflected in some of the later slides in terms of the results that we have been able to achieve.

If you look at this concept, it is very similar to what you are trying to do with part D Medicare, and that is you are having Medicare plans as well as pharmacy plans compete for members based on their formulary that they offer as well as to maintain their costs. And so the Federal Government potentially can get benefit from that kind of competition.

The keys to our success are simple. Our plans negotiate with input from their providers on their formulary design. They have contractual relationships between the providers and the plans, and this is extremely important, because our plans are responsible for assigning each member to a primary care physician. It is the physician who is key to controlling your prescription costs. Once they get on board, they control the generic use. They can help you with controlling your costs. And having a good primary care network is also key.

Non-formulary drugs are allowed and prescribed with prior authorization. So if you look at our generic performance, you will see that our generic performance is very high, over 70 percent, and that in most cases, when a generic is available, the physician will prescribe the generic. So we have a very high generic dispensing rate, when those are available.

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[Slide.]

These are some of the tools that the plans use to control prescription costs, including step therapy, which means try the generic first. If that doesn't work, then go to a brand or a different drug. And this is in consultation with the provider. Because they are assigned to a primary care provider, that relationship is key to controlling costs. Prior authorization procedures are also another tool, establishing appropriate quantity limits so that the plan can see if a member is shopping, so to speak, for drugs. And those limits allow the plan then to interface with the member. This is why our case management system by our plans is so important. When they see a member who is over-utilizing medications, they can then talk to that member. But they are still at risk for any negative consequences with that member not getting access to their medications.

Each of our plans has a closed pharmacy network, which means they contract with their pharmacy network. They are not required to offer any willing pharmacy provider, but all of our pharmacists and pharmacies are covered in our State.

And then finally, as a tool, we also have a mandatory generic use as the first option for services.

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[Slide.]

So a couple of things about our managed care program. There are no limits on prescriptions, as some States have established to control costs. We have no limits. There are very few quality issues or complaints of the 1,200 quality issues we investigated last year.

Only 1 percent had to do with medications. And quality issues are everything from a physician prescribing the wrong dose for a child that has to be addressed, and the plans pick these up. And so those are part of the quality issues we oftentimes will evaluate. Exceptions to the process are considered and physicians are able to request non-formulary drugs as well.

And then we have a highly competitive environment, and this has been due to the fact that, as access, the Arizona Health Care Cost Containment System, we are a part of the competitive environment in Arizona, and so it has established, not only with providers but with pharmacies, a very good competitive environment for our Medicaid, for Medicare, as well as for commercial.

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This is basically the bottom line results that we see, and this is why everybody is very interested in the Arizona model. Now I have run health plans, started health plans. I have run hospitals, county hospitals, clinics, and one of the things about Arizona, it is known in the industry as uniquely managing the population well. In fact, even the Arizona citizens voted to expand access to more people in Arizona in 2002 because of the results that they saw.

I would like to just bring your attention to a couple of things. In our acute care program, our generic use is 93 percent for drugs that compare to other States. We took drugs on our formularies as well as drugs on other State formularies to compare, and so that is not all of the drugs, but that was those drugs we could compare. The average prescription cost, though, is significantly lower because of our generic use and the ability to plan and negotiate good prices. Long-term care, you see the same results: very high generic use and a very low overall cost per prescriptions. And if you look at our taniff population—and this was one population that is always sensitive to us about drugs and drug use—our per-member-per-month cost for drugs is lower than both other States' managed care as well as fee for service, and that is due to the maturing of our program. That doesn't happen right away. But as your program matures, you can really get good results.

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What I asked my Director of Pharmacy to do was to look at where we were today. We have a report that was done by the Lewin Group that really established Arizona as a model in terms of the data that they found with other programs, so I asked my Chief Pharmacist to check again to see how we are doing, and these are the results a month ago that he got: 70 percent generic use as compared to the other States that he was able to get information. Our dispensing fee is $2, which might be low compared to other States, but again, we have a very competitive environment in Arizona, and so when you have competition, you have that benefit. That occurs from that. And we don't have co-pays. And I think that that is a very important thing, because our plans can manage and get us the results that we need without establishing co-pays.

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[Slide.]

Mr. DEAL. Summarize, if you would, please.

Mr. RODGERS. Okay. Let me go to the last slide.

The last slide basically tells you what our strategic focus is: controlling medical cost inflation, improving quality health care and accessibility of primary care services, reducing the number of uninsured in our State, reducing the fragmentation of services, and assuring that there is adequate infrastructure to oversee our programs. It is important to know that the success of this program has been due to Arizona learning how to manage managed care, and I think that is the key to our success.

I want to thank you, Mr. Chairman.

[The prepared statement of Anthony D. Rodgers follows:]

PREPARED STATEMENT OF ANTHONY D. RODGERS, DIRECTOR, ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

Mr. Chairman, Members of the Subcommittee, thank you for the opportunity to meet with you today on behalf of the Arizona Health Care Cost Containment System (AHCCCS). I am appreciative for the opportunity to share how Arizona's Medicaid program has been successful in keeping the cost of prescription drugs significantly lower than other states' Medicaid programs.

The AHCCCS Model

Arizona's Medicaid program operates under a Section 1115 Research and Demonstration Waiver granted by CMS in 1982. This waiver allows Arizona to operate a statewide managed care system and requires that all Medicaid members enroll in a contracted health plan. AHCCCS pays the health plans an actuarially determined per-member, per-month (PMPM) capitation for each enrolled member. Under this model of contracting, the health plans assume the financial risk of delivering the full range of health care services for each member. The current Acute Care Medicaid program and State Children's Health Insurance Program (SCHIP) includes over 1 million low-income members.

In Arizona, the capitation paid to the health plans is for the provision of all Medicaid services, including the prescription drug benefit. The inclusion of the prescription drug benefit in the managed care capitation rate disqualifies AHCCCS from participation in the Medicaid Rebate Program. Nonetheless, this factor has not had a negative impact on AHCCCS. This exclusion makes our health plans 100% at risk for the cost of prescription drugs, creating a strong motivator for them to deliver a cost effective prescription drug benefit focusing on the use of generics.

Benefits to health plans for being at-risk for delivering prescription drug services

Because AHCCCS' health plans assume full financial risk for delivering the entire range of Medicaid health care services, including prescription drugs, AHCCCS allows each health plan, or Managed Care Organization (MCO), to develop its own plan-specific formulary and prescription drug benefit management tools. In addition to this inherent financial incentive, the health plans also have a constant incentive to maintain quality services because they must compete for membership enrollment. Thus, the health plans work to meet the needs of the members and to provide a cost-effective benefit. With this in mind, there is no single, statewide Medicaid formulary. The health plans develop formularies based on input of their provider network, often locally or regionally, that are reinforced with contractual relationships with providers for compliance.

AHCCCS health plans utilize a variety of tools to maintain cost efficiency. The most significant factor may be that AHCCCS health plans mandate generic drug utilization. The overall AHCCCS dispensing rate average for generics is 70+%. When generic drugs are available, our health plans average 98 + % generic dispensing rate. Our experience has been that using generic drugs is more cost effective for Arizona than using brand drugs and receiving a rebate.

In addition, health plans have the ability to develop closed pharmacy provider networks, which routinely provide aggressive Average Wholesale Price (AWP) discounts and are negotiated in highly competitive environments (15-17% for brand and 15-50% or greater for generics). Maximum Allowable Cost (MAC) pricing for generics is also used. The dispensing fees are very low compared to other states, averaging less than $2 per RX.

In addition to the mandated generic utilization and the closed pharmacy provider networks, health plans utilize other management tools to keep their prescription

drug costs low. These tools in and of themselves are not exceptional and are widely used:

- Step Therapy/Treatment Guidelines which look for evidence of failure to achieve desired treatment outcomes with less costly, generic or over the counter drugs and develop compliance with standards of care or medical specialty developed treatment guidelines;
- Prior Authorization Procedures;
- Quantity Limits such as early refill edits and maximum monthly quantities; and
- Disease Management Program/Specialty Case Management for members with Diabetes, Asthma, Heart Disease and others.

When used in conjunction with the emphasis on generic drug use, and motivated health plans, these tools become a significant factor in quality care and cost savings.

Benefits to AHCCCS Members When Pharmacy Services are Well Managed

AHCCCS is the largest single health insurer in the state with membership at almost 20% of Arizona's population. Strong utilization management by our health plans and monitoring of quality benchmarks have kept costs under control so that the members enjoy no limits on the number of prescriptions or, when necessary, brand name prescriptions which they can receive per month. AHCCCS carefully monitors our managed care plans to ensure that members receive the services they need. Very few quality of care issues are related to drug therapy. Out of an estimated 1,200 Quality of Care issues annually, less than 1% is related to prescription drugs.

Arizona Model Produces Cost Savings

A recent study done by the Centers for Health Care Studies (CHCS) and the Lewin Group compared prescription drug costs of the aged, blind and disabled population enrolled in AHCCCS' Acute Care Program to similar populations of other states. By definition, these populations are heavy utilizers of prescription drugs. The CHCS/Lewin evaluation found that AHCCCS' prescription drug costs provided through the managed care model are more cost effective than other states' fee-for-service models. AHCCCS' 2002 per member per month (PMPM) prescription drug utilization cost was $112.21, which is 38% below the National Average of $181.01 and is 11% below the next most cost-competitive state (Michigan). This is even more impressive when one considers that these savings were achieved without the benefit of rebates.

The following table illustrates the various elements of both AHCCCS' prescription drug benefit in a managed care model and other states' prescription drug benefit in a fee-for-service model. The data was self-reported by the State Medicaid pharmacy program administrators from each state in response to a national survey.

State	Generic Utilization	Reimbursement Formula	Dispensing Fee	Copay-ment	Max Days Supply	Monthly Limit	Prior Auth Program
Az	70%	AWP-15-17% (negotiated by each health plan).	$2	$0	Greater of 30 days or 100 units.	None	Yes
Ak	42%	AWP-5%	$$3-$11	$2	30 days	None	Yes
Ca	51%	AWP-17%	$7.25-$8	$0	100 days	6	Yes
Mi	Not reported	AWP-13.5% (independent pharmacies) and AWP-15% for chain pharmacies.	$3.77	$1	Maintenance meds—3 months: all others 34 days.	None	Yes
NJ	48%	AWP-12%	$3.69	$0	Greater of 34 days or 100 units.	None	Yes
Pa	51%	AWP-10%	$4	$1	Greater of 34 days or 100 units.	None	Yes

Challenges to Lowering Prescription Drug Costs for Non-Managed Care Population

While the Arizona model of Medicare managed care has been a success story for our state, it must be acknowledged that it may be difficult to convert from a fee-for-service program to a Medicaid Managed care model. While commitment to the model has paid off relating to both cost-efficiency and quality of care, the first 5 years of operating the AHCCS program were difficult.

Conclusion

There are several points I would like to leave you with today to assist you as you identify strategies to reduce Medicaid prescription drug costs. The first is a paradox. By improving compliance and utilization of prescription drug regimens, drug spending may actually rise. However, this may lead to improvements in health status and decreased overall health care spending. While this is the ultimate goal we are still striving to meet, it sometimes makes it more difficult to evaluate the "success" of "cost-containment initiatives.

Secondly, the ability to have common data elements and the ability to analyze data that cuts across health plans, and across state Medicaid programs, is critical to ensuring that prescription drugs are having the maximum effect of improving health status. Quality performance indicators and benchmarks can be set for managed care organizations and health plans without compromising their ability to deliver health care services. Another challenge that will affect states' ability to manage prescription drug costs is the implementation of Medicare Part D under the Medicare Modernization Act of 2003 (MMA) on January 1, 2006. Due to the fact that the states will no longer be providing coverage to the dual eligible population (members eligible for both Medicaid and Medicare), states are losing critical purchasing power. Arizona is concerned that the phased-down payments will not be indicative of the savings that have been achieved in providing a prescription drug benefit. This will be especially true if the trend to provide brand name drugs over generics is realized. At the same time, the MMA creates the opportunity for states to enhance the coordination of care for the dual eligible population through collaboration with Part D Plan Sponsors. By providing incentives for plans to become Medicare Advantage-Prescription Drug Plans designated as Special Needs Plans, members will be able to access both their Medicaid and Medicare services through one health plan, allowing for greater coordination of care and coordination of benefits. AHCCCS has collaborated with six of its contracted health plans pursuing such designation. The provision of all of the member's services by one health plan supports the notion of person vs. program and allows the maximum opportunity for members to receive quality, coordinated care without navigating two delivery systems.

Another challenge Medicaid faces is the cost of providing long-term care services. Arizona provides long-term care services through a managed care model, the Arizona Long-Term Care System (ALTCS). ALTCS controls the cost of providing long-term care services by utilizing a Pre-Admission Screening document allowing only those members at risk of institutionalization to enroll in ALTCS rather than Acute Care Medicaid. The managed care model allows for imposition of network standards and case management standards that enhance the quality of services members receive. Members may choose to receive Home and Community Based Services (HCBS) rather than enter an institution, which is a savings for Medicaid as well as an effective way to allow members to direct their own care.

I am available to take any questions you may have and want to thank you again for the opportunity to highlight how our program is working for the benefit of Arizonans.

Mr. DEAL. Thank you.

Mr. Fuller.

STATEMENT OF CRAIG L. FULLER

Mr. FULLER. Thank you, Mr. Chairman, Mr. Brown. I represent the National Association of Chain Drug Stores. We have over 200 retail members with over 35,000 stores and 120,000 pharmacists across the country. This is a very, very important issue to us, and we are grateful for the chance to testify.

My statement went on at some length about a variety of issues. I would like to give you some highlights with some very quick charts. If we could turn to the reform principles on the next page.

[Slide.]

I think it is important, as you look at alternatives, to think about three principles. One, the Medicaid payment system reforms should reflect current market prices. They should be prices, as I think you said, Mr. Chairman, that are transparent, that are known, and verifiable. Second, the savings that you seek in the program should

somehow be proportionate to the program's expenditures, and I will explain that in a minute. And finally, behavior in Medicaid that supports the policy objectives you are seeking should be rewarded.

[Slide.]

The next slide just gives you a very quick picture of our view of retail pharmacy today where a little over 15 percent of what is happening in our stores is related to Medicaid, which makes it a very important segment. I should add that in rural communities, this number is larger, and in some urban communities, this number is larger, which puts more pressure on both rural pharmacies as well as urban pharmacies.

[Slide.]

The next slide is really a recap of, I think, some things that have been said. Medicaid drug program spending is up because there are more Medicaid recipients using prescription drugs, there are more prescription drugs being used per recipient, which, in my view, is a good thing, because the value of medication today is very important in terms of the overall healthcare costs. The cost of the prescriptions is up partly because of the ingredient costs and we will show you, we think, not so much because of the dispensing fees.

[Slide.]

In fact, the next slide shows you 22 years' experience of what the average prescription cost where today, or in 2002, the average prescription, both generic as well as brand, was about $57. That has risen over time. The cost of dispensing has stayed rather low.

[Slide.]

And the next slide actually demonstrates how over that 22-year period the dispensing fee paid has actually gone down.

[Slide.]

This next slide is complicated, but it is terribly important. The green bars are the product costs, the drug costs associated with prescriptions dispensed under Medicaid as projected by CMS as well as CBO from 2005 to 2010. That is the product cost of the medication. The bar just to the left in each case of that green bar is the gross margin that the pharmacy receives. We take exception to CBO, we have sent them a letter, and it is appended to your material, this notion that there is a markup. There is a cost associated with dispensing, and it is that gross margin that has to cover that cost, the cost of stocking the medication, paying the pharmacists, doing the transactions, and that sort of thing. That leaves that small yellow bar, which is the net margin.

In the proposal that is before you, to use ASP as a reform mechanism to save money, the red bar just to the left of the yellow bar is, in each case from 2006 to 2010, slightly larger than the yellow bar, and what this suggests to us, using the government's numbers, is that the utilization of ASP pricing, as it has been proposed to save money for retail pharmacy, would actually seek to save more money than retail pharmacy actually makes by dispensing a drug, or said another way, we will lose money every time we dispense a Medicaid prescription. And that, as some say, you can't make up for in volume. And that is going to provide an access problem, because retail pharmacies simply won't be able to provide the level of service or won't, in fact, be able to participate in the program at all.

[Slide.]

The next slide—and I am going to cover this quickly, because ASP has been discussed. But the next slide just mentions some of our concerns about ASP. First of all, it doesn't really recognize classes of trade. This is very important. We don't negotiate with brand manufacturers on price. We buy the medication at the price it is sold to our retailers at, usually through a wholesaler. In retail pharmacy, we pay a higher price than other people buying exactly the same drug—hospitals, PBMs, or others. So any average for us puts us at a disadvantage, because we are paying a higher price, given the "class of trade" that retail pharmacy is in. It is also outdated. It is two or three quarters behind and does lack transparency. It also discourages generic dispensing.

[Slide.]

The next slide talks about AWP. We are all interested in moving off of that. It also references, and we represent to the committee, that using wholesale acquisition cost, or WAC, is actually a number that exists in nature. I know you have heard a lot of acronyms, but this is actually a published price that you can go to and look up, and it is updated frequently. And if you are looking for a way to peg a number as to what retail pharmacy is paying today, that, we believe, is a good way of doing it.

[Slide.]

The next slide mentions ASP. I have referred to that. It talks about the average manufacturers' price. Again, this is not a price that exists in nature, so to speak. It is a calculated price, and there are delays associated with it.

[Slide.]

The next slide, the goal is a pharmacy payment reform, and I want to skip over it, because I made the point that we really do recommend WAC pricing be used for brands.

[Slide.]

But we also, if you go to the next slide, want to emphasize the importance of generics. I think that was just brought out by Mr. Rodgers' statements, but this is what we are spending today on the three types of drugs that are dispensed in Medicaid, $122 for a patented brand drug, $65 for an off-patent brand, and $20 for a generic. I think you can see why it is desirable to increase generic utilization.

[Slide.]

If you go to the next slide, what that says today is that we have, on the left, over 50 percent of the prescriptions being filled with generic drugs. But there is a way to go, because 83 percent of the money is actually spent on buying drugs.

[Slide.]

The next slide simply shows how this works with one type of disease state, gastrointestinal disease. I am not sure exactly why we picked this, but the fact is there are three brands up there. There is one of a generic Prilosec that is lower than the three brands, but the generic brand is $0.56, giving you a fairly dramatic savings.

[Slide.]

The next slide comes from data that we received for the first quarter of this year. I better find out why Arizona isn't better represented on this chart, but it looks at dispensing rates by State.

And we have provided in your packet a list of all 50 States. The average in the first quarter from the NDC Health numbers was 51 percent generic dispensing. What this shows you is there is a wide range in the country, from the 40-percent group to the 60-percent group. If you move generic dispensing up to or closer to 60 percent, as several States have achieved, or as Arizona has achieved at 70 percent, literally, our calculations are there would be a $3.5 billion savings per year.

[Slide.]

The next to the last slide talks just briefly about tiered co-pays. I know that that is something that is of interest. We need to make one important point. There are tiered co-pays today, between 50 cents and $3. The problem is that we can't collect those co-pays from many patients. Indeed, some States actually promote the fact that the law doesn't allow pharmacists to collect that money. There are two big problems. To the pharmacy, that is simply a lost 50 cents or $1 or $3 per prescription. That does add up, and it is significant to us. We eat that cost. For you, the payer, it is a difference between our prescribing a $20 drug or a $120 drug. So the payers' cost, by losing this tool, could easily be $100 per prescription.

So if you are going to look at co-pays, tiered co-pays, and we think that is a reasonable thing to do, it is very important that that tool not be turned to but then negated by making it a matter of law, something that we can't collect.

We do believe, in conclusion, that we are and want to be part of the solution. We do believe the disproportionate savings from pharmacy is going to reduce the access to patients, because pharmacies just won't be able to participate in this program, and we do strongly believe that part of the solution has to be found in rewarding behavior on the part of the pharmacy as well as the patient to pursue the kinds of objectives you are seeking.

Thank you, Mr. Chairman.

[The prepared statement of Craig L. Fuller follows:]

PREPARED STATEMENT OF CRAIG FULLER, PRESIDENT AND CEO, NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr. Chairman and Members of the Subcommittee, My name is Craig Fuller, I am President and CEO of the National Association of Chain Drug Stores (NACDS), and I am very pleased to provide to you with our organization's views regarding Medicaid payment reform options for prescription drugs. NACDS represents more than 200 chain pharmacy companies that operate more than 35,000 community-based retail pharmacies, where the majority of all Medicaid prescriptions are dispensed. Issues and policies that affect Medicaid reimbursement for prescription drugs are of critical importance to our association and our membership.

I. CRITERIA FOR MEDICAID PRESCRIPTION DRUG PAYMENT REFORM

We encourage the Subcommittee to keep the following three points in mind as Medicaid prescription drug payment reform options are considered:

- **Use Current, Market-Oriented, Retail-Based Prices:** Any reforms made to the current AWP-based payment system for Medicaid prescription drugs must result in reimbursement that reflects current, market-based prices at which pharmacies purchase both brand and generic drugs. Reimbursement methods that use retrospectively-determined prices, or are not reflective of the prices paid by the retail class of trade, will underpay pharmacies for Medicaid prescriptions and may create access problems for Medicaid recipients. Moreover, pharmacies must be paid adequately to dispense these prescriptions to Medicaid recipients.

- **Encourage Generic Drug Dispensing:** Payment policies should encourage pharmacy providers to dispense lower-cost generic drugs when possible and appropriate. Every time a pharmacist dispenses a generically equivalent drug instead of the off patent brand name counterpart, the Medicaid program saves an average of about $45. Every time a pharmacist receives permission from the physician to dispense a generic drug that is therapeutically equivalent to a brand name single source drug, the Medicaid program saves an average of about $100.
- **Require Proportional Cost Containment Contribution:** For the purposes of this year's budget reconciliation bill, each sector contributing costs to the Medicaid prescription drug program must make a proportional contribution to cost control. This includes pharmaceutical manufacturers, pharmacists and Medicaid recipients.

States have already taken hundreds of millions of dollars out of Medicaid pharmacy reimbursement over the past several years. Yet Medicaid prescription drug spending continues to escalate because reducing pharmacy reimbursement does little to slow the growth of drug spending. That is because drug spending is being driven by increasing drug product costs and increasing drug use, not dispensing fee or pharmacy payments. Medicaid pays pharmacies for both the drug product dispensed, as well as the cost of dispensing. Pharmacies have no control over 80 percent of the costs of brand name drug prescriptions, which is the cost of the drug products we buy from manufacturers.

Reimbursement reductions reduce pharmacy payments only, not the costs of goods. It is unfair to place 100 percent of the cost containment burden on only 20 percent of the cost of the program; that is, retail pharmacy gross margins.

II. CURRENT STATUS OF MEDICAID PRESCRIPTION DRUG PAYMENT POLICIES

Total Medicaid pharmacy payments are based on two components: drug product reimbursement and dispensing fee. Consistent with the flexibility given to states, some states have higher reimbursement rates for pharmaceutical products and lower dispensing fees, while others have lower reimbursement rates for products and higher dispensing fees. The bottom line is that the total payment made has to be adequate to pay pharmacies to cover their costs of buying the drug, dispensing the drug, and earning a reasonable return on a Medicaid prescription.

Moreover, when policymakers consider whether a particular level of Medicaid reimbursement is "adequate" they often overlook other important factors that have an impact on revenues that a provider *actually* derives from Medicaid. For example, many states charge co-payments for Medicaid prescriptions, ranging from 50 cents to $3 per prescription. NACDS supports the use of reasonable Medicaid prescription co-payments as a way of making individuals take more responsibility for their health care. However, we also know that there are many recipients that truly cannot pay, even these small amounts. Pharmacies must provide Medicaid recipients with their prescriptions, even if a recipient cannot or will not pay the co-payment. Moreover, federal law prohibits Medicaid from reimbursing pharmacies for unpaid co-payments, so unpaid co-payments reduce pharmacies' revenues.

Because many states have been imposing steeper co-payments on recipients over the past few years, the rate of non-collection by pharmacies has been increasing, affecting the overall revenues that pharmacies derive from Medicaid prescriptions. Pharmacies should not shoulder the burden of these uncollected co-payments.

The net profit margin of community retail pharmacies is only about 2 percent. Pharmacies are low-margin health care providers, and even small changes in pharmacies' revenue streams can mean the difference between whether the pharmacy's doors remain open or have to close. Thus, it is vitally important that pharmacy payment rates be adequate to maintain Medicaid recipients' access to pharmacy services.

A. Pharmacies Working With States to Achieve Medicaid Pharmacy Cost Savings

Pharmacy providers are working successfully with many state Medicaid programs to help implement cost savings and quality improvement options that have helped save tens of millions of dollars for states and the Federal government. These include programs to increase use of lower-cost generic medications, disease management programs, step therapy programs, prior authorization and preferred drug list programs, and others.

We view ourselves as partners with the states in achieving savings, although these programs come with significant administrative costs to pharmacies and pharmacists, and little compensation.

Federal policymakers should encourage the appropriate use of lower-cost generic drugs. There is significant room for growth for generics in Medicaid. Generic drugs

account for over half of all prescriptions dispensed in Medicaid, but only about 17 percent of all Medicaid prescription expenditures. This discrepancy is due to the significant difference in average reimbursement paid by Medicaid for patented brand name medications relative to generics. In 2004, the average reimbursement for a patented brand name drug was $122, while the average reimbursement for a generic was only about $20, less than one-sixth the amount for patented brands. Even the generally larger rebates on brand drugs cannot make up such a large difference.

Twenty-three (23) of the top 25 generic products dispensed by Medicaid programs in 2004 had an average reimbursement of $20 or less per prescription. Sixteen (16) of these medications were reimbursed at an average of less than $15 per prescription and 12 were reimbursed at under $10 per prescription. For these reasons, we encourage policymakers to recognize the importance of maintaining incentives within Medicaid to dispense generic-equivalents drugs.

Despite the tremendous cost savings possible from the use of generic drugs, generic dispensing rates in states vary widely. Data from the first quarter of 2005 found that the average state Medicaid generic dispensing rate was about 51 percent. However, the top 5 states were Washington (60.5%), Oregon (59.5%), Alabama (59%), New Mexico (58.9%), and Hawaii (58.3%). On the opposite end of the spectrum, however, the Medicaid generic dispensing rates were lowest in Connecticut (47.1%), California (46.9%), Texas (46.4%), Louisiana (44.5%) and New Jersey (42.4%). These stark differences in generic dispensing rates—18 percent between the highest and lowest states—can be explained by a number of factors. However, if all states were able to increase their generic dispensing rates to 60.5% like Washington, the Medicaid program would save an estimated $3.5 billion this year. A complete analysis of state Medicaid generic dispensing rates is appended to this statement.

Researchers consistently find that increased use of generic drugs for off-patent brand name drugs could provide considerable savings to consumers and plan sponsors, including states and the federal government. In fact, as the budget reconciliation process moves forward, policymakers should consider whether increased use of generic drugs in Medicaid will generate most of the savings that might be needed for the budget target. For example:

- A study published in this month's *Annals of Internal Medicine* examines generic substitution for a large, nationally representative sample of adults. This study found that although over half of this group's outpatient prescriptions from 1997-2000 were for multiple source drugs, only 61 percent were dispensed as generics. If generic equivalent drugs had been dispensed in every instance where an off-patent brand name drug was dispensed, national savings could have been around $8.8 billion per year.[1]

  For dual eligibles at least age 65, the savings from substitution of generic-equivalent drugs was $1.7 billion per year, while for the under-65 Medicaid population, the savings was $388 million per year.
- A study published in 2003 by the journal *Health Services Research* estimated that Medicaid could have saved up to $229 million in 2000 if generic equivalent drugs had been broadly substituted for off-patent brand name drugs.[2]

These studies all focus on substitution of generic equivalent products for off-patent brand name products. Even greater savings could be achieved if patients were able to use a generic drug or lower cost brand name drug that provided similar therapeutic benefit in place of a higher-cost patented, sole source brand name drug.

B. Medicaid Benefits from Generic Price Competition Generated by Retail Pharmacy

Medicaid benefits from the intense generic drug price competition and price transparency generated by retail pharmacies. The purchasing leverage of retail pharmacy forces competition among generic drug makers to earn a pharmacy's business. This lowers generic prices to pharmacies, and these lower generic prices are passed along to consumers.

Medicaid also benefits from generic drug price competition between retail pharmacies because Medicaid programs typically reimburse pharmacies the "lower of" the program's payment formula for a generic drug (i.e., FUL plus dispensing fee or MAC plus dispensing fee) or the pharmacy's "usual and customary" charge to the cash paying public. In many cases the Medicaid program pays a pharmacy's lower "usual and customary" price rather than the amount determined by the generic payment formula. As a result of competitive forces in the generic marketplace, the aver-

[1] Haas, et al., Potential Savings from Substituting Generic Drugs for Brand Name Drugs: MEPS, 1997-2000; Annals of Internal Medicine, June 2005

[2] Fisher, et al., Economic Consequences of Under Use of Generic Drugs: Evidence from Medicaid and Implications for Prescription Drug Benefit Plans, Health Services Research, 2003; 38: 1051-63.

age generic prescription reimbursement in Medicaid has only increased by about $7 per prescription over the last 7 years, from $13 in 1998 to $20 today, while the average brand name prescription reimbursement has almost doubled from $63 in 1998 to $122 today. Clearly, Medicaid is benefiting from the price competition for generic drugs generated by retail pharmacy at multiple levels in the distribution chain.

Almost 60 percent of all Medicaid generic prescriptions have Federal Upper Limits (FULs), meaning that the pharmacy is reimbursed the same amount for a generic medication regardless of the price of the product purchased by that pharmacy. The FUL is set at 150 percent of the lowest price published in the national pharmaceutical pricing compendia for a generic version of a drug product. A FUL is established once there are three nationally-available sources of supply for the generic. The current FUL system, while not perfect, works well in balancing the needs of pharmacies to have sufficient economic incentives to dispense generics to Medicaid recipients, coupled with Medicaid's desire to not overpay for generics.

The FUL gives pharmacies the incentives to drive down the prices of generics below the FUL so the pharmacies do not lose money. Medicaid benefits from this price competition.

At the same time, the fact that the pharmacy can retain any small margin between the FUL and its acquisition cost gives it an incentive to drive a hard bargain with the generic companies, as well as compensates for a dispensing fee component that may be inadequate. In our view, the current incentives are aligned appropriately for both pharmacies and Medicaid to dispense generics.

However, if pharmacy reimbursement were to be based on some markup of actual "acquisition costs," the incentives would change for pharmacy providers in terms of generic dispensing. For example, if Medicaid adopted Medicare Part B's policy to pay for covered drugs at ASP (Average Sales Price) plus 6 percent, a pharmacy will derive more revenue from dispensing a brand name drug with an ASP of $100 ($106) than it would derive from dispensing a generic with an ASP of $20.00 ($21.20). Thus, the economic incentives built into the ASP system would actually raise Medicaid costs by encouraging the dispensing of more expensive brand name drugs.

C. Competition Works for Drugs without Payment Limits

Even in cases where a FUL or MAC (Maximum Allowable Cost) is not established for a generic drug, or is not established as soon as multiple sources of supply become available, competitive forces at the retail level help to lower overall Medicaid costs for generics. A good case in point is what occurred when Prozac (known generically as fluoxetine) became available in generic form in August 2001. Medicaid was paying $2.86 per capsule total reimbursement for brand name Prozac in August 2001, and the price of the first generic (which had an FDA-granted six-month exclusivity period) was $2.46.

During the six-month period of exclusivity, when only one generic version can be sold as a result of government policy, pharmacies are essentially "price takers"—we have little leverage over a single source of supply of a generic drug. However, when there are multiple sources of supply for a generic drug, pharmacies become "price makers." We can create competition between the multiple sellers of these generic products.

After the exclusivity period for the first fluoxetine generic expired in early 2002 and multiple generics came to the market, Medicaid reimbursement for generic fluoxetine decreased rapidly. According to data we have analyzed, the average generic reimbursement for fluoxetine is now about $0.66 per capsule, or almost 75 percent less than the reimbursement paid when the product first became available generically. The rapid reduction in the reimbursement Medicaid pays for this generic resulted from market forces and generic competition that drove down the overall price of generic fluoxetine. Medicaid benefits each and every day from this continued competition. Medicaid's paying $0.66 per capsule total reimbursement for fluoxetine is much less than the current reimbursement rate of $3.37 per capsule for brand name Prozac.

D. Policymakers Should Consider Reimbursement for Total "Market Basket"

We think it is both fair and good public policy to consider the adequacy of reimbursement paid to pharmacies by looking at their entire Medicaid "market basket" of drugs provided by pharmacies, by not singling out the reimbursement paid for certain medications.

With 56,000 community retail pharmacies and upwards of 60,000 individual drug products available in the marketplace, the pharmacy reimbursement system is built on a series of averages and estimates. These include the average discount paid by the average pharmacy on the average wholesale price for prescription products and

the average cost of dispensing a prescription at the average pharmacy. Such a system will have inherent highs and lows in the various components. But in the end, Medicaid and pharmacy providers need to strike a fair balance that would assure—in the aggregate—that Medicaid does not overpay or underpay, and that providers are adequately compensated for the "market basket" of drugs they provide.

In this regard, we sometimes hear criticism that pharmacies are making excessive markups on Medicaid generic drugs. Pharmacies do not "mark up" the prices on prescriptions dispensed to Medicaid recipients. Payment amounts are based on formulas developed by the state using Federal guidelines. Here are some of our perspectives on this issue:

- **Considering Margins Based on Percentages is Misleading:** First, the perceptions about these so-called "excessive markups" are fueled by the use of "percentages" to express the "markup" that the pharmacy retains on generic drugs, rather than considering the absolute dollar margin involved. Using percentages unfairly make the payments made by Medicaid look excessive. For example, if a state paid a pharmacy $5 for a generic that cost the pharmacy $1 to purchase, the markup would be only $4, yet the percentage markup would be 500%. In contrast, if the state paid the pharmacy $110 for a brand name drug that cost the pharmacy $100, the markup would only be 10%, but the absolute difference would be $10, greater than the 400% markup on the lower-cost product.
- **Generic Dispensing Incentives are Necessary and Appropriate:** Because the drug product cost for a generic prescription is lower than a brand, policy makers should be sure that the gross margin made by the pharmacy on a generic prescription is equal to or greater than that made on a brand. Otherwise, the pharmacy may be economically indifferent as to whether a brand or generic is dispensed because the pharmacy would make the same gross margin revenue regardless of the product dispensed. It matters to Medicaid because the state saves close to $45 each time a generic equivalent is dispensed for an off-patent brand.
- **Many Generics are Dispensed at a Loss:** In 2004, twelve of the top 25 generic prescription medications paid for by Medicaid were reimbursed at an average of less than $8 per prescription. With a pharmacy's average cost to dispense a prescription estimated to be around $9.45 per prescription, pharmacies are losing money each time they dispense one of these medications to a Medicaid recipient. These prescription reimbursement losses are offset by other prescriptions where the reimbursement may be higher than the pharmacy's overall costs to dispense.

If this current system based on "averages" were to change, fundamental changes in other parts of the system would also be necessary—such as substantial increases in pharmacy dispensing fees—to assure that pharmacies are adequately reimbursed and that they are still able to provide pharmacy services to Medicaid recipients.

We are also appending to this statement a letter than NACDS sent to the Congressional Budget Office (CBO) last year that raised issues and concerns with a paper that examined Medicaid reimbursement policies.[3] We believe that the paper overlooked many important factors about the current Medicaid pharmacy reimbursement system, and was overly critical of the payments made to pharmacies for generic drugs. We urge that policymakers read the NACDS response to the paper.

III. MEDICAID PRESCRIPTION DRUG PAYMENT REFORM OPTIONS

With that background regarding the current Medicaid pharmacy reimbursement system, it is now important to consider the implications of various other alternatives to AWP (Average Wholesale Price) to reimburse pharmacies under Medicaid. These alternatives include ASP (Average Sales Price), AMP (Average Manufacturers Price), and WAC (Wholesale Acquisition Cost).

A. Use of Average Sales Price (ASP) as Medicaid Prescription Drug Payment Option

To achieve some of its Federal budget savings targets for the next 5 years, the Administration has proposed using ASP, rather than AWP to reimburse pharmacies for Medicaid prescriptions. In fact, unlike most states that reimburse pharmacies for both the cost of the prescription drug and a reasonable dispensing fee, the administration proposes to reimburse pharmacies ASP plus 6 percent for drug and dispensing costs. This proposal would generate $5.2 billion in Federal savings over the next 5 years, or a combined savings of $9.2 Federal and state savings. This amount represents almost 23 percent of pharmacy's Medicaid gross margins over this time period, a significant reduction by any measure.

[3] Medicaid Reimbursements to Pharmacies for Prescription Drugs: CBO, December 2004.

Policymakers should understand that all of the savings under this policy would be achieved at the expense of pharmacists. None of the savings would come from reducing the pharmacy's costs of prescription drugs, which account for 80 percent of the program's total costs, because pharmacies have no upstream leverage with brand name manufacturers. We cannot force brand name drug manufacturers to lower their charges to us for the cost of goods.

Reducing pharmacy Medicaid gross margin prescription revenues by 23 percent could result in significant access problems for Medicaid recipients, as pharmacies may have to reduce hours or close stores in response to this significant loss of gross margin revenues. ASP has other problems as well, which are described below.

- **ASP Does Not Represent Prices at Which Retail Pharmacies Purchase Drugs:** ASP is calculated as a "weighted average sales price" across all payors (except direct Federal sales) for a particular pharmaceutical, net of various discounts and rebates given by the manufacturer to the purchaser. However, retail pharmacies are generally charged higher prices than other pharmaceutical purchasers, and don't have access to the same discounts, rebates, and price concessions of other purchasers. This would mean that pharmacies would buy drugs at a higher price than they would be reimbursed under ASP.
- **ASP does not Account for Other Costs to Pharmacies:** There are other costs involved in getting the drug to the pharmacy that ASP does not account for, such as the pharmacy's costs to manage an inventory, the costs of getting the drug to the local pharmacy site, and the costs of complying with state and Federal pharmaceutical regulations. Even adding a markup factor to the ASP amount (e.g. ASP +6 percent) may not make a pharmacy whole just for acquiring the drug, no less the costs of storing, inventory, warehousing, and distribution of the drug. This could force participating pharmacies to provide these products at a loss, and create potential access problems for Medicaid recipients.
- **ASP is Not Based on Current Market Prices:** ASP is an outdated price, since it is calculated on data that is two calendar quarters old. Thus, it would not reflect the current prices at which retail pharmacies are purchasing prescription drugs. If ASP had been in effect on January 1, 2005 for Medicaid, community retail pharmacies would have been significantly disadvantaged in terms of Medicaid reimbursement for brand name drugs. That is because many brand name manufacturers increased prices in excess of 6 percent at the beginning of the year. Because the first quarter 2005 ASP rates would have been based on third quarter 2004 (July-September) sales data reported by the manufacturers, retail pharmacies would have to absorb any price increases after September 2004, the end of the third quarter 2004, all the way through March 2005.
- **ASP Proposal Does Not Envision Higher Medicaid Pharmacy Dispensing Fees:** The President's budget proposal does not include additional funds for pharmacy dispensing fees that would compensate for reductions in payment for drug products resulting from the new ASP methodology. Medicare Part B moved in January to an ASP plus 6 percent reimbursement for the few oral drugs covered by Medicare Part B, but CMS is paying a supplying fee of $24 per prescription. This was because CMS recognized that the move to an ASP-based system requires a significant increase in the pharmacy's dispensing fee, or Medicare beneficiaries would have a hard time finding a retail pharmacy that would fill their Part B prescriptions.
- **ASP Does Not Encourage Generic Dispensing:** Retail pharmacies are not given incentives to dispense lower-cost generics under an ASP-based system. Because generics have a lower cost basis that brand name drugs, an ASP-based system gives pharmacies incentives to dispense brands because they would make more money under an ASP plus 6% system for brands than generics (i.e. 6% of a $100 brand is $6, but 6% of a $20.00 generic is only $1.20).

We are encouraged that some members of Congress and other policymakers are recognizing that the use of ASP as an alternative reimbursement metric to the current formula may create more issues than it solves.

B. Use of Average Manufacturers Price (AMP) as Medicaid Prescription Drug Payment Option

The use of "Average Manufacturers Price" (AMP) as a potential Medicaid payment or reimbursement option has similar problems to the use of ASP. AMP is defined as the average price paid to manufacturers by wholesalers for drugs distributed to the retail class of trade. AMP was created in OBRA 90 for the purpose of calculating the Medicaid drug rebates paid by manufacturers to states. However, there are several problems that exist with the use of AMP as a reimbursement metric.

- **AMP Reflects Manufacturer's Sales, Not Pharmacy's Purchasing Costs:** Like ASP, AMP is a measure of a manufacturer's revenue for a particular drug

in a particular calendar quarter, and does not represent the prices at which retail pharmacies purchase drugs from wholesalers, or reflect the costs that pharmacies incur in purchasing and maintaining a pharmaceutical inventory. Thus, to approximate a pharmacy's acquisition costs for Medicaid drugs, AMP would have to be increased by a significant percentage.

- **AMP Does Not Account for Manufacturers' Price Increases:** If AMP had been in effect on January 1, 2005 for Medicaid, community retail pharmacies would have been significantly disadvantaged regarding Medicaid reimbursement for brand name drugs because many brand name manufacturers increased prices in excess of 6 percent at the beginning of the year. Because the first quarter 2005 AMP rates would have been based on third quarter 2004 (July-September) sales data reported by the manufacturers, retail pharmacies would have to absorb any price increases after September 2004, the end of the third quarter 2004, all the way through March 2005.
- **AMP includes Mail Order Sales:** Unlike ASP, AMP is calculated for the retail class of trade only; however, like ASP, AMP is a retrospectively determined price and can be up to six months outdated. AMP includes both sales to retail pharmacies and mail order pharmacies, and retail pharmacies do not have access to the same discounts and rebates that mail order pharmacies do. As a result, using AMP may mean that retail pharmacies will be underpaid for Medicaid prescriptions because the reimbursement will be calculated off a "blended" base, including mail order sales. This would mean that the AMP basis used to reimburse pharmacies would be lower than if just true retail community pharmacy sales had been used to calculate AMP.
- **Significant Variation Exists in AMP Calculations:** Many government reports, including a recent report from the GAO, indicate that there is wide variation among the manufacturing community in calculating AMP. Final rules have never been published by CMS regarding the exact methodology that manufacturers should use in calculating the AMP values for their drug products. Therefore, in some cases, manufacturers may be calculating an AMP value that would underpay pharmacies for Medicaid prescriptions. Guidelines should be published that help manufacturers better understand how to calculate AMP so the rebate payments they make to states are accurate.
- **AMP Discourages Generic Dispensing:** Like ASP, using AMP would discourage the use of generics. Because generics have a lower cost basis than brand name drugs, an AMP-based system gives pharmacies incentives to dispense brands because they would make more money under an AMP plus 6 percent system for brands than generics (i.e. 6 % of a $100 brand is $6, while 6% of a $20.00 generic is $1.20). An AMP system does not encourage pharmacies to dispense generic drugs. Moreover, in some calendar quarters, the AMP for a particular generic might be a negative number. That can happen if the manufacturer's discounts and rebates for a given year were paid out disproportionately in a particular calendar quarter. It would be difficult to base a reimbursement amount to pharmacies on a negative number.

C. Retail Pharmacy Encourages WAC-Based Reimbursement for Brand Drugs

NACDS has developed an alternative payment method for Medicaid prescription drugs that is transparent and reliable, reflects current, real-time prices that pharmacies pay for prescription medications, and will be fair to pharmacy and Medicaid. This new model will meet or exceed the Administration's cost-cutting goal by encouraging dispensing of lower-cost generic drugs.

Brand Name Drugs: Unlike ASP or AMP, wholesale acquisition cost, known as WAC, is a published, transparent, real-time price that reflects the prices at which wholesalers buy from manufacturers the brand name drugs that they sell to independent and chain operated pharmacies.

The actual amount paid to pharmacies by Medicaid, however, should be some percentage markup on WAC (i.e., WAC plus a percentage) because WAC represents the wholesaler's costs to buy the drugs. Retail pharmacies have additional costs of acquiring drugs from wholesalers or manufacturers, such as overhead in maintaining a costly pharmaceutical inventory, delivering the drugs to their stores or warehouses, and complying with state and Federal regulations, such as board of pharmacy and DEA requirements. We believe that "WAC plus a percentage" would be an appropriate substitute for AWP, ASP, or AMP in determining reimbursement for brand name drugs.

Generic Drugs: The CMS Federal Upper Limit (FUL) list has been an effective tool in saving Medicaid money on generic drugs. Several hundred generic products currently have a FUL. States can vary these FUL rates consistent with local market conditions, but Medicaid will pay states no more than the FUL amounts for this

market basket of generic drugs with FULs. NACDS has worked closely with CMS over the past several years to make the FUL list more effective in terms of assuring that Medicaid pays a fair price for generics, but also that the generic reimbursements simultaneously encourage pharmacies to dispense generic drugs.

In lieu of WAC, ASP or AMP for multiple source generics, we believe that policymakers should retain the use of this type of list for generic drug reimbursement under Medicaid. However, we encourage that certain changes be made to the way that the list is developed. By using a FUL list or a minimum "federal generic reimbursement level" (FGRL) for all versions of a particular generic, Medicaid assures that pharmacies have an incentive to buy the lowest cost generic available.

This FGRL would be set at a percentage of the median or other market prices for the generic sufficient to encourage generic dispensing. This approach would allow pharmacies to retain some of the difference between the cost of that generic and the FGRL. This creates incentives for pharmacies to dispense generics.

Payment of Adequate Dispensing Fees: NACDS believes that any Medicaid payment reform system that seeks to pay pharmacies closer to their acquisition costs for prescription drugs should pay a higher dispensing fee than currently paid by states. In our view, payment for the drug product plus the dispensing fee must be considered in tandem in order to determine whether reimbursement is adequate. Moreover, we strongly urge that a minimum state Medicaid pharmacy dispensing fee be determined at the Federal level, with provisions made for annual updates. We also urge that states be allowed to increase the fee to account for local concerns, such as assuring adequate access to pharmacy services in rural areas.

The Center for Pharmacoeconomic Studies at the University of Texas at Austin recently conducted a survey of national and regional chain pharmacies to estimate the current costs related to dispensing a medication within those stores. Confidential operational and financial data from the most recent corporate fiscal year was provided to the Center by 40 separate pharmacies representing five geographically-diverse chain pharmacy companies.

The data were collected using a modified survey instrument based upon a financial reporting format that has been used within community pharmacy for well over 20 years. The particular sample used for the analysis was comprised of both high and low-volume Medicaid dispensing pharmacies across the country, representing 13 different states. This sampling method begins to provide us with a description of the broad range of the costs involved in dispensing prescriptions within a chain pharmacy.

Overall, the statistical range of costs of dispensing fell between $8.50 and $10.41 per prescription, with the average within this particular sample being $9.45 per prescription. Given that current payments for dispensing fees fall well below this estimate, the results from this preliminary analysis confirm that more widespread studies are needed to estimate the actual costs of dispensing medications to patients. However, policymakers should consider these findings as any payment system reform proceeds forward, as well as provide for annual updates to the dispensing fees to keep pace with increasing costs to operate a pharmacy, especially pharmacy labor costs.

IV. CONCLUSION

Mr. Chairman, we look forward to working with you and the Members of the Subcommittee to make sure that the Medicaid prescription drug payment system is reliable, transparent, and reflects the current market prices that retail pharmacies pay for prescription drugs. We want to assure that the system encourages generic dispensing, as well as continues to make pharmacy services available to Medicaid recipients in their communities. This is especially important in urban and rural areas where many Medicaid recipients live.

We also want to work with you to make the Medicaid program in general, and the drug program in particular, financially sustainable in the long run. Over 50 million Americans rely on Medicaid for health care services. Drug coverage is an important part of these needed health care services. Pharmacists can be partners with the Federal Medicaid program and the states in trying to deliver the most cost-effective drug benefit possible. We appreciate your considering these views as you move forward with these efforts.

Mr. DEAL. Thank you.

Ms. King.

STATEMENT OF KATHLEEN KING

Ms. KING. Mr. Chairman and members of the subcommittee, thank you for inviting me to be here today to discuss GAO's report on the Medicaid Prescription Drug Rebate Program. The hour is late, and I am going to try to be very brief.

There has been a lot of talk here today about how Medicaid reimbursement is based on the AWP, but I want to talk for a moment on how the rebate is calculated. It is calculated as the difference between the best price, which is defined as the lowest price to any manufacturer, and the AMP, the average manufacturer price, which we have talked about today, which is the lowest price—I am sorry, the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. So the rebate is calculated as the difference between those two, or 15.1 percent, whichever is greater.

The Drug Rebate Program is administered by CMS. And we were asked to conduct a study on that, and we focused mostly on the oversight of the program, and we had three basic findings. One, we found that CMS's oversight does not ensure that the manufacturer-reported prices of drugs or the price determinations that are set are consistent with the rebate wall, the agreement entered into with manufacturers, or the guidance developed by CMS.

In administering the program, we found that CMS conducted only limited checks for reporting errors in the prices that manufacturers reported. And in addition, CMS only reviews the manufacturers' price determination methods when they ask for recalculations of prior rebates. The OIG, the Office of the Inspector General, has also issued a number of reports on the rebate program. They identified a number of factors that limited their ability to verify the accuracy of drug prices, including a lack of clear guidance by CMS on how the AMP should be calculated. In some cases, the OIG also found problems with manufacturers' price determination methods and reported prices. We found that CMS had not followed up with manufacturers to make sure that the problems identified by the OIG had been resolved.

Our second finding is that we found considerable variation in the methods that manufacturers use to determine the best price and the AMP. And I should tell you that under the law, manufacturers are allowed to make certain assumptions, differing assumptions when determining the best price in the AMP. We found that manufacturers made varying assumptions about which sales and prices to include and exclude from their calculations and that manufacturers differed in how they accounted for certain price reductions, fees, and other transactions in determining the best price in the AMP. In some cases, the manufacturers' assumptions could have lowered rebates and in some cases, they could have raised the rebates.

Our third finding is that the rebates that the manufacturers paid to States may not reflect certain financial concessions that operate in today's complex market. For example, the role of pharmacy benefit managers, which was not envisioned to the same extent in 1990 when the rebate law was passed. The guidance that CMS has provided does not clearly identify how the PBMs have to deal with price concessions.

As a result of our report, we made two recommendations.

The first is that we recommended that CMS issue clear guidance on how manufacturers should determine their prices and the definitions of the best price in the AMP. And we also have recommended they update this guidance as additional issues arise. This is important in a market that is changing quickly.

Our second recommendation is that CMS implement, in consultation with the OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of the prices that manufacturers report. HHS agreed with us on the importance of guidance to manufacturers but disagreed with our conclusion that they had exercised inadequate oversight.

This concludes my prepared statement. Thank you.

[The prepared statement of Kathleen King follows:]

PREPARED STATEMENT OF KATHLEEN KING, DIRECTOR, HEALTH CARE, UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE

Mr. Chairman and Members of the Subcommittee: I am pleased to be here today to discuss our report entitled *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States,* which we issued in February 2005.[1] Prescription drug spending accounts for a substantial and growing share of state Medicaid program outlays. The Omnibus Budget Reconciliation Act of 1990 established the Medicaid drug rebate program[2] to help control Medicaid drug spending. Under the rebate program, pharmaceutical manufacturers pay rebates to states as a condition for the federal contribution to Medicaid spending for the manufacturers' outpatient prescription drugs. In recent years, the importance of Medicaid rebates to states has grown as Medicaid spending on prescription drugs has risen. From fiscal year 2000 to 2003, Medicaid drug spending increased at an annual average rate of 18 percent, while Medicaid spending as a whole grew 10 percent annually during that period. In fiscal year 2003, Medicaid drug expenditures were $33.8 billion out of $273.6 billion in total Medicaid spending; under the rebate program, manufacturers paid rebates to states of about $6.5 billion for covered outpatient drugs.[3,4]

Medicaid rebates for brand name outpatient drugs are calculated with two prices that participating manufacturers must report to the federal government for each drug: the "best price" and the "average manufacturer price" (AMP). Best price and AMP represent prices that are available from manufacturers to entities that purchase their drugs. Best price for a drug is the lowest price available from the manufacturer to any purchaser, with some exceptions. AMP for a drug is the average price paid to a manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. Both best price and AMP must reflect certain financial concessions, such as discounts, that are available to drug purchasers. The basic Medicaid rebate for a brand name drug equals the number of units of the drug paid for by the state Medicaid program multiplied by the basic "unit rebate amount" for the drug, which is either the difference between best price and AMP, or 15.1 percent of AMP, whichever is greater.[5] The closer best price is to AMP, the more likely the rebate will be based on 15.1 percent of AMP—the minimum rebate amount.

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[1] See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States,* GAO05102 (Washington, D.C.: Feb. 4, 2005).

[2] Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143-161 (codified at 42 U.S.C. § 1396r-8 (2000)). All states and the District of Columbia participate in the Medicaid drug rebate program, except for Arizona.

[3] State Medicaid programs do not purchase drugs directly but rather reimburse pharmacies when they dispense covered outpatient drugs to Medicaid beneficiaries. These payments, which include an amount to cover the cost of acquiring the drug as well as a dispensing fee, are calculated using state-specific payment formulas.

[4] This rebate amount includes the three types of rebates included in the Medicaid drug rebate program: the "basic" rebate for brand name drugs, the "additional" rebate for brand name drugs, and the rebate for generic drugs.

[5] This testimony focuses on the basic rebate for brand name drugs, not the additional rebate for brand name drugs—which occurs when a brand name drug's AMP rises faster than inflation, as measured by changes in the consumer price index—or the rebate for generics. The total unit rebate amount for a brand name drug includes the basic rebate and any additional rebate.

The Centers for Medicare & Medicaid Services (CMS) administers and oversees the rebate program, entering into rebate agreements with manufacturers,[6] collecting and reviewing manufacturer-reported best prices and AMPs, and providing ongoing guidance to manufacturers and states on the program. The Secretary of Health and Human Services, by law, may verify manufacturer-reported prices and has delegated that authority to the Department of Health and Human Services' (HHS) Office of Inspector General (OIG).

In this testimony, I will discuss our February 2005 report, in which we addressed (1) federal oversight of manufacturer-reported best prices and AMPs and the methods manufacturers used to determine those prices, (2) how manufacturers' methods of determining best price and AMP could have affected the rebates they paid to state Medicaid programs, and (3) how the rebate program reflects financial concessions available in the private market.

In carrying out our work, we reviewed the rebate statute, the standard rebate agreement between CMS and participating manufacturers, CMS program memoranda, OIG reports on the rebate program, and market literature; interviewed officials from CMS and OIG; and conducted an analysis of rebates for brand name drugs, for which we reviewed the pricing methodologies for the 13 manufacturers that accounted for the highest Medicaid expenditures in the last two quarters of 2000. We compared manufacturers' methods of determining best price and AMP to the rebate statute, rebate agreement, and relevant CMS program memoranda. In addition, we examined sales transaction data provided by these manufacturers. We received data for the 10 brand name drugs that produced the highest Medicaid expenditures for the last two quarters of 2000 for each manufacturer, as well as data for 5 additional frequently prescribed brand name drugs—135 drugs in total. We examined the sales transaction data to understand how manufacturers implemented their price determination methods and to calculate the impact of manufacturer practices on rebates. Because we purposely selected manufacturers and drugs that accounted for a large share of Medicaid drug spending, the results of our analysis cannot be generalized. We performed our work from December 2003 through January 2005 in accordance with generally accepted government auditing standards.

In brief, we reported in February 2005 that rebate program oversight does not ensure that manufacturer-reported prices or price determination methods are consistent with program criteria as specified in the rebate statute, rebate agreement, and CMS program memoranda. We found that CMS conducts only limited checks for reporting errors in manufacturer-reported drug prices and only reviews price determination methods when manufacturers request recalculations of prior rebates. In addition, OIG reported that its review efforts were hampered by unclear CMS guidance on how manufacturers are to determine AMP and by a lack of manufacturer documentation. Although OIG in some cases identified problems with manufacturers' price determination methods and reported prices, CMS had not followed up with manufacturers to make sure that those problems had been resolved. We also found considerable variation in the methods that the manufacturers we reviewed used to determine best price and AMP. In some cases, manufacturers' assumptions could have lowered rebates; in other cases, their assumptions could have raised rebates. Manufacturers are allowed to make reasonable assumptions when determining best price and AMP, as long as those assumptions are consistent with the law and the rebate agreement. We found that manufacturers made varying assumptions about which sales and prices to include and exclude from their determinations of best price and AMP. We also found that manufacturers differed in how they accounted for certain price reductions, fees, and other transactions when determining best price and AMP. Finally, we found that the rebates that manufacturers pay to states are based on prices and financial concessions that manufacturers make available to entities that purchase their drugs but may not reflect certain financial concessions they offer to other entities in today's complex market. In particular, the rebate program does not clearly address certain concessions that are negotiated by pharmacy benefit managers (PBM) on behalf of third-party payers—concessions that are a relatively new development in the market.

We concluded that although the rebate program relies on manufacturer-reported prices to determine the level of rebates that manufacturers pay to states, CMS has not provided clear program guidance for manufacturers to follow when determining those prices; in addition, oversight by CMS and OIG has been inadequate to ensure that manufacturer-reported prices and methods are consistent with the law, rebate agreement, and CMS program memoranda. We recommended that CMS take sev-

[6] The rebate agreement is a standard contract between CMS and each manufacturer that governs manufacturers' participation in the rebate program, providing, among other things, definitions of key terms.

eral steps to improve program guidance and oversight, namely, to issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP; update such guidance as additional issues arise; and implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates to states. HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. We acknowledged HHS's oversight actions, but stated that HHS oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states. Some of the manufacturers that supplied data for the report raised concerns about our discussion of certain methods they used to determine rebates, and we clarified our discussion of manufacturers' price determination methods.

BACKGROUND

The Medicaid drug rebate program provides savings to state Medicaid programs through rebates for outpatient prescription drugs that are based on two prices per drug that manufacturers report to CMS: best price and AMP. These manufacturer-reported prices are based on the prices that manufacturers receive for their drugs in the private market and are required to reflect certain financial concessions such as discounts.

Pharmaceutical manufacturers sell their products directly to a variety of purchasers, including wholesalers, retailers such as chain pharmacies, and health care providers such as hospitals that dispense drugs directly to patients. The prices that manufacturers charge vary across purchasers. The amount a manufacturer actually realizes for a drug is not always the same as the price that is paid to the manufacturer at the time of sale. Manufacturers may offer purchasers rebates or discounts that may be realized after the initial sale, such as those based on the volume of drugs the purchasers buy during a specified period or the timeliness of their payment. The private market also includes PBMs, which manage prescription drug benefits for third-party payers and may also operate mail-order pharmacies.[7]

The statute governing the Medicaid drug rebate program and the standard rebate agreement that CMS signs with each manufacturer define best price and AMP and specify how those prices are to be used to determine the rebates due to states. In the absence of program regulations,[8] CMS has issued program memoranda[9] in order to provide further guidance to manufacturers regarding how to determine best price and AMP.[10] The rebate agreement states that in the absence of specific guidance on the determination of best price and AMP, manufacturers may make "reasonable assumptions" as long as those assumptions are consistent with the "intent" of the law, regulations, and the rebate agreement.[11] As a result, price determination methods may vary across manufacturers, particularly with respect to which transactions they consider when determining best price and AMP.

Under the rebate statute, best price is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization (HMO), or nonprofit or government entity, with some exceptions.[12] Best price is required to be reduced to account for cash discounts, free goods that are contingent on purchase requirements, volume discounts and rebates (other than rebates under this program), as well as—according to the rebate agreement and a CMS program memorandum—cumulative discounts and any other arrangements that subsequently

[7] See GAO, *Federal Employees' Health Benefits: Effects of Using Pharmacy Benefit Managers on Health Plans, Enrollees, and Pharmacies,* GAO03196 (Washington, D.C.: Jan. 10, 2003).

[8] In 1995, CMS issued a proposed rule for implementation of the drug rebate program, which included provisions regarding best price, AMP, and manufacturer reporting requirements. See 60 Fed. Reg. 48442 (1995). Only a portion of that rule—concerning the length of time manufacturers are able to report price adjustments to CMS and how long they must retain documentation of their reported prices—has been issued in final form. *See* 69 *Fed. Reg.* 68815 (2004), 68 *Fed. Reg.* 51912 (2003).

[9] As of October 2004, CMS had issued a total of 65 program memoranda—also called "program releases"—to manufacturers to provide guidance on a range of issues relating to the rebate program.

[10] CMS also responds to questions from individual manufacturers on a case-by-case basis. In addition, the agency provides an operational training guide and training for manufacturers and states on resolving disputes over state-reported drug utilization information used to calculate rebate amounts.

[11] The rebate agreement also requires manufacturers to maintain records of their assumptions.

[12] *See* 42 U.S.C. § 1396r-8(c)(1)(C). The rebate agreement further defines best price as the lowest price at which the manufacturer sells the drug to any purchaser in any pricing structure, including capitated payments, with some exceptions.

adjust the price actually realized. Prices charged to certain federal purchasers,[13] eligible state pharmaceutical assistance programs and state-run nursing homes for veterans, and certain health care facilities—including those in underserved areas or serving poorer populations—are not considered when determining best price. Prices available under endorsed Medicare discount card programs, as well as those negotiated by Medicare prescription drug plans or certain retiree prescription drug plans, are similarly excluded from best price. Nominal prices—prices that are less than 10 percent of AMP—also are excluded from best price.

AMP is defined by statute as the average price paid to a manufacturer for the drug by wholesalers for drugs distributed to the retail pharmacy class of trade.[14] The transactions used to calculate AMP are to reflect cash discounts and other reductions in the actual price paid, as well as any other price adjustments that affect the price actually realized, according to the rebate agreement and a CMS program memorandum.[15] Under the rebate agreement, AMP does not include prices to government purchasers based on the Federal Supply Schedule, prices from direct sales to hospitals or HMOs, or prices to wholesalers when they relabel drugs they purchase under their own label.

The relationship between best price and AMP determines the unit rebate amount and thus the size of the rebate that states receive for a brand name drug. The basic unit rebate amount is the larger of two values: the difference between best price and AMP, or 15.1 percent of AMP.[16] The closer best price is to AMP, the more likely the rebate for a drug will be based on the minimum amount—15.1 percent of AMP—rather than the difference between the two values. A state's rebate for a drug is the product of the unit rebate amount and the number of units of the drug paid for by the state's Medicaid program.

Manufacturers pay rebates to states on a quarterly basis. They are required to report best price and AMP for each drug to CMS within 30 days of the end of each calendar quarter. Once CMS receives this information, the agency uses the rebate formula to calculate the unit rebate amount for the smallest unit of each drug, such as a tablet, capsule, or ounce of liquid. CMS then provides the unit rebate amount to the states. Each state determines its Medicaid utilization for each covered drug—as measured by the total number of the smallest units of each dosage form, strength, and package size the state paid for in the quarter—and reports this information to the manufacturer within 60 days of the end of the quarter. The manufacturer then must compute and pay the rebate amount to each state within 30 days of receiving the utilization information.

Manufacturers are required to report price adjustments to CMS when there is a change in the prices they reported for a prior quarter. These adjustments may result from rebates, discounts, or other price changes that occur after the manufacturers submit prices to CMS. Manufacturers also may request that CMS recalculate the unit rebate amounts using revised prices if they determine that their initially reported prices were incorrect because of, for example, improper inclusion or exclusion of certain transactions. In 2003, CMS issued a final rule that, effective January 1, 2004, limits the time for manufacturers to report any price adjustments to 3 years after the quarter for which the original price was reported.[17]

PROGRAM OVERSIGHT DOES NOT ENSURE THAT MANUFACTURER-REPORTED PRICES OR PRICE DETERMINATION METHODS ARE CONSISTENT WITH PROGRAM CRITERIA

As we reported in February 2005, the minimal oversight by CMS and OIG of manufacturer-reported prices and price determination methods does not ensure that those prices or methods are consistent with program criteria, as specified in the rebate statute, rebate agreement, and CMS program memoranda. CMS conducts limited reviews of prices and only reviews price determination methods when manufacturers request recalculations of prior rebates. In addition, OIG reported that its re-

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[13] Sales made through the Federal Supply Schedule are not considered in determining best price, nor are single-award contract prices of any federal agency, federal depot prices, and prices charged to the Department of Defense, Department of Veterans Affairs, Indian Health Service, and Public Health Service.

[14] *See* 42 U.S.C. § 1396r-8(k)(1). The statute states that customary prompt payment discounts are to be subtracted from prices used to calculate AMP. There is no definition in the statute for "retail pharmacy class of trade."

[15] Under the rebate agreement, AMP is calculated as net sales divided by units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements).

[16] *See* 42 U.S.C. § 1396r-8(c)(1).

[17] The 2003 final rule addressed the time frame for reporting price adjustments to CMS and the time frame for retaining documentation of reported prices. *See* 68 *Fed. Reg.* 51912, 55527 (2003).

view efforts had been hampered by unclear CMS guidance on how to determine AMP and by a lack of manufacturer documentation. Although OIG in some cases identified problems with manufacturers' price determination methods and reported prices, CMS had not followed up with manufacturers to make sure that those problems were resolved.

CMS reviews drug prices submitted by approximately 550 manufacturers that participate in the program. Each quarter, CMS conducts automated data edit checks on the best prices and AMPs for about 25,000 drugs to identify reporting errors. These checks are intended to allow CMS to ensure that, for example, prices are submitted in the correct format and that the reported prices are for drugs covered by Medicaid. When data checks indicate a potential reporting error, CMS asks the manufacturer for corrected drug prices, but CMS does not have a mechanism in place to track whether the manufacturer submits corrected prices. CMS sometimes identifies other price reporting errors when it calculates the unit rebate amount for a drug, but the agency does not follow up with manufacturers to verify that errors have been corrected. For example, CMS notifies a manufacturer if the unit rebate amount for a drug deviates from that of the prior quarter by more than 50 percent. It would be up to that manufacturer to indicate whether the underlying reported prices were correct. If the manufacturer determined that there were problems with the reported price—for example, typographical errors such as misplaced decimals—it would send corrected data to CMS.[18] If the manufacturer did not send revised pricing data to CMS, then the unit rebate amount would remain the same.

CMS does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP, even though these methods and assumptions can have a substantial effect on rebates. Furthermore, CMS does not generally check to ensure that manufacturers' methods are consistent with the rebate statute and rebate agreement, but rather reviews the methods only when manufacturers request recalculations of prior rebates. A manufacturer may request a recalculation of a prior rebate any time it changes the methods it uses to determine best price or AMP. CMS requires the manufacturer to submit both its original and its revised methods when requesting a recalculation of prior rebates so that the agency can evaluate whether the revised methods are consistent with the rebate statute, rebate agreement, and program memoranda. Recalculations can involve substantial amounts of money; for example, six approved recalculations we examined reduced prior rebates to states by a total of more than $220 million.

In reports on its audits of manufacturer-reported prices, OIG stated that its efforts were hampered by unclear CMS guidance on determining AMP and by a lack of manufacturer documentation. In its first review of manufacturer-reported prices in 1992, OIG found that it could not verify the AMPs reported by the four manufacturers it reviewed.[19] OIG could not evaluate manufacturers' methods for determining AMP because neither the rebate statute nor CMS had provided sufficiently detailed instructions on methods for calculating AMP. OIG therefore advised CMS that it planned no future AMP data audits until CMS developed a specific written policy on how AMP was to be calculated. CMS disagreed, saying that the rebate statute and rebate agreement had already established a methodology for computing AMP and stressed that this methodology was clarified, at manufacturer request, on an as-needed basis through conversations with individual manufacturers.[20]

In its second review of manufacturer-reported prices, in 1995 OIG attempted to verify one manufacturer's recalculation request. While OIG reported that it could not complete its analysis because of inadequate manufacturer documentation,[21] it was able to identify some manufacturer errors in determining AMP. In its review, OIG found that the manufacturer had miscalculated its revised AMP because it included "free goods" specifically excluded in the rebate agreement, miscalculated cash discounts, and improperly included sales rebates applicable to a period other than the quarter being audited. OIG recommended that CMS have the manufacturer revise its AMP data. Although CMS agreed with OIG's recommendations, as of Octo-

[18] In this situation, the manufacturer also would recalculate the unit rebate amount and, once invoiced by the states with total utilization for the drug paid for by Medicaid, would send the rebate payment to those states based on the recalculated unit rebate amount.

[19] See HHS OIG, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program,* A-06-91-00092 (Washington, D.C.: November 1992).

[20] Although CMS disagreed with OIG, it said it would further clarify AMP calculation in a forthcoming drug rebate program regulation. As of October 2004, the regulation had not been issued; as we reported, CMS officials told us that the agency had no plans to promulgate any such regulation in the near future. Instead, CMS has issued several program memoranda intended to provide guidance on how manufacturers should calculate AMP.

[21] OIG reports on individual manufacturers are not publicly available.

ber 2004, it had not required any such revision of the audited manufacturer's AMP determinations.

In its third review, conducted in 1997, OIG attempted to review a manufacturer's recalculation request but again reported that it was unable to complete its evaluation because of a lack of specific guidance on determining AMP and a lack of manufacturer documentation supporting its revised AMP. In the absence of guidance from CMS, OIG defined retail pharmacy class of trade for this audit to include only independent and chain pharmacies that sold drugs directly to the public. Therefore, OIG recommended that CMS ask the manufacturer to exclude from the calculation of AMP transactions that OIG determined were to nonretail entities such as mail-order pharmacies, nursing home pharmacies, independent practice associations, and clinics. OIG also found that the manufacturer used a flawed methodology to identify certain sales that it had included in the retail class of trade and thus AMP. As a result, OIG recommended that CMS ask the manufacturer to exclude those sales from AMP unless the manufacturer could provide additional documentation to support the inclusion of those sales in AMP. Although CMS did not agree with OIG's definition of retail pharmacy class of trade, CMS concurred with OIG's recommendation to ask the manufacturer to recalculate AMP.[22] As of October 2004, CMS had not required any revision of this manufacturer's AMP determinations.

In its fourth review of manufacturer-reported prices, issued in 2001, OIG investigated how manufacturers were treating repackagers—entities like HMOs that repackage or relabel drugs under their own names—in their best price determinations. The work followed up on previous work OIG conducted in response to a congressional inquiry in 1999. The rebate statute states that HMO sales are required to be included in best price determinations. CMS's June 1997 program memorandum stated that sales to other manufacturers that repackage the drugs are to be excluded from best price determinations. However, the rebate statute, rebate agreement, and CMS program memoranda did not address how HMOs should be treated when they act as repackagers. In a letter issued in response to the 1999 congressional request, OIG reported that excluding drug sales to two HMOs that acted as repackagers from best price determinations lowered state rebate amounts by $27.8 million in fiscal year 1998.[23] In July 2000, CMS issued an additional program memorandum to manufacturers stating that sales to an HMO should be considered in best price determinations regardless of whether the HMO was a repackager.[24] In 2001, OIG reported that states lost $80.7 million in rebates in fiscal year 1999 because of improperly excluded drug sales to HMO repackagers.[25] In September 2004, a CMS official told us that CMS planned to release a program memorandum instructing manufacturers to revise prior rebates for which they had excluded sales to HMOs from best price. However, CMS does not have a mechanism in place to track that manufacturers have made these rebate adjustments and therefore cannot verify that manufacturers have made or will make these adjustments.

As we reported, OIG officials told us that, despite the program releases issued by CMS, they remain unable to evaluate AMP because of the lack of clear CMS guidance, particularly related to the retail pharmacy class of trade and treatment of PBM transactions.

MANUFACTURER PRICE DETERMINATION METHODS VARIED: SOME COULD HAVE LED TO LOWER REBATES

As we reported, we found considerable variation in the methods that the manufacturers we reviewed used to determine best price and AMP. Manufacturers are allowed to make reasonable assumptions when determining best price and AMP, as long as those assumptions are consistent with the law and the rebate agreement. The assumptions often pertain to the transactions, including discounts or other price reductions, that are considered in determining best price and AMP. We found that in some cases manufacturers' assumptions could have led to lower rebates and in other cases to higher rebates. Manufacturers can later revise their assumptions and

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[22] In response to OIG recommendations, CMS said it would provide the manufacturer with a copy of recent guidance on AMP: Medicaid Drug Rebate Program Release No. 29, June 1997. This document, released to all manufacturers at the time OIG was conducting the 1997 review, in some cases differed from OIG's definition of retail pharmacy class of trade. It stated, for example, that sales to nursing home and mail-order pharmacies are to be included in AMP, while OIG's definition excluded these entities.

[23] Letter from HHS OIG to Ranking Minority Member, Committee on Government Reform, House of Representatives, November 22, 1999.

[24] Medicaid Drug Rebate Program Release No. 47, July 2000.

[25] See HHS OIG, *Medicaid Drug Rebates: Sales to Repackagers Excluded from Best Price Determinations,* A-06-00-00056 (Washington, D.C.: March 2001).

request recalculations of previously paid rebates, which can result in states repaying any excess rebates.

We found that manufacturers made varying assumptions about which sales and prices to include and exclude from their determinations of best price and AMP. For example, some included sales to a broad range of facilities in AMP, excluding only transactions involving facilities explicitly excluded by the law, rebate agreement, or CMS program memoranda. In contrast, others included sales to a narrower range of purchasers—only those purchasers explicitly included in AMP by the law, rebate agreement, or CMS program memoranda. Manufacturers also differed in how they treated certain types of health care providers that are not explicitly addressed by the law, rebate agreement, or CMS program memoranda. For example, some manufacturers included sales to physician groups in AMP, while others did not. These assumptions can affect the reported prices and, in turn, the size of rebates paid to states.

We also found that manufacturers also differed in how they accounted for certain price reductions, fees, and other transactions when determining best price and AMP. For example, manufacturers differed in how they accounted for certain transactions involving prompt payment discounts. In some cases, manufacturers' assumptions could have reduced rebates below what they otherwise would have been. In other cases, manufacturers' methods could have raised rebates. For example, some manufacturers included in the determination of best price the contract prices they had negotiated with purchasers, even if they made no sales at those prices during the reporting quarter. This practice could have increased rebates to states.[26]

REBATE PROGRAM DOES NOT CLEARLY ADDRESS CERTAIN FINANCIAL CONCESSIONS NEGOTIATED BY PBMS

As we reported, the rebates that manufacturers pay to states are based on a range of prices and financial concessions that manufacturers make available to entities that purchase their drugs, but they may not reflect certain financial concessions manufacturers offer to other entities in today's complex market. In particular, the rebate program does not clearly address certain concessions that are negotiated by PBMs on behalf of third-party payers, such as employer-sponsored health plans and other health insurers. The rebate program did not initially address these types of concessions, which are relatively new to the market. CMS's subsequent guidance to manufacturers has not clearly stated how manufacturers should treat these concessions in their determinations of best price and AMP. Within the current structure of the rebate formula, additional guidance on how to account for manufacturer payments to PBMs could affect the rebates paid to states, although whether rebates would increase or decrease as a result, and by how much, is uncertain.

Certain manufacturer financial concessions that are negotiated by PBMs on behalf of their third-party payer clients are not clearly reflected in best price or AMP. PBMs, in one of the roles they play in the market, may negotiate payments from manufacturers to help reduce their third-party payer clients' costs for prescription drugs.[27] (In these circumstances, the third-party payer does not purchase drugs directly from the manufacturer but instead covers a portion of the cost when its enrollees purchase drugs from pharmacies.) The basis of these PBM-negotiated manufacturer payments varies. For example, manufacturers may make a payment for each unit of a drug that is purchased by third-party payer enrollees or may vary payment depending on a PBM's ability to increase the utilization, or expand the market share, of a drug. The payment may be related to a specific drug or a range of drugs offered by the manufacturer. The amount of financial gain PBMs receive from these negotiated payments also varies. A PBM may pass on part or all of a manufacturer's payment to a client, depending on the terms of their contractual relationship. Manufacturers may not be parties to the contracts that PBMs have with their clients and so may not know the financial arrangements between the PBMs and their clients.

These types of financial arrangements between manufacturers and PBMs are a relatively new development in the market. When the program began in 1991, PBMs played a smaller role in the market, managing fewer covered lives and providing a more limited range of services—such as claims processing—for their clients. Since then, PBMs' role has grown substantially, contributing to a market that is much more complex, particularly with respect to the types of financial arrangements in-

[26] One manufacturer, however, indicated that it later might revise this practice and request recalculations to recoup any excess rebates it had already paid. Manufacturers have up to 3 years to make such revisions.

[27] GAO03196.

volving manufacturers. PBMs now commonly negotiate with manufacturers for payments on behalf of their clients, in addition to providing other services. Although complete data on the prevalence and magnitude of PBM-negotiated manufacturer payments are not readily available, PBM officials and industry experts have said that these and other manufacturer payments to PBMs are a large portion of PBMs' earnings;[28] further, recent public financial information suggests that manufacturer payments to PBMs as a whole are substantial and key to PBMs' profitability.

CMS has acknowledged the complexity that arrangements between manufacturers and PBMs introduce into the rebate program but has not clearly addressed how these arrangements should be reflected in manufacturer-reported prices. In 1997, CMS issued program memoranda that noted new types of arrangements involving manufacturer payments to PBMs and attempted to clarify whether those arrangements should be reflected in best price and AMP.[29] However, in a program memorandum issued shortly thereafter, CMS stated that there had been confusion concerning the intent of the previous program memoranda and that the agency had "intended no change" to program requirements.[30] At the time, CMS said that staff were reexamining the issue and planned to shortly clarify the agency's position. As of January 2005, CMS had not issued such clarifying guidance on how PBM-negotiated manufacturer payments should be reflected in best price and AMP when PBMs have negotiated on behalf of third parties. CMS officials with responsibility for issuing program memoranda advised us that they could comment only on specific situations. They stated that financial arrangements among entities in the market are complex and always changing; in their view, the market is too complicated for them to issue general policy guidance that could cover all possible cases. Rather, these officials told us that they make determinations about PBM payments on a case-by-case basis, but only when manufacturers contact them regarding this issue.

Within the current structure of the rebate formula, additional guidance on how to account for manufacturer payments to PBMs could affect the rebates paid to states, although whether rebates would increase or decrease as a result, and by how much, is uncertain. Because of the structure of the rebate formula, any change in the determination of best price and AMP could raise or lower rebates for any given drug, depending on how the change affects the relationship between those prices. Incorporating PBM-negotiated manufacturer payments into the rebate determination could decrease the unit rebate amount for a drug if, for example, it reduced AMP but had no effect on best price.[31] Alternatively, if such a change increased the difference between AMP and best price for a drug, the unit rebate amount could increase.[32]

CONCLUDING OBSERVATIONS

As we stated in our report, because the rebate program relies on manufacturer-reported prices, adequate program oversight is important to ensure that states receive the rebates to which they are entitled. However, CMS has not provided clear program guidance for manufacturers to follow when determining prices, and this has hampered OIG's efforts to audit manufacturers' methods and reported prices. In addition, oversight by CMS and OIG has been inadequate to ensure that manufacturer-reported prices and methods are consistent with the law, rebate agreement, and CMS program memoranda. As a result, we recommended that CMS take several steps to improve program guidance and oversight, namely, to issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP; update such guidance as additional issues arise; and implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates to states. We believe that these actions could help ensure that the Medicaid drug rebate program achieves its objective of controlling states' Medicaid drug spending. HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. We acknowledged HHS's oversight actions, but stated that HHS

[28] GAO03196.

[29] Medicaid Drug Rebate Program Release No. 28, April 1997, and Medicaid Drug Rebate Program Release No. 29, June 1997.

[30] Medicaid Drug Rebate Program Release No. 30, September 1997.

[31] A change in guidance regarding how PBM payments should be reflected in best price would not necessarily affect the best price for every drug because best price can be determined by a transaction that is not related to PBM payments.

[32] A greater difference between best price and AMP would not always yield a larger rebate. For example, if the difference between the two prices increased but remained less than 15.1 percent of AMP, the unit rebate amount would still be based on the 15.1 percent of AMP minimum.

oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states. Some of the manufacturers that supplied data for the report raised concerns about our discussion of certain methods they used to determine rebates, and we clarified our discussion of manufacturers' price determination methods.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions you or other Members of the Subcommittee may have.

Mr. DEAL. Thank you, Ms. King.

Ms. Gifford, I understand you are under some time constraints. We will be pleased to hear from you.

STATEMENT OF KATHLEEN D. GIFFORD

Ms. GIFFORD. Thank you, Mr. Chairman and members of the committee.

My name is Kathy Gifford. I am a former State Medicaid Director myself, and am now a Principal of Health Management Associates. Along with my colleague, Sandy Kramer, I recently prepared a report that discusses potential Federal options to help contain Medicaid drug costs, and I would like to share some of those options with you today.

I think maybe you can go right to slide four.

[Slide.]

As you know, drug spending is a significant cost driver in the health system generally and a particular burden for Medicaid programs. Virtually all States have implemented pharmacy cost containment measures, and while the Federal Government has been generally supportive, more could be done, I believe, at the Federal level to assist States and promote efficiencies across the country.

I want to touch very briefly on four general areas: first, as has been discussed here a lot already, assisting States to be more prudent purchasers at the retail level; second, maximizing manufacturer rebates, reducing the ongoing cost burden on States in the new Medicare drug benefit; and finally, promoting the delivery of evidence-based cost effective pharmaceutical care.

Now we have already talked a lot about the issues with AWP, and those have been clearly stated for the committee already. I think the Federal Government could be more proactive in providing States with better data on actual drug acquisition costs, and I sum it up in three categories. One, come up with a new data source, and that is what we have been talking about, ASP. Two, improve the accuracy and reliability of AWP data potentially by linking it to the Medicaid drug rebate. Or three, changing Federal law to allow a limited release to States of confidential drug pricing data that is currently available to CMS for purposes of the Medicaid Rebate Program.

Now please note that the first option, ASPs, implementing that would, in my opinion, be no small undertaking. For all States to benefit, the Federal Government would need to handle the data collection and timely pricing for tens of thousands of drug codes used by a typical Medicaid program compared to the relatively small number of drug codes that are currently subject to ASP pricing under Medicare part B. Ultimately, the benefit to States will depend heavily upon the effectiveness of the Federal Government in calculating and reporting the ASP prices.

Next slide. And one more slide.

[Slide.]

The Federal Government could assist States to maximize manufacturer rebates by increasing the federally required minimum rebate, as was recently suggested by the NGA. Doing so could help States compensate for the loss of market leverage they will experience in their supplemental rebate programs when the new Medicare drug benefit takes effect next year.

The last option on that slide I will touch on briefly relates to the budget proposal to eliminate the best price requirement from the Medicaid rebate formula. While no one really knows what the fiscal impact of this would be, I am concerned that in the short run, dropping the best price requirement could undermine existing State preferred drug lists to the detriment of States from both a fiscal and administrative standpoint.

Next slide.

[Slide.]

I have included Federal policy options relating to the new Medicare drug benefit, because States will be directly affected by Clawback formula by growth in the part D spending. I have therefore suggested removing the MMA non-interference provision preventing HHS from negotiating better drug pricing. Even if HHS chose not to negotiate for better prices, I think the repeal of this provision may, nevertheless, promote better drug pricing for Medicare, as drug manufacturers may be more likely to exercise restraint in their pricing decisions to avoid provoking a response from HHS.

Next slide, please.

[Slide.]

And finally, let me turn to what I suggest presents the greatest hope for long-term drug cost containment, and that is the ability to manage drug utilization using evidence-based tools, basically making sure that the right drug is made available to the right person at the right time and in the right amount, all health payers, public and private, would benefit from an expansion of the existing base of evidence-based research. Few States, however, earn a position on their own to undertake the needed research efforts to fill in the gaps. We have already discussed, I believe, Section 1013 of the MMA that recognized this need, and $50 million was authorized for this purpose in 2004, but only $15 million was actually budgeted in 2005, and a like amount was proposed in the budget for 2006 by the President. I believe a greater investment in comparative effectiveness research now would reap substantial long-term savings.

And that concludes my testimony, Mr. Chairman.

[The prepared statement of Kathleen D. Gifford follows:]

PREPARED STATEMENT OF KATHLEEN D. GIFFORD, SANDY KRAMER, HEALTH MANAGEMENT ASSOCIATES

Spending on prescription drugs is a major cost driver in the health care system generally and a particular burden for state Medicaid programs that provide vital health care coverage for many of the nation's most medically vulnerable individuals. Medicaid accounts for nearly one in five dollars spent on prescription drugs in the United States, and nearly half of those expenditures are for low-income seniors who

are dually eligible for Medicare and Medicaid ("dual eligibles").[1] In recent years, almost all states have worked to implement pharmacy cost containment measures that preserve access to the vital drug therapies upon which Medicaid beneficiaries rely. The federal government has been generally supportive of state efforts, but has initiated few of its own. More could be done at the federal level to assist states and promote efficiencies across the country. This paper discusses federal options that would assist states to (a) purchase prescription drugs more effectively at the retail level, (b) maximize manufacturer rebates, (c) reduce the ongoing cost burden on states of the new Medicare drug benefit, and (d) promote the delivery of evidence-based, cost-effective pharmaceutical care.

BACKGROUND

Since FY 2004, state revenue collections have been slowly recovering from the most severe fiscal downturn in 60 years.[2] Despite improving economic conditions, state revenue remains below its 2000 peak (after adjusting for inflation and population growth)[3] and budgets continue to be strained by Medicaid spending growth that exceeds revenue growth in many states. The long-term outlook offers little hope for a Medicaid spending reprieve. Both the Congressional Budget Office and the Centers for Medicare and Medicaid Services (CMS) project that over the next decade, federal Medicaid spending will grow at an average annual rate of more than eight percent.[4]

Over the past four years, state Medicaid officials have cited prescription drugs as one of the top three Medicaid cost drivers along with enrollment growth and rising medical care costs generally.[5] Indeed, prescription drugs are one of the fastest growing Medicaid service categories; expenditures doubled between 1998 and 2002, and have quadrupled since 1992. As a result, prescription drugs grew from 8 percent of total Medicaid expenditures in 1998 to over 11 percent in 2002.[6] In CY 2003, Medicaid spending for prescription drugs grew by 17.5 percent, similar to growth in the previous two years.[7] A combination of factors drove this growth including increases in the number of beneficiaries, drug utilization growth (i.e., more prescriptions per person), the substitution of newer, more costly drugs for older, less expensive drugs, and increases in drug prices. Medicaid drug spending growth is projected to decelerate to 7.1 percent in CY 2004 due in large part to state drug cost containment efforts.[8] While this is below the overall rate of drug cost growth (11.9 percent), it is still high and more can and should be done.

Net Medicaid spending on drugs reflects payments made to pharmacies at the retail level and rebates paid to states by manufacturers. States have considerable discretion in setting retail pharmacy payments, which must recognize both drug costs and a dispensing fee. For sole-source brand name drugs, states must pay the lower of the pharmacy's "usual and customary charge" to the public or the drug's "estimated acquisition cost" (EAC) plus a dispensing fee. Each state determines its own EAC formula (usually based on the "average wholesale price"), and sets its own dispensing fee. The EAC and the dispensing fee amount vary significantly from state to state. Generic products are often subject to different pricing rules. Some are subject to a "federal upper limit" (FUL) set by CMS for drugs with generic equivalents that meet certain criteria. Most states have also chosen to set their own "maximum allowable cost" prices for generics, which can be lower than the FUL and sometimes apply to generics not covered by the FUL.

States struggling with the rapid growth of Medicaid drug spending hoped that a new Medicare pharmacy benefit would provide significant state fiscal relief. Instead, to help finance the new drug benefit that begins in January 2006, the Medicare Pre-

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[1] Brian Bruen and Arunabh Ghosh, "*Medicaid Prescription Drug Spending and Use*," June 2004, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 7111.

[2] National Governors Association, National Association of State Budget Officers, "*The Fiscal Survey of States*," December 2004.

[3] D. Boyd et al, "State and Local Governments Face Continued Fiscal Pressure," The Rockefeller Institute of Government Fiscal Studies Program, January 2005.

[4] Congressional Budget Office, "*The Budget and Economic Outlook: Fiscal Years 2006 to 2015*," January 2005, and Stephen Heffler, et al., "U.S. Health Spending Projections for 2004—2014," *Health Affairs Web Exclusive*, February 23, 2005.

[5] V. Smith et al, "*The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005*," October 2004, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 7190.

[6] B. Bruen and A.Ghosh, June 2004.

[7] C. Smith et al., "Health Spending Growth Slows in 2003," *Health Affairs*, 24, no. 1 (2005): 185-194.

[8] S. Heffler, et al., "U.S. Health Spending Projections for 2004-2014," *Health Affairs Web Exclusive*, February 23, 2005.

scription Drug, Improvement, and Modernization Act of 2003[9] (the "MMA") requires CMS to recoup from states much of the savings that states would otherwise have realized from shifting prescription drug coverage for dual eligibles to Medicare. This recoupment is commonly referred to as the "Clawback." The MMA provides for a ten-year partial phase-down of the Clawback amount starting at 90 percent in 2006 (in other words, allowing the states to retain 10 percent of the calculated savings), and decreasing to 75 percent in 2015 and thereafter. There is, however, no end to the state Clawback obligation. In practice, many states believe the Clawback formula is flawed and may result in a negative state fiscal impact rather than a savings.

STATE ACTIONS TO CONTROL MEDICAID PRESCRIPTION DRUG SPENDING GROWTH

In almost all states, prescription drugs have been the focus of ongoing, sustained efforts to slow multi-year double-digit cost growth. In 2004, 47 states and the District of Columbia reported implementing prescription drug cost containment measures and 43 reported plans to take additional steps in 2005.[10] These measures include imposing prior authorization requirements and step therapy protocols, limiting the number of brand prescriptions per month, new or higher copay requirements and reductions in retail pharmacy reimbursement policies. States have also hoped to better control drug utilization by implementing disease management and case management programs and provider profiling and counter-detailing initiatives.

Figure 1 below illustrates the results of a 2003 survey of state Medicaid programs comparing drug cost containment measures reported in 2003 to those reported in 2000.[11] Among other things, the survey results demonstrate the widespread adoption of multiple policies over a relatively short period of time.

A rapidly growing number of states have also chosen to implement preferred drug lists (PDLs) and negotiate for supplemental rebates from pharmaceutical manufacturers: 37 states have implemented or plan to implement a PDL and 33 states currently receive supplemental rebates.[12] More recently, a number of states have joined multi-state pooling arrangements to increase their market leverage to maximize supplemental rebates. In April 2004, Health and Human Services (HHS) Secretary Tommy Thompson approved plans by five states (Michigan, Vermont, New Hampshire, Alaska, and Nevada) to pool their collective purchasing power and Minnesota, Hawaii, Montana, Kentucky and Tennessee subsequently joined this pool. In May 2005, HHS Secretary Mike Leavitt approved a new multi-state purchasing pool comprised of Louisiana, Maryland and West Virginia. Over the next year, it is likely that more states will join a multi-state purchasing pool motivated, in part, by the January 2006 implementation of the new Medicare drug benefit that will cut in half *direct* state Medicaid pharmacy expenditures. (States will continue to *indirectly* pay for drug coverage for dual eligibles through the Clawback.) Since greater volume translates to greater leverage to negotiate supplemental rebates, states may be forced to join multi-state pools just to retain their current level of supplemental rebates after 2006.

States and the federal government jointly fund Medicaid, and therefore rising Medicaid prescription drug costs also have adverse fiscal consequences for the federal budget. In recent years, CMS has taken some steps to assist and support states with their pharmacy cost containment activities. In 2002, CMS issued guidance to states supporting supplemental rebate programs.[13] In 2004, CMS approved requests from a number of states to form a multi-state purchasing pool. Also, CMS identified selected best practices for Medicaid pharmacy savings and offered assistance to those states that have not implemented these effective mechanisms.[14] While these

[9] Pub. L. 108-173

[10] V. Smith et al, October 2004.

[11] Jeffrey S. Crowley et al, "*Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003*," December 2003, Washington, D.C., Kaiser Commission on Medicaid and the Uninsured, Pub. No. 4164.

[12] Data compiled by the National Conference of State Legislatures and accessed at http://www.ncsl.org/programs/health/medicaidrx.htm; Testimony of Dennis Smith, Director of the Center for Medicaid and State Operations, Centers for Medicare and Medicaid Services, presented at a hearing on "*Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*," before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

[13] Dear State Medicaid Director letter dated September 18, 2002 accessed at http://www.cms.hhs.gov/states/letters/smd91802.pdf.

[14] Included were (1) the long-standing practice of many states to prior authorize brand name equivalents to generic drugs, (2) negotiation of manufacturer supplemental rebates, (3) implementation of disease management programs, and (4) efforts to promote e-prescribing. *Safe and*

efforts are laudable, more could be done at the federal level to assist states and promote efficiencies across the country.

PRUDENT PURCHASING AT THE RETAIL LEVEL

States largely operate "in the dark" in setting drug cost reimbursement without access to the actual drug acquisition costs paid by pharmacies. States typically cover over 50,000 National Drug Codes—each with its own price that can change unpredictably. It is therefore a challenge to find adequate current information to set drug reimbursement rates at levels that fairly compensate pharmacies without overpaying.

While states often set their own maximum allowable cost prices for generics and selected brand name drugs, they rely on national firms to supply electronic drug pricing files for most drugs. States then determine the pharmacy reimbursement rate by taking a discount from the reported "Average Wholesale Price" (AWP), or by assigning a mark-up to the reported "Wholesale Acquisition Cost" (WAC), and adding a dispensing fee.[15] Reimbursement formulas vary significantly from state to state. Similar pricing policies are used by private sector plans, but their rates are often lower than Medicaid.

Recent reports by the HHS Office of Inspector General (OIG) have highlighted the millions of dollars lost to states and the federal government each year due to Medicaid overpricing.[16] One of the main culprits for the overpricing is the AWP. The AWP is essentially a nationally published list price (largely set by manufacturers) that bears little resemblance to a pharmacy's actual acquisition cost. Manufacturers may even raise an AWP to artificially create a larger *spread* between AWP and actual acquisition cost to increase retail pharmacy profits, thereby making the product more attractive to pharmacies. Widely viewed as inflated and flawed, the AWP was recently abandoned by Medicare Part B (in the MMA) in favor a new "Average Sales Price" (ASP) methodology.

Federal policy could assist states in becoming more prudent purchasers at the retail pharmacy level. Proposals 1 through 3 below present alternatives that would each provide states with better information to set retail pharmacy reimbursement policies by (1) providing a new source of drug pricing data (ASPs), (2) improving the accuracy and reliability of the drug pricing data most commonly used today (AWPs), or (3) releasing (on a limited basis) drug pricing data that is currently confidential (AMPs). The fourth proposal calls for improvements in the current federal FUL program that establishes prices for certain multi-source drugs.

1. Provide states with accurate and timely ASPs for Medicaid covered drugs.

For drugs covered under Medicare Part B,[17] the MMA requires Medicare to use an ASP plus 6 percent payment methodology. "AS" is the weighted average of all non-federal sales from manufacturers to wholesalers (net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product), and is based on quarterly pricing data supplied to CMS by drug manufacturers. While some critics argue that the ASP does not accurately reflect a retail pharmacy's actual acquisition cost, the ASP is likely a better starting point for estimating that cost than the AWP.

Moving to an ASP methodology in Medicaid, however, would be a significant and costly undertaking that would be difficult for states to accomplish on their own. To enable all states to benefit from this methodology, the federal government (acting through CMS) would need to handle the data collection and timely pricing of the over 50,000 National Drug Codes commonly covered by state Medicaid programs. (Currently, CMS collects manufacturer data on only 5,700 National Drug Codes to price 550 Part B drugs.) States would also need to rely upon CMS for timely pricing information on new drugs entering the market and for manufacturer price adjustments that occur from time to time. (Currently, CMS provides only quarterly updates for Part B drugs subject to ASP pricing.) Ultimately, the benefit to states of

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Effective Approaches to Lowering State Prescription Drug Costs: Best Practices Among State Medicaid Drug Programs (9/9/04), www.cms.hhs.gov/medicaid/drugs/strategies.pdf.

[15] For example, a state may reimburse a pharmacy at AWP minus 10 to 15 percent plus a fixed dispensing fee of $3 to $5.

[16] Department of Health and Human Services, Office of Inspector General, "*Variation in State Medicaid Drug Prices*," September 2004, OEI-05-02-00681; see also, testimony presented at hearing on "*Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*" before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

[17] Part B drugs include drugs furnished incident to a physician's service, durable medical equipment drugs, and other drugs covered by statute, such as oral immunosuppressive, cancer, and antinausea drugs.

moving to an ASP methodology would depend heavily upon the effectiveness of CMS in calculating and reporting the ASP prices.

President Bush's 2006 federal budget proposal would *require* states to adopt an ASP plus 6 percent payment methodology (consistent with Medicare Part B) and estimates federal savings of $542 million in 2006 and $5.4 billion over five years. (The proposal, however, does not address whether CMS would be responsible for the accurate and timely calculation of the ASP prices.) While states would benefit from accurate and reliable ASP pricing information to use in place of the current inflated and artificial AWP prices, it would likely be advantageous to allow states to retain some flexibility to revise payment methodologies as the need for improvements becomes obvious or necessary over time and to respond to local state conditions.

2. Incentivize manufacturers to set more realistic AWP prices by linking them to the statutory Medicaid rebate formula.

Created by the Omnibus Budget Reconciliation Act of 1990, the Medicaid Drug Rebate Program requires a drug manufacturer to enter into a national rebate agreement with the secretary of HHS in order for that manufacturer's drugs to be covered under Medicaid. CMS calculates rebate amounts using a statutory formula based on the "average manufacturer price" (AMP), defined as the average price paid by wholesalers for drugs distributed to the retail class of trade. Using the same benchmark (AWP) for both the rebate formula (instead of AMP) and pharmacy reimbursement policy would provide an incentive for manufacturers to establish lower, more realistic AWPs and reduce the ability of manufacturers to "game the spread" between AWP and the actual acquisition cost. Another way to achieve a similar result would be to apply a rebate penalty if the difference between AWP and AMP exceeded 20 percent. Medicare Part B uses a similar technique to validate ASPs by comparing ASP to AMP. By law, AMPs are confidential and therefore state Medicaid agencies are unable to implement this type of reasonableness test for AWPs on their own.

3. Change federal law to allow the release of AMP information to the states.

The AMP data provided to CMS by drug manufacturers to support the Medicaid Drug Rebate Program is likely the most accurate drug pricing data currently available to CMS for non-Medicare Part B drugs. A limited disclosure of this data to states could be required by federal law to help states set drug cost reimbursement at appropriate levels, as has been recommended by the Department of Health and Human Services Office of the Inspector General.[18]

4. Improve the process for placing multi-source drugs on the "Federal Upper Limit" (FUL) list.

The FUL program, administered by CMS, limits Medicaid payments for drugs with generic equivalents that meet certain criteria: there must be three therapeutically equivalent drug products and CMS must verify that there are at least three suppliers. If these criteria are met, the FUL is set at 150 percent of the published AWP price for the least costly therapeutically equivalent product. This formula implemented in the late 1980s should be revised to reflect actual market pricing trends and to use strategies based on AMP markups. Also, in a recent OIG HHS report, CMS was criticized for failing to add many qualified drugs to the list and adding others too slowly.[19] As the OIG recommended, CMS at a minimum could focus its resources on high-volume brand name drugs that are coming off patent that could be placed on the FUL list and result in significant Medicaid savings.

MAXIMIZING MANUFACTURER REBATES

The methodology for the required rebate that drug manufacturers must pay to participate in Medicaid has not been modified for over 12 years, despite rapid growth in prices and costs (see Table 1 below.) This has forced a growing number of states to seek supplemental rebates, which can sometimes be difficult for a state to enact. Proposals 1 through 3 below describe federal policy changes to the current rebate formula that would increase rebate revenues to states. The fourth proposal calls for improvements in the administration of the rebate program and the fifth

[18] Department of Health and Human Services, Office of Inspector General, "*Variation in State Medicaid Drug Prices*," September 2004, OEI-05-02-00681.

[19] Ibid. See also, testimony of George M. Reeb, Assistant Inspector General, presented at hearing on "*Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much*" before the Subcommittee on Oversight and Investigations, Energy and Commerce Committee, U.S. House of Representatives, December 7, 2004.

proposal raises a concern with the rebate formula modification proposed in the Bush administration's 2006 budget proposal.

Table 1.

Type of Drug	Federal Rebate Formulas[20]		
Generic Drugs Non-Innovator	Average Manufacturer Price (AMP) times 11%		
Brand Name Drugs Single Source & Innovator	Basic Rebate (Step 1) Greater of: • AMP times 15.1% • AMP minus Best Price	Additional Rebate (Step 2) Rebate Penalty, if AMP price increases exceed the CPI-U	Total Rebate = Step 1 + Step 2

[20] Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, Operational Training Guide, September 2001.

[20] Centers for Medicare & Medicaid Services, Medicaid Drug Rebate Program, Operational Training Guide, September 2001.

1. Increase the minimum federally required rebate.

When the new Medicare prescription drug benefit is implemented in 2006, direct state Medicaid drug expenditures will be cut in half. The lost prescription volume will likely decrease the market leverage that states have to negotiate supplemental rebates. An updated minimum rebate would help states compensate for the loss of market leverage and ensure that all states, as well as the federal government, pay a fair price for prescription drugs covered by Medicaid. The National Governors Association, on a bipartisan basis, supports increasing the rebate.[21]

2. Implement an indexed best price calculation in the rebate formula.

To discourage manufacturers from raising AMP amounts, the rebate formula contains a penalty for AMP price increases that exceed the consumer price index for urban consumers (CPI-U). The penalty is equal to the amount that AMP increased over and above the CPI-U. A similar penalty, however, is not applied for increases in the "best price" component of the formula even though drug manufacturers have consistently increased best price in excess of the CPI-U since the inception of the Medicaid Drug Rebate Program.[22] Indexing the best price component of the rebate calculation would therefore increase drug rebates for many brand name drugs.

3. Add an inflation-related adjustment to the federal rebate formula for generic drugs.

Unlike the current rebate formula for brand name drugs, the current formula for generic drugs contains no penalty adjustment for AMP price increases that exceed the CPI-U. Adding such a penalty could increase rebate revenues to states, but would also discourage generic manufacturers from increasing prices in excess of the rate of inflation.

4. Implement systematic oversight of self-reported manufacturer pricing data to assure the accuracy of Medicaid drug rebates.

Currently, the calculation of Medicaid drug rebates relies upon self-reported AMP and "best price" data supplied to CMS by drug manufacturers. In recent years, a number of drug manufacturers have agreed to pay millions of dollars in legal settlements to resolve allegations involving the underpayment of Medicaid rebates arising from the failure to properly report best price. A recent report from the Government Accountability Office (GAO) also found that current rebate program oversight by CMS does not assure that manufacturer-reported drug prices are consistent with applicable laws and program policies.[23] Consistent with GAO recommendations, CMS should implement a plan to systematically scrutinize AMP and best price data reported by manufacturers to enforce the accurate payment of Medicaid drug rebates to states.

5. Maintain the "best price" calculation in the current rebate formula.

The president's 2006 budget recommendations propose to eliminate the best price requirement from the Medicaid drug rebate formula and replace it with a budget neutral flat rebate to allow private purchasers to negotiate lower prices from manufacturers. Flat rebates, however, could dramatically affect the structure of state PDLs and the savings they currently generate for states. PDL savings are based on shifting utilization to those drugs with the lowest net cost after federal and supplemental rebates. If federal rebates change, preferred products may no longer be cost effective compared to non-preferred drugs within a class and cost increases could result.

IMPACT OF THE MEDICARE DRUG BENEFIT

When the Medicare prescription drug benefit takes effect in January 2006, state Medicaid programs will no longer provide drug coverage for dual eligibles but will continue to help finance a substantial portion of the new Medicare drug coverage through the Clawback. States will therefore lose the ability to manage the prescription drug benefit for duals, even as they must continue to finance it. The Clawback formula includes future annual adjustments based upon per capita spending growth

[21] National Governors Association. 2004. EC-3. Medicaid Drug Rebate Program. http://www.nga.org/nga/legislativeUpdate/1,1169,C__POLICY__POSITION^D__3716,00.html

[22] Department of Health and Human Services, Office of the Inspector General, Cost-Saver Handbook, "*2004 Red Book*."

[23] United States Government Accountability Office, "*Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*," February 2005, GAO-05-102.

for the Medicare drug benefit. Thus, states have a direct interest in how the Medicare drug program is managed: higher per capita growth in Medicare drug spending means a larger Clawback obligation for states.

The first two proposals below describe steps that the federal government could take to constrain the growth in per capita Medicare drug spending, and thereby directly benefit states by moderating future growth in the Clawback. Proposals 3 and 4 suggest that the MMA should be amended to eventually require the federal government to assume the full financial cost of the Part D benefit for dual eligibles.

1. Eliminate the MMA prohibition preventing CMS from negotiating for better pharmaceutical pricing.

Section 1860D-11(i) of the Social Security Act, as added by the MMA, bars the secretary of HHS from interfering with the negotiations between drug manufacturers and pharmacies and sponsors of prescription drug plans, or from requiring a particular formulary or price structure for covered Part D drugs. The CBO has estimated that there would be negligible savings if this provision was struck,[24] but others disagree. They point to the substantial discounts obtained by other countries who negotiate on behalf of their citizens and by the U.S. Veteran's Administration as compelling evidence of the savings potential for Medicare.[25] Even if HHS chose not to exercise its authority to negotiate for better prices (or exercised its authority poorly), the repeal of Section 1860D-11(i) may, nevertheless, promote better drug pricing for Medicare by changing the context in which drug pricing decisions are made—pharmaceutical manufacturers may be more likely to exercise restraint in their pricing decisions to avoid provoking a response from HHS.

2. Hold states harmless from the cost of future changes to the Medicare drug benefit that have the effect of driving up the rate of Medicare drug spending growth.

State officials are all too familiar with the phenomenon of special interest groups advocating, often successfully, at the state level for state insurance laws mandating specific benefits. The likelihood of this happening at the federal level with regard to the new Medicare drug benefit is surely high. Because the Clawback calculation is based on a comprehensive Medicaid drug benefit that is likely to be more generous than the basic Medicare benefit offered in 2006, states should not be forced to pay twice if future federal actions are taken to enhance the Medicare benefit in any way that would increase costs to states under the Clawback formula. For example, many states exclude certain classes of drugs (such as mental health drugs) from their PDLs and prior authorization programs. The Clawback obligation for these states will include the cost of this open access policy even though dual eligibles may not have the same open access to these drugs under the new Medicare benefit. If a mandate for open access to certain drugs or drug—classes is added to the Medicare benefit in the future, the cost of that mandate could increase the cost of the Clawback obligation to states forcing some states to pay for open access a second time.

3. Eliminate the MMA exclusion of certain drug classes from the Medicare Part D drug benefit.

The MMA excludes coverage for a number of drug classes that are optional but commonly covered under Medicaid, including over-the-counter drugs, barbiturates used for seizures and benzodiazepines for anxiety. According to a recent study, more than half of dually eligible nursing home residents will be affected by the excluded drugs provision in the law because they are currently receiving at least one medication that will be excluded from coverage under Medicare Part D.[26] The exclusion of benzodiazepines and barbiturates has been identified as a particular concern due to their widespread use in elderly populations and the potential for therapeutic destabilization if discontinued.

For dual eligibles who need one of these excluded medications after January 1, 2006, they must either turn to Medicaid for coverage or prescribers will be forced to use alternative medications that will be less effective, more costly and, for some

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[24] CBO Letter dated January 23, 2004 to the Honorable William H. Frist, M.D. accessed at http://www.cbo.gov/showdoc.cfm?index=4986&sequence=0.

[25] See Families U.S.A., *Another Hole in the Medicare Drug Benefit,* March 2004 accessed at http://www.familiesusa.org/site/DocServer/Another_Hole.pdf?docID=2885.

[26] R. Stefancacci, "*The Cost of Being Excluded: Impact of Excluded Medications under Medicare Part D on Dually Eligible Nursing Home Residents,*" Health Policy Institute at the University of the Sciences in Philadelphia, February 16, 2005, citing an analysis conducted by Omnicare, Inc., a national long-term care pharmacy provider.

patients, even toxic.[27] Thus, states will either bear the cost of providing the excluded drugs or incur greater nursing home or other costs due to adverse health consequences. For these reasons, the MMA should be amended to provide coverage for these excluded drug classes, at least for dual eligibles and other persons receiving Part D low-income subsidies.

4. Amend the MMA to phase out the Clawback obligation completely.

The MMA currently provides for a ten-year partial phase-down of the Clawback amount starting at 90 percent in 2006 and decreasing to 75 percent in 2015 and thereafter. The timing of the phase-down could be accelerated or continued beyond 2015 with the goal of completely eliminating this unprecedented Medicare financing mechanism and fiscal obligation on states.

COMPARATIVE EFFECTIVENESS

Advances in technology are transforming the delivery of health care in the United States but are also the most important long-term driver of health care costs. While the growth in prescription drug costs has recently moderated, this could turn out to be a temporary "lull" rather than a long-term trend due to technology advances.[28] Efforts to assist states to become more prudent Medicaid purchasers must therefore go beyond improved pricing strategies (such as changing from an AWP to an ASP-based pricing system), to also include the creation of new evidence-based tools that will assist states in appropriately controlling utilization.

After four years of widespread, continuous efforts to cut Medicaid spending growth, an increasing number of states are turning to evidence-based disease management and case management programs with the hope that improving the quality of care will result in lower long-term costs for care. In the pharmacy arena, a consortium of 15 organizations, including 13 states, has formed to create the Drug Effectiveness Review Project (DERP) whose purpose is to carry out systematic reviews of drug classes to inform state drug coverage decisions, usually in connection with a state's Medicaid PDL. These systematic reviews, conducted by Evidence-based Practice Centers (mostly university-based), array, evaluate and summarize the aggregate results of published and unpublished studies pertaining to the drug class under review. The DERP reports its findings concerning safety and effectiveness, but does not make policy or coverage recommendations. By September 2004, the DERP had completed twelve reviews and a number of review updates and had ten reviews in progress.

At the federal level, interest in evidence-based health care management continues to grow as well. Most recently, Section 1013 of the MMA requires the HHS secretary to set priorities and target areas where evidence is needed to improve the quality, effectiveness and efficiency of health care provided by Medicare, Medicaid, and the State Children's Health Insurance Program (SCHIP). The HHS secretary is directed to:

> "...conduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to"
>
> (i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and
>
> (ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs."

The MMA language recognizes the need to synthesize existing scientific research to inform policy and coverage decisions in public programs, but also recognizes that there are gaps in the current research base. In a recent article, the director of the Agency for Healthcare Research and Quality summarized the challenge as follows:

> "For many policy issues, there is too little evidence to be of much help. The challenge now is to ensure that clinicians and policymakers can easily find out what we do know, support research to answer what we do not know, and promote change in the health care system that will continue to narrow the gap between what we know and what we do."[29]

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[27] Ibid.

[28] According to a recent study from the Tufts Center for Study of Drug Development, advances in biotechnology research and development will result in nearly 50 new biotech medicines receiving market approval from the U.S. Food and Drug Administration. Tufts Center for Study of Drug Development, March 7, 2005 press release, "*Biotechnology Advance have Improved R&D Success Rates, According to Tufts CSDD*."

[29] Carolyn M. Clancy and Kelly Cronin, "Evidence-Based Decision Making: Global Evidence, Local Decisions," *Health Affairs*, 24, no. 1 (2005): 161.

State Medicaid programs and beneficiaries would benefit greatly from an expansion in the base of evidence-based research. In particular, this information could be used to help further define "smart" PDLs rather than states relying too heavily on price considerations when making PDL coverage policies. Few if any states, however, are in a position, on their own, to undertake the needed research efforts. Clearly, it is more appropriate for the federal government to call upon its considerable technical, policy and fiscal resources to tackle this challenge for the benefit of all federal, state and private health care payers, purchasers and patients. While the federal government has taken steps in this direction, it has not gone far enough in light of the enormity of the health care fiscal challenges that loom ahead, and therefore the proposal below calls upon the federal government to commit greater resources to this effort.

Commit greater federal resources and leverage greater private resources to carry out the purposes of Section 1013 of the MMA.

Federal, state and private efforts in recent years have expanded the information base available to policymakers making health policy and coverage decisions, but a greater investment is needed to keep up with the pace of technological change. While the MMA authorized $50 million in FY 2004 to carry out Section 1013, only $15 million was actually budgeted for this effort in 2005 and the president's 2006 budget maintains funding at the $15 million level. At a minimum, funding to carry out Section 1013 should be increased to the amount authorized by the MMA. Greater investments would likely lead to greater cost containment benefits in the future.

CONCLUSION

Medicaid spending growth is straining both state and federal budgets and growth in prescription drug spending continues to be a major culprit in that overall growth. While states have made great strides in reforming their prescription drug programs and have achieved significant savings, more could be done at the federal level to assist states. The federal government can help states obtain better drug pricing information and can also assist states in maximizing manufacturer rebates by adjusting the current rebate formula and better enforcing rebate program requirements. By ensuring the cost-effective management of the Medicare Part D drug benefit, the federal government can also mitigate the future growth of the states' Clawback obligations. Finally, like all payers, Medicaid's greatest hope for long-term cost containment benefits lies in the ability to manage drug utilization using evidenced-based tools. The federal government can play an instrumental role in supporting research efforts that will fill in the gaps in the existing research base and by supporting efforts to synthesize and analyze currently available research to better inform coverage decisions.

Mr. DEAL. I thank you, Ms. Gifford.

Mr. Calfee.

STATEMENT OF JOHN "JACK" E. CALFEE

Mr. CALFEE. Thank you, Mr. Chairman, for inviting me to testify at today's hearing. I will briefly summarize the main points in my written testimony, which I have submitted for the record.

We all know that government reimbursement mechanisms often create vested interests, inefficiencies, and unexpectedly high costs. What seems reasonable when a program is created eventually becomes unreasonable as conditions change and the various parties take advantage of opportunities to reduce costs or increase compensation. One of the most common problems is the growth of cross-subsidies. These can be difficult to reduce or eliminate, regardless of how adverse their consequences may be. In the end, however, the only reasonable solution is to rework the program or eliminate cross-subsidies and replace them with a transparent system of direct, cost-based reimbursement.

The Medicare part B reimbursement plan for oncology drugs is an example of how systems can go astray and how difficult it can be to fix things. In Medicare part B, overcompensation occurred largely because reimbursement was based on AWP. As drug sellers

competed by lowering prices far below AWP, the resulting distortions finally compelled Congress to legislate a cost-based reimbursement system as part of the Medicare Modernization Act of 2003.

More recently, Medicaid reimbursement for drugs obtained through retail pharmacies had begun to move along a similar path toward excessive reimbursement for filling prescriptions, especially prescriptions, as we have heard, for newer and more expensive generic drugs. We have heard about the recent CBO report, which documented the average pharmacy markup today in Medicaid is approximately $32 for newer generic drugs in the year 2002 compared to $10 for older generic drugs and $14 for old drugs. This pattern appears to reflect the oddities of an AWP-based reimbursement system rather than differences in actual cost.

I urge Congress and CMS to change the current Medicaid pharmacy reimbursement plan to one that focuses more directly on covering reasonable costs. One way to do this would be to use the average sales price, or ASP, as defined in the Medicare Modernization Act, assuming this is a reasonable measure of drug acquisition costs by pharmacies. Another would be to use a suitably defined AMP, or average manufacturer price. Either approach would probably be superior to the highly artificial AWP prices now used.

This change should be combined with reasonable compensation to pharmacies for the services they perform in filling Medicaid prescription. Although a fixed percentage market might be appropriate in some cases, such a plan, as we have heard, carries the danger of distorting incentives yet again, in effect rewarding pharmacies for filling more expensive prescriptions. Something closer to a fixed payment per prescription may be a better solution.

I believe that new reductions of what Medicaid pays drug manufacturers would be inadvisable. Even today, those amounts are typically well below the lowest prices in the private sector. We should beware, I would suggest, of yet more reductions in the payoffs to research firms for developing the kinds of drugs that are most useful to Medicaid beneficiaries. As valuable as today's drugs are, it is perfectly clear that Medicaid patients desperately need a new generation of such crucial tools as anti-psychotics, anti-depressants, and diabetes treatments.

Finally, I urge Congress and the States to make reasoned use of co-payments in order to control drug costs. Of course, such a tool should take account of the limited resources of patients who, for the most part, are served by Medicaid precisely because they lack substantial income and assets, but a nuance co-payment program, drawing on the extensive experience of the private sector, would control the overuse of some drugs without impeding the use of essential drugs whose value both to patients and the Medicaid system greatly exceeds their costs.

That concludes my oral statement, Mr. Chairman.

[The prepared statement of John "Jack" E. Calfee follows:]

PREPARED STATEMENT OF JOHN E. CALFEE, AMERICAN ENTERPRISE INSTITUTE

I am honored to testify in these hearings on "Medicaid Prescription Drugs: Examining Options for Payment Reform," held by the Committee on Energy and Commerce's Subcommittee on Health. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on phar-

maceutical markets and other topics. The views I present are my own and do not necessarily represent those of the American Enterprise Institute.

1. GOVERNMENT REIMBURSEMENT PROGRAMS OFTEN CREATE CROSSSUBSIDIES AND OTHER DISTORTIONS

It is only natural that the details of federal reimbursement programs will reflect the specific circumstances in which those programs are created. Such details will inevitably create vested interests among both payers (who may realize savings not offered by the marketplace) and recipients (who may do better than they would in a competitive market). As conditions change, the program's essential features may persist because of these vested interests, even if a very different arrangement would emerge if the program were to be re-created under current conditions. As events proceed, very large inefficiencies can become very difficult to dismantle.

A common feature of such hide-bound systems is crosssubsidies, in which one set of parties receives compensation or reimbursement in excess of reasonable levels at the expense of other parties, whose own reimbursements may be enlarged to compensate for the cross-subsidies. Another common feature is that suppliers and other parties act in economically rational ways to take advantage of crosssubsidies, to reduce the burden of funding crosssubsidies, and so on. Over time, these reactions can substantially increase the scope and magnitude of distortions including crosssubsidies.

2. CROSSSUBSIDIES AND SIMILAR MECHANISMS GREATLY COMPLICATE THE TASK OF SETTING REASONABLE AND EFFICIENT REIMBURSEMENT LEVELS

In reasonably competitive private markets, affected parties tend to eliminate or contain crosssubsidies and similar distortions, or reduce their effects to manageable levels. Inefficient government reimbursement methods, however, often persist despite growing inefficiencies. As systems become more complex, essential elements become difficult or impossible to measure. Administrative costs in health care systems, for example, may change radically in the face of new technology, altered patient or physician preferences, and innovative organizational methods. The task of disentangling subsidies, crosssubsidies, and straight-forward reimbursement may become nearly impossible. Even the most competent analysts may find it impossible to construct accurate measurements of the magnitude or even the direction of crosssubsidies.

3. ELIMINATING OR MINIMIZING CROSSSUBSIDIES IS GENERALLY A GOOD IDEA

Because managing the inefficiencies arising from crosssubsidies and related distortions in public reimbursement programs usually proves impossible in the long run, the best strategy is to eliminate crosssubsidies altogether. Assuming that private markets are not an alternative, a suitable goal is to assure that each party is reimbursed for acquisition and administrative costs in the most reasonable and feasible manner.

4. FEDERAL MEDICARE AND MEDICAID DRUG REIMBURSEMENT PROGRAMS ILLUSTRATE THESE PROBLEMS

It became apparent more than a decade ago that the Medicare Part B program, which among other things reimburses physicians for infusion drugs (mainly cancer treatments), systematically over-compensated physicians and clinics.[1] This engendered attempts by all parties to take advantage of the system, and even discouraged superior drug development because infusion products became favored over home-injectibles or even simple pills. A striking feature of this system was that sellers competed to provide products at less than the list prices upon which reimbursement rates were based, and employed marketing tools to make physicians aware of the benefits of prescribing brands with large reimbursement margins. The list prices that underpinned reimbursement rates were obtained from the "Average Wholesale Price" (or AWP) lists now published by Thomson Micromedex's *Red Book* and First DataBank's *Blue Book: Essential Directory of Pharmaceuticals.* All this was widely known at the time. A series of public hearings and reports starting in 1989 (U.S. Senate 1989), along with TV and other news stories (e.g., NBC News, Jan. 15, 1997), and a 1997 radio address by President Clinton, repeatedly highlighted the basic dynamics of a situation in which vested interests made it difficult to dismantle a crosssubsidy system. Only in the past year has Congress provided means for CMS

[1] Useful sources include: MEDPAC 2003 (especially chap. 9); USGAO 2001; and USGAO 2002.

to adopt a more direct cost-based reimbursement mechanism (CBO, December 2004; *Federal Register,* Jan. 7, 2004).

Recent reports from the Congressional Budget Office (December 2004 and June 2005a), the Government Accountability Office (February 2005), and the USDHHS Office of the Inspector General (September 2004) have made clear that similar trends have come to characterize Medicaid reimbursement for pharmaceuticals obtained by patients through retail pharmacies. Among these trends are increasing pharmacy margins. This in itself does not necessarily indicate a problem, but margins appear to have become unreasonably large for generic drugs, especially newer generics. This can be seen in Table 1, which is based on the December 2004 CBO report. Whereas average markups or margins increased from $8.70 in 1997 to $13.80 in 2002, prescriptions for newer generics involved average margins of $32.10 in 2002. Such large disparities appear to make little sense because the actual costs of filling prescriptions are relatively consistent across the bulk of generic and branded drug.

Table 1

Medicaid's Prescription Drug Reimbursements, Wholesalers' and Pharmacies'' Acquisition Costs, and Margins, 1997 and 2002

(all amounts in dollars per prescription)

	Reimbursements to Pharmacies		Acquisition costs		Margins	
	1997	2002	1997	2002	1997	2002
All drugs	37.00	60.90	28.30	47.10	8.70	13.80
Generic drugs						
Newer	N/A	45.70	N/A	13.60	N/A	32.10
Older	11.90	14.20	4.30	4.40	7.60	9.90
Brand-name drugs	61.90	97.30	52.20	83.40	9.80	13.80

Source: All data are taken from Congressional Budget Office, ''Medicaid's Reimbursements to Pharmacies for Prescription Drugs,'' December 2004, Table 1.

N/A = not estimated because most ''newer'' generics were unavailable in 1997.

The June 2005 CBO report (CBO 2005a, p. 3) documents that the source of the large and growing disparities in pharmacy margins is the widespread practice among the states of basing reimbursement upon the same AWP lists that used to be the basis for Medicare Part B reimbursement. Although AWP price lists may once have been *bona fide* attempts to describe common transaction prices from wholesalers, it is well known that current list prices are often substantially above acquisition costs. As long as pharmacy reimbursement is based upon AWP, however, we can expect generic manufacturers whose drugs are available at prices substantially below AWP to make pharmacies aware of this fact and to encourage the filling of prescriptions with high-margin generics. The December 2004 CBO report indicates that this tendency is increasing, with substantial potential impact on overall Medicaid costs.

5. ALTERNATIVES TO AWP FOR REIMBURSEMENT PURPOSES

I urge Congress and the states to reform the Medicaid drug reimbursement process to more closely reflect costs. Adopting a more accurate measure of drug acquisition costs is an essential part of this. The government reports cited above describe alternative acquisition cost indicators in some detail. The most promising appears to be "average sales price," or ASP. According to the June 2005 CBO report (n. 6), ASP is defined in the Medicare Modernization Act of 2003 as the average price charged to nonfederal buyers, taking into account volume discounts, prompt-pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates other than those paid under the Medicaid rebate program. Some of these adjustments, however, such as rebates and chargebacks, may be relatively unimportant for generics. Such adjustments are probably largely confined to the on-patent branded drug market, where large gaps between prices and manufacturing and marketing costs encourage private bargaining that can yield a substantial variation in prices among buyers of the same drug (cf. Frank 2001). In any case, however, the ASP measure, unlike AWP, is clearly tethered to actual market transactions and thus is not nearly as artificial as AWP prices. Basing reimbursement for drug acquisition on ASP prices would probably be a substantial improvement over the current system.

6. PHARMACY REIMBURSEMENT

The changes just outlined would require changes in how pharmacies are reimbursed for filling Medicaid prescriptions. Again, I suggest basing reimbursement largely on reasonable costs. In some situations, a simple percentage add-on may be appropriate. But a percentage markup can seriously distort incentives because the effect is to generate larger pharmacy margins for more expensive drugs regardless of the costs of filling prescriptions. This could distort Medicaid generic drug usage toward higher cost drugs with little or no off-setting benefit. It might make more sense to explore some mix of percentage and fixed-amount reimbursement if that can be achieved without introducing new and even larger distortions.

7. PHARMACEUTICAL ACQUISITION PRICES IN MEDICAID ARE ALREADY LOW ENOUGH

I also urge Congress and the states to avoid making further cuts in the prices paid by Medicaid to drug manufacturers. A series of measures in the past two decades has already pushed most of these prices below even the lowest private sector prices. This is because manufacturers, if they are to participate in Medicaid at all, must sell their drugs at prices that are usually adjusted below the "best price" in private sector sales—(cf. CBO June 2005a, p. 11, and CBO June 21, 2005 on the increasing magnitude of "additional rebates" beyond meeting best-price levels in the private sector). This arrangement causes the Medicaid system to provide minimal payoffs for developing drugs to be used by the Medicaid population. In the long run, this could prove unfortunate. Certain conditions, notably schizophrenia, disproportionately afflict the Medicaid population (indeed, schizophrenia may be a prime reason why some people enter the Medicaid system in the first place). New drug development for these conditions is sorely needed. Even existing medicines can be costeffective in the sense of moderating or even reducing overall Medicaid costs, and they may improve beneficiaries' lives in ways that are otherwise difficult to achieve with patients who often defy traditional treatment. Steady reductions in the rewards for drug development for the Medicaid population are therefore inimical to advances in public health.

8. COST-CONTROL:

The fact that Medicaid pays relatively little for pharmaceuticals reduces the potential gains to be had from additional measures to control drug costs. Nonetheless, co-payments offer an obvious tool for cost control. Congress might consider granting the states expanded authority to use this tool. It would make sense to borrow from what has been learned by the private sector in its extensive experimentation with drug co-pays. Given that lower than normal co-pays would be appropriate for the typical Medicaid beneficiary, a nuanced approach could be useful. For some drugs, a significant co-pay on the order of three to ten dollars might cause patients to consider whether an expensive anti-histamine, pain reliever, or anti-ulcer drug is worth the extra cost. For other drugs (such as anti-psychotics, perhaps, in addition to obvious candidates like vaccines), the Medicaid system might be better off if patients are encouraged by zero co-pays to fill their prescriptions and stick with their therapies.

References

Clinton, Pres. William J. (1997) Radio address of Dec. 13, 1997.

Congressional Budget Office (2004) "Medicaid's Reimbursements to Pharmacies for Prescription Drugs," December 2004.

Congressional Budget Office (2005a) "Prices for Brand-Name Drugs Under Selected Federal Programs," June 2005.

Congressional Budget Office (2005b) "The Rebate Medicaid Receives on Brand-Name Prescription Drugs," June 21, 2005 (letter to Sen. Charles E. Grassley).

Federal Register, Jan. 7, 2004, p. 1084-1132, Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 405 and 414, "Medicare Program: Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004; Interim Final Rule."

Frank, Richard G. (2001) "Prescription Drug Prices: Why Do Some Pay More Than Others Do?" *Health Affairs,* v. 20, n. 2 (March-April), p. 115-128. Available (for subscribers) at content.healthaffairs.org/cgi/reprint/20/2/115.pdf

MEDPAC (Medicare Payment Advisory Commission) Variation and Innovation in Medicare, June 2003.

NBC News, Jan. 15, 1997, "Fleecing of America."

U.S. Department of Health and Human Services, Office of the Inspector General (2004) "Variation in State Medicaid Drug Prices," September 2004.

U.S. Government Accounting Office (GAO, 2000) "Expanding Access to Federal Prices Could Cause Other Price Changes," GAO/HEHS 00-118, August.

U.S. Government Accounting Office (GAO) (2001) "Medicare Physician Fee Schedule: Practice Expense Payments to Oncologists Indicate Need for Overall Refinements," GAO-02-53, October.
U.S. General Accounting Office (USGAO) (2002) "VA and DOD Health Care: Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges," testimony before the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives, July 22, 2002.
U.S. Government Accountability Office (2005), "Medicaid Drug Rebate Program:
Inadequate Oversight Raises Concerns about Rebates Paid to States," February 2005.
United States Senate, Special Committee on Aging (1989), Senate Majority Staff Report, "Prescription Drug Prices: Are We Getting our Money's Worth?"

Mr. DEAL. Thank you very much.

Very impressive panel. Let me start off with the questioning, and I will say, on Ms. Gifford's behalf, she had to leave to catch an airplane, and I don't think anybody anticipated that she would have to rush before the hearing was over with to catch the airplane, but that is what has happened today.

Mr. Rodgers, we have been hearing great things about Arizona from Mr. Shadegg for a very long time, and I am beginning to understand now why he has been saying that. Let me just sort of review a few things. I mean, it seems like that all we really need to do is sort of patent the Arizona model and it would work for the rest of the country. Let me review what you said. You have the highest generic usage in the country, apparently, and that is one of the things we have been trying to encourage is greater generic use. You have a very high degree of patient satisfaction, less than 1 percent attributable to the pharmaceutical part of the complaints. You are doing it in an environment in which you have no co-pays, which is certainly one of the concerns that the pharmacies have as we talk about the idea of maybe raising co-pays, of the collectability of that and whether or not that is going to just have to be absorbed by the local pharmacist who never really effectively can collect that. You don't have that problem, because you don't have co-pays. And you don't have to deal with this issue that we are talking about whether to raise the rebates or not raise the rebates. You don't get any rebates. Am I correct on all of those features?

Mr. RODGERS. Yes, you are.

Mr. DEAL. Well, there has got to be something, other than the good air, in Arizona that makes it all work. Let me ask a few questions that come to my mind.

You are doing it through private plans. How many different plans do you have in the State?

Mr. RODGERS. We have seven different acute care plans. We have six long-term care plans. And these are both for-profit, non-profit, as well as public plans. Some of our public organizations, counties, have their own plan.

Mr. DEAL. And I believe I understood you to say that all of your pharmacies are included in some plan. Is that correct?

Mr. RODGERS. That is correct.

Mr. DEAL. So there is nobody left out of this approach?

Mr. RODGERS. That is correct.

Mr. DEAL. Okay. Mr. Fuller, I guess I will ask you the next question, then. Are there any chain drug stores that don't go into Arizona because they have this plan in place that you know of?

Mr. FULLER. I am certain that no one is staying out of Arizona because of this plan, and indeed, I think most of them, if not all of them, are participating in the plan.

Mr. DEAL. What is your reaction to the $2 payment to the pharmacists for filling the prescription? I would assume that in addition to that there is compensation through the plans back to the pharmacists in addition to the filling of the prescription. Is that right, Mr. Rodgers?

Mr. RODGERS. The dispensing fee is a flat fee that the plans pay, but depending on what they have negotiated and rates, there may be dollars in there with the pharmacy, retail pharmacy. It is a negotiation, so different plans have different negotiations.

Mr. DEAL. And they may even include incentives if they use a higher proportion of generics, I assume, is one of the, maybe, incentives that are there?

Mr. RODGERS. Well, actually, it is the physicians that determine the generic use.

Mr. DEAL. Okay. All right.

Mr. Fuller, what is your reaction to that arrangement?

Mr. FULLER. Very good question, and we have recently seen work completed out of the University of Texas that amalgamated information from, I think, 40 different chains on what the cost of prescribing was in these programs. Now it is important to understand that there is a lot of flexibility that the States have, as you heard about in Arizona. But the ranges of costs in prescribing were from $8.50 to about $10.50. The average is $9.45, so in another way, the pharmacy has to recover the cost of what it paid for the drug, and it probably has to find a way to recover about $9.45, or it is losing money. That doesn't mean that the dispensing fee has to be $9.45, because there are other ways of getting there. I think the one concern I would have would be if it was interpreted to mean that simply a $2 dispensing fee covered the pharmacists' costs that would be an error.

Mr. DEAL. Right.

Mr. FULLER. There has got to be a mechanism in place for the——

Mr. DEAL. Which is part of that negotiation that Mr. Rodgers——

Mr. FULLER. Exactly.

Mr. DEAL. [continuing] referred to.

Mr. FULLER. Well, it is not to say that it is not fair, but pharmacies can only participate, and I have already said they do participate in this, if they can recover their costs, the cost that they paid for the product, recover the cost of dispensing the medication, and make some small margin, and the profit margin is very, very small.

Mr. DEAL. You are probably not prepared to do this today, but would you give me a follow-up on what your pharmacists in Arizona have to say about the plan that they participate in and their degree of satisfaction? I think that would be a very interesting item.

Mr. FULLER. Certainly, Mr. Chairman.

Mr. DEAL. And I might just close in my 10 seconds. Ms. Baldwin asked the question of CBO about how do you make any relationship to what we can predict in Medicare part D. I think you have made the point in your presentation that if we want some comparisons as to what to expect in Medicare part D—yours is a very good example of that—and if that is an example, you are currently 38

percent below the national average on pharmaceutical cost, as understand it. And in fact, you are 11 percent below the next most cost-effective State, that being Michigan. So I suppose we sort of produce an answer to say that if we want some degree of speculation, maybe the Arizona plan would be a good way to reach that conclusion. Would that be an accurate statement?

Mr. RODGERS. I think Arizona is unique because of the fact that we have managed care, and the MMA plan anticipates managed care as well as managed pharmacy benefits. So our members are already used to that. The key is that, again, the provider is the one who gets the leverage to prescribe brand or prescribe generic, and the key is will the providers' behavior change because they are in MMA? We don't know yet, but that is our concern.

Mr. DEAL. Thank you. My time has expired.

Mr. Brown.

Mr. BROWN. Mr. Rodgers, thank you for explaining obviously a very good system.

In spite of facts to the contrary, there is a pretty strong ideological bias on this committee that the private sector always does things better and can be counted on to deliver darn near anything to the public, and serving the public interests. I appreciate your comments about what you have done with managed care in Arizona with for-profits and not-for-profits. Do you just turn these programs over to the private sector for-profits and not-for-profits and let them go to work? Or what kind of oversight do you have to make sure that they are serving the people of Arizona?

Mr. RODGERS. Thank you for that question. No, I think the role that the State plays is to assure that the member first is getting the services that they are supposed to get. We contract with our health plans to assure that services are rendered, so we have a significant oversight responsibility. What we gain from the health plans is their negotiating power. They have information, and they can position in a way that oftentimes is difficult for a single State to position themselves. So we have been able to take advantage of that, but the reality is that the State has to be part of this as a public-private partnership, and that is how we refer to ourselves, as a public-private partnership, taking the best of what health plans have to offer, public, non-profit, as well as for-profit, as well as the best of what the State can offer in terms of assuring that things are done according to our requirements.

Mr. BROWN. Thank you. In the interest of Mr. Burgess and Mr. Bilirakis, and I think the chairman wants to try to finish before we go vote, because you would all have to wait for another 45 minutes to an hour, and my guess is you probably don't want to do that, let me just kind of go less than my 5 minutes. I appreciate what you said about Arizona not having co-pays. I think that is very significant, especially in light of the fact that the Governors came in here saying that we needed co-pays and that we needed to up the co-pays. And there is all kind of evidence that that drives people out of the system and ends up often costing the system more, because they don't get health care when they need it; they get it at more expensive times. So I just wanted to thank you for your comments about that, and I think you can be used as an example for a whole lot of us in a whole lot of places.

Thank you, Mr. Chairman.

Mr. DEAL. Thank you, Mr. Brown. I appreciate your cooperation on that.

Mr. Bilirakis.

Mr. BILIRAKIS. Thank you.

Mr. DEAL. We are going to try to finish, by the way——

Mr. BILIRAKIS. Yes.

Mr. DEAL. [continuing] because we have about five votes.

Mr. BILIRAKIS. Yes, we will try to get this thing done.

Ms. King, does Medicaid overpay? Briefly.

Ms. KING. I can't answer that question based on the study that we conducted.

Mr. BILIRAKIS. Okay.

Ms. KING. It is not an issue we have looked at.

Mr. BILIRAKIS. What does GAO think of the Arizona plan? Is it working? Is the quality there? Is there good customer satisfaction, et cetera?

Ms. KING. I hate to give you another "I don't know", but we haven't evaluated it.

Mr. BILIRAKIS. Oh, you have not evaluated it? That is not something you are charged to do, though, is it?

Ms. KING. Typically, we do our work at request of Members of Congress.

Mr. BILIRAKIS. Yes, and you have not been requested to do it.

Mr. Fuller, how do your pharmacists like the Arizona plan, the pharmacists in Arizona?

Mr. FULLER. Well, I think it is a plan they certainly participate in, and it is certainly meeting the needs of many people in Arizona. It is a managed care plan. Some are speculating that the Medicare programs may, in fact, move to managed care, because you are really working on all of the healthcare costs associated with that patient. There do have to be incentives, clearly, to drive generic utilization, and I think understanding how those incentives work inside of managed care is important, particularly if there is a desire to turn away from the co-payments. The stand-alone plans that don't have some of the incentives that managed care would provide, would have a——

Mr. BILIRAKIS. You are giving me a lawyer's answer. Your pharmacists, are they relatively happy with the plan or is it just that that is the only thing that is available?

Mr. FULLER. It is hard to find pharmacists that are relatively happy today. I would say they are participating in the program, and the economic model is one that, clearly, most can live with. I don't think there is a problem with participation. I do promise to get back to the chairman and through him to the committee on a little bit more analytical document there.

Mr. BILIRAKIS. And I would like to ask—there will be a number of inquiries coming at you all, which you would be responding in writing. I would also like to get the chain drug stores' comments on the rebate system. What do you think about the rebate system, and do you like it, and that sort of thing?

In the interest of time, I will just go ahead and yield back for Mr. Burgess, Dr. Burgess. Thank you.

Mr. DEAL. Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman.

Mr. Rodgers, I must admit, when you started your testimony, there were several things you said that sent cold chills down my spine and the step therapy. Of course, my familiarity with that is as a physician. When an insurance company did step therapy, they were basically practicing medicine without a license, but it sounds like, in your models, as that concept was developed further, that you do have buy-in from your providers. And I think that the chairman's enthusiasm for your program is well founded, but the key there is apparently how you treat your providers and how you use the word leverage. Break that down for the committee, and tell us how you have managed to do that.

Mr. RODGERS. Really quickly, managed care has gotten a bad reputation because of how it has been managed, if you will. And it has, oftentimes, inappropriately leveraged providers by lowering rates and creating additional hassle. The key to controlling Medicaid cost is really having your providers buy into how your medical models work. And so we don't balance our budget on the back of our provider rates. But because we save in so many other areas, including in-patient utilization, emergency room utilization, the pharmacy costs, we are able to then allow our providers, especially our primary care physicians, who are so important, to have appropriate rates. And so that is the first premise of the program.

I think the other is the fact that we have multiple plans allows the provider to choose between plans. If they don't like a particular plan, if they feel that plan has too many hassle factors, if you will, they can choose to contract with a different plan. And many of them do. They have their plans they like and two or three that they will contract with. Then the member chooses the plan based on the provider networks. So it is a balanced approach to the market. It allows the member to make a choice based on provider network and to choose a provider within the plan. It allows the provider to choose the plan they want to contract with. And the plans themselves then compete for both providers as well as members.

Mr. BURGESS. And Mr. Chairman, I would just point out that I think the State of Arizona is very fortunate to have Mr. Rodgers in charge of that plan. I suspect it would not work as well without his steady hand on the helm, and perhaps we ought to see if we can steal him away. It is time for you to shine at the national level.

As far as the issue of co-pays go——

Mr. RODGERS. My Governor is in town. I——

Mr. BURGESS. I understand. As far as the issue of co-pays goes, I, too, am grateful, and I understand the issue of co-pays. I do think we have to be careful to completely abandon the concept, though I feel that the community pharmacists' pain, or the chain store pharmacists' pain that if the co-pay is not paid, you are essentially the one who is paying that. And of course, that would be true at the physician or hospital level as well.

Mr. Calfee, just so that we are sure to include you in this, your neighbor there, Ms. Gifford, who had to leave, made the statement that one of the things that she thought would be important would be for the Director of HHS to be able to negotiate drug prices. Do you have an opinion about that?

Mr. CALFEE. Yes. I think that would be a bad idea. I think we are much better off if we have a situation more like the one that was just described in Arizona where you have competing buyers and competing sellers. If you have only one buyer, the danger is that you are going to start forcing prices down toward marginal costs, and what that does is it reduces the payoff from research and development, and at some point, you are going to start to dry up the supply of innovative drugs.

Mr. BURGESS. Thank you. And then, Mr. Fuller, just one last point, and you might get to the committee. We weren't supposed to use any more three-letter acronyms, but you brought us a new one with your wholesale acquisition cost. And that seems to be, as you used the term, a real world representation of what things actually cost. And you might just provide the committee a little bit more information about that, and perhaps, Mr. Chairman, that is something we should look into as well. So I thank you for bringing that to our attention.

Mr. FULLER. We certainly will do so.

Mr. DEAL. Well, thank you. I appreciate the members' cooperation, and I certainly appreciate, once again, the participation of this panel. It really is one of the better hearings I think we have had on this issue. We are beginning to broach the subject, as you can tell, and try to educate ourselves, and you have been very helpful in that endeavor. And we thank each of you.

We apologize again for the time delay. You may very well be asked to respond to some written questions that the committee members may have, and we would appreciate your doing that as well.

Thank you again for your presence. This hearing is adjourned.

[Whereupon, at 6:09 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

Hearing Before the Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
"Medicaid Prescription Drugs: Examining Options for Payment Reform"
June 22, 2005

Questions Submitted for the Record to
Dr. Douglas Holtz-Eakin, Director
Congressional Budget Office
August 1, 2005

Honorable John D. Dingell

Question 1:
In the Congressional Budget Office (CBO) report on pharmacy reimbursement, you discuss the issue of how drug manufacturers and pharmacists can "game" the Medicaid reimbursement for drugs through the federal upper limit (FUL), eroding potential savings to Medicaid from the use of generic medicines. The FUL limit, as you know, is an upper bound on how much Medicaid will reimburse for generic or multi-source drugs.

The problem, as I understand it, is that when a new medicine comes to market, before it has an upper bound or "FUL" limit, it is paid based on the list price set by drug manufacturers, and drug manufacturers inflate this list price offering pharmacies the opportunity for greater reimbursement if they choose to dispense that medicine.

Some have suggested requiring the Centers for Medicare and Medicaid Services (CMS) to update the FUL list more frequently, to move drugs more quickly from the higher "list price" to a more accurate price limit. Even though some states have already taken action to establish limits lower than the CMS-established FUL, do you believe that we could still achieve some federal and state savings by requiring more frequent updates by CMS of the list?

Does CBO have other suggestions for how to address this "gaming" that occurs in the system?

Answer:
A number of studies have found that CMS does not issue FUL prices for some multiple-source drugs as rapidly as possible. Setting FUL prices for those drugs in a more timely manner would reduce Medicaid spending on prescription drugs. However, some of the potential savings are already being realized through states' maximum allowable cost (MAC) programs.

Giving the states and CMS the ability to estimate pharmacy acquisition costs through average prices actually charged by manufacturers, rather than list prices, could be helpful.

Question 2:
As you are aware, the Medicare Modernization Act includes a provision known as the "claw back" by which states must pay back to the federal government a portion of the savings they receive from the transition of low-income Medicare beneficiaries (who today get their medicines from Medicaid) to the Medicare drug benefit. Under the law, the base year for determining these payments is 2003. A number of states, however, have taken innovative steps to lower drug spending in Medicaid since that time. Those states will not get credit for these savings and will be forced to "overpay" the federal government.

Has the Congressional Budget Office examined this issue? Could you tell me what the cost implications would be if Congress were to move the base year for the claw back calculation to 2004?

Answer:
The MMA requires states to pay the federal government a portion of their expected savings from the federal government for assuming the costs of covering prescription drugs for the dual eligibles. Those payments, broadly referred to as "clawback" payments, are determined on a state-by-state basis according to a formula that relies on estimated per capita spending on drugs under Medicaid for dual eligibles. That per capita amount is determined using calendar year 2003 as a base and is inflated for years 2004 through 2006 by per capita growth in spending in the National Health Expenditure (NHE) accounts and for 2007 and subsequent years by per capita growth in drug spending under the Medicare prescription drug program.

CBO estimates that, on average, per capita spending for dual-eligibles grew faster in 2004 than the statutory inflator. Therefore, changing the base year for the clawback from 2003 to 2004 would result in higher payments from the states to the federal government, CBO estimates. While some states might pay less to the federal government under this policy, states overall would pay more than they are required to under current law.

Honorable Charlie Norwood

Question 1:
Dr. Holtz-Eakin, in your testimony, you describe the significant pharmacy markups that you say that you identified on some Medicaid generic drugs in 2002 in your December 2004 report.

Part 1. In the chart you showed to the Committee, you included data on the average markup for all Medicaid brand prescriptions, but not for "all" generic prescriptions, just those with "excessive" markups. What was the markup for all Medicaid generic drugs in 2002?

Answer: The chart that CBO showed the committee included the average markup on newer generic drugs of $32.10 and on older generic drugs of $9.90. When averaged across all generic drugs, the average markup in 2002 was $13.80. Those figures appear in Table 1 and Table 4 of CBO's report *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (December 2004).

Part 2. If you had these data with you regarding the average markup on all generics at the hearing, why didn't you also show them in the chart that you showed the Committee?

Answer: Those data are included in the CBO report submitted as part of the testimony for this hearing.

Part 3. Once you show the markups for all generics for the 2002 data, how did these markups compare to brand name drugs for the same period?

Answer: The markups across all generic drugs look similar to those for brand-name drugs in 2002.

Part 4. You said that the "markups" for all generic drugs increased by 79% between 1997 and 2002. What was the actual dollar increase in these markups during this time?

Answer: CBO estimated that the average markup on generic drugs increased from $7.70 to $13.80 between 1997 and 2002–or by $6.10 per prescription.

Part 5. If the markups for brands were higher than generics, then is it possible that it might have created incentives for pharmacies to dispense higher cost brands?

Answer: The markup on brand-name drugs is higher than that for older generic drugs, on

average. CBO's estimated markups include what is retained both by pharmacies and by wholesalers. The relative profitability to pharmacies of those two types of drugs is not clear since CBO has not separated out what the pharmacies themselves retain on average.

If a brand-name drug were more profitable to dispense than its generic counterpart, the pharmacist would have an incentive to dispense the brand-name drug. However, when the same upper limit is placed on the reimbursement of both a brand-name drug and the generic version (through the FUL or a state MAC list), such a policy usually makes it less profitable to the pharmacy to dispense the brand-name drug.

Part 6. What percentage of all Medicaid prescriptions did the generics with "excessive" markups represent as a total of all Medicaid prescriptions?

Answer: Those drugs with the highest markups were newer generic drugs. According to the report that CBO submitted as part of the testimony, in 2002 new generic drugs accounted for about 8 percent of all Medicaid prescriptions dispensed (Table 3).

Part 7. Why in your opinion are the markups for these more recent generics more excessive than older generics? What role does six-month FDA pediatric exclusivity play in this situation?

Answer: CBO has not analyzed in detail the underlying causes of the higher markups on newer generic drugs.

Part 8. Did the CBO look at whether the total reimbursement to pharmacies across all Medicaid prescriptions was adequate?

Answer: CBO does not have data on the cost of distributing and dispensing drugs, nor on the cost of operating pharmacies that serve Medicaid patients. Therefore CBO was not able to compare the estimated markups to the cost of distributing and dispensing drugs in the 2004 report. Nonetheless, it is worth noting that Medicaid payment levels are sufficient to encourage widespread participation of pharmacies in the Medicaid program.

Question 2:
Dr. Holtz-Eakin, in your remarks before the Committee, you indicate that retail pharmacies "negotiate" with brand name drug companies for the prices of the prescription medications that they buy. My understanding is that retail pharmacies have little or no negotiating leverage with brand name manufacturers. Can you provide me with specific evidence showing that retail pharmacies have purchasing leverage with brand name manufacturers?

Answer:
The statement about negotiations was in reference to a slide presented at the hearing showing the payment flows for prescription drugs in the Medicaid system. The comment referred to

prescription drugs in general, not just to brand-name drugs. The principal point is that the price at which prescription drugs are exchanged between the drug manufacturer and the pharmacy is determined in the private marketplace as opposed to being set according to a government-specified formula.

Question 3:
Dr. Holtz-Eakin, has CBO done any modeling on the impact of using AMP or ASP as a reimbursement metric on the impact on generic use in Medicaid? What would be your assumptions regarding the impact on pharmacy dispensing of lower-cost generics in Medicaid if the system moved to either of these two metrics for pharmacy reimbursement?

Answer:
In general, state Medicaid programs' payments to pharmacies have two components: reimbursements to pharmacies for the cost of acquiring the drug, and payments to pharmacies for dispensing drugs to Medicaid beneficiaries. Moreover, CBO assumes that the goal of states is to keep pharmacies participating in the Medicaid program. To do so, the overall payments must cover both pharmacies' acquisition costs and the cost to the pharmacy of dispensing drugs. (That dispensing cost includes normal profit.)

Under current law, the former component is generally based on average wholesale price (AWP), a federal upper limit price, or a maximum allowable cost set by the state. For many drugs, that component of the payment substantially exceeds pharmacies' actual acquisition costs. As a result, states are able to establish dispensing fees that are generally below pharmacies' costs of dispensing drugs, while ensuring that the combined payment for acquisition and dispensing costs is sufficient to keep pharmacies participating in the Medicaid program.

Moving from AWP to AMP or ASP is an attempt to enable states to more accurately reimburse pharmacies for acquisition costs. However, the general budgetary effects depend also on incentives for pharmacies—such as those developed to encourage pharmacies to dispense generic drugs. In CBO's view, when estimating a proposal, the effects of that proposal on the pharmacies' incentives are as important as the effects on the ability of state Medicaid programs to accurately reimburse acquisition costs while paying a reasonable amount for the service of dispensing a drug.

Honorable Mike Rogers

Question 1:
The AWP reimbursement system seems incredibly dysfunctional. Generic drugs are supposed to be a cheaper alternative for brand-name prescription drugs, yet Medicaid has created a system where generic prices are inflated to artificially high levels. As a result, generics are far less effective at driving competition and lower prices. How can the current system be reformed to more accurately reflect the pharmacists' acquisition costs, while at the same time encourage appropriate generic utilization?

Answer:
Generic manufacturers compete for market share by setting low prices. But that price competition is not fully reflected in the list prices upon which states base their Medicaid pharmacy payment rates. States do not have access to average market prices, such as the AMPs. And while CMS collects the AMPs under Medicaid's rebate program, it is not permitted under current law to use the AMPs when setting the federal upper limit on reimbursement for multiple-source drugs. Proposals to move from a system based on list prices to one based on AMP or ASP would enable states and CMS to act on more accurate information on pharmacy acquisition costs.

The effect that a proposal has on a pharmacist's incentive to dispense a generic drug is also important. Currently, when states set an upper limit on the payment rate for a multiple-source drug, that encourages the pharmacist to dispense a less expensive generic drug over its brand-name counterpart. In addition, some states have set higher dispensing fees for generic drugs than for brand-name drugs.

United States Government Accountability Office
Washington, DC 20548

July 22, 2005

The Honorable John D. Dingell
Ranking Member
Committee on Energy and Commerce
House of Representatives

Dear Mr. Dingell:

I am writing in response to your July 11, 2005 request asking for our comments on two follow-up questions from the June 22, 2005 Subcommittee on Health's hearing entitled "Medicaid Prescription Drugs: Examining Options for Payment Reform." For your convenience, I have included your original questions with our responses below.

Question 1: As you have testified, the Centers for Medicare and Medicaid Services (CMS) has been lax in their oversight of the Medicaid drug rebate program. Could you please detail the shortcomings of CMS's current oversight of the Medicaid rebate program and tell me what specific additional steps you believe CMS should take in this area?

GAO Response: In February 2005, we reported that the minimal oversight by CMS and the Department of Health and Human Services Office of the Inspector General (OIG) of manufacturer-reported prices and price determination methods does not ensure that those prices or methods are consistent with program criteria, as specified in the rebate statute, rebate agreement, and CMS program memoranda.[1] As we reported, CMS conducts limited reviews of prices and only reviews price determination methods when manufacturers request recalculations of prior rebates OIG has issued four reports on audits of manufacturer-reported prices since the program's inception in 1991. OIG reported that, in the course of its work, its efforts were hampered both by unclear CMS guidance on determining average manufacturer price (AMP) and by a lack of manufacturer documentation. In some instances, OIG found problems with manufacturers' price determination methods and reported prices. However, CMS has not followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved.

[1]See GAO, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Washington, D.C.: Feb. 2005).

CMS's Review of Manufacturer-Reported Prices Is Limited: As we reported, as part of CMS's administration of the Medicaid drug rebate program, the agency reviews drug prices submitted by approximately 550 manufacturers that participate in the program. Each quarter, CMS conducts automated data edit checks on the best prices and AMPs for about 25,000 drugs to identify reporting errors. These checks are intended to allow CMS to ensure that all drugs for which manufacturers report prices are in its database of Medicaid-covered drugs and to ensure that those prices are submitted in the correct format. The agency's automated data checks also are intended to ensure that the correct price is used when there are multiple prices for the same drug. When data checks indicate a potential reporting error, CMS sends an edit report to the manufacturer asking for corrected drug prices. However, CMS does not have a mechanism in place to track whether, in fact, manufacturers submit corrected prices.

We also reported that CMS sometimes identifies other price reporting errors when it calculates the unit rebate amount for a drug, but the agency does not follow up with manufacturers to verify that errors have been corrected. CMS will notify a manufacturer of any missing price data for drugs in its database or any large deviations from previous unit rebate amounts. For example, CMS would send a report to a manufacturer that had a unit rebate amount for a drug that deviated from that of the prior quarter by more than 50 percent. It would be up to that manufacturer to indicate whether or not the underlying reported prices were, in fact, correct. If a manufacturer determined that there were problems with the reported price for a drug—such as incorrect unit pricing or typographical errors like misplaced decimals—it would send corrected data to CMS prior to or with future price submissions. In this situation, the manufacturer also would recalculate the unit rebate amount and, once invoiced by the states with total utilization for the drug paid for by Medicaid, would send the rebate payment to those states based on the recalculated unit rebate amount. If a manufacturer did not send revised pricing data to CMS, then the unit rebate amount would remain the same. In 2000, CMS generated approximately 150 reports detailing these 50 percent deviations, according to an agency official. The agency did not track how many unit rebate amounts were changed as a result or any effect on rebates.

Price Determination Methods Are Reviewed Only When Manufacturers Request Recalculations: As we reported, CMS does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP, even though these methods and assumptions can have a substantial effect on rebates. While the rebate agreement requires manufacturers to maintain documentation of the assumptions underlying their price determination methods, CMS does not verify that such documentation is kept and rarely requests it. Furthermore, CMS does not generally check to ensure that manufacturers' assumptions and price determination methods are consistent with the rebate statute and rebate agreement.

CMS reviews the methodologies employed to determine best price and AMP only when manufacturers request recalculations of prior rebates. A manufacturer may request a recalculation of a prior rebate- any time it changes the methods it uses to determine best price or AMP. CMS requires the manufacturer to submit both its original and its revised methods for determining those prices when requesting a recalculation of prior rebates, so that it can evaluate whether the revised methods are consistent with the rebate statute, rebate agreement, and program memoranda. Six approved recalculations that we reviewed reduced prior rebates to states by a total of more than $220 million. An additional approved recalculation required the manufacturer to pay states an additional $388,000.

OIG Reports That Its Efforts Have Been Limited by Unclear Program Guidance: OIG has issued four reports on audits of manufacturer-reported prices since the program's inception in 1991. Three of the four OIG reports documented limitations to OIG's ability to verify drug prices. OIG reported that its efforts were hampered by unclear CMS guidance on determining AMP, by a lack of manufacturer documentation, or by both. In particular, OIG found that a lack of specificity on how the "retail pharmacy class of trade" was defined limited its efforts to verify AMP. Both the rebate statute and rebate agreement define AMP as the average price paid by wholesalers for drugs distributed to the retail pharmacy class of trade, with some exceptions. OIG officials told us that program memoranda issued by CMS have not provided sufficient guidance on AMP to allow OIG to audit manufacturers' methods for determining AMP. Despite these limitations, in some instances OIG was able to identify some problems with the accuracy of manufacturers' reported prices; however, CMS has not followed up with manufacturers to make sure that these problems with prices and price determination methods have been resolved.

Recommendations: As reported in February 2005, based on our work we recommended that CMS take several steps to improve program guidance and oversight, namely issue clear guidance on manufacturer price determination methods and the definitions of best price and AMP; update such guidance as additional issues arise; and implement, in consultation with OIG, systematic oversight of the price determination methods employed by pharmaceutical manufacturers and a plan to ensure the accuracy of manufacturer-reported prices and rebates to states. In its comments on a draft of the report, HHS agreed with the importance of guidance to manufacturers, but disagreed with our conclusion that there has been inadequate program oversight. While the draft report cited oversight activities HHS has undertaken, we believe that its oversight does not adequately ensure the accuracy of manufacturer-reported prices and rebates paid to states.

Question 2: If this is how CMS administers the prescription drug component of a program of this magnitude, I have concerns about how CMS will be administering a $535 billion Medicare prescription drug benefit using private entities over which it has even less control. Does the Government Accountability Office believe that CMS

has the institutional capability to oversee the Medicare prescription drug benefit effectively? Are there weaknesses at CMS that need to be addressed? Are there any steps you recommend that CMS take at this point to protect the Federal Government and beneficiaries against fraud?

GAO response: Since 1990, GAO has designated Medicare a high-risk program that is vulnerable to exploitation and mismanagement, in part due to its size and complexity. We have previously noted that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) created new challenges for administering the Medicare program.[1] One key challenge is the prescription drug benefit, which has an estimated cost to the federal government of $8.1 trillion in today's dollars to pay for the benefit over the next 75 years.

In past reports, we discussed a number of issues that related to CMS's management of Medicare. We reported to you in 2001 that CMS faced challenges in managing Medicare and that its record of success in the past had been mixed.[2] We stated that although the agency had performed some of its core missions well, it had experienced difficulties in paying claims properly, overseeing Medicare claims administration contractors, and ensuring quality of care in some areas. We also noted the importance of the agency having the necessary tools to carry out its mission; we stated that both adequate resources—in terms of both dollars and human capital—and an organizational focus on results and accountability were critical to the agency's success. We noted a number of factors, including shortages of staff in key areas such as data analysis and managed care arrangements, that at the time limited the agency's ability to improve its operations. More recently, we reported on problems with CMS's efforts to educate Medicare beneficiaries through 1-800-MEDICARE, including inaccurate answers provided by customer service representatives, insufficient training for those representatives, and the need for new types of monitoring of the answers they provided to beneficiaries.[4] In both reports, we noted our recommendations on these issues, as well as some actions the agency had taken in response to these issues.

Many of our past recommendations related to CMS's oversight of Medicare are also applicable to the new drug benefit. Our past work on Medicare management, for example, suggests that effective oversight of entities contracted by CMS is critical. Since private entities will actually provide the drug benefit to beneficiaries, effective oversight of these contracted organizations by CMS will be crucial to the success of the drug benefit. Other previous recommendations from our work on Medicare management, including payment accuracy and effective beneficiary education, will also be important. CMS faces many challenges with the new Medicare drug benefit,

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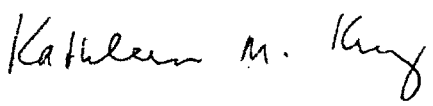
[1]See GAO, *High-Risk Series: An Update*, GAO-05-207 (Washington, D.C.: Jan. 2005).
[2]See GAO, *Medicare Management: CMS Faces Challenges to Sustain Progress and Address Weaknesses*, GAO-01-817 (Washington, D.C.: July 2001)
[4]See GAO, *Medicare: Accuracy of Responses from the 1-800-MEDICARE Help Line Should Be Improved*, GAO-05-130 (Washington, D.C.: Dec. 2004).

not only because of the large amount of federal money involved, but also because the benefit itself is complex and unlike other benefits that CMS has previously administered. Consequently, CMS's development and implementation of effective oversight capacity and systems for the new Medicare drug benefit is essential.

If you or your staff have further questions, please contact me at (202) 512-7118 or via e-mail at kingk@gao.gov.

Sincerely yours,



Kathleen King
Director, Health Care

Craig L. Fuller
President & CEO

September 6, 2005

The Honorable Nathan Deal
Subcommittee on Health, Chairman
Committee on Energy and Commerce
United States House of Representatives

Dear Chairman Deal:

The National Association of Chain Drug Stores (NACDS) is writing to provide responses to two questions submitted by Congressman Mike Rogers as a result of my testimony before the June 22nd hearing before the House Committee on Energy and Commerce, "Medicaid Prescription Drugs: Examining Options for Payment Reform".

The questions and answers are appended to this letter. We appreciate the opportunity to provide testimony at the hearing and ask that you call on us if we can provide further information to you.

Best Regards,

Craig L. Fuller

Enclosures: University of Texas Cost of Dispensing Assessment
Issue Brief on Differences in Costs Between Medicaid and Third Party Payors

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Question 1: In his remarks before the Committee, Dr. Holtz-Eakin of CBO indicated that retail pharmacies have negotiating leverage with brand name manufacturers. Can you please describe the type of leverage that retail pharmacies have with brand name drug manufacturers.

Mr. Chairman, contrary to the statements made by the CBO director, retail pharmacies have no price negotiating leverage with manufacturers of single source brand name drugs. That is, we are not able to negotiate with these manufacturers to reduce the prices that retail pharmacies pay to purchase these medications. These medications are patented and available from only one source of supply.

When a physician writes a prescription for a single source drug, pharmacies have to fill these prescriptions as written. Pharmacists cannot substitute other drug products, such as generics or other lower-cost brand drugs, without the permission of the physician in these cases. While retail-based pharmacists could seek permission from physicians to switch a single source brand name drug to a generic drug or another lower cost brand name drug, they would have to call the prescribing physician each time to discuss the treatment options with the physician. The pharmacist would then have to generate a new prescription if the physician chose an alternative drug.

Some "closed" health care systems such as hospitals and HMOs might use restrictive formularies that require contracted or affiliated prescribing physicians to adhere to the institution's or plan's formulary, including for single source drugs. In these cases, the physicians agree to prescribe or have used in their patients the drugs that are included on the institution's or plan's formulary. These facilities and health plans have more leverage with manufacturers over pricing of single source drugs.

On the other hand, Medicaid benefits from the intense generic drug price competition and price transparency among retail pharmacies. The purchasing leverage of retail pharmacy forces competition among generic drug makers to earn a pharmacy's business. This competition lowers prices paid by pharmacies for generic drug products and these lower generic drug prices are passed along to consumers.

Medicaid also benefits from generic drug price competition between retail pharmacies because Medicaid programs typically reimburse pharmacies the "lower of" the program's payment formula for a generic drug (i.e., FUL plus dispensing fee or MAC plus dispensing fee) *or* the pharmacy's "usual and customary" charge to cash customers. In many cases Medicaid pays a pharmacy's lower "usual and customary" price rather than the amount determined by the generic payment formula. As a result, the average generic prescription reimbursement in Medicaid has only increased by about $7 per prescription over the last 7 years, from $13 in 1998 to $20 today, while the average brand name prescription reimbursement has almost doubled from $63 in 1998 to $122 today. Clearly, Medicaid is benefiting from the price competition generated by retail pharmacy at multiple levels in the distribution chain.

Question 2: Why do chain pharmacies fill Arizona ACCCHS Medicaid prescriptions for $2 when they take $4 or $5 from other states to fill Medicaid prescriptions? What is your current estimate of the cost of dispensing a Medicaid prescription?

We are often asked why pharmacies might fill a prescription for a lower dispensing fee in private third party prescription plans as compared with Medicaid programs. The cost of dispensing prescriptions varies by state and by third party program. Thus, it is not uncommon to find that pharmacies accept different rates from different payers both across the states and within a specific state.

Many factors must be considered when a pharmacy determines whether or not to accept a particular reimbursement from a third party program. For example, the amount of the dispensing fee paid is only one component of reimbursement. While the prescription dispensing fee may only be $2, pharmacies consider negotiated rates in the aggregate. That is, pharmacies take into account both the product payment and the dispensing fee when deciding whether to accept contract rates.

Moreover, given the high percentage of generic dispensing in AHCCCS, pharmacies may have lower "costs of goods" to serve AHCCCS recipients. That is, because prices paid by pharmacies are typically much lower for generics compared to brand name drugs, higher generic dispensing levels may reduce pharmacies' costs of participating in AHCCCS relative to other state Medicaid programs. Pharmacies may also earn better overall total margins on the AHCCCS book of business because of the higher generic dispensing rates. Plans also may offer other bonus payments to pharmacies that achieve certain targeted generic dispensing rates.

The fact that there are no beneficiary co-payments for pharmacy services in AHCCCS also can help reduce pharmacies' costs of participating in AHCCCS compared to other states' Medicaid programs. There are many cases where pharmacists cannot collect recipients' co-payments in other states. When a pharmacist cannot collect a copayment, it is the same as a reduction in the dispensing fee received, since Federal law prohibits states from reimbursing pharmacies for uncollected co-payments.

In the final analysis, while there is a high level of participation by almost all pharmacies in Arizona, our members indicate that payments made by AHCCCS are below costs. A recent assessment conducted by the University of Texas at Austin's Center for Pharmacoeconomic Studies found that it cost about $9.62 for a retail pharmacy to dispense a prescription. Medicaid prescription dispensing costs tend to be higher for various reasons. We have appended a copy of that assessment to this letter. We also have included an issue brief that describes the differences in costs to pharmacies between dispensing a Medicaid prescription and a commercial third party prescription.

PREPARED STATEMENT OF THE ASSOCIATION FOR COMMUNITY AFFILIATED PLANS

The Association for Community Affiliated Plans (ACAP) is pleased to submit this statement for the record to the House Energy and Commerce Committee on the topic of the hearing entitled Medicaid Prescription Drugs: Examining Options for Payment Reform. ACAP represents 19 Medicaid-focused managed care plans that serve over two million Medicaid beneficiaries in states across the country. The mission of our organization is to improve the health of vulnerable populations through the support of Medicaid-focused community-affiliated health plans committed to these populations and the providers who serve them.

ACAP is supporting a policy change that will help Federal and State governments save billions of dollars on prescription drugs provided to Medicaid beneficiaries enrolled in Medicaid health plans. This policy change would give Medicaid health plans direct access to the Medicaid drug rebate. The following statement outlines the history of the drug rebate and the justification for the policy change.

Created by the Omnibus Budget Reconciliation Act (OBRA) of 1990, the Medicaid Drug Rebate Program requires a drug manufacturer to have a rebate agreement with the Secretary of the Department of Health and Human Services for States to receive federal funding for outpatient drugs dispensed to Medicaid patients. At the time the law was enacted, managed care organizations were excluded from access to the drug rebate program. In 1990, only 2.8 million people were enrolled in Medicaid managed care and so the savings lost by the carve-out were relatively small. Today, 12 million people are enrolled in capitated managed care plans.

Under the drug rebate, States receive between 18 and 20% discount on brand name drug prices and between 10 and 11% for generic drug prices. At the time the rebate was enacted, many of the plans in Medicaid were large commercial plans who believed that they could get better discounts than the federal rebate. Today, Medicaid-focused plans are the fastest growing sector in Medicaid managed care. According to a study by the Lewin Group, Medicaid-focused MCOs typically only receive about a 6% discount on brand name drugs and no discount on generics. Because many MCOs (particularly smaller Medicaid-focused MCOs) do not have the capacity to negotiate deeper discounts with drug companies, Medicaid is overpaying for prescription drugs for enrollees in Medicaid health plans.

The Lewin Group estimates that this proposal could save the federal and state governments and plans up to $2 billion over 10 years. This legislation has been endorsed by organizations representing both state government and the managed care industry, including the National Association of State Medicaid Directors, the Association for Community Affiliated Plans, Medicaid Health Plans of America, the National Association of Community Health Centers, and now, the National Governors Association.

As Congress is forced to make tough choices to control the costs of the Medicaid program, this proposal offers a "no-harm" option to control costs and ensure that there is not a prima facie pharmacy cost disadvantage to states using managed care as a cost effective alternative to Medicaid fee-for-service. We urge Congress to implement it as part of any Medicaid reform proposal that moves forward.

PREPARED STATEMENT OF RONALD POLLACK, EXECUTIVE DIRECTOR, FAMILIES USA

Thank you for allowing us to submit this statement for the record. Families USA is a ational organization for health care consumers. Our mission is ti ensure that all Americans have access to high-quality affordable health care. Like everyone at the hearing, we aer deeply concerned about the future of the Medicaid progran and look forward to working with the Energy and Commerce Committee to strengthen and impr4ovr Medicaid on behalf of the 53 million vulnerable children, seniors and people with disabilitieswho rely on the program for their health care needs.

As you know, the Budget Resolution requires the Senate Finance Committee to identify $10 billion in budget cuts over the next 5 years. Similarly, it requires the House Energy and Commerce Committee to propose $14.7 billion in cuts over the same periob. Although the Budget Resolution does not explicitly direct these cuts to come from any specific programs, Medicaid has clearly been targeted and, in large part, that is why we are all here today.

First, it is important to emphasize that there is no requirement to cut as much as $10 billion from Medicaid. The cuts can occur through savings in other programs and as much of these expected savings as possible should come from programs not targeted toward low-income Americans. What is more, the budget process is not an appropriate forum for a conversation about "reforming' or in any way restructuring Medicaid. The program should be thoughtfully scrutinized to see if there are ways

to make it more cost-effective and efficient—and if so, those changes should be enacted.

There is, however,, one area where most agree some savings can be found without reducing services essential to those enrolled in the program. That is the area of prescription drug spending. There is widespread agreement that Medicaid pays too . . .

. . . in front of this Committee last week contains several very helpful recommendations regarding prescription drugs. We look forward to working with the Governors on their proposed improvements aimed at decreasing the costs of prescription drugs that are purchased by Medicaid.

There are lots of specific changes that could be instituted to help the federal government and the states reduce the rapidly increasing costs of prescription drugs. Such policies would need to be crafted carefully with appropriate safeguards to ensure that people are able to get the drugs they need and Medicaid gets the best price possible for drugs, and to encourage responsible prescribing, dispensing, and utilization of drugs. Strategies that may be worth considering include: changing the formula for calculating Medicaid "best price" and Medicaid rebates; changing the reimbursement rates to pharmacists for dispensing drugs; and improving the management of the prescription drug rebate program.

Families USA looks forward to working with this Committee to achieve as many savings as possible from prescription drugs. However, to the extent that Congress seeks budget savings from the other parts of the Medicaid program, certain principles should guide its work. Those principles include the following:

Health and long-term care coverage must continue to be guaranteed for those who qualify for Medicaid. Like Medicare, Medicaid assures that people who qualify must be enrolled and not be placed on waiting lists. Any changes in this basic principle would leave vulnerable people without access to health care, undermining the very purpose of the Medicaid program.

Financing should continue to be fully shared between the federal government and the states without caps. Today, the federal government guarantees to states that it will pay at least half of Medicaid's costs. Policies that shift costs and risks to the states or that impose caps on federal payments to the states (such as block grants) will lead to fiscal burdens on the states that they cannot afford and will result in significant cutbacks of coverage and a weakening of the health care system.

Benefits and cost-sharing should reflect the needs and economic circumstances of the people served by Medicaid. The Medicaid benefit package should be comprehensive and ensure that people are able to access benefits they need. Needed medical services should be available and affordable to the elderly, children, people with disabilities, and other adults covered by the program whose low incomes make it impossible for them to afford significant out-of-pocket costs. Changes that would effectively deny access to needed care or saddle low-income people and their families with costs they cannot afford to pay are counterproductive and inconsistent with the program's mission.