FULL COMMITTEE HEARING ON MEDICAID DRUG REIMBURSEMENTS: ARE CMS CUTS BAD MEDICINE FOR SMALL BUSINESSES AND BENEFICIARIES?

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FULL COMMITTEE HEARING ON MEDICAID DRUG REIMBURSEMENTS: ARE CMS CUTS BAD MEDICINE FOR SMALL BUSINESSES AND BENEFICIARIES?

Wednesday, July 18, 2007

U.S. HOUSE OF REPRESENTATIVES,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The Committee met, pursuant to call, at 10:00 a.m., inRoom 2360, Rayburn House Office Building, Hon. Nydia M. Velázquez [Chairwoman of the Committee] Presiding.

Present: Representatives Velázquez, Shuler, González, Cuellar, Braley, Clarke, Chabot, Davis, Fallin, and Buchanan.

OPENING STATEMENT OF CHAIRWOMAN VELÁZQUEZ

ChairwomanVELÁZQUEZ. Good morning. I call this hearing to order to address Medicaid Drug Reimbursement: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?

The matter we discuss today stems from the legacy of the last Congress. In February 2006, President Bush signed the Deficit Reduction Act, which directed the Centers for Medicare and Medicaid Services to recalculate the way it reimburses pharmacies for providing generic prescription drugs to Medicaid beneficiaries.

While evidence indicates that the old formula used by CMS resulted in some level of overpayment, the new formula clearly cuts too far. On July 6, the Centers for Medicare and Medicaid Services released a final rule which radically changed the old formula and could prove devastating to pharmacies and Medicaid recipients.

The new formula significantly reduces the reimbursements to the point where the General Accounting Office has determined pharmacies will be paid back for only 64 percent of their costs of acquiring generic prescription drugs. That represents a 36 percent shortfall.

I have many concerns that the impact of this rule could have on small businesses offering prescription drug coverage. These pharmacies have low profit margins and small retailers will be hit particularly hard. They tend to serve a higher proportion of Medicaid beneficiaries and get more of the revenue from prescription drugs. As a result of this change, many could be forced to close their doors.

This will not only hurt pharmacies, but it will affect overall access to care for Medicaid recipients. If these businesses close or drop out of the program, drug coverage will be reduced. Medicaid

is a critical component of our national health care system serving over 50 million. Without it, the vast majority of these people would join the ranks of the 46 million uninsured Americans.

What doesn't make sense to me is that while the intent of this new formula is to save money it, in fact, encourages the use of more expensive brand name drugs. The average Medicaid generic prescription is $20, while the average brand prescription is $120. While this may be good for the pharmaceutical companies, costs will be increased for the Federal Government and the states.

I believe the HHS Inspector General's report is a good starting point for us when we examine possible solutions to this problem. The IG recommends that CMS should find a better way to reflect the actual costs of these drugs. The IG's recommendation will remove outliers in drug prices that do not reflect the realities of the marketplace. It also provides an opportunity for pharmacies to alert the states and CMS when they can demonstrate their inability to acquire drugs at prices at or below reimbursement levels.

Tellingly, the IG says new federal reimbursement limits should be monitored closely. Their report noted that such costs could lead to access problems for Medicaid beneficiaries. These findings are also supported by the General Accounting Office. As the rule is written, it threatens the ability of thousands of small pharmacies to keep operating.

While the previous reimbursement formula may have overpaid pharmacies for generic drugs, the new one will make the issue worse. Our government should not be eliminating one problem only to create another. The General Accounting Office and HHS have shown there are better ways to ensure pharmacies are adequately paid for these generic drugs.

Unfortunately, CMS is prepared to move forward despite these objections. Today's hearing will hopefully shine some light on why the CMS should reconsider the rule.

I look forward to today's testimony and thank the witnesses for their participation. And now I yield to Mr. Chabot for his opening statement.

OPENING STATEMENT OF MR. CHABOT

Mr.CHABOT. Thank you, Chairwoman Velázquez, both for yielding and for holding this hearing on the Centers for Medicare and Medicaid Services, the CMS, rule implementing the Deficit Reduction Act's modification of the reimbursement limits for certain prescription drugs in the Medicaid program.

This hearing continues a long-standing effort by this Committee to convince CMS that good regulatory practice requires the agencies to promulgate rules that do not adversely affect the thousands of small business providers of necessary health care in the United States. Drug prices represent a rapidly increasing portion of monies devoted to health care in the United States. It is not surprising to find, then, that the Medicaid program also faces rapidly rising costs for drug reimbursement.

Under the Medicaid program, states are authorized to provide for reimbursement of prescription at levels established by CMS under authority delegated from Congress. According to the Government Accountability Office, the GAO, the cost of such reimbursement in

the Medicaid program rose by 870 percent in the 15-year period from 1990 through 2004.

Congress recognized that such growth was not sustainable, and in the Deficit Reduction Act of 2005—an act which I supported—it modified the payment from 150 percent of the list price to 250 percent of the average manufacturer's wholesale price, referred to by its acronym AMP. Savings are enhanced by calculating the 250, not on average of all drugs in therapeutic class, but, rather, on the lowest AMP in a therapeutic class.

The Congressional Budget Office, the CBO, estimated that the modification will represent about $1 billion in savings for the first few years of implementation, and then about $300 million thereafter. Congress directed CMS to promulgate regulations to implement the modifications in reimbursement rates.

A perusal of the rulemaking record, including comments from witnesses before us today, revealed substantial concern that the new methodology will not provide dispensers of pharmaceuticals with sufficient revenue to cover the costs of dispensing drugs under the Medicaid program, nor are these concerns simply the cry of the economically self-interested.

The Office of Advocacy of the United States Small Business Administration, the Inspector General of the Department of Health and Human Services, and the GAO also have noted that the formula will not allow them to recoup their drug acquisition costs, much less cover all of the costs associated with filling Medicaid prescription.

The result of the final rule will have unusually perverse results—results that could not have been intended by Congress in legislation entitled "Deficit Reduction." Pharmacies could reject Medicaid patients, leaving such individuals without access to drugs. Doctors, recognizing this, will then begin to require that specific brand-name drugs will be used, thereby raising the costs of drugs under Medicaid, the opposite result from what Congress intended.

Entitlement spending needs to be controlled, but it also must be controlled in a sensible manner that actually achieves limits on spending. Instead, we have a policy that provides rational economic actors, the necessity of finding ways around these limits, that will ultimately not lead to reductions in entitlement spending.

I am sure that CMS will testify that they are just implementing the law that Congress wrote, and they have no discretion to modify the policy to reduce adverse consequences on small business. That is an argument that CMS has made to Congress one too many times in the past six years, including this Committee.

For one, I am tired of hearing that. Even a quick perusal of the rather dense verbiage of the Medicare and Medicaid statutes will show that CMS is replete with discretion. But unlike other federal agencies, the Medicare and Medicaid statutes are ripe with exemptions from judicial review. It is about time that CMS rulemaking is subjected to the same scrutiny applicable to all federal agencies.

I look forward to working with the Chairwoman and other members of this Committee on ensuring that the provisions of the Administrative Procedures Act apply with full force and vigor to CMS. Otherwise, CMS will be back before this Committee on some other

rule blaming Congress while Congress argues that CMS has discretion to avoid any potential adverse consequences to health care providers.

I want to thank the witnesses, including Dennis Smith of CMS, for agreeing to testify on such short notice. While I understand that the preparation may be a hardship, I think the efforts of the witnesses will be very helpful to this Committee's understanding of the final rule and its effects on small business.

Again, I want to thank you for holding this hearing, Chairman Velázquez, and I yield back the balance of my time.

ChairwomanVELÁZQUEZ. Thank you, Mr. Chabot. And now I recognize Mr. Braley for an opening statement.

Mr.BRALEY. Thank you, Madam Chairwoman, and thank you for holding this important hearing. I would like to recognize and thank one of my constituents, Matt Osterhaus, for taking time from his busy pharmacy practice to join us today, and I am looking forward to his testimony, along with the testimony of all of our witnesses.

I am deeply concerned by the Center for Medicare and Medicaid Services' proposed changes in the reimbursement formula for prescription drugs in the Medicaid program. CMS claims that this new definition of the average manufacturer price is meant to approximate the prices at which retail pharmacies purchase generic medications from manufacturers and wholesalers.

Unfortunately, however, the final rule is flawed and will result in an AMP that does not reflect the true prices. In fact, a December 22, 2006, GAO report shows that the proposed rule on the AMP would reimburse pharmacies as an average of 36 percent below their cost for generic drugs, which account for 63 percent of all prescriptions dispensed in the United States.

I have repeatedly urged CMS to reject this proposal to classify reimbursements based on the AMP, which would lower reimbursements paid to pharmacies for generic drug purchases. In my State of Iowa, it is estimated that pharmacists will receive an $11.8 million cut in reimbursements in the first year of implementation alone. This could force many pharmacies out the Medicaid business, which would reduce access to care for Medicaid beneficiaries.

In many underserved areas, it could force pharmacies out of business altogether. Also, by making generic drugs unprofitable, Medicaid has created an incentive to dispense more expensive brand-new drugs which are not subject to the new formula. So, ironically, this new formula which was established to save money could actually end up increasing costs to both the state and the Federal Government for prescription drugs.

I have specifically fought for Iowa pharmacies on this issue, urging CMS to approve a measure that was passed in the Iowa General Assembly to offset reductions for reimbursements for generic medications. This plan would increase the pharmacy-dispensing fee to compensate for any reduction in the drug product cost reimbursement. However, this provision needs approval by CMS before taking effect.

Although I am pleased that the State of Iowa has stepped up to the plate to make sure pharmacies receive appropriate reimbursements for generic drugs, I think it is extremely unfortunate that CMS has put my state in this position. I am concerned that Iowa's

increasing its payment to pharmacists could place budgetary pressure on other important Medicaid services provided by the State.

I look forward to hearing from our witnesses today, and I am hopeful we can shed some light on this proposed change to reimbursements for pharmacies.

Thank you, Madam Chairwoman, and thank you to everyone who is participating in the hearing today.

ChairwomanVELÁZQUEZ. Thank you. Our first witness is Mr. Dennis Smith. He is the Director for the Center for Medicaid and State Operation, or CMSO. Mr. Smith has been the Director since July 29, 2001. He is involved in the development and implementation of national policies governing Medicaid, the State Children's Health Insurance Program certification, and the Clinical Laboratories Improvement Act. Previously, he served as the Director of the Department of Medical Assistance Services for the Commonwealth of Virginia.

Welcome, sir.

STATEMENT OF MR. DENNIS SMITH, DIRECTOR, CENTER FOR MEDICAID AND STATE OPERATIONS

Mr.SMITH. Thank you, Madam Chairwoman, and other members of the panel, and I appreciate very much the opportunity to be with you today, and to talk about the AMP rule, which was—the final rule was published earlier this month. The regulation actually takes effect until October 1. But what we also did was leave open to comment some of the very issues that you have highlighted this morning about the definition of AMP itself.

One of the issues that we struggled with, frankly, was the ability to do the type of data analysis that everyone would want us to do in reference to the GAO study and the IG. And you will find that many of our responses hinge around the lack of data that we are able to—that we have to be able to analyze the full impact of the final rule.

So what we did in using our discretion really was to continue the comment period which allows them to—allows everyone then to be able to start having access to the data to get a firm handle on the impact of the rule.

As Madam Chairwoman referenced, this rule really sort of originated with the study of the Office of the Inspector General, that in December of 2004 testified in front of the House Energy and Commerce Oversight Investigation Committee.

The IG found that what the states used to establish their Medicaid drug reimbursements generally bear little resemblance to the prices incurred by the retail pharmacies to purchase drugs, and, in fact, that the OIG had found in audit reports that it had estimated that the pharmacists' actual acquisition costs for brand-name drugs was an average of 21 percent below average wholesale price, and for generic drugs an average of 65 percent below AWP.

The effect of the difference between the pharmacy invoice costs and the amount that Medicaid would have paid for those drugs was about $1.5 billion. For drugs specifically under the federal upper limit, which is really the focus of the new rule, the Inspector General estimated that the invoice price for multiple source drugs with the FULs was 72 percent below AWP.

In another report on the variation between what state drug prices were being paid, the OIG found that the difference between the highest and lowest paying states ranged by drug from 12 percent to 4,073 percent for the 28 drugs that they had sampled. That really is the backdrop of the report.

The OIG, in helping to inform us about moving from a FULs that is based on the average wholesale price to the average manufacturer price compared the 25 most commonly prescribed drugs that the old FUL, the lowest pharmacy acquisition cost, compared to that—the old FUL for that drug was as high as 5,232 percent from the lowest acquisition. On the average acquisition, they were still finding drugs that were 1,400 percent higher than the average acquisition cost.

So I think everyone did come to a reasonable conclusion that the old federal upper limit truly was flawed as it was based on the AWP, which was commonly referred to as "Ain't What's Paid." I think many folks came together to recognize that a system that is built on more exact pricing would be better for everyone.

In terms of want to assure the Subcommittee—I am sorry, assure the Committee on small business that we carefully reviewed the comments from—assigned by Madam Chairwoman on December—on February 23 of this year, on the comments that were provided. I want to assure you also that the administration very much cares about the impact on small businesses.

Throughout this process, we have met with the national representatives of retail pharmacists, we have met with state representatives of the retail pharmacists, we have met with pharmacists themselves. We are trying to get the rule to accurately reflect what was passed by Congress, with also the recognition that Medicaid in fact was paying a higher price than other payers were. And being a program for poor people, that generally Medicaid is getting the best price for the services that they have purchased on their behalf.

So we have been meeting with the representatives and the pharmacists themselves. There are a number of things I think that clearly the GAO report did raise a great deal of concerns about the rule, and our response was, "Wait until you actually see the rule itself."

We did change—we did propose an outlier policy to in effect disregard the lowest drugs that perhaps would not be available to the majority of the purchasers. We had proposed an outlier policy in the proposed rule. We increased that outlier proposal in the final rule, so we think that in fact does deal effectively with the outlier effect, that no one wants to count the FULs based on those costs that really pharmacists do not have access to.

We also had—again, on the definition of AMP itself, there is a balancing between the use of the definition of AMP for which there has been a definition of AMP that has been used in the program for many years. And that definition has been used on the rebate side of the proposal.

I think folks commonly accepted the sort of common sense approach to use the same definition on both the payment side as well as the rebate side, which is what we have done. So if you artificially take more things out of the definition of AMP, then you are

also giving up rebates that are then paid by the manufacturers back to the Medicaid program. So these are not—these are tradeoffs that everyone knew that we would have to take account of.

In terms of the response on the effect of the small businesses, again, we are very concerned about the 18,000 small business pharmacies in the United States. In our economic impact, we estimated—and I believe that it continues to be the case—that the rule itself would reduce overall pharmacy revenues by about $800 million in the first year, and that does reflect about 1 percent of the sales by independent pharmacies for their prescription sales itself.

The National Community Pharmacist Association indicates their prescription sales to be $85 billion. That figure I think is from 2004, so it is more than that today. But, again, their prescription sales are about $85 billion, so the savings does represent about 1 percent of prescription drug sales.

Other small businesses are impacted in the rule as well. We have hospitals that fit the definition of small businesses, physicians who would fit the definition of small businesses, so our rule—we did, again, with some acknowledgement that the data is not complete for us to give as specific impact as what we would all have liked.

The Committee also asked us in the comments to consider alternatives to the rule itself. And I did want to share with the Committee, I think the—again, to bring perhaps a little bit more clarity to how the federal upper limits are actually used in the Medicaid program. The federal upper limits, those are limits in the aggregate to all drugs that are covered by the FULs, which are about roughly 700 drugs out of the entirety of all the drugs that are available on the market. So we are talking about roughly 700 drugs.

The FULs is calculated on all of those drugs together, so while there might be differences in lower drugs, and there could be also payments—higher payments, that they in effect cancel each other out, what we are looking at is the aggregate amount. The aggregate amount that we—

ChairwomanVELÁZQUEZ. Mr. Smith, would you try to summarize?

Mr.SMITH. Certainly, Mr. Chair.

ChairwomanVELÁZQUEZ. It has been close to more than seven minutes already, so—

Mr.SMITH. I apologize. The aggregate in the amount is then what the states themselves, we would pay to reimburse the states up to that amount. The federal upper limit does not include expenditures for dispensing fees. The federal upper—so the states themselves, the federal upper limit rule does not impact the overall approach to Medicaid reimbursement, which rules on the states to set their costs for reimbursement.

So the states themselves—and, again, in particular the states have the authority under current law, and some states do this already, and they will have it in the future even when the rule is in effect. So the states can pay independent pharmacists more than other types of pharmacists. They could pay their rural pharmacists more than their urban pharmacists.

So there are many different ways that the states are likely to react, and, in fact, some already have started to adjust to the rule

to assure that their community pharmacists continue to participate in the Medicaid program and to continue to assure that our Medicaid beneficiaries have access to the needed prescription drugs that they need.

Thank you very much.

[The prepared statement of Mr. Smith may be found in the Appendix on page 45.]

ChairwomanVELÁZQUEZ. Thank you. Mr. Smith, in the regulatory flexibility analysis contained in both the proposed and interim final rule, CMS analyzed the retail pharmacy industry as a whole and did not quantify the impact on small independent retail pharmacies. However, the Regulatory Flexibility Act requires agencies to consider the impact of the rules on small entities. As such, CMS failed to meet the obligations under the law by refusing to examine how small businesses will be affected.

So I ask you why you didn't assess the impact to independent retail pharmacies separately as required by the law.

Mr.SMITH. Madam Chairwoman, I believe that we did meet the requirements of the law, and we specifically referred to the savings that would be attributed to the 18,000 pharmacies that are considered to be small businesses. So I think we did address what the law required us to do.

As I also indicated, the data analysis—we can never get enough data. We always want more data, which again is why we have provided for additional comment on the rule.

ChairwomanVELÁZQUEZ. That is what the General Inspector's Office and the General Accounting Office and Inspector General of HHS concluded, that you did in fact conduct the impact analysis on small businesses? You know, sir, you come here, and let me tell you, people love to talk about standards and accountability. But the law is clear in terms of the Regulatory Flexibility Act. The size standard is very clear, and we do not find that you conducted the type of analysis that is required by the Regulatory Flexibility Act.

So let me just say this to you: I will encourage you to go back and do the analysis that it is required by law, because this Committee is going to be on top of this issue, and we are going to have you come back to this Committee over and over again.

Mr.SMITH. I am not an expert on the requirements of the regulatory act itself. I believe in our—

ChairwomanVELÁZQUEZ. Well, you should have legal counsel, because it is very clear.

Mr.SMITH. I appreciate that very much, Madam Chairwoman. We did in the final rule specifically refer to the small retail pharmacies—approximately 18,000—and we specifically addressed the financial impacts on those pharmacies.

ChairwomanVELÁZQUEZ. Mr. Smith, recent studies have shown that the average dispensing fee is less than half of the national average of actual dispensing costs. Given that pharmacies may soon be no longer adequately reimbursed for their acquisition costs, what is the CMS doing to ensure that states' dispensing fee structures are actually covering costs?

Mr.SMITH. I think that this is an area that, again, many in the industry have—and the states, as well as us, have sort of recog-

nized, that over time when you look at the—how prescription drugs are paid for, acquisition costs that—the payment based on acquisition costs continue to go higher and higher and higher while dispensing fees actually have been pretty flat over time.

So the high reimbursement on the acquisition side to some extent was masking what—the true costs and dispensing fees were held very level. I think what will happen—and in discussing with the states from my own experience as Medicaid Director in a state, from my own experience dealing with our state legislature in how they react, I think there will be a reassessment, again, as I said, to assure that there is access and to make certain that our small business pharmacists continue to participate in the program.

ChairwomanVELÁZQUEZ. You are not going—

Mr.SMITH. I am sorry.

ChairwomanVELÁZQUEZ. —that this will—

Mr.SMITH. In our own materials, we have pointed out to the states, again, that the FULs do not include dispensing fees, and have encouraged them to adjust dispensing fees where they believe is appropriate.

ChairwomanVELÁZQUEZ. So you don't feel that this is a way for the Federal Government to dump costs on the states?

Mr.SMITH. I think it is a way of balancing what the true costs are on the acquisition side. And, as I said, I think states will adjust on the dispensing side.

ChairwomanVELÁZQUEZ. Okay. So let me—I hope that you can help me understand the intent of the Deficit Reduction Act. That was to cut costs of the Medicaid program, and the law gave CMS a significant amount of discretion to create the formula for reimbursement rates for these generic drugs.

However, the final rule creates an incentive to move toward brand-name drugs. As the average brand-name drugs costs the government six times of a generic drug, why was the rule created in such a way that more pharmacies would likely dispense these expensive drugs?

Mr.SMITH. I have had that discussion personally with representatives of the retail, and I have heard that theory. I have just really never quite understood it from an economic standpoint. So I have just—I have just said we would have to politely disagree.

ChairwomanVELÁZQUEZ. So are you telling me you are right, but the General Accounting Office is wrong? The Inspector General of HHS is wrong? The only one that is right here is you.

Mr.SMITH. I am giving you my opinion, Madam Chairman, of—

ChairwomanVELÁZQUEZ. Well, this is not a matter of opinion. This is a matter of analysis.

Mr.SMITH. And for our—

ChairwomanVELÁZQUEZ. Facts.

Mr.SMITH. In our analysis, the Office of the Inspector General said on the acquisition side Medicaid was spending $1.5 billion too much. The rule itself saves about half of that amount, so there was an adjustment based on what the Inspector General—they said we were overpaying by 1.5.

ChairwomanVELÁZQUEZ. Sir, let me ask you—

Mr.SMITH. The rule—

ChairwomanVELÁZQUEZ. —explain to me how a pharmacy is going to sell drugs when they know that they are going to lose money on that drug.

Mr.SMITH. I think, Madam Chairwoman—

ChairwomanVELÁZQUEZ. What is the incentive?

Mr.SMITH. —they wouldn't do that, by laws of economics. But I don't think that the final rule—that it will in fact be the impact. The FULs is not a drug-by-drug limitation. It is a limitation in the aggregate to what we pay the states.

ChairwomanVELÁZQUEZ. So will you agree that this may drive up costs to the Medicaid program for certain use of drugs?

Mr.SMITH. I don't agree with that.

ChairwomanVELÁZQUEZ. You don't agree with that. So the whole world is wrong.

Mr.SMITH. As I said, I have had those discussions, and I think that it would be a—states also, again—states have mandatory dispensing—mandatory generic dispensing laws themselves, etcetera. So I think there is a balance that, again, I think—what the future lies, no one has perfect clarity of that. But I think through experience we think that the final rule will do what it was set out to accomplish.

ChairwomanVELÁZQUEZ. Let us talk about the cost to the states. It seems to me that the new rules put a burden on the states to figure out how to cover acquisition costs by pharmacists. Does the new rule set any kind of guidance for the states? What are the states doing to make up for the shortfall?

Mr.SMITH. Well, the states themselves, of course, will want to assure that there is no shortfall. And in terms of the states, we will be providing the data to the states about what the AMPs are, not only for the drugs on the FULs but for all drugs, which in—again, we talk about transparency in health care. This is transparency in health care.

So I don't think the impact on the states—they want this data. States have been asking for AMP data, which by law we were required to maintain in confidence and were not allowed—

ChairwomanVELÁZQUEZ. Since you are talking here about transparency, are you giving clear guidance to the states under this rule?

Mr.SMITH. That certainly is my intent, Madam Chairwoman. And we have had briefings with the states, and, as I said, they want this AMP data.

ChairwomanVELÁZQUEZ. Can you talk to us under the Regulatory Flexibility Act, if you have given or examined any alternatives to the proposed rule?

Mr.SMITH. We did. We talked a great deal about what the AMP—the definition of AMP, for example, what fits in there. And as I said earlier, the definition of AMP has been long-standing in the Medicaid program on the rebate side of the program. So if—

ChairwomanVELÁZQUEZ. Okay. Can you mention to me at least one alternative that will minimize the impact of the rule on small businesses and small pharmacies?

Mr.SMITH. Certainly, our outlier policy that, again, we use through our discretion, we think is very much a mitigating effect on the FULs.

ChairwomanVELÁZQUEZ. In the report, the Inspector General of HHS concluded that was inadequate.

Mr.SMITH. What we also said with the Inspector General was they also didn't have the benefit of the final rule itself when they did their analysis, again, which is why we have extended the comment period so that sort of analysis will be available before the final rules go into—before the first new FUL goes into effect.

ChairwomanVELÁZQUEZ. How would you respond to those who will be testifying in the second panel that will say that this rule could cause many small pharmacies to close their doors?

Mr.SMITH. I respectfully disagree with that assessment. As I said, this rule, in the aggregate, represents about 1 percent of all sales that they make. I also am from a small town. I very much understand small businesses, and that they are the backbone of the American economy.

I don't think the states will jeopardize the access of the Medicaid beneficiaries, and I think that they will continue to pay overall reimbursement to the pharmacists to make sure they continue to participate.

ChairwomanVELÁZQUEZ. I really appreciate you coming here and saying you understand small businesses, but this is not about that. This is about impact analysis under the law.

And now I recognize Mr. Chabot.

Mr.CHABOT. Thank you, Madam Chair. And let me just note for the record, as I think everybody knows, members of Congress are on various committees, and I am also on the Judiciary Committee and the Foreign Affairs Committee. And we are marking up the Patent Reform Bill, and we have several important amendments to the bill, so I am going to, unfortunately, have to leave here shortly, and some of my colleagues will be filling in as the ranking member for different parts of the morning. So I want to thank them for that. I greatly appreciate it. So I just have a couple of questions.

Mr. Smith, do you concur with the findings of the GAO and the Office of Advocacy of the United States Small Business Administration that the reimbursement rate does not recoup the costs of acquisition of covered pharmaceuticals, much less the cost of the pharmacies to dispense the drugs?

Mr.SMITH. We have disagreed with what GAO—their analysis in the studies that they have published, again, on the basis that they didn't—they didn't know what was in the final rule, and, again, didn't have the—no one has the data, including GAO, to make their final analysis, again, which is an important reason as to why we have delayed the effectiveness of the first new federal upper limit.

Mr.CHABOT. Okay. Thank you. So just to be clear, so you do not concur with that, is that correct?

Mr.SMITH. That is correct, yes, sir.

Mr.CHABOT. Thank you. Now, next, do you know how Congress arrived at the 250 percent of average manufacturers' price for the reimbursement?

Mr.SMITH. In the Deficit Reduction Act, the Senate and the House passed very different types of proposals. What came out of conference differed between both approaches. Both approaches were designed to create savings for the Medicaid program. The final amount, I couldn't speak to how precisely they arrived at 250

percent, but I think that is an important consideration to bear in mind.

We are talking about two and a half times of what the lowest acquisition cost is. So that leaves I think a very significant cushion between the lowest and the upper limit now, which is two and a half times that.

Mr.CHABOT. Thank you. Next, in failing to quantify the economic impact on small retail pharmacies, what efforts did CMS undertake to determine what economic data was available?

Mr.SMITH. We did look at—again, I assure you we looked at the data that we have, and we certainly did understand the impact to be on the pharmacists' side, and the 18,000 small pharmacists. We, again, consulted with our Office of the Actuary. We looked hither and yon for as much data as we could get.

As I said, we did talk with the pharmacy organizations themselves. I do believe we went looking for as much data as we possibly could get.

Mr.CHABOT. Has CMS considered amending its final regulatory flexibility to address any inadequacies in the statutory reimbursement rate?

Mr.SMITH. We left some very important parts continued to be open for comment that, again, the data that everyone would want to have. With their AMP reporting, under the new rules, then we will start having that data. So that is why we left it open to comment between now and the first new federal upper limit.

ChairwomanVELÁZQUEZ. Mr. Chabot?

Mr.SMITH. Certainly, our intent was to be able to have that sort of data analysis to then determine whether or not we should make any further changes.

Mr.CHABOT. Yes, Madam Chair.

ChairwomanVELÁZQUEZ. I just would like, before my blood pressure goes up—

Mr.CHABOT. I would yield to the—

ChairwomanVELÁZQUEZ. —for the record to reflect what you, in your statement on the final rule, said about the data. We are on—although it is clear the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate the effects on small pharmacies, particularly those in low income areas where there are high concentrations of Medicaid beneficiaries. This is your own rule.

Mr.SMITH. And, Madam Chairman, I think I also said we realize that we all want more data than what we had at our disposal.

Mr.CHABOT. Madam Chair, I am being called down to the Judiciary Committee, so I am going to yield back my time.

Mr.SMITH. And now I recognize Mr. Shuler.

Mr.SHULER. Madam Chair, thank you. Back to the data, if you recognize that the backbone and the success of our, you know, economy depends upon the small businesses, then why didn't you request and ask for more data?

Mr.SMITH. The data has to relate to what the final definition is. If it doesn't reflect what the final definition is, then the data continues to be flawed, which is why when a number of groups and individuals, including the pharmacies themselves, asked us not to publish data as the law required, going back to January of this

year, their rationale was the data will be flawed because you don't have a final definition.

We agreed with that, which is why we have not released the AMPs under the old definition. But we won't have the data until we have—

Mr.SHULER. Until after the rule?

Mr.SMITH. Which is why we have delayed the comment period, which is why we have delayed the effectiveness.

Mr.SHULER. So will there be a rule on—a judgment on the final rule after the fact?

Mr.SMITH. Yes, sir. That is what an interim final with comment is, that it allows, then, to make further adjustments without going through the entire APA process all over again.

Mr.SHULER. So why can't you submit the data from the AMP to the states? Is it HIPAA, because of HIPAA compliance?

Mr.SMITH. We can. But, again, folks have not wanted us to submit AMP data under the old definition of AMP. The pharmacy community itself didn't want us to allow that, I believe.

Mr.SHULER. So it is more important to—hey, I mean, there is nobody that supports the pharmacists more than I—I mean, both the chains and the small communities. But, I mean, don't you think it is more important to make sure that we have the proper data for them, and for the patients as well?

Mr.SMITH. Absolutely. And—

Mr.SHULER. So which is more important?

Mr.SMITH. I think that what is important is to have accurate data to balance any other decision makers on the final rule. I would be very surprised, though—and you can ask the next panel—I would be very surprised if they told you that they wanted us to release the old AMPs.

Mr.SHULER. We will ask that.

Madam Chair, I would request that if—

Mr.SMITH. We realize that we all want more data on—

Mr.SHULER. Yes, don't you think we should delay the rule until we have the final data?

Mr.SMITH. The rule, in fact, has been delayed to some extent. And we have delayed different parts of it. As I said, the law said—had given us a January date to start releasing publicly data. We believed it was—our concern was that data would be inaccurate, and that could have a negative impact as payers start looking at data that would be inaccurate, and then start making decisions about their own pricing.

We did delay that. We have also delayed the publication of the new first federal upper limit—would have, could have, should have gone into effect July 1. That really is now the end of the year. In between time, now everyone—manufacturers will then start reporting their data based on the new AMP definition. Then, that data will be available for analysis to make a final determination.

Mr.SHULER. Madam Chair, I would request that you would submit the information on the impact on small business to the Committee. I know there is—you said there is not a lot, but the quantifiable evidence and effects on small business, we would like to receive that information.

Mr.SMITH. We did—as I said, we responded to—in the final rule—

Mr.SHULER. Not just the information from what is in the final rule, but the entire information that actually impacts small business.

ChairwomanVELÁZQUEZ. Without objection.

Mr.SMITH. I will do the very best I can to provide whatever data that we are going to be able to have.

Mr.SHULER. Madam Chair, I yield back.

ChairwomanVELÁZQUEZ. Thank you. Mr. Buchanan.

Mr.BUCHANAN. Yes, thank you, Madam Chair. I think the concern with all of us is I know I have a pharmacist in our community that is out of business. There is so much pressure already on a lot of these small retail pharmacists because of whatever reason—national chains, other issues.

That is why it is concerning all of us up here, because sometimes it is just that tipping point that one more something like this put on them puts a lot of them out of business. And I know right down the street from me we just had one close in the last six months. I am not saying it is because of this. It might be part of this, but I am concerned that we are going to—we are not going to see a lot of retail pharmacists.

I would be interested to see 18,000 retail pharmacists, how many have—how many there were five years ago and what it is today. So I think—I don't even know, but I have got to imagine that trend is coming down.

I guess the big thing is getting back to this when you looked at the final rule. Did you spend much time working with the states or anybody—any other entities to get a sense of the impact on the analysis? Or was this something that you did yourself or—

Mr.SMITH. We did, Mr. Buchanan. We asked data from the states themselves. We asked manufacturers to verify their data. We had the benefit of hearing from the community pharmacists themselves as they came in. States themselves—some states have said very—may have very little impact on us, because we already have our own what are called maximum acquisition cost lists that are below the old FULs.

So the impact will vary by state, comparing their acquisition cost limitations that they already had in place versus the new FUL. So we did go looking—we—

Mr.BUCHANAN. Yes. When you said you had the community pharmacists come in, how did that work out? I mean, how many did you have come in over what period of time, and in terms of doing an analysis?

Mr.SMITH. I don't recall how many meetings I have had, but I—

Mr.BUCHANAN. Well, what is the reaction?

Mr.SMITH. —had several—

Mr.BUCHANAN. What was the reaction, the feedback you had from the community?

Mr.SMITH. Certainly, the reaction was of concern. Certainly, the rule was, and the law was, designed to generate savings. We understand that and know that would be a concern.

Mr.BUCHANAN. The other question I had, why are brand-name drugs not part of the modified reimbursement plan? What is the rationale there?

Mr.SMITH. Because to be on the federal upper limit you have to have a competitor. So the FULs is only to those roughly 700 drugs, not the entire 55,000 drugs. So you have to have a competitor to be on the FULs in the first place.

Mr.BUCHANAN. How did they decide on the 700 drugs? Why was it not 700, 800, what was the—

Mr.SMITH. They come on as a generic manufacturer to—as a—you have a brand-name drug all by itself, and then you have a generic manufacturer that comes in and is doing the generic equivalent of that. They go to the FDA, and then FDA says now there is a generic equivalent, so that is how you get on the FUL is by having a generic competitor.

Mr.BUCHANAN. And you touched on this, but what is your view of the discretion that CMS has in developing the average manufactured price?

Mr.SMITH. I think we—I think the—again, what we did was to introduce an outlier, a policy in the first place, in the proposed rule, which we increased in the final rule. We went from 30 percent to 40 percent. That was in our discretion.

In terms of who is in within the definition of AMP, we disregarded sales to nursing homes. We disregarded certain sales that would have had an impact on the AMP. However, if you swing too much to the other side, and start taking more and more transactions out of the list, then Medicaid will start losing rebates from the manufacturers.

Mr.BUCHANAN. Thank you, Mr. Smith. And I yield back, Madam Chair.

ChairwomanVELÁZQUEZ. Thank you. Mr. Braley.

Mr.BRALEY. Thank you, Madam Chairwoman. Mr. Smith, I was pleased to hear that you looked hither and yon for as much data as you could get. Frankly, I have not heard that word used since the last time I watched the movie Robin Hood.

But I think that one of the things that you are not getting from this bipartisan panel is that all of us are concerned about the AMP formula, the criteria you use to define the formula, and its adverse impact upon the community pharmacists that we represent.

And I think that attitude on the part of the agency you are here to represent is reflected in the fact that on May 18, 2007, over 100 of my colleagues, including Ms. Fallin, Mr. Shuler, myself, in a bipartisan spirit, probably one of the most bipartisan outreach efforts I have seen since coming to Congress in January, asked a simple request of Leslie Norwalk, and that was to recognize the practical reality of the implementation of this rule when it is going to be applied by many states whose legislatures are no longer in session.

Your rule comes out on July 1, 2007. My legislature adjourned in May and won't reconvene until January. And I think that is the case in many smaller states, and in probably some of the larger states of this country. And one of the reasons why we made this outreach effort in a bipartisan fashion was to address the simple, practical realities of giving states an adequate opportunity to pro-

vide the input and feedback to your rule after final publication, before implementation.

And from my understanding, rather than acceding to our request to delay that until December 31, 2007, your agency has decided to begin the implementation in October. Is that true?

Mr.SMITH. If I can take a minute to explain, and the impact on the states and how, again, this is enforced with the states, because I think you raise a very important point. The data that we all want we can't get until you get to a final definition.

We have delayed the effectiveness of the new federal upper limit. The new federal upper limit itself, in terms of our relationships with the states, is a calculation that we do—that we would do in terms of enforcement with the states once a year. So while the new FUL—the first new FUL will come out roughly December, we would not be taking any action against a state roughly for a year after that.

So I think legislatures will come back in time to make any modifications that they deem to be necessary, before we take any adverse action against a state.

Mr.BRALEY. In fact, several of these states, including my State of Iowa, the State of Kansas, which the original co-authors of this letter—Jerry Moran and Nancy Boyda—represent, and the State of Louisiana have plans to revise their dispensing fee requirements in anticipation of just what we are talking about. Can you describe how these states are going to be able to try to bridge a gap that nobody here seems to be able to understand or define?

Mr.SMITH. I think between now and the end of the year we will start having—we will get the data that everyone is looking for in time for them to make any adjustments. As you indicate, states are already, in anticipation of savings on the acquisition side, re-balancing that to—at least to some extent with increase in dispensing fees, which I said in my earlier remarks have really been flat for several years now.

So states have the—all of the authority they need to make those changes in dispensing fees, and by the time they come in next year they will have the data before CMS has taken any enforcement action against them.

Mr.BRALEY. Have you had the opportunity to review any of the proposals from the states that are submitting requests?

Mr.SMITH. We have, yes, sir.

Mr.BRALEY. And have you seen anything in any of the components of those state programs that you believe will be particularly effective in addressing some of the issues we have been discussing here today?

Mr.SMITH. Well, the states have the authority to set their reimbursement rates, which generally includes acquisition costs and dispensing fees. The dispensing fees do need to be reasonable and are supported by data. The extent to which Iowa or any other state that comes in and says, "Look, we need to increase our dispensing fee, we believe we need to increase our dispensing fee to our rural pharmacists to assure access," then they would have the right to do so. They would submit a state plan amendment, and we would approve that state plan amendment.

ChairwomanVELÁZQUEZ. Ms. Fallin.

Ms.FALLIN. Thank you, Madam Chair. Thank you for coming today to visit with us about a very important issue. We appreciate you being here. I have a question about legal authority and about CMS. And what legal authority does CMS have to delay the statutory deadlines on this rulemaking?

Mr.SMITH. The statutory deadlines we take very seriously, and do our very best to meet them. The statutory definition was to have an AMP rule by July 1. We were a couple of days late, but I think any significant delay beyond that then calls into question whether or not we met our statutory obligation.

Ms.FALLIN. Well, if CMS missed that deadline, which you did—I think it was July 7 by the time it was—received July 6 to register the rule, and then publication in the Federal Register on July 17—and if we missed those deadlines, I guess would that mean that we could also play with other statutory deadlines, too, in other areas?

Mr.SMITH. The risk of missing the statutory deadline I think is an issue for lawyers to kind of debate and that I am not really the expert to do that.

Ms.FALLIN. Okay.

Mr.SMITH. Sorry.

Ms.FALLIN. That is all right. Thank you.

Thank you, Ms. Chairman.

ChairwomanVELÁZQUEZ. Mr. González.

Mr.GONZÁLEZ. Thank you very much, Madam Chair. And welcome, Director Smith. Quickly, you know, this is all a result of the Deficit Reduction Act. When we were debating that—I still remember that well, because I serve on Energy and Commerce, and the way I figure it really happened like this, and this is where we find ourselves today.

The White House said, "We are going to reduce spending X amount of dollars." Then, it filters down to Congress. And you look at each Committee that has certain jurisdiction, and they say, "You have jurisdiction over these departments or agencies, and we are going to cut X amount of dollars." Whether it is realistic or not, it does not matter. These are arbitrary, mandatory figures pulled out somewhere, and that is the genesis of this thing.

And what you are dealing with, of course, is the end product. So Energy and Commerce comes out, we have got jurisdiction on Medicaid, and they say, "We are going to cut $10 billion." We are trying to figure out, how did you get to that figure? Well, we are not real sure, but we think we need to cut $10 billion, because in the big picture that is how much you have to save from your particular program under that particular agency that comes under the purview of your Committee.

We debated and debated. The Chairman at that time, Chairman Barton, a fellow Texan, promised me that less is more when it comes to Medicaid. So on the Committee we have Mr. Ross from Arkansas, who has—I think his wife is a pharmacist, and they own a small community pharmacy. And I wish he was here today, because he could explain this in a way that no one else can, because he is intimately acquainted with all of the details of what it takes to be a pharmacist in today's economy.

So that is where we are today. Now, I hope Mr. Barton is right that less is more. He promised he would come to my district to ex-

plain this when the impact of the rulemaking—and I told him that it—you know, I really don't want to be the second Alamo in San Antonio, Texas.

But, nevertheless, this is where I am getting at. I know what you have to do with deadlines and such. You are just going to find these savings, because we mandated that when we passed that act. And the $10 billion was going to come out of Medicaid no matter what, at someone's cost.

Now, I am going to tell you, we will hit the physician, the caregiver, we will hit the pharmacist, but the one that really suffers, of course, is going to be the patient. But that is where we are today.

Now, let us just figure out how we can soften this, and this is all about damage control. My concern is this, and I do appreciate your testimony—but based on some of the questions that we have here, the consequences of what we are doing here, findings of the GAO, which you have to respect—I mean, you can disagree to a certain extent, but somewhere along the way you have to figure there has got to be some legitimacy to what they are finding here.

But the consequences of where you are pushing the pharmacists, and what is the role of the pharmacist? That is the other thing. I am going to tell you something, I don't think there is going to be a member here, Republican or Democrat, that doesn't appreciate the role of the pharmacist in our communities. It is a lot easier for the patient to get a lot of the information from the pharmacist than it is usually to get it from the doctor—in making the appointment, keeping the appointment, being seen, and spending any quality time with the physician.

There is more quality time being spent today by the patient with the pharmacist. And at our town hall meetings, I can tell you the stories that are recounted. And we are going to impact that relationship, I believe, to the neediest patient out there.

But this is what I am getting at. You have indicated that I guess there is two parts to this formula—the cost of the drug itself, but then this dispensing fee, and I am not sure if you hinted at or you spoke directly to the fact that, are you going to be able to pass on some of the costs that may be suffered to reimburse the pharmacist for the cuts they are going to have on the acquisition as opposed to the dispensing fees?

That really doesn't help any as far as any real savings, and I want your opinion on, to what extent is that going to happen? Is it going to be allowed? We have had this experience in the past with the oncologists in the payment of the drug, compensating for administering the drugs, and we are in a huge mess over that. But I just want your take on the consequence on the dispensing fee side of the equation.

And, secondly, something that the Chairwoman touched on, are you pushing the pharmacists to be prescribing brand-name medicines which are going to be more expensive? So I don't know where all of the savings is at the end of this whole thing. I understand the charge and the mandate that you received over there as a result of what we did with the Deficit Reduction Act, which obviously some of us opposed and such.

But, again, I just want to know the consequences on dispensing fees and the fact, are you truly going to be pushing people to utilize more brand-name and, thus, negating what the generic drug prescription is supposed to be delivering in the way of savings.

Mr.SMITH. Thank you, sir. On the—and pharmacists do get paid in two components in general—on the acquisition cost, and that is what the Inspector General—that is sort of where the ball started rolling. When then Inspector General said you are paying—Medicaid is paying $1.5 billion too much based on acquisition cost, them looking at acquisition cost.

Then, the states are also looking at the dispensing fee, and the other side of the payment—what a state determines under Medicaid what a provider actually gets paid. So they set the reimbursement rates to the states, and a state can say—they have all of the authority to say, "We need to increase our dispensing fee. We are concerned about access, particularly in the rural areas, so we are going to pay our rural pharmacists more."

We are particularly concerned about the impact on the independent pharmacists, so we can—we will pay them more than what we will pay a chain. So the states still have the authority to make the adjustments and decisions that they believe are needed to assure access for our Medicaid beneficiaries.

Mr.GONZÁLEZ. Doesn't that work against your very savings goal? I mean, what I am saying is, all right, let us say GAO, everybody, and probably the individuals who are going to testify in a few minutes, are correct—that it is not going to be adequate compensation for the generic drug and such with the new formula that you have come out now. So can you just push and make up for some of that shortfall on the dispensing side? And if you can, and which they will if you can, then where are the savings?

It is all—I mean, a dollar is a dollar is a dollar. We can split up the cost between dispensing and the cost of the drug itself, but at the end of the day, isn't it basically the same budget, the same amount of money? And the troubles that we have been experiencing in Texas regarding the state's failure to really meet its obligation under the Medicaid program, and making sure that it is available, it is only going to get worse.

And so I guess I just—I don't see, isn't it the potential is any perceived savings be gobbled up by some other component?

Mr.SMITH. I think that we have accomplished something that is very important in the rule on the acquisition cost in itself. Now we will have much better information about what the true acquisition cost is in itself. So that is an important—that is an important gain in itself.

The extent to which states then make a determination that they have to raise a dispensing fee, they will—again, I think then they will go through the analysis that they very well may need to increase the dispensing fee, but not the entire amount to offset the savings that is paying on the acquisition cost more specifically.

ChairwomanVELÁZQUEZ. Time has expired.

Mr.GONZÁLEZ. Thank you.

ChairwomanVELÁZQUEZ. Mr. Smith, I have two more questions. First, we all know that there was a statutory requirement for

issuing the rule. My question is: was there a statutory requirement for the implementation of the rule?

Mr.SMITH. Well—

ChairwomanVELÁZQUEZ. Yes or no? Simple answer.

Mr.SMITH. I think there is an expectation that we implement—

ChairwomanVELÁZQUEZ. No, no, no, no.

Mr.SMITH. —the statute.

ChairwomanVELÁZQUEZ. That is—

Mr.SMITH. I am not—

ChairwomanVELÁZQUEZ. No, I am talking to you about statutory requirement of implementing the rule. And if there is not, my question is: would you hold off at that line of implementation until you have all the data that you admitted here you don't have? So that, then, you can have a final rule that accounts for the needs of small pharmacies?

Mr.SMITH. I think we were required to issue the implementation. I am sorry—to issue a final rule, which is what we did July 1.

ChairwomanVELÁZQUEZ. Yes, but that is not my question.

Mr.SMITH. In terms of the effective date, we have delayed the effective date by delaying when the first new federal upper limit will go into effect.

ChairwomanVELÁZQUEZ. Well, I am not talking about issuing the rule and the effective date. I am talking to you about the implementation of the rule.

Mr.SMITH. I am sorry. The implementation—the new federal upper limit is implementation.

ChairwomanVELÁZQUEZ. Okay. Let me ask you another question since cost saving is an issue here, right? Can you tell me why do you think funding was cut for only generic drug reimbursement and not for brand name drugs?

Mr.SMITH. I think this did stem from a realization that where there is competition between generics and brand names, that is how you get on a FUL in the first place; that Medicaid was overpaying and not getting the best price, which is in many respects an underlying assumption about the Medicaid program that Medicaid should be getting the best deal for reimbursements.

ChairwomanVELÁZQUEZ. So let me ask you a last question now. Could there have been cost savings if the reimbursement formula for brand name drugs was altered?

Mr.SMITH. Presumably. I mean, Congress could have enacted a number of different ways to find savings.

ChairwomanVELÁZQUEZ. So why do you think we did not? You have been saying all along, "I think, I think, I think," in the many questions that I have been asking you.

Mr.SMITH. I think there was a clear indicator from the Office of Inspector General that drugs that have competition on the folds, Medicaid was overspending by a million and a half dollars.

ChairwomanVELÁZQUEZ. Ms. Clarke, do you have any questions? You will be recognized for five minutes.

Ms.CLARKE. Thank you very much, Madam Chair.

Madam Chair, why don't you come back to me? I am sorry. I defer at this time.

ChairwomanVELÁZQUEZ. Yes. So we are going to finish this round, and, Mr. Smith, you are going to be excused. Are you ready? Okay.

Mr.SMITH. Thank you, Madam Chair.

A little freshman SNAFU, and I want to thank you and the Ranking Member for holding this hearing, and it will have an impact on all of our congressional districts.

On July 6 of 2007, CMS released a final rule on Medicaid drug pricing that would redefine the average manufacturer's price, also known as the AMP, and cut Medicaid reimbursements to pharmacies for generic drugs by $8 billion over the next five years.

Unfortunately, the final rule remains fundamentally flawed. It includes a final definition of AMP that could severely underpay retail community pharmacies if used as a reimbursement metric. In my community, this is a huge, huge concern.

These reductions could force many pharmacies to close or reduce hours, jeopardizing Medicaid beneficiaries' access to retail pharmacies. If payments to pharmacies end up below their cost for generic drugs, pharmacies could earn a greater margin by dispensing a higher priced brand medication in Medicaid, about $150, which is more than seven times higher than the average payment for generic medication, around $20.

As you know, too, Madam Chair, there are about 8,750 community pharmacies active in our state. Community pharmacies employ more than 117,000 employees, including over 13,000 employees who work at independent pharmacies. Medicaid is 15.9 percent of the marketplace.

ChairwomanVELÁZQUEZ. Mr. Smith, I'm very concerned that the final rule that CMS has promulgated as it relates to how Medicaid reimburses pharmacies for generic medications will threaten the ability of low income beneficiaries and seniors in my district in Brooklyn, New York to access prescription drugs and services at their local retain pharmacies.

CMS was instructed by Congress and the Deficit Reduction Act of 2005 to define AMP to accurately reflect retail pharmacy acquisition costs. However, based on my understanding of the final rules, CMS chose to completely ignore congressional intent and has done nothing to help mitigate the unprecedented level of cuts to community pharmacies.

Do you believe that the final rule that CMS has issued provides for an accurate benchmark to reimburse pharmacies and provide an adequate level of reimbursement to pharmacies to help insure their continued participation in the Medicaid program?

Mr.SMITH. I believe the final rule is a reflection of payment on the acquisition costs. The acquisition costs for the drugs on the federal upper limit, that limit would now still be two and a half times the lowest drug that is available. So on the acquisition side we do believe that is a margin that is allowable.

Secondly, it is all drugs on the FUL in the aggregate. So there is a relationship that this is not a drug by drug. This is all of the drugs together in the aggregate.

Ms.CLARKE. And inherent in that is an unintended consequence.

Mr.SMITH. Well, again, I think we will all have a much clearer understanding of what actual acquisition costs are, which I think

is a good thing for everyone, and the savings themselves to the independent pharmacists represents about one percent of their pharmacy sales.

Ms.CLARKE. Mr. Smith, I have been hearing from my pharmacies that the implementation of the tamper proof prescription pad requirement mandated by Congress in the recently enacted Iraq supplemental earlier this year could cause some difficulties. Pharmacies tell me there may not be enough pads available for all prescribers at the time of the October 1st launch, and that pharmacies could be faced with either turning Medicaid beneficiaries away who show up with prescriptions written on non-compliant pads or risking a subsequent denial of reimbursement of prescriptions dispensed under those circumstances.

Would CMS be willing to delay implementation of the requirement or to at least phase it in over a period of 180 days beyond the mandated October 1st effective date?

And would CMS be willing to use some discretion in enforcing the requirement over the first six months?

Mr.SMITH. As you are aware, Congress just passed that law very recently. We are going to do our very best to meet the effective date, and we are doing our very best to comply with what Congress told us to do.

We have worked with the pharmacists. We have heard from the pharmacists. We have heard from the states. The tamper proof, a number of states have said in many effects we already do this. So it will have no impact on it.

So this is going to impact pharmacists in those states that have not already moved to the tamper proof, which the intent itself is to prevent fraud and abuse in the Medicaid programs. So the impact is on states that do not already have tamper proof, and we are working hard with them to find ways that they can come into compliance.

Ms.CLARKE. So you are up here to help mitigate those circumstances.

Mr.SMITH. We will continue to assess the ability to make that date and adjust.

Ms.CLARKE. Accordingly. Thank you.

Thank you very much, Madam Chair, and I will yield back.

ChairwomanVELÁZQUEZ. Any other member?

Mr. Smith, I will excuse you, but before you leave this room, again, I just want to reiterate the impact that this is going to have not only on local pharmacists, but Medicaid recipients throughout this country, and I will hope that you will provide more time before implementing the AMP until you have the data that is required by the Regulatory Flexibility Act.

If I am one of those pharmacists sitting here in this room, by the way, I just will ask you. Have you heard of any pending lawsuit in light of the Regulatory Flexibility Act?

Mr.SMITH. I understand that is something that is being considered.

ChairwomanVELÁZQUEZ. Okay. Well, with that, you are excused.

Mr.SMITH. Thank you very much.

ChairwomanVELÁZQUEZ. And I will ask the next panel to come forward and take your seats, please.

Okay. We are going to proceed with our second panel. Our first witness is Percy Bellow. Is he here?

Okay. So let's go with Mr. Osterhaus. Mr. Osterhaus is a community—sorry. And I will recognize Mr. Braley for the purpose of introducing his constituent.

Mr.BRALEY. Thank you so much. It is my distinct pleasure to introduce one of my constituents who is uniquely qualified to testify here today.

Matt Osterhaus is a community pharmacist and consultant and co-owner of Osterhaus Pharmacy in Maqueketa, Iowa.

Osterhaus Pharmacy has been a family owned operation since 1965, and Matt is actively involved in community development, as well as an adjunct faculty member at the University of Iowa College of Pharmacy, and he has had the great fortune of practicing with his father, also a community pharmacist who served in the Iowa legislature and has a great background in how these Medicaid adjustments impact patients, as well as community pharmacists.

And we welcome you here today

STATEMENT OF MATTHEW OSTERHAUS, PHARMACIST, OSTERHAUS PHARMACY, ON BEHALF OF ASSOCIATION OF COMMUNITY PHARMACISTS CONGRESSIONAL NETWORK

Mr.OSTERHAUS. Thank you very much, Congressman Braley.

Members of the Small Business Committee, thank you for allowing me to testify this morning on behalf of the Association of Community Pharmacists Congressional Network and the independent pharmacies they represent across the country.

Since the launch of Medicare Part D, the prescription program in January of 2006, hundreds of pharmacies have closed. It is my belief and the belief of thousands of pharmacists and pharmacy owners across the nation that if the economic environment of pharmacy remains as it is today and CMS implements average manufacturer's price, or AMP, a reported in the recent ruling, the citizens in the nation may see an unprecedented loss of pharmacies, in particular, independent community pharmacies.

The one-two punch of Medicare Part D along with AMP, the way that has been thrown out at us really threatens the survival of the community pharmacy. The loss of these businesses will potentially impact the access for our citizens, our patients who depend on pharmacies for their prescription and health care needs.

I see independent community pharmacy as kind of the classic example of small business in the United States. We have survived through a lot of ups and downs for several centuries. I think we have survived because we do add value along with the dispensing of medications and the care for our patients.

Many of these businesses serve as the anchor of their small towns, including Osterhaus Pharmacy who is, I guess the downtown anchor of Maqueketa, Iowa. We are in a community of 6,000 people. We employ 25 people in our pharmacy, including seven pharmacists. We provide medication therapy management for patients with private insurance, with Medicaid, with Medicare Part D. Approximately 30 percent of my patients have Medicaid as either their primary or their secondary insurance.

As we face crises over the years, we have come out of those, but I see none other that has ever been as hard hitting as the potential AMP legislation. With the creation of Medicare Part D, the PBMs, or pharmacy benefit managers, began setting reimbursement on a huge percentage of the prescriptions that we dispense to our patients.

And there are a lot of small businesses, pharmacies, across this nation who closed their doors due to the slow and low reimbursements in this plan. It has been estimated that a third of our health care dollars are being spent on administration, benefit management, and frequently not allowing benefits.

I feel we need to reallocate our health care resources and refocus them on the care of patients. I think we also need to insist that the providers provide value for the dollars spent.

Independent pharmacy is somewhat unique as a small business group in that we have very little control over the cost of what we pay for the medications. There is a limited number of wholesalers or sources for the prescription drugs, and we have almost no control over the price that is set that we are paid for it.

Yet when it comes time to squeeze savings from the system in this escalating cost environment, both state and federal government turn to pharmacy as if we had full control.

Now, through CMS and the establishment of AMP, generic pricing structures is striving to save billions of dollars by cutting payments on medications to pharmacies across the country, and many people think that there is a lot of fat to be cut.

But if we set up the system the way that is certainly out there right now, if we pay $100 to bring a medication in to our pharmacy from the wholesaler and Medicaid decides to reimburse us 85, and then we wait four to six weeks to be paid for it, we cannot stay in business very long.

Utilizing a formula to establish product reimbursement is fundamentally flawed. Bringing it in at less than the acquisition that pay my wholesaler is not a recipe for success. Utilizing mail order pharmacies and hospital out-patient pharmacies in the formula I think is a significant flaw, and it is an inequity that needs your attention today, and I certainly appreciate the opportunity and the attention you have given it in this hearing.

I think it is obvious that a small business of any type cannot survive if the revenue that comes in does not match the cost of the product being sold and the overhead that we need to provide quality service to our patients or the consumer.

I submit to you that hundreds of independent pharmacies may be lost if AMP is implemented as currently designed. This is a blow to small business, but it is devastating to the patients served by these small business.

Pharmacists across the country are agonizing over the thought of not being able to serve their patients, and those patients will be distraught over the thought of losing their pharmacies.

People up here maybe on the Hill or people at CMS may think that there is not an access issue in pharmacy. When I come to Washington, D.C., I can see four pharmacies on one corner sometimes, but in Iowa, a prime example of rural America, there are several counties that only have one pharmacy, and these patients

understand that if they lose that pharmacy it could be 30 to 40 miles to the closest pharmacy.

I think of my own patients. I think of Don who has a seizure disorder, was totally uncontrolled. Our pharmacists worked with him to help him adhere to this regimen. He has not been back in the emergency room or the hospital sense.

I think of Peggy, my patient with multiple sclerosis. We have collaborated with her physician to better control her pain, who helped her quit smoking. Community pharmacies care. Pharmacists care and want to partner with Medicaid to take care of these patients.

I feel we serve a vital role in our health care system. These are small businesses that provide entry level health services to the patient. We need to have a system of reimbursement that is fair so that we can continue to be in business. The average number of employees in an independent pharmacy is 12, but they all expect to receive their paychecks every week, and we expect to be able to give them a decent living.

There are a lot of ways that pharmacists could help save health care dollars.

Am I pushing my time?

ChairwomanVELÁZQUEZ. Mr. Osterhaus, we have five minutes and it is up, but I will give you an extra minute so that you could summarize.

Mr.OSTERHAUS. Thank you.

The Iowa Medicaid pharmaceutical case management project is working to provide extra value to the patients of Iowa that are covered under Medicaid. Pharmacists want to partner with Medicaid to take good care of these patients.

I would ask you to direct CMS to rework the formula for AMP and to delay implementation until states can establish an equitable fee for the services we provide. We can increase the value and increase the quality of care given to these patients, but we need to work on it together.

Thank you again for the opportunity to testify today.

[The prepared statement of Mr. Osterhaus may be found in the Appendix on page 49.]

ChairwomanVELÁZQUEZ. Thank you, sir.

Our next witness is Anthony Civello, Chairman, President and Chief Executive Officer of Kerr Drug, Inc., in Raleigh, North Carolina. He is testifying on behalf of the National Association of Chain Drug Stores. Mr. Civello is the Chairman of the NACDS Board of Directors. He has served on this institution sine 1998.

Welcome, sir, and you will have five minutes to make your presentation.

STATEMENT OF ANTHONY CIVELLO ON BEHALF OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr.CIVELLO. Thank you very much, Madam Chair, and members of the Committee. I thank you for your interest, and I thank you for your understanding.

As you said, I am a CEO of a chain of drugstores. There are 102 drugstores. They are all based in North and South Carolina. Sixty-

five percent of these stores, however, are in rural North Carolina. So we service many Medicaid patients.

I would like to ask the Committee if you mind if I do not use my prepared notes and I maybe just refer to some of the comments that Mr. Smith made earlier on. And I, quite frankly, as amazed that Mr. Smith feels he is an expert on community pharmacy economics. He made a joke about AWP, ain't what paid. We call AMP ain't my price because it does not reflect what we are paying.

Also, the comments about independent pharmacies or chain pharmacies will lose one percent of their sales based on the implementation of AMP, and that is categorically wrong. Our rural stores particularly fill up to 50 percent of their total prescriptions in Medicaid prescriptions. Our Durham County stores fill 30 to 40 percent of their prescription. Sixty-one percent of all of our prescriptions are generic.

The OIG and the GAO has said that AMP will equal 36 percent below our cost. I cannot see how he gets the math to work to state that one percent will be affected, and I take offense to that.

First of all, NACDS has worked with Grant Thornton and our Coalition for Community Pharmacy, and we have done a nationwide study on the cost to fill prescriptions. We did it with 23,000 pharmacists participating, and we used over 832 million prescriptions. We accounted for all costs, and it cost $10.50 on average to fill a prescription. This flat out will not work with an AMP that is 36 percent below our cost.

The comment was made that there was a comment period. Well, I'd like to reflect on that a minute. That is, for the last two years we have provided comments. I believe the comments have been heard but not listened to.

We have provided data indicating that the AMP as being described in the role, in the projected role, at the time by CMS was flawed and inaccurate, but again, it fell on deaf ears.

The bottom line is just very simple, and I repeat what Mr. Osterhaus said at the outset. The bottom line is this is going to be very damaging to community pharmacy. I have been in the business for 40 years as a pharmacist, and I do not only represent the chain drug industry today. I represent also all of pharmacy as a pharmacist.

And I can tell you that we have not faced the situation like this in my history. It is very damaging and will be very damaging. That is the bottom line.

The comment was made that this will not serve as a disincentive to generics. That is patently incorrect. This will be a disincentive for generics. The fact is across our nation generic utilization varies from a low of 45 percent in New Jersey to a high of over 60 percent in the State of Washington. There is a lot of room for savings by increasing utilization in generics.

This AMP role will decrease that incentive. It will, in fact, incentivize brands. The comment was made earlier that brands cost six times more. That is fact. That I agree with.

It will do something else for brands that you should be aware of, and I believe you are. It will lower rebates. The lower the AMP, the lower the rebates. So we will have increased utilization of

brands and less rebates. I just cannot make the math work and to accept any of Mr. Smith's remarks.

There are solutions. Quite frankly, we have approached the administration on many occasions and again fallen on deaf ears. We need action now. As an industry I call upon you for all of community pharmacy to act now.

We need legislation. The implementation is upon us. It will be here by year end. We have got to act now. We need legislation. There are a number of things that we could bring to the table. We need people that will listen to us. Every day we negotiate with our state legislators, and the comment was made we are not dumping on our states. We are. We are, in fact, dumping on our states.

And our states are trying because we are a part of that business. We are members of the community, and they are reacting by trying to increase the dispensing fees. But this is clearly dumping.

Let me just give you a couple, if I could take 30 seconds here, a couple of areas that I would suggest the Congress address. Clarify the definition of AMP and include only sales to wholesalers for drugs distributed.

Quite frankly, just make it be the price we pay. It is that simple. Do not publish a list that is below our cost.

Establish federal payment limits on drugs with as little as two sources of supply. We need you to go back to the pre-DRA, which is three sources of supply versus the two that the AMP ruling has in it right now.

I will conclude by saying, again, I appreciate your listening. I stand ready to answer any questions today and in the future as it relates to this dire situation.

Thank you.

[The prepared statement of Mr. Civello may be found in the Appendix on page 55.]

ChairwomanVELÁZQUEZ. Thank you, Mr. Civello.

Our next witness is Mr. Charlie Sewell. He is the Senior Vice President of Government Affairs at the National Community Pharmacists Association. The National Community Pharmacy Association represents 24,000 independent pharmacies and 50,000 community pharmacists and their patients across the country.

Prior to joining NCPA, Mr. Sewell was President of ACG Enterprises.

Welcome, sir, and you will have five minutes for your presentation.

STATEMENT OF CHARLIE SEWELL ON BEHALF OF NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Mr.SEWELL. Thank you, Madam Chair and Committee members.

We really appreciate the opportunity today to talk about our concerns with the AMP rule.

You mentioned that we represented 24,000. We used to represent 24,000. Today unfortunately we only represent a little over 23,000. Frankly, community pharmacy was doing very well for the last five years, until a year ago. We were holding steady in terms of our number of pharmacies.

In fact, we were showing a little bit of growth, and now what has happened in the last year, we had an intervening variable, Medicare Part D. In the last year we have lost 1,152 pharmacies across the nation. That is five percent of independent pharmacy. We certainly have been staggered with the low and slow reimbursements associated with Medicare Part D, but we are still trying to do the best for out patients.

Unfortunately, we are looking at a situation now with the Medicaid proposal that is now in the final rule where we are going to be knocked to the canvas and knocked to the canvas hard, and we are going to find it very difficult to get up.

We have ten percent of our pharmacies, over 2,300 pharmacies across the country. Over 50 percent of their business is Medicaid. If they are going to be reimbursed at 36 percent below their cost and with the minuscule state dispensing fees as they are now, there is now way they are going to be able to stay in business.

You know, CMS talk about having a further comment period. That further comment period is going to be way too late for a lot of these pharmacies because they are going to start going out of business almost overnight.

Congressman González mentioned that it is all about quality time with our pharmacists. We do spend an extraordinary amount of time with our patients. It is because of our pharmacists that patients day in and day out avoid adverse drug interactions. It is because of our pharmacists that patients take their much needed medicines on time and properly.

When that relationship is done away with, and that is what is going to happen, Medicaid patients are going to suffer, but also patients across the board are going to suffer, as has been mentioned by Mr. Braley. We have a lot of pharmacies. We have a lot of pharmacies. We are the only pharmacy within 30, 40 miles. If we are not there, there is nobody to go to for their medical needs. The pharmacist is really the front line to defense.

Uncle Sam unfortunately has become our business partner. That was not our choice. Now about 50 percent of the average independents' pharmacy, their business is government, either Medicaid, Medicare or Tri-Care.

And what we have discovered is Uncle Sam is a lousy business partner. He does not do a very good job, and now we have been handed the average manufacturer's price. Now, we knew it was going to be bad. We just did not know how bad it was.

When Congress voted on this measure in the Deficit Reduction Act, they had no numbers. They had no AMP data because the AMP data was always confidential information that was reported between the manufacturer and CMS. We asked CMS to release data to us on a confidential basis so we could respond with their specific concerns and show them exactly what this impact was going to be. They failed to provide us that data.

I mean, they say that we did not want it published. Of course we did not want inaccurate data published. It would be misleading, but we wanted the data so that we could show them the net effect. Unfortunately, we were not able to do that. So the only data that is out there is what GAO and OIG have, and they have shown exactly, exactly the same results when you look at GAO they say they

are going to be reimbursed at 36 percent below our cost for 59 of the 70-some total drugs that they looked at. They actually looked at 77 drugs which represented over 50 percent of the marketplace in Medicaid. On average we are going to be reimbursed at 36 percent below our cost.

OIG looked at the top 25 high expenditure drugs in the Medicaid program. They said that for 19 of the 25 we would be reimbursed below our costs, and then if you look at the five out of the other six and you factor in our cost to dispense that Mr. Civello related, you are looking at a situation where we are going to lose money on those drugs as well because they are not going to come close to covering the 1050 that it costs to run your pharmacy. That is what it costs to run the pharmacy, to pay for the pharmacist, to pay for the rent or the mortgage, to keep the utilities paid for. I mean, that is simply the operation of a pharmacy, and if you don't cover the cost of the drug and what it costs to actually operate the pharmacy, you can't stay in business.

I mean, you hope you also eke out a meager profit. That is certainly not being allowed by this rule.

CMS made a number of sweeping generalizations in the rule, and you heard some of those today from Mr. Smith. They essentially reject out of hand OIG and GAO. Yet they have never provided any specific reputation to either of those studies. They just say they disagree with them.

CMS suggests that the shortfall can be made up by increasing dispensing fees a the state level. Talk about an unfunded mandate, that is an unfunded mandate to the states given their budgetary pressure.

And what we find of interest is they are really talking out of both sides of their mouth. There was an increased dispensing fee. It was just offered up by Louisiana, and their plan? Guess what. CMS rejected it. So they say they are going to allow the states to increase the dispensing fees. In fact, the first opportunity they had they rejected the plan that was put forward by the State of Louisiana out of hand.

They go on to say in the rule that there is a significant impact. They did not address that impact at all. They shirked their responsibilities with regard to the Regulatory Flexibility Act. I mean, there has been no analysis whatsoever of the 18,000 pharmacies all whom we represent and what kind of impact this is going to be.

We are looking at it and saying it is going to wipe out almost our entire net profits. Any business that does not make a profit does not stay in business.

With that, Madam Chair, I would be glad to answer any questions at the appropriate time.

Thank you very much.

[The prepared statement of Mr. Sewell may be found in the Appendix on page 61.]

ChairwomanVELÁZQUEZ. Thank you, Mr. Sewell.

Our next witness is Mr. Ed Hagan. He is the Director of Pharmacy at the Associated Food Store in Salt Lake City, Utah. He is testifying on behalf of the Food Marketing Institute, which has member companies with retail pharmacists. The Food Marketing

Institute conducts programs in research, education, industry relations, and public affairs on behalf of its 1,500 members.

Prior to joining Associated Food Store, Mr. Hagan was the Director, Pharmacy at Woodtry Food and Drugs.

Welcome.

STATEMENT OF ED HAGAN, ON BEHALF OF FOOD MARKETING INSTITUTE

Mr.HAGAN. Good morning, Chairman Velázquez and members of the Committee.

I very much appreciate this opportunity to testify before the Committee about an issue of significant importance to all of its supermarket pharmacies, particularly those that are small businesses and the Medicaid beneficiaries that we serve.

FMI is extremely concerned about basing reimbursement for prescription priced drugs on the artificial concept of AMP. We believe that this use of AMP in the way it has been implemented by CMS will cause severe hardships for pharmacies and Medicaid recipients alike.

Associated Foods is a member owned cooperative based in Salt Lake City, Utah. In addition to the independent stores we serve, we own 21 stores and with three other wholesalers co-own the Western Family private label. Seventy-five of our stores across eight states and Guam have pharmacy operations. These pharmacies range in size from some locations filling as few as 70 prescriptions a day to larger that fill between four and 500.

While some of our stores are located in large metropolitan areas, Associated Foods also includes stores with pharmacies in small towns, such as Twin Bridges, Montana, Kamas, Utah, and Raymond, Washington. Many of our stores in these small towns represent the only pharmacies available.

Medicaid represents a little over ten percent of our business overall, but this figure jumps to more than 15 percent in many of our rural areas. Our generic percentage, currently is 61 percent of our prescriptions are filled with generic drugs.

Pharmacy profit margins, particularly in the case of small supermarket pharmacies, are a small percentage of total store revenues and a far lower percentage than most other pharmacy retail businesses. The gross margin for associated food store pharmacy operations is in the range of 20 percent with net profits lower than two percent.

A recent GAO study on this issue suggests that many pharmacies will lose money when AMP based FULs are implemented. Because pharmacy margins are razor thin, many pharmacies will not be able to sustain such losses and will either have to leave the program or go out of business.

Most of the associated food stores with pharmacies are single store owned operations. These stores generally encounter the same per store expenses of the stores of larger chains, the same salaries for pharmacists, same liability and other insurance requirements, the same operating costs, but without the ability to minimize the losses imposed by AMP policies through economies of scale and better purchasing power of larger chains.

The opinion on how the states and various private payers react to the implementation of AMP as a benchmark: my rough estimate is that this policy has the potential to decrease pharmacy margins by five to seven percentage points, which would cause many of the small stores represented by Associated Foods to lose money.

Even if the damage is solely limited to Medicaid, this would be a devastating cut for retail pharmacy and could result in the failure of some of our small business members.

Facing these cuts, Associated Foods' pharmacies and other FMI may find it extremely difficult to serve Medicaid patients. This issue will only be compounded as states such as California seek to move to an AMP based payment for all prescription drugs that are not subject to the FUL and as other payers turn to AMP for their own purposes.

Complicating the AMP problem is the fact that dispensing fees do not begin to cover the costs we incur when dispensing a Medicaid or, for that matter, any other prescription. By dictating that CMS use AMP for both the Medicaid rebate program and FUL for multiple source drugs, the Deficit Reduction Act left the agency with an almost impossible balancing act.

We believe that CMS failed to adequate use its discretion to mitigate the severity of the problem. Our industry believes that the competing roles of AMP as currently defined can really never be successfully reconciled.

To reconcile the AMP problem, we believe Congress needs to act in creating a separate benchmark for pharmacy reimbursement, separate from the calculations needed for Medicaid rebates. The use of this new benchmark would remove the need for some of the contortions CMS undertook in its proposed rule to balance the needs of pharmacies and drug manufacturers, and it would allow for a clear and accurate reimbursement metric without interfering with the Medicaid rebate program.

While we believe that a division of the two sets of responsibilities currently assigned to AMP is most appropriate, if Congress decides not to undertake a change of this magnitude, Congress should at least take steps to mitigate the negative effect of the AMP policy on retail pharmacies. These steps can include a more accurate definition of the retail pharmacy class of trade that excludes from AMP rebates and discounts that simply are not available to us at retail pharmacy.

This definition should exclude all mail order pricing, including PBM discounts to mail order, and all other entities such as hospitals and nursing homes that are not typical retail pharmacy.

In conclusion, I appreciate the opportunity to testify on this important health care issue on behalf of the FMI members who operate in store pharmacies in their supermarket. We are hopeful that the House Small Business Committee and the Congress will act to address the potentially devastating cuts that retail pharmacy is now facing as a result of the changes to the Medicaid prescription reimbursement policies.

I will be happy to answer any questions the Committee may have.

[The prepared statement of Mr. Hagan may be found in the Appendix on page 69.]

ChairwomanVELÁZQUEZ. Thank you, Mr. Hagan.

Mr. Sewell, I would like to address my first question to you. I understand that independent community pharmacists get 92 percent of the revenue from prescription drug sales and tend to serve a higher proportion of Medicaid beneficiaries than all of the retail pharmacies. My question to you is with many community pharmacists working only within two or three percent profit margins, what will be the consequences if this new formula is implemented?

Mr.SEWELL. The average community pharmacies' net profit is under three percent right now, and when you translate that to dollars, it is about $128,000 is all you are able to eke out in the way of profit for a year.

We are looking at a situation where almost all of that is going to disappear under this rule. You know, we deliver Medicaid services to such a higher percentage of Medicaid patients, and while the national average is about eight percent, we really are delivering right now about 16 percent in terms of our average store. That is how many Medicaid patients we are dealing with, 16 percent of our total business.

So a disproportionate amount of the cuts are going to fall on our shoulders, and we are going to be first in line to go out of business. We are already going out of business because of Part D, and now we are going to see this added to that let of lows.

ChairwomanVELÁZQUEZ. Ms. Civello, given the numerous challenges with producing a stable and accurate AMP, what alternative benchmarks do you feel would be better suited for calculating Medicaid reimbursement fees?

Mr.CIVELLO. And I am very happy to answer that. I would like to reflect on the question you asked Mr. Sewell first.

ChairwomanVELÁZQUEZ. Sure.

Mr.CIVELLO. And clearly state that the National Association of Chain Drug Stores, the majority of our members have less than 50 stores. So there is much serious concern on our members' parts because we are all part of community pharmacy.

In fact, the 92 percent number you mentioned at Kerr Drug is 85 percent. So we're like a bit independent. The average for al of NACDS is over 70 percent. It's a serious issue for all of community pharmacy.

In regard to your question what benchmark, you know, very clearly what we as an industry are prepared to step to the plate to do is accept reimbursement for the product cost that equates to what we pay. Now, there are a number of formulas that can be used. There's a number of terms. WAC is a term, but I don't think we should talk just about what might replace AMP. I think we need to talk about the fact that AMP is flawed and does not represent what we pay for the product. The industry, community pharmacy, is prepared to accept reimbursement at what we pay for the product.

ChairwomanVELÁZQUEZ. Thank you.

Mr. Hagan, FMI estimates that supermarket pharmacies account for roughly 14 percent of all out-patient prescription drugs dispensed in the United States. It is anticipated that the percentage will increase over the next few years.

How will the implementation of this rule impact small businesses in the supermarket industry?

Mr.HAGAN. One of the things that I noted when doing the research for this testimony is, like I stated, that in our rural areas we have much higher percent of Medicaid prescriptions. In our rural areas we also tend to have lower prescription volumes than, say, our metro Seattle, metro Salt Lake stores, but yet we have the same fixed costs. So our labor percentage tends to run quite a bit higher in a rural area, and those are the people that are going to lose money, close the doors, or stop accepting first.

And so the more that grows in the rural area, the faster that they are going to make some real decisions.

ChairwomanVELÁZQUEZ. Okay. Mr. Osterhaus, I really am interested in hearing directly from independent retail pharmacists. I want to ask you two questions. First, how will the new reimbursement formula impact your business?

And, two, do you think that you will be able to continue to participate in the Medicaid program if the new formula is implemented?

Mr.OSTERHAUS. Well, I do not think there is any question that implemented the way it is now, we would have to make a serious decision about what we can do to stay in business. As I said, 30 percent of our patients have either Medicaid as a primary insurer or secondary insurer. So it affects a lot that we do every day.

We are from a poor county, and it is just the way it is. I think the impact would be significant. I do not think that in my case in a town the size that I live in that I could really stay in business and not take care of Medicaid patients. I think in my heart these are the patients who need us more than anybody else, and I could not stay in business and turn people away.

I mean, we are the only independent pharmacy in Maqueketa. So they would have no place else to go to see a pharmacist who takes the time to counsel them, to identify problems and solve problems.

ChairwomanVELÁZQUEZ. Thank you.

I will now recognize Mr. Shuler.

Mr.SHULER. Madam Chair, thank you.

And to the gentlemen, thank you for your testimony and, more importantly, thank you for your commitment to communities. Far too often I think we forget how much work and dedication our pharma system, what they mean to our community. I mean just in your testimony you talk about how many people really and truly, they have their doctors, but they certainly lean on their pharmacists a great deal on all of their problems and issues, and far too often we don't tell you thanks enough, and so thank you for the pharmacists.

And to Kerr Drugs, living in Bryson City, growing up there, obviously Kerr Drugs was our pharmacist, and that was the only pharmacist we've had for quite some time, and so you've really been a staple in our community. I commend you not only for the work that you do in the pharmacist, but sponsoring Little League programs and stuff like that, I think it goes a long way, and so I commend you and thank you.

You know, Mr. Osterhaus has talked about how it is going to impact him, but from FMI, how will it affect you on the reimbursement side?

And maybe some of the others of you, how is the reimbursement? Is it six weeks with you? Maybe having a little more leverage with the larger, more franchises. How is it impacting you?

Because that has to be a tremendous amount. I mean, my local pharmacy, we spoke about this particular issue. He was to the point that not only was he banking with one bank, but he was banking with three just because of lines of credits to be able to run and operate his business.

Mr.HAGAN. That is a very accurate observation, and I believe the lag time between filling a prescription and when you are reimbursed does vary between a number of insurers, but very accurate to say four to six weeks after you fill a prescription you will get the check.

So there again it is the more business you do, the more exposure you have and we find that to be just exactly the same.

Mr.SEWELL. If I might add, we have just done a study of all of independent pharmacy and sine the advent of Part D, we have now had to take out a credit line on average of $70,000, but for many of our pharmacies, it is in the hundreds of thousands of dollars. We are banking the program while the Part D plans, the PBMs are getting paid up front and sitting on that money because they have a vested interest in doing so, so that they can make interest on the float.

That does not make any sense.

Mr.SHULER. Mr. Civello.

Mr.CIVELLO. Thank you, and thanks for your comment about Kerr Drug in Bryson City. I appreciate that.

I think you need to understand what the days outstanding were with Medicaid prior to the dual eligibles went from Medicaid to Medicare, and it was anywhere between ten and 14 days.

When you take that ten and 14 days and more than double it to 30-plus days, it is a big number whether you are one or whether you are 100 stores. To Kerr Drug, we already have a credit line. There is $5 million more on that credit line because of that delay. It is significant dollars. It is costing our industry a lot of money, and it is not right because the government still pays in a timely fashion, seven to ten days. Where is the money for the other 20 days?

Mr.SHULER. It is being floated, I guess.

[Laughter.]

Mr.SHULER. Well, thank you all for your testimony, and once again, on behalf of the Committee, thank your pharmacists and your staff for the hard work and dedication they do for our people.

I yield back.

ChairwomanVELÁZQUEZ. Thank you.

Mr. Braley.

Mr.BRALEY. Mr. Shuler and I share the distinction of both having under performed in the recent congressional baseball game we claimed due to injuries we received before the game, but his comment about Little League baseball sponsorship took me back 40

years to Brooklyn, Iowa when Crosson's Rexall Drug had their name on the back of Little League baseball uniforms when I was growing up in a town of 1,500, and I think that type of story is what we really need to be talking about because we run the risk of losing the valuable role that many pharmacists play not just in taking care of patients, but in the role they play in making their communities a wonderful place to live and work.

And, Mr. Civello, you made the comment that your comments have been heard but not understood, and that they have fallen on deaf ears. Well, I invite you to join the club.

[Laughter.]

Mr.BRALEY. On February 16th of 2007, I was proud to send a letter to Administrator Norwalk, along with 70 other members of Congress, asking on behalf of Medicaid beneficiaries and retail pharmacies in our districts and writing to express our deep concern about CMS' proposed changes in the payment for prescription drugs in the Medicaid program and concluding with the request that the proposed payment formula would be devastating to many retail community pharmacies, Medicaid beneficiaries.

And in response to that we got a classic nonresponse from the Administrator, and I received this copy on April 12th of 2007, and it gives you some sense of our frustration in dealing with the same issues you're talking about.

"Dear Mr. Braley:

"Thank you for your letter on behalf of your constituents regarding the definition of average manufacturing price."

And then it goes on to recite what that means, and it concludes by saying, "A summary of the comments and our responses will be included in the final rule which we expect to publish by July 1st, 2007. I appreciate you sharing your comments. I will also provide this response to the co-signers of your letter."

The letter itself did nothing to address the concerns raised by 70 members of Congress. So if you think you are frustrated, join the party.

I talked to you about the letter that 109 members of Congress signed as a response to this letter on May 18th of 2007. My staff and I have not received any response to that letter, despite the pending date of the release of the final rule.

And then on July 11 of 2007, I wrote to the Administrator after the final rule is released asking for clarification about how the proposed Iowa plan that I mentioned was going to be impacted by all of this we are talking about.

So we share your frustration, and we want to work with you because I can tell you based upon 109 signatures across the board on a bipartisan basis, people understand your concerns and we need to do more to help you.

I want to start, Mr. Osterhaus, by asking you this question. We have talked a lot about the adverse impact on rural communities. Over ten percent of Iowa's 1,066 pharmacies are in rural areas and are operated independently, and I assume your pharmacy fits both of those bills.

Mr.OSTERHAUS. Yes.

Mr.BRALEY. Can you tell us what in your opinion CMS should do to insure that access to drug care in rural communities is not jeopardized by this new reimbursement rule?

Mr.OSTERHAUS. Well, I think my comments would stand that we need to have a fair reimbursement policy, and I think that as Mr. Mr. Civello said, I think pharmacy is ready to be transparent on the product cost side. But it is a two-headed animal. The fee has got to take care of the cost of what it takes to be in business. If we want to have community pharmacists on the ground being partners in this program to make the program both successful and efficient and of high quality, we need to have fair reimbursement.

How they come about getting what really is acquisition price is one thing, but shoveling off to the states to let them decide what they are going to pay for a fee really splits this into two pieces that I think we are just looking for another problem.

So I would certainly say that Mr. Hagan's comment about taking a total different look at AMP with not bringing it into the rebate picture, which is a whole other rat's nest that probably should not be part of our health care system to begin with, I think maybe makes some sense. But if we're going to utilize what we call acquisition cost, it needs to be accurate, and if the only thing we have to go on is the GAO report, which says that did not happen.

Mr.BRALEY. Madam Chairwoman, I see that my time has expired, but I just want to make this closing observation and join in Mr. Shuler's comments about the tremendous benefit that we receive from the pharmacists and pharmacy employees that you all represent.

When I was running for Congress, I spent a lot of time in December of '05 and January and February of 2006 touring community pharmacies in my district, and I saw dedicated, committed individuals who were spending inordinate amounts of time, up to 80, 100 hours a week, trying to make sure that the patients they served got the best information about the difficult choices they were being faced under Medicare D.

I want to applaud everyone that you represent and please take back our best wishes and our thanks for the valuable service they provide and under very difficult circumstances.

ChairwomanVELÁZQUEZ. Thank you, Mr. Braley.

And now I recognize Ms. Clarke.

Ms.CLARKE. Thank you, Madam Chair.

I just want to commend you and the Committee for really highlighting this issue. I want to thank our panelists for really bring to us in real time, you know, the absolute impact of this rule.

Let me just say that I think it is imperative that we address this. This is a crisis upon a crisis upon a crisis not only for the delivery of pharmaceuticals in our communities. I think about the public health implications of it because we in the government have now put a huge obstacle in the way of our community's receiving quality medications that are required to contain certain types of public health diseases and illnesses in addition to the wellness factor for our communities. It just compounds what we know is the challenge for most communities, be they rural or urban like mine.

And so I want to thank you once again. The remedies, I think, are well spelled out in these gentlemen's testimony here today, and

I do not want to reiterate them. I want to thank you for being on the forefront and really driving home for us this impending crisis.

And, Madam Chair, once again thank you and thank you to my colleagues as well.

ChairwomanVELÁZQUEZ. Thank you.

Any other member wishing to make any other questions?

No. Okay. So I want to thank all of you for coming here today. This we understand is an important issue, and you know, sometimes all of these federal agencies come here, they issue regulations, and then when we ask them if they consider other alternatives, well, you know, they put the blame on Congress.

I want to say this. I know that this Committee does not have jurisdiction over this issue, but we do have jurisdiction over the Regulatory Flexibility Act, and we will continue to press upon CMS to refrain from implementing this rule until they have all the facts, all the data, and they really conduct an impact analysis on the adverse effect of this rule on small and community pharmacists.

So with that I will ask unanimous consent that members have five legislative days to submit a statement for the record. Without objection, so ordered.

And this hearing is now adjourned.

[Whereupon, at 12:12 p.m., the Committee was adjourned.]

STATEMENT
Of the Honorable Nydia M. Velázquez, Chairwoman
United States House of Representatives, Committee on Small Business
Full Committee Hearing: "Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries"
Wednesday, July 18, 2007, 10:00am

I call this hearing to order to address "Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?"

The matter we discuss today stems from the legacy of the last Congress. In February 2006, President Bush signed the Deficit Reduction Act which directed the Centers for Medicare and Medicaid Services to recalculate the way it reimburses pharmacies for providing generic prescription drugs to Medicaid beneficiaries. While evidence indicates that the old formula used by CMS resulted in some level of overpayment, the new formula clearly cuts too far.

On July 6th, the Centers for Medicare and Medicaid Services released a final rule which radically changed the old formula and could prove devastating to pharmacies and Medicaid recipients.
The new formula significantly reduces the reimbursements to the point where GAO has determined pharmacies will be paid back for only 64% of their costs of acquiring generic prescription drugs. That represents a 36% shortfall!

I have major concerns with the impact this rule could have on small businesses offering prescription drug coverage. These pharmacies have low profit margins and small retailers will be hit particularly hard. They tend to serve a higher proportion of Medicaid beneficiaries and get more of their revenue from prescription drugs. As a result of this change, many could be forced to close their doors.

This will not only hurt pharmacies, but it will affect overall access to care for Medicaid recipients. If these businesses close or drop out of the program, drug coverage will be reduced.
Medicaid is a critical component of our national health care system serving over 50 million. Without it, the vast majority of these people would join the ranks of the 46 million uninsured Americans.

What doesn't make sense to me is that while the intent of this new formula is to save money, it in fact encourages the use of more expensive brand name drugs. The average Medicaid generic prescription is $20, while the average brand prescription is $120. While this may be good for pharmaceutical companies, costs will be increased for the federal government and the states.

I believe the HHS Inspector General's report is a good starting point for us when we examine possible solutions to this problem.
The IG recommends that CMS should find a better way to reflect the actual costs of these drugs.

The IG's recommendation would remove outliers in drug prices that do not reflect the realities of the marketplace. It also provides an opportunity for pharmacies to alert the states and CMS when they can demonstrate their inability to acquire drugs at prices at or below reimbursement levels.

Tellingly, the IG says new Federal reimbursement limits should be monitored closely. Their report noted that such cuts could lead to access problems for Medicaid beneficiaries. These findings are also supported by the General Accounting Office.

As the rule is written, it threatens the ability of thousands of small pharmacies to keep operating. While the previous reimbursement formula may have overpaid pharmacies for generic drugs, the new one will make the issue worse. Our government should not be eliminating one problem, only to create another.

The GAO and HHS have shown there are better ways to ensure pharmacies are adequately paid for these generic drugs. Unfortunately, CMS is prepared to move forward despite these objections. Today's hearing will hopefully shine some light on why the CMS should reconsider the rule.

I look forward to today's testimony and thank the witnesses for their participation.

I yield to Mr. Chabot for his opening statement.

Opening Statement

Hearing Name	Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?
Committee	Full Committee
Date	7/18/2007

Opening Statement of Ranking Member Chabot

I would like to thank the Chairwoman for holding this hearing on the Centers for Medicare and Medicaid Services' (CMS) rule implementing the Deficit Reduction Act's modification of the reimbursement limits for certain prescription drugs in the Medicaid program. This hearing continues a longstanding effort by this Committee to convince CMS that good regulatory practice requires the agency to promulgate rules that do not adversely affect the thousands of small business providers of necessary health care in the United States.

Drug prices represent a rapidly increasing portion of monies devoted to health care in the United States. It is not surprising to find then that the Medicaid program also faces rapidly rising costs for drug reimbursement. Under the Medicaid program, states are authorized to provide for reimbursement of prescription at levels established by CMS under authority delegated from Congress.

According to the Government Accountability Office (GAO), the cost of such reimbursement in the Medicaid program rose by 870 percent in the 15-year period from 1990 to 2004.

Congress recognized that such growth was not sustainable and, in the Deficit Reduction Act of 2005, an Act which I supported, modified the payment from 150 percent of the list price to 250 percent of the average manufacturer's wholesale price (referred to by its acronym AMP). Savings are enhanced by calculating the 250, not on average of all drugs in a therapeutic class, but rather on the lowest AMP in a therapeutic class. The Congressional Budget Office (CBO) estimated that the modification will represent about $1 billion dollars in savings for the first few years of implementation and then about $300 million thereafter.

Congress directed CMS to promulgate regulations to implement the modification in reimbursement rates. A perusal of the rulemaking record, including comments from witnesses before us today, revealed substantial concern that the new methodology will not provide dispensers of pharmaceuticals with sufficient revenue to cover the costs of dispensing drugs under the Medicaid program. Nor are these concerns simply the cry of the economically self-interested. The Office of Advocacy of the United States Small Business Administration, the Inspector General of the Department of Health and Human Services, and the GAO also have noted that the formula will not allow them to recoup their drug acquisition costs, much less cover all the costs associated with filling a Medicaid prescription.

The result of the final rule will have unusually perverse results – results that could not have been intended by Congress in legislation entitled Deficit Reduction. Pharmacies could reject Medicaid patients (leaving such individuals without access to drugs). Doctors, recognizing this, will then begin to require that specific brand name drugs will be used

thereby raising the costs of drugs under Medicaid – the opposite result from what Congress intended.

Entitlement spending needs to be controlled. But it also must be controlled in a sensible manner that actually achieves limits on spending. Instead, we have a policy that provides rational economic actors the necessity of finding ways around these limits that will ultimately not lead to reductions in entitlement spending.

I am sure that CMS will testify that they are just implementing the law that Congress wrote and they have no discretion to modify the policy to reduce adverse consequences on small business. That is an argument that CMS has made to Congress one too many times in the past six years, including to this Committee. For one, I am tired of hearing that. Even a quick perusal of the rather dense verbiage of the Medicare and Medicaid statutes will show that CMS is replete with discretion. But unlike other federal agencies, the Medicare and Medicaid statutes are rife with exemptions from judicial review. It is about time that CMS rulemaking is subjected to the same scrutiny applicable to all other federal agencies. I look forward to working with the Chairwoman and other members of the Committee on ensuring that the provisions of the Administrative Procedure Act apply with full force and vigor to CMS. Otherwise, CMS will be back before this Committee on some other rule blaming Congress while Congress argues that CMS has discretion to avoid any potential adverse consequences to health care providers.

I want to thank witnesses, including the Dennis Smith of CMS, for agreeing to testify on such short notice. While I understand that the preparation may be a hardship, I think the efforts of the witnesses will be very helpful in this Committee's understanding of the final rule and its effects on small businesses.

With that, I yield back.

Statement of The Honorable Jason Altmire
House Committee on Small Business Hearing
"Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for
Small Businesses & Beneficiaries?"
July 18, 2007

Madam Chair, I am pleased to have the opportunity today to discuss Center for Medicare and Medicaid Services' recently released final rule regulating pharmacies' Medicaid drug reimbursement rates. As the final rule becomes effective on October 1, it is vital to have this discussion today and examine the potentially deleterious effects the rule will have on pharmacies, including community pharmacies.

On its face, this appears to be another instance of an agency making a one-size-fits-all rule that in the end serves to induce participants to drop out and thus reduce access and services for beneficiaries. For the small pharmacies that make the great bulk of their revenue from prescription drug sales and the communities that rely on them, this rule could have grave consequences.

Madam Chair, I look forward to today's discussion and hope that this Committee can come up with some possible solutions that protect small businesses and protect Medicaid beneficiaries. I yield back the balance of my time.

# # #

Statement of Rep. Bruce Braley

July 18, 2007

Opening Statement: Hearing on "Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?"

Thank you Madam Chairwoman, and thank you for holding this hearing.

I would like to thank Matt Osterhaus for taking time out of his busy schedule and away from his pharmacy in Maquoketa, Iowa to testify before the Small Business Committee.

I am deeply concerned by the Center for Medicare and Medicaid Service's (CMS's) proposed changes in the reimbursement formula for prescription drugs in the Medicaid program. CMS claims that this new definition of the Average Manufacturer Price (AMP) is meant to approximate the prices at which retail pharmacies purchase generic medications from manufacturers and wholesalers. Unfortunately, however, the final rule is flawed and will result in an AMP that does not reflect the true prices.

In fact, a December 22, 2006 GAO report shows that the proposed rule on the AMP would reimburse pharmacies at an average of 36 percent below their costs for generic drugs, which account for 63 percent of all prescriptions dispensed in the United States.

I have repeatedly urged CMS to reject this proposal to classify reimbursements based on the AMP, which would lower reimbursements paid to pharmacies for generic drug purchases.

In my state of Iowa it is estimated that pharmacists will receive an $11.81 million cut in reimbursements in the first year of implementation alone. This could force pharmacies out of the Medicaid business, which will reduce access to care for Medicaid beneficiaries. In many underserved areas, it could force pharmacies out of business altogether.

Also, by making generic drugs unprofitable, Medicaid has created an incentive to dispense more expensive brand name drugs, which are not subject to the new formula. So, ironically, this new formula which was established to save money could actually end up increasing costs to both the states and the federal government for prescription drugs.

I have specifically fought for Iowa pharmacies on this issue, urging CMS to approve a measure that was passed in the Iowa General Assembly to offset reductions in reimbursements for generic medications. This plan would increase the pharmacy dispensing fee to compensate for any reduction in the drug product cost reimbursement. However, this provision needs approval by CMS before taking effect.

Although I am pleased the State of Iowa has stepped up to the plate to make sure pharmacies receive appropriate reimbursements for generic drugs, I think it is extremely unfortunate that CMS has put the State in this position. I am concerned that Iowa increasing its payments to pharmacists could place budgetary pressures on other important Medicaid services provided by the State.

I look forward to hearing from our witnesses today and am hopeful that we can shed some light on this proposed change in reimbursements to pharmacies.

Thank you Madam Chairwoman, and thank you to the witnesses for coming in today.

Supplemental Statement of
Dennis G. Smith
Director, Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services

Before the
House Committee on Small Business
On
"Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?"

August 21, 2007

I am providing this written statement at the request of the Committee to supplement the oral statement I provided to the Committee at your hearing on July 18, 2007.

As the Committee is well aware, CMS recently published a final rule which implements provisions of the Deficit Reduction Act of 2005 (DRA) (P.L. 109-171) that redesign how CMS pays for certain Medicaid prescription drugs. The Agency is committed to a smooth implementation of this rule so that Medicaid can more accurately reimburse pharmaceutical acquisition costs. We share Congress' commitment to ensuring beneficiaries have access to local pharmacies, but want to be sure States have the tools to ensure appropriate reimbursement to pharmacists for prescription drugs so the Agency and States can target resources effectively within the Medicaid program.

Deficit Reduction Act Requirements

Before describing the final rule on Medicaid drug reimbursements that CMS published on July 17, 2007, it is important to clarify the context for this rule. This rule was proposed and put forward by CMS because Congress identified and mandated new reimbursement limits for certain prescription drugs in the DRA. Changes to the average manufacturer price (AMP) of pharmaceuticals, to the focus of my comments, are but one piece of a much larger Medicaid drug reimbursement rule.

A series of 2004 studies performed by the Government Accountability Office (GAO) and the U.S. Department of Health & Human Services (HHS) Office of the Inspector General

(OIG) noted inconsistencies in the methods used by manufacturers to determine AMP due to confusion about which sales should be included in AMP. The reports showed that Medicaid payments to pharmacies for generic medications were much higher than the prices pharmacies actually paid for these generic prescription drugs. In fact, GAO and OIG found that States were using artificially inflated commercial drug pricing guides to set drug reimbursement levels. When Congress wrote these statutory changes into the DRA, it was responding to these reports and the need for more transparency in Medicaid prescription drug pricing. Congress decided to more closely align reimbursement methodologies with actual pharmacy acquisition costs.

It is in this environment that CMS pursued the regulatory process, as specifically required by the DRA, to implement these provisions.

The Medicaid Drug Reimbursement Rule and its Impact

The rule clarifies AMP for brand-name and generic prescription drugs, which is used to calculate the Federal Upper Payment Limit (FUL) for certain prescription medications. Under the final rule, CMS will post AMPs on a web site that consumers can access. In addition, the new upper limit will allow Medicaid to pay more appropriately for prescription drugs dispensed to the estimated 40 million individuals who get their drugs through the Medicaid program.

Overall Impact

Prior to the DRA, the FUL was established by regulation and has been used since the 1970s. At present there are 584 FUL groups. In 2005, only 8.3 percent of Medicaid drug spending was for drugs subject to a FUL. The new rule continues our past policy of allowing States flexibility to set reimbursement for particular drugs higher or lower than the FUL to reflect market conditions in the States. The upper limit is an aggregate cap on Medicaid spending for FUL drugs. Federal matching funds will not be available for any excess in spending above the aggregate FUL cap.

The DRA established a new FUL calculation, which is the maximum amount that the Federal government will pay States in Federal matching funds, also known as Federal financial participation (FFP), for drugs subject to a FUL that are dispensed through State Medicaid programs. The new FUL is calculated at 250 percent of the lowest AMP in a prescription drug class. The savings represent about 1 percent of pharmacy sales.

CMS believes that the implementation of this rule will result in a significant reduction in total Medicaid drug expenditures in Federal fiscal years (FY) 2007 - 2011. CMS' independent Office of the Actuary (OACT) has estimated savings of $8.4 billion over the next five years ($4.9 billion in Federal savings and $3.5 billion in savings for States) as a result of this rule. Even with these reimbursement changes, the Medicaid program is still expected to spend more than $140 billion in State and Federal funding for drugs over the same time period, FY 2007 through FY 2011.

The provisions of this regulation take effect on October 1, 2007 and the first monthly AMP reporting period will be for October 1-31, 2007, which means that States will have until January 30, 2008 to put the updated FULs into effect.

Ongoing Flexibility for States

I believe that States are the laboratories of innovation and I am committed to ensuring that they retain maximum flexibility in implementing their Medicaid programs in a manner that is consistent with the unique features of their State populations. In drafting the final rule, CMS was careful to protect the interests of States and recognize the States' authority to set their reimbursement levels and dispensing fees for pharmacists. Under the provisions of the statute, States retain the flexibility to pay above or below the FUL for individual drug classes and still are eligible to receive Federal financial participation (FFP) as long as overall reimbursements for generic prescription drugs are under the aggregate cap.

Effects on Small Business Entities

Based on the Small Business Association's (SBA) size standards, CMS estimates that up to 18,000 small retail pharmacies will be affected by this regulation, as the final rule will result in lower FULs for most prescription drugs subject to the limits, thus reducing Medicaid payments to the pharmacies for these medications. The revision to the FULs would generally reduce those limits and, thereby, reduce Medicaid reimbursements for drugs subject to the limits. However, in moving to the proposed to the final rule CMS excluded pharmacy benefits managers (PBMs) and nursing home pharmacies from AMP calculation in order to reduce the impact of the AMP calculation on small businesses.

We estimate that the annual effect of lower FULs and related changes may reduce overall pharmacy revenues by approximately $800 million in 2007, increasing to a $2 billion reduction annually by 2011. These reductions, while large in absolute terms, represent only a small fraction of overall pharmacy revenues. According to recent data by the National Association of Chain Drug Stores, total retail prescription sales in the United States, including chain drug stores, independent pharmacies, and supermarkets totaled approximately $200 billion in 2006.

CMS is interested in having a smooth transition in the implementation of this final rule, and also a better understanding of the full impact of this final rule. As a result, we intentionally issued components of the final rule with comment to allow CMS to benefit from further public comment regarding certain newly defined policies. CMS recognizes the important role small pharmacies play in helping Medicaid beneficiaries manage chronic conditions, and is hopeful that the extra flexibility given to States in the regulation will enable States to respond with new reimbursement structures that take into account the role community pharmacists play in provisions of health care.

Conclusion

In conclusion, CMS believes that the final rule appropriately implements the DRA provisions. We value the service of small pharmacies to the Medicaid population and we do believe that we have provided States with sufficient flexibility to provide fair and sufficient reimbursement to these pharmacies.

Matt Osterhaus, Owner
Osterhaus Pharmacy
House Committee on Small Business
Concerning
Medicaid Drug Reimbursements
July 18, 2007

Chairwoman Velazquez, Ranking Member Chabot, and Members of the Small Business Committee, good morning and I thank you for allowing me to testify here this morning on behalf of the Association of Community Pharmacists Congressional Network and the independent pharmacies they represent across the country.

Since the launch of the Medicare Part D prescription program in January 2006, hundreds of pharmacies have closed. It is my belief – and the belief of thousands of pharmacists and pharmacy owners across the nation – that if the economic environment of pharmacy remains as it is today and CMS implements Average Manufacturers Prices (or AMP) as reported in the recent ruling, the citizens of this nation will see an unprecedented loss of pharmacies, in particular independent community pharmacies. This one-two punch that CMS has thrown threatens the survival of the community pharmacy. The loss of these small businesses will inflict loss of access for citizens who have depended on these pharmacies for their prescriptions and heath care needs.

Independent community pharmacy is the perfect example of small business in America. These businesses have survived over the centuries because they have provided care to those in need and added value to the health care system. Many of these small businesses serve as

an anchor in hundreds of small towns across the nation as a provider of jobs, a payer of taxes, and center of the community. My practice is the only independent pharmacy in my community of 6,000 people. We are the downtown "anchor" of Maquoketa, employing 25 people including seven pharmacists. We provide medication therapy management for patients with private insurance, Medicaid and Medicare part D.

Independent community pharmacy has faced many crises over the years, but there is no greater threat to the shear existence of the independent community pharmacy than the threat it faces today.

Several years ago, as health care began to change in our country, the first to absorb the economic impact was pharmacy. Pharmacy Benefit Managers (known as PBMs) began approaching employers guaranteeing savings by cutting prescription cost. These savings were not produced by working with patients to create a better health care regimen, they were not created by patient education on healthy lifestyle choices – no, they were created overnight by the PBMs cutting reimbursements paid to the pharmacies for prescriptions filled. This was the only source of savings to the employer.

Pharmacy then saw, by no fault of their own, medication prices escalate at a rate never in the past. Once again, private insurance companies and government programs such as Medicaid began to attack pharmacy for these price increases. Most states lowered Medicaid fees as well as implementing Maximum Allowable Cost programs to minimize the payment for products used to fill the Medicaid prescriptions.

At this point, many pharmacies across the Nation had to address their business practice due to lost revenue and shrinking gross margins. As usual, most pharmacy owners made the decision with their heart as opposed to making sound business decisions. They chose to continue serving their patients in the hope that the problem would be solved in the near future and they could continue running their pharmacies as they had being doing for years, putting the needs of the patient first. I should point out that during this period of time, many pharmacies across the nation closed their doors because they could not absorb the loss of revenue and many people lost the pharmacy access they had grown to expect.

Then Congress passed the Medicare Modernization Act and created the Part D pharmacy benefit. This became the death nail to hundreds of small business – pharmacies – across the nation, closing their doors due to the slow and low reimbursements paid by the PBMs. It has been estimated we are spending 1/3 of the health care budget on administration and benefit management. We need to re-allocate our health resources and refocus them on care.

I point out that the small business of independent community pharmacy is unique in that it has little control over the cost paid for a product or control over the price set to sell the product. Yet, when it comes time to squeeze savings from the system in this escalating cost environment, both State and Federal government turn to pharmacy as if they had full control over pricing.

Now once again, the Federal government through CMS and the establishment of the AMP generic pricing structure is striving to save billions of dollars by cutting payments of generic medications to pharmacies across the country. Members of Congress believe pharmacies can absorb this cut and go on. Many people do not understand business operations and or the term "gross margin." It is very simple: if I buy a medication in my pharmacy for $100 and get reimbursed $85, then have to wait 6 weeks to be paid, it is just a matter of time before I have to close my pharmacy. There is no gross margin. CMS through AMP is once again going to reduce the payment, in a severe fashion, utilizing a formula to establish product reimbursement which is below my acquisition cost from the wholesaler. The formula uses pricing from mail order and hospital outpatient pharmacies. This is an inequity which needs your attention today. A small business of any type cannot continue to operate if the revenue coming in does not at least match the cost of the product being sold and the overhead needed to serve the consumer.

I would submit to you that hundreds of independent community pharmacies will be lost if AMP is implemented as currently designed by CMS. This is a blow to small business, but devastating to those patients served by these small businesses. Pharmacists across the nation are agonizing over the thought of not being able to serve their patients. And those patients will be distraught over the thought of losing their pharmacies. Members of Congress may not believe access is a problem because they see multiple pharmacies at the same intersection in larger cities. Iowa is a prime example of rural America, with several counties with only one pharmacy. These patients understand what it will mean to their health care if that pharmacy disappears – they could easily be 30-40 miles away form the

next closest pharmacy. I think of my patient Don, whose seizure disorder was uncontrolled. We have worked with him to adhere to his regimen and have kept him out of the emergency room. I think of Peggy, my patient with MS; we have collaborated with her physician to control her pain and to help her quit smoking.

Independent community pharmacies serve a vital role in the health care of our nation. These pharmacies are small businesses that provide entry level health services to their patients. The way the current system pays for the services and medications is based on the price of the medication. The pharmacist has to purchase and maintain an inventory so the medication will be available when the patient needs it. They must be paid enough, as any small business, to pay for the medication and to create enough gross margin to pay overhead, including an average of 12 employees who must receive their paychecks every week.

AMP has the potential to destroy the business of independent community pharmacies in this country. There are many ways a pharmacist can help save health care dollars – as they already do in many State Medicaid programs. Incentivizing community pharmacists to be partners with Medicaid in providing quality care is working in Iowa. The Iowa Medicaid Pharmaceutical Case Management project is adding value to the dollars spent on medications. But without fair reimbursement for the drug product and an adequate professional fee for the service rendered, the infrastructure of pharmacy in this country will be lost.

If AMP will supposedly generate $8.4 billion dollars by devastating basic access to the healthcare delivery system, what will the Federal government do the next time they must find savings? The pharmacies that could help create ongoing savings by working with their patients and their physicians to optimize drug therapies, educate patients to be active participants in their healthcare and intervening on the behalf of those who can't will be gone and this one-time savings will simply be followed by the continual rise in healthcare costrs. I would ask you not to let this happen to some of the most important small business in the nation, those that take care of your health and the health of your constituents.

Thank you again for the opportunity to testify before you today.

Testimony of:

Anthony Civello
Chairman, President, and Chief Executive Officer

Kerr Drug, Inc.
Raleigh, NC

On:

Medicaid Drug Reimbursements: Are CMS Cuts Bad Medicine for Small Businesses and Beneficiaries?

To:

United States House of Representatives
Committee on Small Business

Wednesday, July 18, 2007

Introduction

Chairwoman Velazquez, Ranking Member Chabot, and Members of the Committee, my name is Anthony Civello, and I am Chairman, President, and CEO of Kerr Drug. Kerr Drug operates 102 pharmacies in North and South Carolina. I am also a former Chairman of the Board for the National Association of Chain Drug Stores (NACDS). NACDS represents chains numbering from four to over 5,000 pharmacies, but consistent with my mission as past Chairman I speak to you with one voice as a pharmacist and partner of all of community pharmacy.

Thank you for the opportunity to share our serious concerns about the final rule issued this month by the Centers for Medicare and Medicaid Services (CMS). The rule establishes guidelines by which average manufacturer price, or AMP, will be used to cap Medicaid payments to pharmacies for "multiple source" (primarily generic) prescription medications. These rules were promulgated by CMS to implement pharmacy reimbursement provisions included in the Deficit Reduction Act of 2005 (DRA).

We appreciate the Committee's support for the community pharmacy industry, especially the many small pharmacies located throughout the country. Sixty-five percent (65%) of Kerr Drug's pharmacies are in rural towns. For Medicaid beneficiaries in these towns we are the most accessible supplier of prescription medications, health information and critical healthcare services. Like any business operator the equation is simple: revenue must exceed expenses to maintain a healthy business. For many pharmacies the changes in the DRA and the final rule regarding reimbursement for prescriptions place their long-term health at risk.

We are especially grateful to you, Chairwoman Velazquez, for your leadership on this issue, in particular the strong letter you sent to CMS during the public comment period last February. Your letter correctly pointed out that the proposed AMP rule was fundamentally flawed, especially in its complete failure to provide a thorough analysis of the economic impact the rule would have on small pharmacy businesses, as required under the Regulatory Flexibility Act.

Despite your efforts, I am disappointed to report that the final rule is no better than the proposed rule. In fact, while the final rule makes some changes to certain areas related to the definition of AMP, community pharmacies, both large and small, are still facing an unprecedented $8 billion in reimbursement cuts. By our calculations, payments for generic medications will be cut by 30% – a level that will simply be unsustainable for many pharmacies serving low-income communities.

This final rule makes it abundantly clear that now is the time for Congress to reverse these unreasonable and counter-productive cuts. We understand that this Committee does not have legislative jurisdiction over the Medicaid program. Yet we call on all Members of Congress, especially the House Leadership and the Energy and Commerce Committee, to support and pass legislation this year to ensure that pharmacies are paid fairly and adequately. This legislation is necessary so pharmacies can continue to serve some our nation's most vulnerable citizens in the Medicaid program.

We also understand that scaling back these cuts will require that additional revenues be found to satisfy "pay as you go" budget rules. Surely there are several ways to increase revenues to offset legislation that more fairly reimburses pharmacies, but we hope Congress will appreciate this important fact: While there are costs associated with addressing this problem, the cost of inaction is quite likely even greater. If pharmacies reduce services, stop accepting Medicaid patients, or go out of business because of inadequate reimbursement policies, Medicaid patients will do without care. Illnesses will get worse and health costs will increase as more hospitalizations and physician office visits are required.

Summary of the Problem

The final rule issued by CMS is fundamentally flawed. As defined in the rule, AMP values would not be reflective of the prices that community pharmacies pay to acquire drug products. This flawed definition could lead to severe underpayments to community pharmacies if AMP is used to set payment levels. The failure to accurately define AMP is compounded by other provisions included in the final rule. The DRA limits Medicaid payment for generic drugs at 250 percent of the lowest AMP for a particular drug. In today's market small community pharmacies cannot purchase at the lowest price. Moreover, the DRA dramatically expands the number of drug products subject to federal limits. Since there is no corresponding requirement that states must adjust dispensing fees to accurately compensate for the actual costs of operating a pharmacy and providing professional pharmacy services, the result will be catastrophic to America's pharmacies.

As noted, CMS projects that payments for generic drugs will be cut by a total of $8 billion over the period from 2007-2011. In spite of the Chairwoman's efforts, the final rule still fails to adequately document the impact on community pharmacies. A 30 percent reduction in payments to pharmacies for generic drugs could be devastating to many community pharmacies, given that pharmacies already operate on slim net profit margins (typically 2 or 3 percent).

Recent studies by the Government Accountability Office (GAO) and the Department of Health and Human Services' Office of Inspector General (OIG) conclude that in many cases these new federal limits will not be sufficient to compensate pharmacies for their costs of buying generic drugs. Although CMS has attempted to discredit these reports, it offers no proof that community pharmacies will be fairly compensated under the final rule. In fact, the savings from pharmacy reimbursement cuts projected in the final rule are the same as those projected in the proposed rule. In other words, the changes in the final rule do nothing to mitigate the substantial cuts imposed on community pharmacies.

In short, the DRA and the recent final regulations severely reduce pharmacy payments for generic drugs without compensating by increasing dispensing fees. These reductions could force many pharmacies to close or reduce hours or services, jeopardizing Medicaid beneficiaries' access to medications and pharmacy services. These changes could also reduce incentives for pharmacies to dispense lower-cost drugs.

Legislative Action is Needed

The regulatory process has failed to reach an outcome that is fair and reasonable for community pharmacies, and which places a severe economic burden on many smaller pharmacies, both chain-operated and independent. We believe that Congress needs to act now to provide a legislative fix that reduces the economic burden on community pharmacies, thereby preserving the broad access to pharmacy services that Medicaid beneficiaries currently enjoy.

What the Final Rule Does and Does Not Do

The final rule fails to address the concerns raised by community pharmacies in our comments submitted in response to the proposed rule.

Community pharmacies asked CMS to define AMP so that it would be a credible benchmark to set reimbursements for community pharmacies. The final regulation fails to meet this standard. The definition of AMP is ambiguous and allows manufacturers to include numerous sales and discounts to purchasers other than traditional community pharmacies. Community pharmacies do not have access to the prices or discounts that these other purchasers pay for medications. As a result, the final definition of AMP will result in a benchmark that will not ultimately reflect the prices at which community pharmacies purchase medications.

While the final regulation allows manufacturers to exclude certain sales, discounts, and rebates that are not associated with community pharmacy sales, it is not clear that manufacturers will be able to identify and document sales, rebates, and other discounts to various purchasers. As a result, manufacturers may include "excludable" sales and discounts in calculations of AMP, further lowering AMP in relation to pharmacy's approximate acquisition costs.

The final rule encourages – but does not require – states to increase their dispensing fees to offset the reduction in generic drug reimbursement. As a result, pharmacies could earn a greater margin by dispensing a higher-priced brand medication as compared to a lower-priced generic medication. A system that is not aligned to support high quality cost-effective generic medications when appropriate spells total financial disaster for every state Medicaid budget. The average reimbursement for a brand name medication in Medicaid (about $150) is more than seven times higher than the average payment for a generic medication (about $20). For every one percent of additional generic medications dispensed, the Medicaid program saves hundreds of millions of dollars.

Congress Can Help

There are several legislative fixes that we would recommend Congress consider:

- **Create a More Accurate AMP Definition:** The AMP definition in DRA should be unambiguous. Only manufacturers' sales to wholesalers for drugs distributed to traditional community pharmacies, such as independent and chain pharmacies, should be included in

AMP. AMP should not include such items as sales to mail order pharmacies, pharmacies in hospitals or clinics, or other pharmacy types, as was proposed in the final regulation.

- **Modify the Basis of Generic Drug Reimbursement:** Legislative changes should be made in the basis for calculation of the federal limits. Payments to pharmacies for generics must be sufficient to cover their costs of purchasing the drug, dispensing the drug, and providing an incentive to dispense generics. Benchmarks such as median or average AMP would capture a wider range of pharmacy prices, provide more adequate payments to pharmacies, and assure that unusually low prices or products with limited supply are not used to establish payment limits.

- **Revise the Definition of "Multiple Source" Drug:** Currently, federal limits are only set on multiple source drugs that have three or more sources of supply. The DRA (and final rule) requires limits on multiple source drugs with as little as two sources of supply. This change will vastly expand the number of products with federal limits, creating additional economic burdens on pharmacies and potentially reducing incentives to dispense generics. NACDS believes that the definition should be changed back to the pre-DRA definition.

  Federal limits help to promote competition in the market and encourage pharmacies to obtain the best price for the generic they buy. However, in many cases, products that have two "sources" of supply are still only produced by one manufacturer, or are in short supply. This market situation gives the manufacturer significant market power over the price and the availability of this so-called multiple source drug. Encouraging competition is difficult in this case, and pharmacies may not be able to purchase below the FUL. For that reason, there should be at least two different manufacturers of a multiple source drug and three sources of supply before an FUL is set on a product.

- **Provide for More Accurate Pharmacy Dispensing Fees:** Use of AMP data to set federal limits may have been intended to provide greater transparency of drug prices. However, neither the DRA nor the final regulation assures accuracy and transparency in the determination of the dispensing fee component. A recent national study found that the average cost of operating a pharmacy and providing professional pharmacy services is about $10.50 per prescription, but the average dispensing fee paid by Medicaid programs is about $4.50 per prescription. States should be required to set dispensing fees based on current surveys of pharmacies' dispensing costs, including a reasonable return.

- **Prevent the Flawed AMP Data from Being Posted:** The DRA directs CMS to publicly post these flawed AMP data for brands and generic drugs. Unless corrected by new legislation, these flawed AMP data may be used by states and other payers to set reimbursements to pharmacies. This could result in significant underpayments to community pharmacies, costing pharmacies billions of additional dollars in lost revenues.

Conclusion

NACDS urges Congress to revisit the DRA and repeal or reduce the reductions targeted for payments for generic drugs. Congress should act before new federal limits are released at the end of 2007. Otherwise, these reductions could reduce Medicaid recipients' access to pharmacies. Reduced reimbursements for generic drugs also could result in increased use of more expensive brand name drugs.

AMP should only reflect manufacturers' sales to traditional community pharmacies, not the sales to other purchasers that have nothing to do with community pharmacy. Only Congress can make the definition more consistent with the intent of DRA by amending the current definition of AMP, which we encourage Congress to do as part of the upcoming SCHIP authorization.

The suggestions that I have offered are just some examples of ways in which Congress could reduce the impact of the federal Medicaid payment cuts on community pharmacy operators, especially the small companies represented here today. We recognize that other ideas might work as well, and look forward to working with Congress and the rest of the industry to develop solutions that ensure continued access to drugs for Medicaid beneficiaries and fair compensation for community pharmacies.

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Testimony of Charles B. Sewell, Senior Vice President of Government Affairs for the National Community Pharmacist Association

July 18, 2007

Hearing before the House Committee on Small Business Regarding Use of Average Manufacturers Price in Medicaid

Good Afternoon, Madam Chair and other members of the committee. Thank you for conducting this hearing. We appreciate the opportunity to share our concerns with forthcoming changes to the Medicaid program and the impact they will have on independent pharmacies.

My name is Charles Sewell, Senior Vice President of Government Affairs for the National Community Pharmacists Association, or NCPA. I am honored to testify today on behalf of our members, their employees, and most importantly our patients. NCPA represents the nation's community pharmacists, including the owners of more than 23,000 pharmacies, with 55,000 pharmacists, over 300,000 employees and millions of patients who rely on us for their prescription care.

Independent pharmacists provide vital prescription services in both rural and urban areas, including services offered almost exclusively by independents, such as compounding, medication therapy management, durable medical equipment and home delivery. The nation's independent pharmacies dispense 40% of the nation's retail prescription medicines.

Because of the face-to-face relationship with their local independent pharmacist, patients are more likely to take their medicines on-time, more likely to take them properly, more likely to refill meds before they run out and more likely to avoid harmful drug interactions. Patient access to their trusted independent pharmacist helps to lower health care costs by promoting patient health every day.

Through this attentive patient care and dedication to their communities, independent pharmacies are able to compete with chains, mass merchants and mail order. In fact, the independent pharmacy sector was quite stable in the 5 years prior to Medicare Part D. Independent pharmacists have considerable staying power: A full 68% have been in business for more than 20 years. Only 6% of our pharmacies have been in business less than 5 years.

Pharmacies are closing: Part D and CMS' AMP

In 2006, however, 1,152 independent pharmacies have been sold or permanently closed. This net loss of three independents per day is directly attributable to Medicare Part D, chiefly

from payment delays, lower reimbursements, and patients being unfairly steered into mail order or away from independents.

It can easily be said that Uncle Sam is the new business partner of each independent pharmacy owner. This is not by our choosing. Between Medicare and Medicaid, the average independent will see half our patients' care controlled by government programs.

The giant Pharmacy Benefit Managers or PBMs who administer the Part D program have long used their size and positioning to foist take-it-or-leave-it contracts upon independent pharmacies. Medicare Part D has tremendously grown the power of the big PBMs. All Medicaid prescriptions for dual-elligibles are now paid by PBMs under Part D. The government and third parties now dictate the reimbursement for 92% of all retail prescriptions.

To make matters worse, CMS has just published the final rule on Average Manufacturers Price, or AMP. AMP will serve as the new basis for the Federal Upper Limit (FUL) on generic drugs dispensed under the Medicaid program. These changes were among the many onerous provisions of the Deficit Reduction Act of 2005.

The original purpose of AMP was to serve as an index for manufacturer's rebate liability. CMS acknowledges that their AMP will now serve these two distinct purposes, but fails to reconcile the definition of AMP so that it is appropriate as an accurate benchmark for reimbursement. CMS also did not include any policing of manufacturers calculating or reporting process thereby allowing manufacturers to potentially underreport AMP to minimize their rebate liability.

CMS' AMP is simply not appropriate for pharmacy reimbursement. Period.

The DRA sets the new FUL at a maximum of 250% of the lowest AMP for therapeutically equivalent and nationally available generics. This 250% is a best-case scenario as some states will likely set reimbursement below the FUL. The HHS Office of Inspector General recently reported that even with the 250% multiplier, the FUL would still fall below pharmacy acquisition cost for 19 of the 25 high-expenditure generic drugs studied. For 5 of the other 6 drugs in the study, the pharmacy would only cover the cost of the drug, but would still realize a loss once the cost-to-dispense is considered.

Retail pharmacy cost-to-dispense averages $10.50 nationwide according to a 2007 study by the international accounting firm Grant Thornton. The dispensing fee paid under state Medicaid programs is far lower at an average of $4.50. When these numbers are applied to the findings of the OIG study, only 1 of the top 25 high-expenditure Medicaid drugs would post a meager profit under the new FUL.

These findings confirm those of a December 2006 GAO study (released January 2007) which found that the new FUL would fall below acquisition cost for 59 of the 77 generics profiled. The AMP-based FUL was 65% below acquisition cost for the 27 high-expenditure drugs studied, 15% below acquisition for the 27 most-frequently prescribed generics, and an average of 36% below pharmacy acquisition cost across the entire sample.

CMS has disputed the findings of both reports; however, the methodologies used by each agency are congruent with provisions contained in the rule. CMS failed to refute any of the reports specific findings, instead using sweeping generalizations to dismiss two independent government agency reports as flawed and irrelevant. The HHS Secretary also offered wholesale rejection of the GAO study during testimony before the House Committee on Energy & Commerce without providing any specific refutation of the study's findings.

CMS suggests states should examine dispensing fees as well as estimated pharmacy acquisition cost to ensure that pharmacy costs are sufficiently covered. CMS even included a cost-to-dispense definition similar to the definition within Medicare Part D for state's consideration. CMS did not, however, provide any guidance or incentive for states to ensure pharmacy operational and acquisition costs are covered.

Last year the Louisiana Legislature passed a measure which would have increased dispensing fees to $10 for brand name prescriptions and to $15 for generic medicines, thus covering pharmacy's operating costs and encouraging generic utilization. Just last week, CMS rejected the Louisiana plan. This does not bode well for states hoping to preserve patient access by covering pharmacy's cost to dispense.

Significant impact upon independent pharmacy

In both its proposed and final rule, CMS failed to examine the negative impact the rule would have upon community pharmacy – and in particular upon independent community pharmacy. Instead, CMS states on page 522 of the final rule (CMS- 2238-FC):

> Although it is clear that the effects will be small on the great majority of pharmacies, whether chain or independent, we are unable to estimate quantitatively effects on "small" pharmacies, particularly those in low-income areas where there are high concentrations of Medicaid beneficiaries. We received general comments that these pharmacies will be greatly impacted by the provisions of this rule; however, we did not receive documented estimates of these effects. Because of the lack of evidence as to the true effect, we have retained our prior conclusion that this proposed rule is likely to have a "significant impact" on some pharmacies.

CMS has shirked its responsibilities under the Regulatory Flexibility Act's requirement for analysis of significant economic impact by not analyzing that impact in neither its proposed nor final rule. CMS has admitted that there will be a significant impact upon small pharmacies, yet it has twice chosen not to analyze that impact because it was not presented with "documented evidence." NCPA believes that CMS has violated at least the spirit and intent of the Regulatory Flexibility Act.

It is CMS' position that under the Regulatory Flexibility Act and the standard for HHS regulations, CMS is required to analyze the impact upon small businesses if implementation of the regulatory rule will result in a negative impact upon gross revenues of 3% or more. Even if one accepts this standard, based on data from the 20006 NCPA Digest, the rule will have at least that amount of impact upon the median independent pharmacy. The impact will be greater upon

rural independent pharmacies and those independent pharmacies serving a higher than average amount of Medicaid patients.

Loss of gross revenues under CMS' AMP

More than 50 percent of the business of some ten percent (10%) of independent pharmacies is from Medicaid, with the majority of those prescriptions being filled as generics. The average amount of Medicaid business for an independent pharmacy is 23%. These independent pharmacies and their patients – many of which have a small volume of business – will be disproportionately affected.

The total revenue from generic Medicaid prescriptions is low relative to the total median independent pharmacy business because generic drugs are significantly cheaper than brand name drugs. (based on CMS data from January to June 2006, the average prices paid for a generic and brand name drug under Medicaid are $21.92 and $155.98, respectively). Because profit margins are higher with generic drugs, the implementation of the rule will affect independent pharmacists to a much greater degree than might be assumed based on gross revenue calculations. More importantly, reimbursements below acquisition costs will depress generic utilization rates, leading to higher costs as more brand name drugs are dispensed. This shift will ultimately hurt taxpayers.

Any revenue projections must assume that all other prescription sales and non-prescription sales will stay constant after implementation of the rule. This is an assumption made not in the belief that all other sales will stay flat, but rather for the sake of making as uncomplicated a calculation as possible. In reality, for those stores that can stay in business, a loss of Medicaid patients would mean, for example, a loss of those patients that also acquire diabetic and related Medicare Part B supplies. The impact upon the business is difficult to measure, but it surely must reach beyond the linear loss of Medicaid generic drug reimbursements.

Dramatic loss of net profits under CMS' AMP

Under SBA standards, CMS can and should have considered the effect on profits of small pharmacies by the proposed and final rules. Under that standard, it is even clearer that small independent pharmacies will suffer significant economic impact under the final rule.

The Small Business Administration's standards for implementing Executive Order 13272, which President Bush signed on August 13, 2002: 1) gave new direction for federal agencies in their efforts to assess the impact of their proposed rulemakings on small business and other small organizations under the Regulatory Flexibility Act, and 2) directed the SBA's Office of Advocacy to provide agencies with information on how to comply with the President' directive. In that rule, the SBA directed federal agencies to look to the impact upon profits of small entities caused by a new rule.

Under the standard of impact upon profits, small independent pharmacies will indeed suffer significant economic impacts which CMS should have analyzed. Once again, assuming

that all other prescription and non-prescription sales would stay constant, implementation of the final rule would cause the total net profit of the average independent pharmacy to fall by nearly 94%. No business can stay in business for very long without making at least a small profit.

Impact on generic savings

The new FUL will force states to underpay pharmacies for many generic drugs. This will in turn force pharmacies from the Medicaid program. Many independents will close their doors entirely. We expect to lose over 2,300 pharmacies with high Medicaid volume (over 50%) almost immediately when this scheme goes into effect.

The new FUL provisions will only affect generic prescriptions. Brand prescriptions are unaffected. Independents currently have a small financial incentive to favor generic medicines over more expensive brand name medications. The DRA will force generic reimbursements to below pharmacy cost, eliminating this cost saving incentive and depressing generic utilization rates. Community pharmacists have now been told by CMS they should never take the time to encourage generics once a brand script has been written.

Nationwide generics account for 55% of all Medicaid prescriptions, but some states have achieved a rate greater than 60% with a national high of 65% generic utilization. For each percentage point increase in generic utilization, Medicaid will realize hundreds of millions of dollars in real savings every year. The opposite is however also true. The new FUL will depress generic utilization, leading to a gradual but substantial increase in prescription costs as more brands are dispensed.

CMS has slated the rule for implementation but has made the rule final yet open for 180 days for further public comment. This position is puzzling considering lack of serious consideration that CMS afforded to the first round of over 1600 public comments. In the guidance that will result from these comments, however, we expect CMS to address several areas, including the lack of significant impact analysis.

Greater accuracy by reporting package size

Each medication is identified by a National Drug Code, or NDC. A 9-digit NDC identified the drug, manufacturer and strength. An 11-digit NDC further identifies the package size. AMP was previously calculated at the 9-digit level, however CMS invited comments on the use of the 11-digit NDC which would ensure greater accuracy by taking the most economical and most popular package sizes into account. CMS states their belief that an 11-digit NDC would not pose any difficulty for manufacturers and would also give greater transparency to the system by allowing states more accurate data for reimbursement purposes.

Despite voicing support for an 11-digit NDC in the final rule, CMS defaults to the less accurate 9-digit NDC citing a lack of legislative history which would indicate Congressional intent to use an 11-digit system. CMS has not used their authority to implement a more-accurate model. To provide the greatest accuracy in pharmacy reimbursement, Congress should instruct CMS to use an 11-digit system.

Mail order facilities are not retail pharmacies

The vast majority of prescriptions filled by mail order in the United States are through PBM-owned mail order facilities. As such mail order facilities do not dispense prescriptions to the general public. The Pharmaceutical Care Management Association, PCMA, representing both PBMs and independent mail order operations, has submitted comments to CMS expressing this point. PCMA has also issued a public statement calling on CMS to remove mail order sales from the AMP definition.

Mail order pharmacies purchase directly from the manufacturer, often at discounts not available independent retail pharmacies. These sales therefore deflate AMP making it further unrepresentative of retail pharmacy acquisition cost.

One commenter states that if Congress had intended mail order prices to be included in AMP, they would have specified such, as was done in the creation of Average Sales Price (ASP) under Medicare Part B. CMS flatly disagrees, restating the belief that mail order dispenses to the general public and as such are part of the "retail pharmacy class of trade."

CMS also makes reference to "past policy" in regards to mail order inclusion, but fails to make any specific references to any such past policy.

Further on the issue of PBMs, CMS details how a lack of PBM transparency has made it difficult for manufacturers to define and determine. Manufactures have a variety of agreements with PBMs by which rebates, chargebacks, service fees and other considerations are exchanged for formulary placement, promotion of market share and the like.

Rather than use this rule as an opportunity to afford some true transparency to the prescription drug marketplace, CMS believes this is outside the scope of the AMP rule. To the contrary, given PBMs prominent role in prescription pricing both as formulary brokers and as the primary promoters of mail order facilities, transparency of PBM dealings is central to determining the true cost realized by the manufacturer.

On the issue of transparency, CMS invited public comment on the proposed rule without providing a single set of real AMP data. CMS did not even make available a simple subset of AMP data under a confidentiality agreement for public consideration. Congress essentially approved the use of AMP as a baseline for reimbursement without any AMP data and before any agency evaluated the AMP index for that purpose.

PBM rebates do not impact generics

CMS touted the removal of PBM price concessions from AMP calculation as favorable to retail pharmacy. However CMS also admits that these price concessions rarely affect the AMP of generic medications on which the new FULs will be assigned. Were CMS to make a genuine effort to assure retail pharmacy acquisition costs were covered, they would have removed mail order sales from the final definition of AMP. Nearly all price concessions paid to PBMs are manufacturer rebates used to drive market share of brand name medications. Rebates rarely, if ever, impact the AMP of generics.

CMS highlighted comments are not representative

If one were to read only the 587-page final rule, one might easily have the impression that overall there were more comments submitted in support of the proposed rule than were submitted in opposition. CMS created this illusion by first stating that "one commenter supports", and then detailing the minor technical issue upon which the commenter said CMS' proposal made sense.

Those highly selective excerpts, however, were not representative of the rule. All members of the pharmaceutical community – pharmacists, patients, manufacturers, distributors, doctors, etc., submitted comments largely in opposition to the proposed rule. CMS received over 1600 comments covering over 3800 pages. In a review of all public comments, NCPA found only a handful of commenters who were generally in favor of the proposed rule. CMS repeatedly and selectively highlighted accord with minor technical elements of the rule, and failed to even remotely represent the degree of opposition it received from groups, such as independent pharmacists, to the many larger elements of the proposed rule.

Several commentators objected to AMP's use as an index for manufacturer rebate liability and as a benchmark for reimbursement. CMS admits (page 155) that AMP will not necessarily reflect pharmacy acquisition cost, but that the 250% multiplier and outlier policy would help correct these discrepancies.

As the GAO and OIG reports have however concluded, even with the 250% multiplier, the new FUL will fall below acquisition cost in most cases.

Patient access necessary to contain costs

CMS has asserted that the DRA will not reduce patient access to prescription care. Unfortunately, just saying it just doesn't make it so. A full 75% of independents are in communities of less than 20,000, that is, rural areas. Independents are the only pharmacies willing and able to serve these smaller communities. When independents close, patients lose access.

In larger communities, when independents are sold to larger chains, patients lose access to the many niche services independents offer, such as compounding, charge accounts, durable medical equipment and especially home delivery.

The average cost of an emergency room visit is well over $500. As avenues to preventative care are restricted, such as access to prescription care, reactionary measures and their related expense will continue to burden the Medicaid system. When patients lose their pharmacist, they end up in the emergency room with much higher health care costs. A simple generic maintenance medication, such as those for blood pressure or cholesterol, when regularly refilled and taken properly can help avoid the hospitalization and long-term-care costs of a heart attack or stroke.

As community pharmacies close, patients will be shuffled to a different, now overwhelmed pharmacy, if their community has one. As prescription care is less readily

available, some patients will discontinue their meds or fail to have basic prescriptions filled. Emergency room costs will rise, hospital costs will rise, long term care costs will rise and costs for taxpayers will rise—all from a loss of access to prescription care.

A legislative fix is necessary

Madam Chair, the use of AMP in Medicaid as defined by CMS will be devastating to community pharmacy and the patients who rely on us for their prescription care. Congress must pass legislation that addresses the negative impact caused by using the AMP benchmark for pharmacy reimbursement. This legislation should ensure an accurate pharmacy reimbursement benchmark and ensure patient access to life-saving, cost effective prescription medicines. Such legislation should:

- Define the benchmark for pharmacy reimbursement so it accurately reflects pharmacy acquisition costs.
- Exclude all sales to mail order facilities, as well as any PBM rebates and price concessions that are not provided to retail pharmacy in the definition of the reimbursement benchmark.
- Include provisions to drive generic utilization which would increase government savings.

Thank you for your time and attention. I am glad to take any questions you may have.

Your Neighborhood Supermarkets

TESTIMONY

ED HAGAN, DIRECTOR OF PHARMACY
ASSOCIATED FOOD STORES, INC.
BEFORE
HOUSE COMMITTEE ON SMALL BUSINESS
JULY 18, 2007

"MEDICAID DRUG REIMBURSEMENTS:
ARE CMS CUTS BAD MEDICINE FOR SMALL BUSINESSES AND BENEFICIARIES?"

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Your Neighborhood Supermarkets

Good Morning, Chairwoman Velázquez, Congressman Chabot, and members of the committee. I am Ed Hagan, Director of Pharmacy for Associated Food Stores, testifying on behalf of the Food Marketing Institute (FMI).

I very much appreciate the opportunity to testify before the committee about an issue of significant importance to all of its supermarket pharmacies—particularly those that are small businesses—and the Medicaid beneficiaries that we serve. FMI is extremely concerned about the implementation of Deficit Reduction Act (DRA) provisions that would base reimbursement for prescription drugs on the artificial concept of Average Manufacturer Price (AMP). We believe that this use of AMP, particularly in the way it has been implemented by the Centers for Medicare and Medicaid Services (CMS), will cause severe hardships for many pharmacies and the Medicaid recipients alike.

Associated Food Stores is a member owned cooperative that is based in Salt Lake City, Utah. In addition to the independent stores we serve, we own 21 stores and with three other wholesalers co-own the Western Family private label. 75 of our stores across 8 states and Guam have pharmacy operations. These pharmacies range in size, with some locations filling as few as 70 prescriptions per day to larger operations that fill between 400 and 500 prescriptions daily. While some of our stores are located in large metropolitan areas, Associated Foods also includes stores in small towns such as Twin Bridges, Montana, Kamas, Utah and Raymond, Washington. Many of our stores in these small towns represent the only pharmacies available. Medicaid represents about 10% of our business overall but this figure jumps to more than 15% in many rural areas.

Associated Food Stores is a member of FMI, an association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies - food retailers and wholesalers – in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion – three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets such as the ones served by Associated Foods. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate over 19,000 in-store pharmacy departments. FMI estimates that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats and the convenience of one-stop shopping, the association anticipates that the number of pharmacies located in supermarkets will continue to increase in the coming years as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

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Your Neighborhood Supermarkets

Implications of the AMP Policy for Retail Pharmacy

Pharmacy profit margins, particularly in the case of small supermarket pharmacies, are generally only a very small percentage of total revenues, and a far lower percentage than most other pharmacy retail businesses. The gross margin for Associated Food Stores pharmacy operations is in the range of 20 percent—with net profits at about two percent. Consequently, efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution. The recent work by the Government Accountability Office (GAO) comparing AMP-based Federal Upper Limits (FULs) to pharmacy acquisition costs suggests that many pharmacies will lose money when AMP-based FULs are implemented. Because overall pharmacy margins are so small, many pharmacies will not be able to sustain losses under Medicaid, and will face the choice of leaving the program or going out of business.

Most of the Associated Food Stores with pharmacies are single store operations. These stores generally encounter the same per-store expenses as the stores of larger chains—the same salaries for pharmacists, the same liability and other insurance and the same operating costs—but without the ability to minimize the losses imposed by AMP policies through economies of scale and the better purchasing power of larger chains.

Depending on how states and various private payers react to the implementation of AMP as a benchmark, my rough estimate is that the policy being implemented has the potential to decrease pharmacy margins by five to seven percentage points—which would cause many of the small stores represented by Associated Foods to lose money. Even if the damage is limited solely to Medicaid, this would be a devastating cut for retail pharmacy and could result in the failure of some of our small business members.

Thus, to the extent that FULs are below pharmacy acquisition costs for generic drugs, Associated Food Stores pharmacies and other FMI members may find it increasingly difficult to serve Medicaid patients. This issue will only be compounded as states such as California seek to move to an AMP-based payment rate for prescription drugs that are not subject to the FUL and as other payers turn to AMP for their own purposes. As state dispensing fee reimbursements are even farther below the costs our members incur to dispense prescription drugs to Medicaid Patients, small supermarket pharmacies are at even greater risk if the ingredient reimbursement rate is lowered.

By dictating that CMS use AMP for both the Medicaid rebate program and the FUL for multiple source drugs, the DRA left the agency with an almost impossible balancing act. While we believe that CMS failed to exercise adequately its significant discretion to mitigate the severity of the problem, FMI believes that the competing roles of AMP as currently defined can never be successfully reconciled. We therefore urge the Congress to repeal the DRA's AMP-based in reimbursement policy and create another benchmark for pharmacy reimbursement—a benchmark

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that more closely reflects pharmacy acquisition cost. At a minimum, we believe that the Congress should enact refinements to Medicaid pharmacy reimbursement that mitigate the significant cuts that pharmacies are now facing as a result of the implementation of the DRA AMP policies.

The Policy Problem

AMP was originally created as a benchmark for the Medicaid rebate program, designed to provide savings to the states and the Federal government on prescription drug purchases for Medicaid beneficiaries. Under the balance created in the original legislation, manufacturers pay a base percentage of AMP as a rebate or pay rebates based on the difference between AMP and a manufacturer's so-called "best price." Additional rebates are imposed on products that are subject to price increases over time greater than the Consumer Price Index. In exchange, participating manufacturers are able to have their products covered by state Medicaid programs without having to negotiate discounts for formulary access.[1] Manufacturer reports are made under a set of esoteric rules that have become only marginally clearer as a result of the CMS rulemaking. What is clear, however, is that as a result of the Medicaid rebate program, manufacturers have a strong incentive to keep AMP as low as possible.

CMS acknowledged the inherent conflict in using AMP for the purposes of rebates and pharmacy reimbursement in its proposed rule implementing the prescription drug provisions of the DRA. In its final rule, the agency indicates that it believes the revised definition of AMP "accurately reflects the dual purposes of AMP." However, the fact remains that AMP, as it is defined by CMS, bears no relationship to pharmacy acquisition cost for Medicaid covered drugs.

As I have discussed above, the use of AMP as a reimbursement measure represents a significant threat to pharmacies and the Medicaid beneficiaries they serve. FMI believes that the Congress must act to address this threat.

Possible Solution: Separating Rebates from Acquisition Cost

One solution to the conflicting roles of AMP would be to eliminate the conflict by creating two separate benchmarks. The first would be akin to the pre-DRA quarterly AMP used for rebate purposes. A second benchmark, Average Manufacturer Price Available to Retailers (AMPAR) could also be manufacturer reported but would be focused more closely on the purchase prices of retail pharmacies. The use of this second benchmark would remove the need for some of the contortions CMS undertook in the proposed rule to attempt to balance the needs of pharmacies and

[1] While many states have used "preferred drug lists" to secure even deeper discounts from manufacturers, this does not change the dynamic of the current policy problem.

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drug manufacturers. It would allow for a clear and accurate reimbursement metric without interfering with the Medicaid rebate program.

This solution would be somewhat similar to others being considered based on pharmacy surveys, but would have the benefit of being based on product by product manufacturer reports. FMI is sensitive to the fact that this will add somewhat to manufacturer reporting requirements, but we believe that this benchmark would be more reliable than surveys and easier for CMS to administer—while protecting Medicaid beneficiary access to a wide range of pharmacies.

While we believe that a division of the two sets of responsibilities currently assigned to AMP is most appropriate, if Congress decides not to undertake a change of this magnitude, Congress should at least take the following steps to mitigate the negative impact of the AMP policy on retail pharmacies.

Possible Solution: Mitigating Measures

1. Define Retail Class of Trade Accurately

AMP is defined in statute based on the prices paid by "wholesalers for drugs distributed to the retail pharmacy class of trade." Defining "retail pharmacy class of trade" accurately is important because those outside of this class can command prices that are well below the prices that pharmacies – particularly small pharmacies – and others within the retail class of trade can obtain. For example, PBMs and mail order houses can harness large bulk buying power to obtain prices for drugs that are far lower than the prices Associated Food Stores can obtain for our small independent supermarket pharmacies. Including these prices in determining the average manufacturer price seriously undermines AMP and results in a reimbursement level far lower than the amount our members pay. Indeed, GAO determined that AMP was 36 percent lower than the prices paid by retail pharmacies, which will be lower again for small independent supermarket pharmacies.

While FMI is pleased that CMS removed some PBM and other third party discounts from the definition of AMP, we continue to believe that mail-order pharmacies, physician offices, outpatient clinics and a variety of other entities that CMS has included in AMP are outside the retail class of trade. Excluding discounts to these entities from AMP could help to mitigate the severe cuts that pharmacies are currently facing as a result of the CMS final rule.

2. Use Average AMP of Therapeutic Alternatives to Set FULs

The DRA modified the FUL calculation for drugs by referencing CMS regulations on the subject. The statute required CMS to substitute 250 percent of AMP in place of the previous

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benchmark for FULs, which was 150 percent of the published price. Under prior CMS regulations, FULs were set on the basis of the lowest cost therapeutic alternative. While FMI believes that CMS retained the discretion to use the weighted average AMP of therapeutic alternatives, the agency apparently does not share this view and instead set AMP on the basis of the lowest cost therapeutic alternative. This will give undue weight to outlier prices among a series of alternatives and may set FULs on the basis of products that are not available to pharmacies nationwide. Therefore, one interim step would be to require the agency to use the weighted average of therapeutic alternatives when setting FULs based on AMP.

3. Use Quarterly FUL Updates

CMS rejected comments which urged it to update FULs quarterly, to avoid the volatility that will potentially result from monthly updates. FMI believes that CMS should generally update FULs quarterly, but with discretion to allow the agency to address errors or potential product access problems more quickly.

4. Delay Publication of AMP Data

FMI also believes that Congress should place a moratorium on the publication of AMP information until the consequences of publishing the information are fully understood. FMI believes that the publication of AMP data has the potential to distort the marketplace for generic drugs, with potentially serious anti-competitive effects. Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data are published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition—the prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

5. Improved State Oversight

States now have the discretion to use AMP as a benchmark for estimated acquisition cost for all Medicaid drugs—not just the multiple source drugs that will be the subject of CMS FUL findings. FMI believes that states using AMP in this way must be specifically required to put in place mark-up percentages and dispensing fees that will ensure that pharmacies are adequately reimbursed for the cost of dispensing drugs under the Medicaid program. This reimbursement

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should also provide incentives for the use of generic drugs, which provide significant savings to state and federal governments, but are the main focal point for potential pharmacy losses under the framework CMS is now implementing.

Even states that do not seek to use AMP as an ingredient cost benchmark must ensure that their dispensing fees adequately cover the costs of pharmacy services. Current state dispensing fees average about $4.50 per prescription, far below estimated pharmacy costs of $10-$15 per prescription.

Conclusion

In conclusion, I appreciate the opportunity to testify on this important health care issue. And on behalf of FMI members who operate in-store pharmacies in their supermarkets, we are hopeful that the House Small Business Committee and the Congress will act to address the potentially devastating cuts that retail pharmacy is now facing as a result of the DRA's changes to Medicaid prescription drug reimbursement policies.

I am happy to answer any questions the committee may have.

Attached document: FMI formal comments to Proposed Rule to Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program.

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National Grocers Association

July 17, 2007

Honorable Nydia M. Velasquez
Chair, Committee on Small Business
U.S. House of Representatives
Washington, D.C. 20515

Dear Chair Velasquez:

The National Grocers Association (N.G.A.)[1] applauds you and the members of the House Small Business Committee for holding hearings on the Centers for Medicare and Medicaid Services (CMS) rule on reimbursement for Medicaid prescription drugs. This rule is of particular concern to N.G.A. members who operate pharmacies within their grocery stores and supermarkets because the prescribed calculation and reporting of the Average Manufacturer Price (AMP) and the related proposed revision to set the Federal Upper Payment Limits (FUL) for Medicaid drugs that will adversely affect consumers and retail pharmacists. For those reasons, N.G.A. strongly opposed the proposed rule issued by CMS.

The final rule was just published today in the Federal Register and consists of 105 pages of analysis and regulations. For small businesses the final rule will have especially negative impacts on their pharmacy operations and their Medicaid recipients. I respectfully request that this letter on behalf of N.G.A.'s community-focused retail pharmacies be included in the record. N.G.A. also urges the Committee to support amendments to the law that would eliminate the CMS rule based upon the Average Manufacturer Price as the standard for reimbursing retail pharmacies. Your support and that of the House Small Business Committee to amend the law would assure consumers access to Medicaid generic drugs and not adversely affect community-focused retail pharmacies, who otherwise would be forced to sell below their acquisition costs.

Medicaid recipients that count on N.G.A. members who operate pharmacies within their grocery stores and supermarkets for their prescription benefits will be adversely affected by the implementation of the rule on Average Manufacturer Price (AMP) and the new generic Federal Upper Limits (FULs). Consumers who are serviced by N.G.A.'s community-focused retailers are at risk of having the availability of Medicaid generic drugs curtailed because pharmacy acquisition costs will be more than the prices received under the Federal Upper Limits.

Therefore as a result, N.G.A. recommends Congress act to revise the AMP definition to accurately reflect prices paid to manufacturers by wholesalers for sales to the retail pharmacy class of trade, and suspend the proposed Federal Upper Limits for generic drugs in light of the inaccurate and arbitrary AMP.

Under present law the AMP for covered outpatient drugs is defined to be "the average price paid to the manufacturer for the drug in the United States by **wholesalers** for drugs distributed to the retail pharmacy class of trade." Effective January 1, 2007, DRA provided that manufacturers now must calculate AMP without regard to customary prompt pay discounts that are given to **wholesalers**. Thus, the law on its face states that CMS can only utilize in the calculation of AMP the prices that are paid by **wholesalers to manufacturers** for drugs that are in the end sold to the retail pharmacy class of trade.

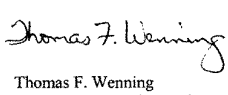
The General Accounting Office (GAO) conducted a study of how the DRA calculation of the AMP and FULs would work. Beginning January 1, 2007 FUL for a drug is to be calculated as 250 percent of the lowest AMP from a drug's therapeutically equivalent versions. The Congressional Budget Office estimated that when implemented,

AMP-based FULs could reduce total Medicaid spending for prescription drugs by $3.6 billion from 2007 to 2010 and by about $11.8 billion from 2007 to 2015. Some estimates are that it will reduce Medicaid generic payments to pharmacies by $8 billion over the next five years. It also demonstrates the harm facing Medicaid recipients. The GAO has rightly identified the use of this methodology and has raised concerns among retail pharmacies serving Medicaid beneficiaries. The GAO compared estimated AMP-based FULs with average retail pharmacy acquisition cost data from the first quarter of 2006 for 77 drugs.

The GAO results show the arbitrariness and unfairness of the CMS rule:

- The AMP-based FUL data for the first quarter of 2006 was lower than the average retail pharmacy acquisition cost for 59 of the 77 drugs studied. On average, the AMP-based FULs were **36 percent lower** than the average retail pharmacies' acquisition costs. For 43 of the 77 drugs, the AMP-based FULs were **below the lowest acquisition cost** available to retail pharmacies.
- The results were even worse for the 27 high expenditure drugs in the study with the AMP-based FULs being, on average, **65 percent lower** than the average retail pharmacy acquisition cost. The AMP-based FULs were **below the lowest acquisition cost** available to retail pharmacies for 21 of the 27 high expenditure drugs.
- For 27 frequently used drugs the AMP-based FULs were, on average, **15 percent lower** than average retail pharmacy acquisition costs. The AMP-based FULs fell **below the lowest acquisition cost** available to retail pharmacies for 11 of the 27 frequently used drugs.
- For 23 drugs that were both Frequently Used and High Expenditure the AMP-based FULs were, on average, **28 percent lower** than average retail pharmacy acquisition costs. The AMP-based FULs were **below the lowest acquisition costs** available to retail pharmacies for 11 of the 23 drugs.

It is clear that the DRA and CMS rule will adversely affect Medicaid recipients by imposing regulations that in effect, will force retail pharmacies to have to sell Medicaid generic drugs at or below their acquisition costs. As a result prescription services and accessibility to Medicaid beneficiaries are in jeopardy. N.G.A.'s community-focused retailers cannot afford to operate pharmacies under government AMP and FUL regulations that establish reimbursement levels below their acquisition costs.



Thomas F. Wenning
Senior Vice President and General Counsel

[1] N.G.A. is the national trade association representing and serving the retail grocery/food companies and wholesale distributors that comprise the independent sector of the food distribution industry. An independent retailer is a privately owned or controlled food retail company operating in a variety of formats. The meaning of "independent retailer" is more a question of ownership and philosophy of operation, rather than number of stores or type of format. Most independent operators are serviced by wholesale distributors, while others may be partially or fully self-distributing. A few are publicly traded, but with controlling shares held by the family, and others are employee owned. Independents are the true "entrepreneurs" of the grocery/food industry and are dedicated to their customers, associates and communities. N.G.A. members include retail/grocery food companies and wholesale distributors, affiliated associations, as well as manufacturers, service suppliers, and other entrepreneurial companies that support N.G.A.'s Philosophy and Mission.