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SOUND POLICY, SMART SOLUTIONS: SAVING MONEY IN MEDICAID

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WEDNESDAY, JULY 20, 2005

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, D.C.

The committee met, pursuant to notice, at 2:32 p.m., in room SD–106, Dirksen Senate Office Building, Hon. Gordon H. Smith (chairman of the committee) presiding.

Present: Senators Smith, Kohl, and Lincoln.

OPENING STATEMENT OF SENATOR GORDON H. SMITH, CHAIRMAN

The CHAIRMAN. Thank you all for coming to today's hearing. It is a pleasure to welcome you to the Aging Committee for its second in a series of hearings on the Medicaid program.

I told some of our witnesses that there are two scheduled votes probably in the next 10 to 15 minutes. I think what we will do is proceed with our opening statements, perhaps even get into the statement of our first witness, and then perhaps take a brief recess, and then we will continue this very important hearing. Unfortunately, the Leader checks with neither Senator Kohl nor myself when scheduling votes around the Aging Committee.

But we are glad you are all here because there are few issues more important than this one as we look to the reconciliation process and making sure that the Finance Committee does with its authority what is prudent and what is careful.

I am pleased that our distinguished witnesses are able to join us and share their insight into how this program works and where improvements can be made to make it more efficient and reduce fraud and abuse. As I have said many times, our goal as elected officials and, in fact, stewards of our community's most vulnerable should be to improve Medicaid, not undermine it or take steps that are penny-wise and pound-foolish.

Therefore, this hearing will focus on sound policy and smart solutions. We will hear from both Government and outside experts who will help us understand two key components of the program: how Medicaid pays for prescription drugs and how the so-called spend-down process works. In doing so, we will discuss areas where policy changes are needed and that hopefully will result in budget savings.

I disagree with those who claim the program is broken or should be dismantled, but, on the other hand, I do not believe Medicaid is perfect. I will continue to explore areas where changes can be

made and savings can be found. As I mentioned, we will be reviewing how State governments pay for prescription drugs. Many Government entities have studied this process. Just last month, the Office of the Inspector General for the Department of Health and Human Services testified that the Medicaid program remains vulnerable to abuse and continues to pay too much for drugs.

Therefore, a report by the General Accounting Office highlighted the need for better oversight of Medicaid best price system to ensure appropriate rebates are being made. These are all indications that Congress must take a close look at the system and determine if improvements should be made.

Concerns also have been raised about the loopholes that exist in the Medicaid spend-down process that allow people to exploit the process by hiding assets so they can prematurely qualify for the program. We must closely review and consider these issues and develop responses that block intentional fraud while protecting people who truly qualify for care. It is a delicate balance but one that we must strive to achieve.

I think all would agree that this has been an arduous process since February's consideration of the budget, and it is one fraught with potential mistakes that could negatively impact our Nation's oldest and most vulnerable. That is why it is so critical that we proceed cautiously and thoughtfully when considering Medicaid changes.

While we have just 2 months before the Finance Committee is required to report its reconciliation bill to the Budget Committee, much work remains. To further this process and ensure that it can be a bipartisan effort, I am actively seeking out colleagues from both sides of the aisle who are interested in working together to craft a bipartisan solution for reconciliation. I am pleased with the responses I have received from my Democratic colleagues, but I know with them much work remains between people of good will on the committee.

I look forward to working with my colleagues on the Aging Committee, and especially Herb Kohl, our ranking member, on this most critical issue.

Senator Kohl, the mike is yours.

OPENING STATEMENT OF SENATOR HERBERT H. KOHL

Senator KOHL. I thank you very much, Mr. Chairman.

Medicaid's importance as a safety net cannot be overstated. Nearly 53 million low-income Americans, including children, pregnant women, individuals with disabilities, and the elderly, rely on Medicaid for their health care needs. Like you, Mr. Chairman, I am concerned about the budget resolution's requirement to cut Medicaid by $10 billion over the next 5 years. One of the reasons I voted against the budget is because it is wrong to cripple Medicaid based on an arbitrary budget target. Any changes to the Medicaid program should be based on sound policy that will improve and preserve the program for the neediest among us.

Certainly we have a responsibility to ensure Medicaid's dollars are being spent appropriately. One promising area for finding cost savings is the prescription drugs Medicaid buys. Like individuals across the country, Medicaid is struggling to afford the soaring

costs of prescription drugs, so we look forward to hearing from our experts today who will make recommendations on ways that we can keep Medicaid's drug costs down.

It is also important that Medicaid not become a program only for those who can hire clever estate planners in order to maneuver their assets to qualify for Medicaid. We are pleased that the elder law attorneys have joined us to discuss practical ways that we can remove loopholes that allow abuse, helping us to save Medicaid money and avoid harming the beneficiaries who truly need the services.

One thing we must remember as we discuss these issues is that not all growth in Medicaid spending is the result of fraud or overpriced drugs. Medicaid spending has also grown for several legitimate reasons. First, enrollment is rising as more Americans lose their health insurance. Second, as America ages, Medicaid's long-term care costs continue to rise. Most importantly, Medicaid costs are being driven by the same skyrocketing health care costs that every health insurance plan in our country faces today.

So, clearly, we can still do better to ensure that Medicaid dollars are spent wisely. Tighter controls on estate planning and payments for prescription drugs are but two reforms that we need to consider. But we also need to think long term. We can reduce the number of working families who rely on Medicaid by helping small businesses provide health insurance. I am proud to cosponsor legislation with Senators Durbin and Lincoln, the Small Business Employee Health Plan bill, that would help in this effort. We can also change the way we pay for long-term care by making less expensive home and community care more available.

Above all, we must proceed carefully and preserve Medicaid for the families who most need it. If we are required to find savings now, we need to do it in a way that will not harm the beneficiaries who rely on this program.

I thank you, Mr. Chairman, and along with you I look forward to our witnesses today.

The CHAIRMAN. Thank you, Senator Kohl.

You might notice the lights, all of you, on the clock. It means there is probably about 5 minutes left in this first vote. With your indulgence, we will recess briefly. There are two votes. We will vote late and then vote early and be right back.

We will stand in recess. [Recess.]

Thank you, ladies and gentlemen, for your patience. We are reconvened, and we have been joined by Senator Lincoln. Do you have an opening statement?

OPENING STATEMENT OF SENATOR BLANCHE L. LINCOLN

Senator LINCOLN. Very briefly, Mr. Chairman. A special thanks to you and to our ranking member, Senator Kohl, as always. I thank the two of you all for your diligence in holding what I think are such timely hearings.

Medicaid has really been called the work horse of the American health care system, and I think that is such an accurate description. Medicaid provides health care to people who would otherwise go without in most instances.

I look forward to hearing about potential Medicaid savings that can be found in the prescription drug policies. However, I am also interested in making sure that any savings found does not disproportionately hit our pharmacists, especially that serve rural areas. We know that in many of our rural States the only line of defense in terms of health care left on the weekends is oftentimes our local pharmacist, and it is really critical that they do not be disproportionately hit.

I am also interested in hearing about the evidence-based medicine because our State of Arkansas is one of the 14 States participating in this project. Although it is too soon to see if this will result in prescription drug savings for the State, I think it has a lot of potential for State savings and better treatment for Medicaid beneficiaries.

So, Mr. Chairman, thanks to both of you. I very much appreciate all of your diligence and hard work in really tackling the difficult issues.

Thank you.

The CHAIRMAN. Thank you, Senator Lincoln. It is a privilege and a pleasure to have you on this committee, and the insights you bring, particularly of rural America, are of real value to us.

Our first panel and our first witness is Douglas Holtz-Eakin. He is the director of the Congressional Budget Office. Thank you, Doug, for your patience, and the mike is yours.

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

Mr. HOLTZ-EAKIN. Chairman Smith, Senator Kohl, Senator Lincoln, CBO is pleased to be here today to talk about the important question of the cost of the Medicaid system and, in particular, prescription drugs provided to Medicaid beneficiaries. The bulk of my remarks will focus on the current system for the procurement and payment for prescription drugs in Medicaid and will amount to walking through the diagram that we have displayed on the screens and hopefully is in front of you.

There are two parts to the diagram. Blue arrows indicate the flow of pharmaceuticals themselves, and that is the simple part of the story. They are manufactured by drug manufacturers, dispensed through a distribution system that includes wholesalers and pharmacies and ultimately come to Medicaid beneficiaries to meet their therapeutic needs. The more complicated part of the story is shown with the broken green arrows, which is the financing of this manufacture and distribution of prescription drugs in Medicaid.

When a beneficiary fills a prescription, in some States they will be responsible for a small co-payment. That is shown flowing from the beneficiary to the pharmacy. That is a sidelight in the main story today. The bulk of the financing is in the triangle flowing between Medicaid, pharmacies, and drug manufacturers, and in each case those entities will have both monies flowing in and monies flowing out. Under current policies, this is the heart of the reimbursement system, and I would really focus my remarks on that. We can turn to any changes that one might be interested in making in the questions that would follow.

We could start with the pharmacies, which in this case also include wholesalers. As you can see, they have both monies flowing in, reimbursements from Medicaid agencies—and I want to emphasize that this diagram is a stylized representation of what will be 50 different State systems and it will fit no single system perfectly. But, by and large, pharmacies get reimbursed for their brand name and generic drugs. They receive a reimbursement that is roughly the average wholesale price, a sticker price for prescription drugs, minus 10 to 15 percent. They also typically receive a fee of $3 to $5 which covers costs of consultation, storage, and filling the prescription.

This will also have some impacts depending on whether it is a payment for a generic drug or a brand name drug. For generics, there are limits set both by the Federal upper payment limit dictated by CMS, or some States have a maximum allowable cost that limits that reimbursement as well. But one set of flows come into pharmacies for reimbursement for those drugs they provided to beneficiaries. That is the money in. The money going out is dictated by the deal they can cut with drug manufacturers, and those payments out to manufacturers are a market price negotiated by the pharmacies and the wholesalers with the manufacturers themselves.

Drug manufacturers, on the other hand, have monies flowing in to them on the basis of these same negotiations, some sort of market transaction, and then are obligated to provide some reimbursement to the Medicaid program as a whole in the form of rebates. The rebates take two different branches. There is a flat rebate of about 11 percent for generic drugs. For brand name drugs, there is a two-part rebate system. The basic rebate is 15.1 percent of the average manufacturing price of those drugs, or where it is larger, the difference between that manufacturing price and the best price provided to their customers. Then there is an additional rebate which is owed on those drugs whose price has gone up faster than overall inflation. So manufacturers are negotiating to the best of their ability with the pharmacists and earning their receipts that way. They are then obligated to repay the Medicaid program itself in the form of these rebates. The net cost to the system overall, Federal Medicaid plus the State Medicaid, comes from the interaction of these two forces: payments dictated by a formula to the pharmacist and the reimbursements that come back from the manufacturers that are dictated by market prices, what they negotiate.

Now, the remainder of what I would like to show you are just some details of different parts of that triangle. The first is this wedge on the right side between what Medicaid sends out to pharmacists and what actually flows into drug manufacturers. That gap, if we go to the next slide, is what we have labeled markup, so you can look at the top one and see that for the year 2002, on average Medicaid's payment to pharmacies for all drugs was $60.90. That consisted of two pieces: a piece which actually flowed into the manufacturers, $47.10, and the difference, the column labeled markup, that which would accrue to all pieces of the distribution chain—wholesalers, pharmacies—of $13.80.

There are some striking differences in this table in the composition and levels of these overall payments. The two things that I

would bring to your attention are first that brand name drugs, which constitute about 50 percent of all the prescriptions, total about 85 percent of all the dollars, and so they are where the bulk of the money is. The average total payment there is $97 compared to a bit under $20 for generic drugs. So it is cheaper to go to generics. However, if one looks at just the markup portion, the portion that arises due to pharmacies and wholesalers, you can see that the striking number that jumps out is the $32.10, which is the markup on newer generic drugs.

This is really a good news/bad news story. The good news is that given the incentives of a pharmacist who can capture part of this markup, there is an incentive to provide these newer generic drugs, and they are cheaper to the program as a whole than are brand name drugs. So steering the business in that direction clearly provides benefit overall from the point of view of the cost of the program.

On the other hand, it is likely the case that the structure of the reimbursement system, the fact that manufacturers have an incentive to put a high sticker price, a high AWP on their newer generic drugs, and then negotiate a very low actual transactions price, would lead to this large gap, reimbursements being made on the high sticker price, the acquisition being dictated by the market transaction. The residual is this bad news, which is the perhaps larger than necessary markup that shows up on these particular drugs.

In going forward with any changes the committee might consider, one thing to keep in mind is the degree to which changes in that kind of a system would alter the incentives of all the players, not just the pharmacists but negotiations between pharmacists and manufacturers, and then the reimbursement by the system as a whole.

Then, in closing, the last piece of detail is the detail in the transactions that go on between manufacturers and the Medicaid program as a whole. These rebates, as I said, take two forms. The basic rebate is a flat 15.1 percent rebate in those cases where that is larger than the gap between the market price and the best price, and the other instance of the rebates the difference, and then additional rebates which come to under 12 percent are for those drugs where the cost has gone up faster than overall inflation. You can see that as a result the Medicaid program as a whole has received substantial rebates, 30 percent off the average manufacturer prices for these brand name prescription drugs.

So the system is an intricate reimbursement system with three important players: manufacturers, pharmacists, and the Medicaid program as a whole. In thinking about strategies to alter this system to save money, it is important to recognize the incentives that are in place for all three of the players, and as a result the net impact on savings that might come out of it.

We thank you for the chance to be here today and look forward to answering your questions.

The CHAIRMAN. Doug, one of the popular proposals for saving money in Medicaid is to increase the percentage of the average manufacturer's price used to calculate rebates to States. Do you think that that is a good approach, a rational approach?

Mr. HOLTZ-EAKIN. I think the key for thinking about strategies toward the reimbursements is to step back and make sure that the policies are targeted toward the problems. In the diagram, you can see there are a couple. The first is the rebate, as you mentioned. You could raise the 15.1 percent rebate to something like 20 percent, and we have done an estimate that suggests that the cost savings would be on the order of a bit above $3 billion over 5 years.

On the other hand, to the extent that an observation jumps out of the current system, it is that there is this mismatch between the reimbursements to the pharmacists, which are based on a sticker price, and the rebates, which are based on this actual transaction price. Bringing the system into alignment, using the same prices for all pieces of the overall financing, is probably a sensible way to focus thoughts about future policy.

The CHAIRMAN. As I recall this was one of the ideas that the President had in his proposal, but CBO did not score it as saving any money. Am I remembering that correctly? If that is right, why doesn't it save money?

Mr. HOLTZ-EAKIN. The President's budget contained proposals that would have affected both the rebates collected from drug manufacturers and reimbursements to pharmacies. Concerning rebates, manufacturers currently pay a rebate on brand-name drug sales equal to the larger of either the flat rebate, currently 15.1 percent of the average manufacturer price (AMP), or a higher percentage of the AMP reflecting the "best price" received by any private buyer. The President's budget proposed to eliminate the best-price requirement and increase the flat rebate, although no percentage was specified. The proposal was intended to be budget neutral, and CBO scored no savings for it. Note that the President's proposal is distinct from the proposal in the contained in CBO's latest Budget Options volume, which would increase the flat rebate from 15.1 percent to 20 percent while keeping the best-price requirement.

The President's budget also contained a proposal that would limit reimbursements to pharmacies the average sales price (ASP) plus six percent.

The CHAIRMAN. Right.

Mr. HOLTZ-EAKIN. Each of those, the ASP and the 6 percent, merit some comment.

On the 6 percent, using 6 percent as the reimbursement for the cost of filling a prescription makes it dependent on the value of the prescription drug. It gives you a clear incentive to fill with high-cost drugs. That moves the wrong direction, and since the cost of filling a prescription probably does not depend on what is in the bottle, the fixed dollar cost, $3 to $5 per prescription, makes more sense.

On the ASP side, ASPs are not probably the best indicator of the actual transactions costs between pharmacists and manufacturers. They are a well-defined entity for the Medicare program, but that is a different set of drugs with a different set of customers, and so it does not match up real well for the Medicaid needs.

The CHAIRMAN. Still on the President's proposals, he made a number of proposals for saving money in Medicaid, but the CBO did not score them as saving money. Can you explain to the com-

mittee how the CBO arrived at its decision regarding the IGT proposal?

Mr. HOLTZ-EAKIN. At the time the President provided his budgetary proposals, the attempt to recapture the intergovernmental transfers was specified in concept, but there was not available to us the sort of detailed legislative language or even more detailed policy proposal that would have permitted us to score it. So our approach was rather than to say it is zero or a number is to say we are unable to score this in the absence of greater detail. CMS continued to work with us for some weeks after the President submitted his budget, but we have never received anything that looks like conclusive enough a proposal or language.

The CHAIRMAN. You cannot tell one way or the other whether it will save money. It may save money, but you do not have enough of a bill to be able to calculate it.

Mr. HOLTZ-EAKIN. Yes.

The CHAIRMAN. Are there any other Medicaid proposals out there that you would urge us to look at that would save money without hurting people?

Mr. HOLTZ-EAKIN. Well, I think that in the drug area, three things stand out. Two I have already mentioned: thinking about the different pieces correctly, so perhaps using something closer to a market price for reimbursements instead of a sticker price, using an AMP or something like that; making sure that reimbursements for filling prescriptions match the cost of filling prescriptions, based on values. The other that has been around for a while is to talk about the Medicaid best price provisions which provide clear incentives for everyone to level up to best price, instead of bringing costs down. Those are the three in the drug area that I think stand out at the moment.

The CHAIRMAN. Have you read these two stories in the last 2 days in the New York Times about the massive amount of fraud in Medicaid in the State of New York? As I read them, it seemed apparent that it was really a product of lack of enforcement. Is there something I am missing? If enforcement is the issue, what does a State like New York, or any other, have to do? Do they need a big computer like Texas has that is very, very expensive but really does reduce fraud?

Mr. HOLTZ-EAKIN. I did read the stories, and there was a horse race in my depression, first as CBO Director and seeing the money, and second as a long-term resident of Syracuse, recognizing that is my State.

State programs differ greatly, so, you know, I would hesitate to make a blanket statement about what it would take to do things better. Enforcement in New York is particularly complicated because of the heavy role of the counties in the Medicaid system, relatively unusual.

But certainly to the extent that low-cost enforcement—emphasis on "low cost"—can readily bring actuality into line with the program intent, that is a place to look. It is not something that we came today with a lot of material on, but we would be happy to talk with you about that.

The CHAIRMAN. Wouldn't a State have enough incentive to close this hemorrhage?

Mr. HOLTZ-EAKIN. Forty-four cents on the dollar—

The CHAIRMAN. I mean, that seems to me like New York with their budget problems ought to be all over this story and closing up this hemorrhaging that is happening through Medicaid, and not through serving people, just through fraudulent payments to doctors.

Mr. HOLTZ-EAKIN. You know, I would have to say that having 44 cents out of every dollar is a tremendous financial incentive, but New York State has faced lots of budget woes with which you are familiar.

The CHAIRMAN. Is there something we need to do to help States to close that up? I mean, it is just appalling what I read.

Mr. HOLTZ-EAKIN. I don't think there is any direct Federal policy that interferes with better enforcement at the moment.

The CHAIRMAN. Senator Kohl.

Senator KOHL. Thank you, Mr. Chairman.

Obviously the cost of prescription drugs accounts for much of Medicaid spending, and you and witnesses today will testify or have testified to changes that can be made in how Medicaid pays for prescription drugs in order to save money. Has your CBO analyzed how much these changes will save Medicaid, both over the next 5 years and in the longer term?

Mr. HOLTZ-EAKIN. Which changes? I am sorry.

Senator KOHL. Changes that we can make in how we pay for prescription drugs through Medicaid, how much money are we talking about in your judgment?

Mr. HOLTZ-EAKIN. It depends on the extent of the proposal, quite frankly. Medicaid is 10 to 15 percent of drug spending. It is a very large fraction of the overall national drug bill. The reimbursements to pharmacies are a quarter of Medicaid spending, so there are substantial dollars in play both for the program as a whole and within it for different participants.

As I said, if you take the reconciliation mark as the benchmark, changes in the rebate formula could get you 20 to 30 percent of the needed reconciliation savings in a very straightforward fashion, and other policies could probably contribute as well.

Senator KOHL. All right. As the nation ages, the growing need for long-term care will strain our Medicaid budgets. A large share of Medicaid's long-term care spending is for nursing home care, which we know is expensive and often not the care preferred by most people who wish to stay in their homes. Many States, like my State of Wisconsin, have expanded home and community-based care through Medicaid waivers, and they believe that they save Medicaid dollars by so doing.

Has CBO been able to determine the long-term savings of home and community-based care?

Mr. HOLTZ-EAKIN. We will happily look into any specific proposal. In the area of long-term care and Medicaid, two broad phenomena always arise. The first is the degree to which you can save in costs per person, whether it be in this case by using home-based care instead of being in a nursing home, and the second is whether you end up covering more people. There are at the moment a large number of individuals who receive only donated care as their primary form of long-term care assistance and have a clear preference

to be in their home. Many of them are severely impaired and helped only by relatives. To the extent that you start picking up that population, covering them under a Medicaid program gets more expensive. To the extent that you move people who would have been in nursing home into a home-based care system that is cheaper per person, you save money. Almost all the proposals hinge on the balance of those competing incentives in expanding the use of home care.

Senator KOHL. All right. You point out that Medicaid drug spending will drop next year as dual-eligible beneficiaries move from Medicaid to Medicare. But States are required to pay most of those savings back to the Federal Government through the claw-back provision, as you know. Because the claw-back formula is in part based on spending growth for the Medicare drug benefits, States, therefore, have a direct interest in how the Medicare drug program is run.

Has CBO done an analysis on how Medicare drug spending could affect State Medicaid spending and whether allowing HHS to negotiate lower drug prices could produce additional savings for State Medicaid programs as it relates to claw-back?

Mr. HOLTZ-EAKIN. We have done nothing particular on HHS and claw-back, but certainly our estimates of the impact of the MMA on the Nation as a whole showed the impact over the long term of the claw-back, not State by State, but we do have the aggregates. In some years, the monies flowing back to the Federal Government modestly exceed that which would come from the Federal Government early on. But on balance it goes the other way.

Drug spending has been going up very rapidly, 15 percent per year over the past 5 years, and we have looked fairly carefully at the design of the prescription drug benefit in Medicare and whether it would be possible for an enhanced negotiating authority by the Secretary of HHS to lower the costs of that drug insurance bill. Broadly the answer has been no. The key is whether the prescription drug plans in MMA have sufficient incentives—and they have tremendous financial incentives—and whether they have sufficient tools to pursue those incentives in order to negotiate the best possible deal on behalf of their beneficiaries.

The structure of the MMA as passed by the Congress suggests that they have great incentives and tools to do that. It does not look that as a broad-brush matter any additional negotiating authority on the part of the Secretary of HHS would change the broad scope.

Now, that does not mean for particular drugs and particular instances that would not be the case, but it does not look to us that based on the design so far there is tremendous latitude for a big change from that direction.

Senator KOHL. Thank you.

I thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Lincoln.

Senator LINCOLN. Thank you, Mr. Chairman, and thank you, Mr. Holtz-Eakin, once again for coming to share your expertise with us.

You probably know that one of the panelists that is going to be following you will be discussed evidence-based medicine, and they

just called a vote and I am not sure if I will be able to stay for the entire hearing. But my State of Arkansas is one of the States implementing this as a way to cut down on prescription drug costs. I did not know if you had looked into or were aware of any savings that could be gained from evidence-based medicine.

Mr. HOLTZ-EAKIN. We are essentially at the midpoint of beginning to understand this, and we look forward to seeing the results of these pilots in various places to get better evidence on the degree to which there really will be savings from evidence-based medicine and other new techniques that you might bring to both Medicare and Medicaid.

Senator LINCOLN. So you are not really at a point to give us guidance in terms of which directions to go on that?

Mr. HOLTZ-EAKIN. Certainly not in a position to make a definitive call one way or the other and certainly not to give you a sense of the magnitudes, how much money would be saved.

Senator LINCOLN. Right. Well, I do not know if there is anything there, but you know as well as we all that generic drugs are significantly cheaper than brand name drugs. Are there any proposals on the Federal level to encourage the use of generic drugs that would really result in some savings?

Mr. HOLTZ-EAKIN. There are a variety of ways to encourage the use. One could provide greater copays for brand name drugs, lower copays for generics, and steer beneficiaries that way. One could just change the maximum Federal reimbursement for drugs in order to steer people toward generics. There is the ability at the State level to have mandatory substitution to a generic where it is available.

So there are a variety of potential mechanisms. Particular proposals in the context of reconciliation we will have to look at, but certainly there are elements of policies that would move the system in that direction.

Senator LINCOLN. Well, I noticed in what you were showing us in your slides there, you said that the markup for the newer generic drugs was much higher than the markup for the older ones. Is there any explanation for why that is the case?

Mr. HOLTZ-EAKIN. I think that is the straightforward result of the incentives in the current system. Manufacturers have an incentive to put a high sticker price on their new generic drug, and then cut an aggressive deal on the actual transaction, knowing that the pharmacist will be reimbursed on the sticker price and only have to pay the manufacturer the lower transaction prices. That gives pharmacists a clear incentive to take their generic drug and use it in filling prescriptions. So that markup comes out of the mismatch between reimbursement on stickers and actual transactions on a market. Fixing that would fix that incentive as well.

Senator LINCOLN. Just I guess in closing as we move forward to what we have to what we have to do in Finance and budget reconciliation, can you describe how the Congressional Budget Office is going about in terms of scoring those potential savings in preparation for reconciliation? I guess specifically are you approaching the savings—how are you going to be approaching the savings that we on the Finance Committee have to find?

Mr. HOLTZ-EAKIN. We are actively working with members of the Finance Committee on both sides of the aisle with their prototype proposals. To the extent that you have areas of interest, I would encourage you to have your staff in contact with the CBO early. The sooner we can see the scope of the proposals you are interested in, the more we can get the data in line to actually give you good estimates. As usual, knowing details, writing it down, is an important first step to making sure there is no mismatch between what you would like to accomplish and what is actually written into legislative language.

That is an ongoing process that has been going on for a while in some cases, but which I would expect to heat up as time passes.

Senator LINCOLN. Thank you.

Thanks, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator.

Are there other questions anyone has? [No response.]

Doug, we appreciate your time so very much.

[The prepared statement of Mr. Holtz-Eakin follows:]

CBO TESTIMONY

Statement of
Douglas Holtz-Eakin
Director

Payments for Prescription Drugs Under Medicaid

before the
Special Committee on Aging
United States Senate

July 20, 2005

This statement is embargoed until it is delivered at 2:30 p.m. (EDT) on Wednesday, July 20, 2005. The contents may not be published, transmitted, or otherwise communicated by any print, broadcast, or electronic media before that time.

CONGRESSIONAL BUDGET OFFICE
SECOND AND D STREETS, S.W.
WASHINGTON, D.C. 20515

Mr. Chairman, Ranking Member Kohl, and Members of the Committee, thank you for the opportunity to be here today to discuss the government's system for purchasing prescription drugs under the Medicaid program. Medicaid's spending on prescription drugs has increased rapidly in recent years, growing at an average annual inflation-adjusted rate of 15 percent between 1998 and 2004 to a level of about $30 billion. That spending will undergo a significant onetime drop—of roughly one-half—with the introduction of the Medicare drug benefit in 2006, as dually eligible beneficiaries switch their coverage to Medicare. Nonetheless, upward pressure on prescription drug spending will continue to pose budgetary challenges for the federal government as well as for state governments under Medicaid.

In my testimony today, I will discuss some important features of the process by which Medicaid purchases prescription drugs in the fee-for-service sector of the program, including the way it reimburses pharmacies for drug purchases and the rebate it receives from drug manufacturers. I will also briefly address how the prices that Medicaid pays for drugs compare with the prices paid by other purchasers.

Medicaid's System for Purchasing Prescription Drugs

In the fee-for-service portion of the program, Medicaid pays private pharmacies for prescription drugs that the pharmacies have dispensed to Medicaid beneficiaries.[1] The process by which drug products and payments flow between drugmakers, pharmacies, state Medicaid agencies, and beneficiaries is illustrated in Figure 1. (This is a stylized depiction of the highly varied state programs and may not fit any one program precisely.)

The system works in the following way. A Medicaid beneficiary obtains a prescription drug from a participating pharmacy, which has previously purchased the drug in the marketplace from a manufacturer or wholesaler. The pharmacist receives payment from the state Medicaid agency based on the state's formula for approximating the cost of acquiring and dispensing the drug. The drugmaker pays rebates directly to the state Medicaid agency, which also receives matching payments from the federal government. (Those rebates are taken into account when federal matching payments to the states are calculated. Thus, the federal government shares the savings from the rebates with the states.)

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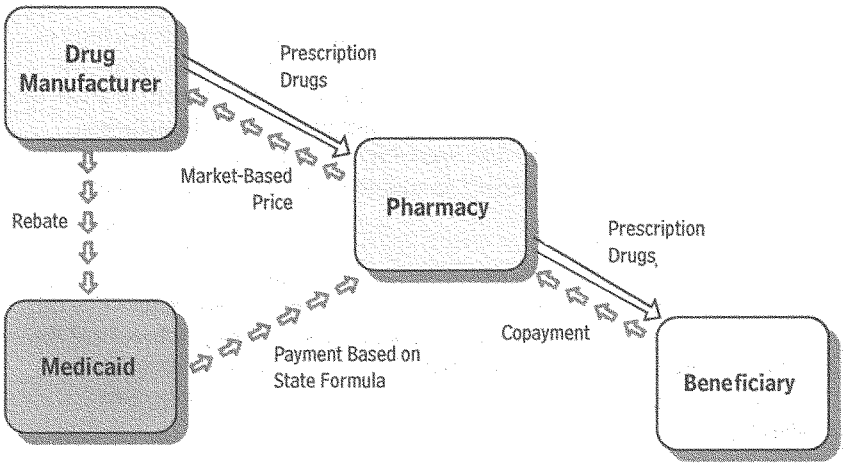
1. In some cases, state Medicaid programs pay a capitated amount to a health maintenance organization to manage the drug benefit for certain beneficiaries. Such cases are not part of the analysis presented here.

Figure 1.

Medicaid's System for Purchasing Prescription Drugs



Source: Congressional Budget Office.

Medicaid's Payments to Pharmacies

Federal regulations allow states broad discretion in setting payments to pharmacies for Medicaid drug purchases, and states vary significantly in the formulas they use to determine the payments. Generally, though, the payment has two components. One component is a dispensing fee, usually a fixed amount of $3 to $5, which is meant to cover costs associated with storage, consultation, and dispensing. The second component is an approximation of the prevailing market price for the drug, which is meant to cover the cost that the pharmacy faces in acquiring it. Currently, the proxy used for that second component is usually based on the average wholesale price (AWP) of the drug. The AWP is essentially a sticker price and does not directly correspond to any actual market transaction. As a list price, it offers the advantage of being readily available. But it suffers the drawback of being an imperfect representation of the true cost a pharmacy faces when acquiring a drug. In practice, the AWP is usually higher than actual market-transaction prices. In recognition of that fact, the second component of Medicaid's payment for brand-name drugs is often set at roughly 10 percent to 15 percent below the AWP.

For brand-name drugs, pharmacies typically pay a fairly constant proportion of the list price, and states can adjust their pharmacy payment rates to reflect the gap between acquisition costs and list prices. For generic drugs, however, the list price is not a good predictor of what pharmacies actually pay. In recognition of that fact, both the Centers for Medicare and Medicaid Services (CMS) and the states set payment limits on generic drugs, although those limits—especially for newer generic drugs—often take considerable time to establish. When pharmacies are paid for newer generic drugs on the basis of the average wholesale price, Medicaid's payments can greatly exceed the actual cost of the drugs.

In a recent analysis, the Congressional Budget Office (CBO) compared Medicaid's payments to pharmacies with the amounts actually received by the manufacturers of the drugs.[2] The difference between Medicaid's payment and the amount received by manufacturers is referred to as the markup on the drug and reflects what is retained by all parts of the drug distribution chain, including wholesalers, where relevant.

CBO found that in 2002 Medicaid paid pharmacies about $61 per prescription, on average (see Table 1). That payment consisted of two parts: an amount that went to the manufacturer to acquire the drug, which averaged $47 per prescription, and the amount retained by pharmacies and wholesalers—the markup—which averaged about $14 per prescription. Thus, on average, pharmacies and wholesalers retained about 23 percent of the amount that Medicaid paid pharmacies for prescription drugs in 2002.

While brand-name drugs were much more expensive than generic drugs, the amount retained by pharmacies and wholesalers on a per-prescription basis was about the same—at $14 per prescription—for the two categories of drugs. (It is also the case that the bulk of the cost of distributing and dispensing drugs does not differ much between brand-name and generic drugs.) Overall, brand-name drugs cost the Medicaid program about $97 per prescription, with the amount received by manufacturers constituting most of that cost. Generic drugs cost Medicaid about $20 per prescription, with the amount retained by pharmacies and wholesalers constituting the bulk of that cost.

Generic drugs are an important source of revenue for pharmacies. About half of all Medicaid prescriptions are for generic drugs, and generic drugs make up about half of the total markup revenues retained by pharmacies and wholesalers. By contrast, brand-name drugs constitute nearly 85 percent of Medicaid's total spending on prescription drugs.

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

Table 1.

Components of Medicaid's Payments for Prescription Drugs, 2002

(Dollars per prescription)

	Medicaid's Payments to Pharmacies	Acquisition Costs[a]	Markups	Percentage of Prescriptions Dispensed
All Drugs	60.90	47.10	13.80	100
Generic Drugs	19.90	6.00	13.80	47
Newer	45.70	13.60	32.10	8
Older	14.20	4.40	9.90	39
Brand-Name Drugs	97.30	83.40	13.80	53

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

Note: Numbers in the tables of this testimony may not add up to totals because of rounding.

a. To estimate acquisition costs, CBO used the average price that manufacturers earned on sales of outpatient drugs to wholesalers and pharmacies, as reported to CMS under Medicaid's rebate program; see Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs* (December 2004).

Markups for newer generic drugs were substantially higher than markups for older generics. Older generic drugs cost $14 and had an average markup of about $10—less than that for any other category of prescription drugs. New generic drugs cost $46 on average and had an average markup of $32—much higher than for any other category of drugs.

When the amount a pharmacist retains on a generic drug is higher than the amount retained on its brand-name counterpart, the pharmacist has a clear incentive to dispense the generic drug. Thus, the higher markups on newer generic drugs probably give pharmacists a strong incentive, where possible, to steer beneficiaries to those drugs.[3] From the perspective of the system as a whole, that outcome may be desirable because it makes the total cost of the prescription much lower than if the brand-name drug were used. Maintaining such incentives

3. For generic drugs, because pharmacies frequently have the choice of acquiring what is essentially the same drug from several manufacturers, manufacturers may also have an incentive to increase the gap between their list prices and the prices they charge pharmacies as they compete for pharmacies' business. This is particularly true before an upper limit has been placed on pharmacy payments for the generic drug.

might be an important consideration in assessing Medicaid's payment system for prescription drugs.

Medicaid's Rebate from Manufacturers

Payments to pharmacies are one part of the financial flows in Medicaid. Another part is the rebate that manufacturers pay to the Medicaid program. In order to have their products covered by Medicaid, drug manufacturers must enter into a rebate agreement with CMS.

The size of the rebate is determined by two confidential prices reported quarterly to CMS by the manufacturer. The first is the average manufacturer price (AMP), which is the average price that a drugmaker receives on a drug in a given quarter for sales to the retail pharmacy class of trade. The second is the lowest transaction price, or "best price," charged to any buyer in the private market (including any rebates or discounts).[4]

For brand-name prescription drugs, the amount that drugmakers are obliged to rebate to Medicaid has two components: the basic rebate and the additional rebate. (For generic and over-the-counter drugs, drug manufacturers must pay a rebate of 11 percent of the AMP.)

Under the basic rebate formula, the required payment is the larger of either a "flat rebate" amount—currently 15.1 percent of the AMP—or the difference between the AMP and the best price extended to any private buyer. For example, suppose that the AMP for a given drug is $2 per unit, and the reported best price in the private market is $1 per unit. The best-price discount in this case would be $1, or 50 percent of the AMP. Because the percentage discount in this case exceeds the flat rebate of 15.1 percent, the rebate (for all units of this drug purchased on behalf of Medicaid beneficiaries) would be 50 percent of the AMP. If the AMP was $2 and the best price was $1.80, then the best-price discount would reflect only a 10 percent discount relative to the AMP, and the appropriate rebate would be 15.1 percent of the AMP.

Depending on how much they increase the prices that they charge private purchasers over time, manufacturers may have to pay an additional rebate to Medicaid beyond the basic rebate. Every drug covered by Medicaid has a base-period AMP that is determined by the drug's original market price and that serves as a reference point for calculating the additional rebate. For a given quarter, no additional rebate is owed if the drug's current AMP does not exceed

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4. Manufacturers sometimes charge nominal prices for drugs such as those provided to charities or other not-for-profit entities. Those nominal prices are not part of the best-price calculation.

Table 2.

Estimated Average Unit Rebate Received by Medicaid for Brand-Name Prescription Drugs, 2003

(As a percentage of the average manufacturer price)

Basic Rebate	Additional Rebate	Total
19.6	11.7	31.4

Source: Congressional Budget Office, *The Rebate Medicaid Receives on Brand-Name Prescription Drugs* (June 21, 2005).

its inflation-adjusted base-period level, as measured using the consumer price index for urban consumers (CPI-U). If the AMP does exceed that inflation-adjusted level, then an additional rebate equal to the excess amount is owed.

According to CBO's estimates, in 2003 the average rebate received by Medicaid for brand-name prescription drugs was 31.4 percent of the AMP (see Table 2).[5] The average basic rebate was 19.6 percent of the AMP, or slightly less than two-thirds of the total rebate percentage. The remainder, 11.7 percent of the AMP, was attributable to the additional rebate.

The average basic rebate percentage has remained fairly stable at about 20 percent of the AMP in recent years. The additional rebate percentage, however, has risen somewhat. The latter outcome would be expected to occur in periods during which average manufacturer prices increased rapidly compared with overall inflation. The slight growth in the total unit rebate from the mid-1990s to 2003 is attributable to a higher additional rebate.

How Medicaid's Net Payments Compare with Those of Other Purchasers

After accounting for the rebates, how does the amount that Medicaid pays for drugs compare with the prices paid by other federal programs and private-sector purchasers? CBO finds that the net prices Medicaid pays for brand-name drugs are, on average, about as low as Federal Supply Schedule prices.[6] (The Federal Supply Schedule is a list of negotiated prices at which any direct federal

5. See Congressional Budget Office, *The Rebate Medicaid Receives on Brand-Name Prescription Drugs* (June 21, 2005).

6. See Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005).

purchaser can buy prescription drugs.) And Medicaid prices are significantly lower on average than the lowest prices paid to manufacturers by private-sector purchasers (as reported by manufacturers under Medicaid's rebate program). So in terms of net payments to manufacturers for brand-name drugs, Medicaid does as well as many other federal purchasers and better than the private sector. However, some federal agencies, such as the Department of Veterans Affairs—which makes active use of formularies—pay net prices to manufacturers that on average are even lower than the net price paid by Medicaid.

The CHAIRMAN. There is another vote on, but what Senator Kohl and I will do is he will go now and I will go when he gets back. So our next panelist is Julie Stone-Axelrad, a specialist in social legislation of the Congressional Research Service. Welcome, Julie. Thank you for your patience and for your presence.

STATEMENT OF JULIE STONE-AXELRAD, ANALYST IN SOCIAL LEGISLATION, DOMESTIC SOCIAL POLICY DIVISION, CONGRESSIONAL RESEARCH SERVICE, WASHINGTON, DC

Ms. STONE-AXELRAD. Good afternoon, Senator Smith, Senator Kohl, and Senator Lincoln. My name is Julie Stone-Axelrad, and I am a health policy analyst at the Congressional Research Service. My testimony today deals with the issue of Medicaid estate planning, a means by which some elderly people divest their income and assets both to qualify for Medicaid sooner than they otherwise would and to protect their assets from estate recovery.

As you know, the Medicaid program is means tested. It covers about 54 million people across the Nation. Although the program is targeted toward low-income individuals, not all of the poor are eligible, and not all of those covered are poor. Medicaid beneficiaries include children and families, people with disabilities, pregnant women, and the elderly.

Today's discussion about Medicaid estate planning focuses on a subset of Medicaid beneficiaries age 65 and over who need long-term care and have income greater than SSI's cash benefit of $579 a month. Medicaid law allows States to cover people whose income reaches, or is sometimes greater than, about 218 percent of the Federal poverty level, but only if they require the level of care that is offered in a nursing home. States may also extend coverage to people who have medical expenses that deplete their income to specified levels. Once eligible for Medicaid, beneficiaries are required to apply their income above certain amounts toward the cost of their care.

In addition to income, individuals must also meet States' asset standards. These standards usually follow SSI program rules and generally allow individuals to retain $2,000 in countable assets as well as certain types of noncountable or exempt assets, such as a home or care of unlimited value, and certain types of trusts.

Other rules apply to married couples in which one person seeks Medicaid long-term care and the other does not. These rules are intended to prevent impoverishment of the spouse not seeking Medicaid by allowing him or her to retain higher amounts of income and assets than allowed for Medicaid beneficiaries.

Not all Medicaid beneficiaries have engaged in estate planning. Some people meet Medicaid's eligibility requirements because their initial income and assets are equal to or below a State's specified levels. Some reach the thresholds after depleting their income and assets on the cost of their care, thus "spending down." My testimony today is about a third category of people who divest their assets to qualify for Medicaid. We do not have sufficient data to assess the number of people in each of these three groups.

To ensure that Medicaid applicants do not give away assets to gain eligibility, Congress established asset transfer rules that impose penalties on applicants who either give away or transfer their

assets for less than the market price. Specifically, the rules require States to delay coverage of nursing home care and other long-term care services for certain individuals who apply for Medicaid after improperly disposing of assets on or after a look-back date.

I mentioned earlier that beneficiaries are allowed to retain certain assets and still qualify for Medicaid. Medicaid's estate recovery program is intended to enable States to recoup those private assets from the estate of a beneficiary upon the person's death. Under Federal law, States are required to recover the amounts they spend on long-term care services from the beneficiary's probate estate, which often includes the home, if there is one. If States choose, they may go beyond the probate estate to collect other assets as well, such as those that may have a designated beneficiary, like an annuity or trust. But not all States do this.

Despite Congress' efforts to discourage Medicaid estate planning through the design of eligibility, asset transfer, and State recovery provisions, current law does not preclude all available means people may use to protect assets. A variety of methods may still be used to avoid estate recovery or to obtain Medicaid coverage while using personal resources for other purposes, such as giving gifts to children or protecting assets for an inheritance. The following are some examples of techniques that people may use to divest assets:

First, people may transfer assets to minimize the impact of the penalty period. Medicaid law specifies that penalties for improper transfers begin on the first day of the month in which assets are transferred. These penalties are periods of ineligibility, in months, for certain long-term care services. People could transfer a part of their assets while keeping enough to pay for their care during the ineligibility period.

Second, people may transfer funds sufficiently in advance of the look-back period to avoid penalties. Any transfers made within 36 months of application to Medicaid and 60 months for certain trusts are subject to penalties. Any transfers made prior to these look-back periods are not subject to penalties.

Third, people may convert countable assets into noncountable assets or income, such as using money in a savings account to purchase an annuity for fair market value.

Fourth, people may use assets above Medicaid thresholds for any purpose. For example, if individuals have $10,000 and the State's asset threshold is $2,000, then to become eligible these people must deplete the excess $8,000. They can either spend that $8,000 on the cost of their care or on anything else they choose, such as home improvements or personal items.

In addition to these techniques, promissory notes could be used, a life estate could be established, or a married couple could divorce and give all of their assets to the spouse not seeking Medicaid.

Another option could be spousal abandonment in which a spouse simply refuses to provide financial support for the spouse seeking Medicaid.

A number of these methods are probably unintended consequences of provisions in Medicaid law, designed to assist certain people who have low income or have high medical or long-term care expenses. The availability of these methods under current law also reflects a lack of consensus about the amount of assets that should

be held by people who face high long-term care costs before qualifying for Medicaid. In addition, the law likely reflects the difficulty in writing legislative language to discourage all methods for transferring assets without inadvertently restricting access to Medicaid's safety net.

A variety of policy options have been proposed to discourage Medicaid estate planning and the improper transfer of assets. When evaluating which legislative options, if any, to adopt, there are some policy questions you may want to consider.

First, tightening Medicaid laws regarding eligibility and asset transfers will likely deter people from deliberately manipulating the rules to qualify for Medicaid. Such changes, however, are likely to impose stricter penalties on people who made transfers without any intention of ever needing Medicaid's assistance. You may want to consider how you want the law to treat people in this latter group.

Second, who will actually pay for the care of elders when Medicaid will not? One possibility is that beneficiaries would pay for their own care during the penalty period by either recovering their transferred funds or liquidating any exempt assets they may have to pay for care. Another possibility is that providers, such as nursing homes, will assume more cases of uncompensated care, either reducing or eliminating the profits of proprietary homes, or relying more heavily on the charitable donations of not-for-profit homes. Others may rely on informal caregivers to provide the care they need, and still others may forego care altogether.

Third, you may want to consider the high costs of long-term care services, often reaching over $60,000 a year for a private stay in a nursing home. If changes to current law result in further restricting access to Medicaid's long-term care coverage, what, if anything, should be done to assist older people with these costs?

Finally, it is unlikely that the adoption of just one or two of the policy options currently being discussed will lead to significant reductions in Medicaid estate planning. It is likely that narrow changes to current law will still allow people to find ways to divest assets. To achieve significant reductions in Medicaid estate planning, a package of changes is more likely needed. In designing such a package, you may consider measures to make transferring assets more difficult, measures to strengthen penalties for people who make inappropriate transfers, as well as measures that provide a safety net for applicants for whom the State determines that significant hardship could result without Medicaid's assistance.

At the request of the committee, I have prepared some comments on some of the legislative options that have been proposed.

One option is changing the beginning of the penalty period from the time the Medicaid applicant made the transfer, which is how current law says it begins now, to the time the applicant is determined eligible for Medicaid. So changing the beginning of the penalty period.

The proposal could increase the likelihood that people who improperly transfer assets would be penalized, possibly serving as a stronger deterrent to asset transfers. Strengthening the penalty period could either delay or even prevent Medicaid from paying for care of certain individuals, thus potentially incurring savings to the

program. On the other hand, providers may end up paying for care not paid for by Medicaid, and some people might not be able to obtain the care they need. These implications may have unintended consequences on provider budgets and access to care.

Extending the look-back period. Another options would be to extend the look-back period for transferred assets beyond the 3- to 5-year period in current law. This would require people who want to divest assets and avoid the penalty period to plan even earlier than they must under current law, making it more difficult. A longer look-back period could lead States to identify more transfers and thus impose more penalties. Savings to Medicaid might be found.

However, the farther into the past the transfer was made, the less likely the applicant may be to recover the transferred funds to pay for care during the penalty period. Extending the look-back period could also place an additional administrative burden on eligibility workers, slowing down the process as workers review and have difficulty obtaining past financial documents from applicants.

Other legislative options include: placing a universal cap on the value of all exempt assets; counting assets not current counted; requiring applicants to apply a portion of their home equity to the cost of their care before Medicaid will pay; restricting sequential transfers; and requiring an applicant to make the State the beneficiary of any remaining funds of an exempt asset.

Each of these proposals could reduce the total amount of assets that could be protected either at the point of application to Medicaid or at the point of estate recovery. However, there would still be no guarantee that funds above the protected amounts would be used to pay for the cost of care.

Since each of these options would target a different method people might use to protect assets, together these proposals might represent a comprehensive approach to addressing Medicaid estate planning. On the other hand, without more information about which methods are most commonly used, we do not know which options would be most effective and which, if any, might have unintended implications on access to care.

Finally, there are insufficient data available to accurately estimate the prevalence of asset transfers today and none that can reasonably predict whether and how much this incidence might grow in the future. We do know that a significant amount of anecdotal evidence exists about people engaging in Medicaid estate planning. We also know that an industry of elder lawyers specializing in Medicaid has developed across the Nation. Court cases at Federal and state levels also point to the prevalence of transfers. In addition, we know that States have expressed a strong interest in curbing Medicaid estate planning and have taken a number of measures to try to do so.

Any protection of assets that results in Medicaid paying for care that would otherwise have been paid with private funds increases Medicaid's program costs. Unfortunately, without better data we cannot accurately estimate how much Medicaid estate planning costs the program now and how much savings could be generated from further restricting transfers in the future. Changes to current law could deter people from transferring assets, strengthen penalties for doing so, and possibly increase the likelihood that private

funds would be used to pay for care. At the same time, it is still unclear how such changes might impact access to care for older people with long-term care needs.

The CHAIRMAN. Thank you. A very excellent report, Julie. I wonder if as you consider all of the proposals and the President's plan on Medicaid, are there any that stand out to you as particularly effective in saving money that you can quantify that do not hurt people that really do have no recourse but Medicaid?

Ms. STONE-AXELRAD. Well, first, I cannot quantify. CBO does that and I think they are going to have a hard time because we do not have good information about how much any of the practices cost the program now. There are certain things that might be technical changes to the way in which assets are counted that might be less likely to have implications on access to care. I think we could think about that a little bit more. I could—

The CHAIRMAN. Are there any States that come to mind that are doing a particularly good job in the asset transfer area?

Ms. STONE-AXELRAD. There are a lot of States that have tried to make changes, and Oregon is a classic example of a State that has been more aggressive in trying to discourage asset transfers. But there are limitations to what States can do because of the current law. For example, with annuities the law gives the Secretary discretion—or authority to define annuities either as trusts or not. The guidance that the Secretary is able to give is limited because of the way current law is designed, and so States have dealt with annuities in different ways. Some States deal with them as trusts, and this makes them subject to the—

The CHAIRMAN. Has my State done a good job, in your view, or a poor job in asset transfer issues?

Ms. STONE-AXELRAD. They are one of the leaders in discouraging asset transfers.

The CHAIRMAN. So they are doing a good job.

Ms. STONE-AXELRAD. They are discouraging, probably so, if you look at it—

The CHAIRMAN. I guess if you are being discouraged, you think they are doing a bad job.

Ms. STONE-AXELRAD. It depends. You know, I think the issue to consider is people who are faced with very high long-term care costs have a fear about losing their savings, losing their home. So Oregon is a State that has been more aggressive in trying to recoup the assets of those elderly individuals. So it depends on how you look at it.

The CHAIRMAN. Sure. I am going to go vote, and Senator Kohl is in charge.

Ms. STONE-AXELRAD. Thank you.

Senator KOHL [presiding]. Thank you, Mr. Chairman.

We could all agree that it is important to prevent people from gaming the estate planning system, but I am concerned that when researchers at the Georgetown University Long-Term Care Financing Project looked at this issue, they found no empirical evidence to prove that "the elderly are planning their estates for the purpose of gaining easy access to Medicaid." Instead, the research found that today's seniors simply lack the necessary liquid assets to pay for expensive long-term care services.

Is this assessment consistent with the data that you have looked at?

Ms. STONE-AXELRAD. There is not good comprehensive data that looks at the amount of assets that have been transferred or the number of people who have transferred assets. So Georgetown was looking at some data that is a little bit old, and not their fault. It is limited because the surveys that are available—there are just not current surveys available that look at what is going on right now.

I do not know if I am answering your question.

Senator KOHL. I would guess you say that is somewhat inconclusive, you are not sure what—

Ms. STONE-AXELRAD. Well, I think what we know is that the amount of assets and income of the elderly for the most part is limited. Most of the asset value is in the home. There I think the majority of the elderly have a limited amount that could potentially even be transferred, a limited amount that they could spend on nursing home care. So probably, you know, for the bulk of the population, the elderly population do not have much to transfer.

Senator KOHL. Right.

Ms. STONE-AXELRAD. But, you know, the home is always a question. The amount that it is worth really varies by geographic region and many other factors.

Senator KOHL. I was only, again, making the point that some people say the elderly plan their estates for the purpose of gaining easy access to Medicaid. Perhaps it would be somewhat more accurate to say there may be some, but there is no evidence to indicate that this is widespread. Would you be inclined to agree with that?

Ms. STONE-AXELRAD. I think there is a strong indicator—States' interest in this issue is a strong indicator that, at least in certain States, they probably have reason to want to curb this practice. But, no, there is no data on a national level that says how many people are doing this and how much they are transferring.

I said in the testimony there are certain indicators like the fact that there are Medicaid—there are elder lawyers who specialize in Medicaid, and they are across the country. There may be certain States that have more of an issue with this than others. But I cannot say that there is any evidence to suggest that this is very expensive. I cannot say that there is evidence that suggests that it is not.

Senator KOHL. OK.

Ms. STONE-AXELRAD. I am sorry I cannot answer that.

Senator KOHL. We understand that extending the look-back period for asset transfers which the President has proposed would provide $1 to $2 billion in savings over the next 5 years. But if we do not know what the evidence is to tell us how many people are actually gaming the system, then how can we know that this will work to save Medicaid all that money over the long term? Isn't that true?

Ms. STONE-AXELRAD. Well, I think a simple change—it is not a simple change. I am sorry. A change to the law that extends the look-back period logically means that when States go over people's records, their financial records, they are going to find more transfers because that just simply makes sense, I think.

Now, the question is: Will there be cost shifting, and at the end what will happen to those people who experience penalties? Could that potentially increase costs to Medicaid or to Medicare? Or could there be increased hospital costs? Those are the kinds of things that we do not know.

But if you just extend the look-back period, then it seems logical that you review more financial records, you are going to find more transfers and impose more penalties.

Senator KOHL. I thank you, and I thank you very much for appearing here today.

[The prepared statement of Ms. Stone-Axelrad follows:]

Medicaid Estate Planning and Legislative Options Testimony Before the Senate Special Committee on Aging

July 20, 2005

Julie Stone-Axelrad
Analyst in Social Legislation
Domestic Social Policy Division

Good afternoon Senator Smith, Senator Kohl and Members of the Committee. My name is Julie Stone-Axelrad and I am a health policy analyst at the Congressional Research Service. My testimony today deals with the issue of Medicaid estate planning, a means by which some elderly people divest their income and assets both to qualify for Medicaid sooner than they otherwise would and to protect their assets from estate recovery.

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Not all Medicaid beneficiaries have engaged in estate planning. Some people meet Medicaid's eligibility requirements because their initial income and assets are equal to or below a state's specified thresholds. Some reach the thresholds after depleting their income and assets on the cost of their care, thus "spending down." My testimony today is about a third category of people who divest their assets to qualify for Medicaid. We do not have sufficient data to assess the number of people in each of these groups.

To ensure that Medicaid applicants do not give away assets to gain eligibility sooner that they otherwise would, Congress established asset transfer rules that impose penalties on applicants who either give away or transfer their assets for less than the market price. Specifically, the rules require states to delay coverage of nursing home care and other long-term care services for certain individuals who apply for Medicaid after improperly disposing of assets on or after a look-back date.

I mentioned earlier that beneficiaries are allowed to retain certain assets and still qualify for Medicaid. Medicaid's estate recovery program is intended to enable states to recoup these private assets from the estate of a beneficiary upon the person's death. Under federal law states are required to recover the amounts they spend on long-term care services from the beneficiary's probate estate, which often includes the home, if there is one. If states choose, they may go beyond the probate estate to collect other assets as well, such as those that may have a designated beneficiary, like an annuity or trust. But not all states do this.

Despite Congress' efforts to discourage Medicaid estate planning through the design of eligibility, asset transfer, and estate recovery provisions, current law does not preclude all available means people may use to protect assets. A variety of methods may still be used to avoid estate recovery or to obtain Medicaid coverage while using personal resources for other purposes, such as giving gifts to children or protecting assets for an inheritance. The following are some examples of techniques that people may use to divest assets.

Minimize the Impact of the Penalty Period

First, people may transfer assets to minimize the impact of the penalty period. Medicaid law specifies that penalties for improper transfers begin on the first day of the month in which assets are transferred. These penalties are periods of ineligibility, in months, for certain long-term care services. People could transfer a part of their assets while keeping enough to pay for their care during the ineligibility period.

Avoid Penalties by Transferring Assets Outside the Look-Back Period

Second, people may transfer funds sufficiently in advance of the look-back period to avoid penalties. Any transfers made within 36 months of application to Medicaid, and 60 months for certain trusts, are subject to penalties. Any transfers made prior to these look-back periods are not subject to penalties.

Convert Countable Assets into Non-Countable Assets and Income

Third, people may convert countable assets into noncountable assets or income, such as using money in a savings account to purchase an annuity for fair market value.

Use Funds Above Medicaid Thresholds for Any Purpose

Fourth, people may use assets above Medicaid thresholds for any purpose. For example, if individuals have $10,000 and the state's asset threshold is $2,000, then to become eligible individuals must deplete the excess $8,000. They can either spend the $8,000 on the cost of their care or on anything else they choose, such as home improvements or personal items to maintain a certain living standard.

In addition to these techniques, a married couple could divorce and give all of their assets and income to the spouse not seeking Medicaid. An other option would be for a spouse to refuse to provide financial support for the spouse seeking Medicaid.

A number of these methods are probably unintended consequences of provisions in Medicaid law, designed to assist certain people who have low-income, or who have high medical or long-term care expenses. The availability of these methods under current law also reflects a lack of consensus about the amount of assets that should be held by people who face high long-term care costs before qualifying for Medicaid. In addition, the law likely reflects the difficulty in writing legislative language to discourage all methods for transferring assets without inadvertently restricting access to Medicaid's safety net.

Considerations for Legislation

A variety of policy options have been proposed to discourage Medicaid estate planning and the improper transfer of assets. When evaluating which legislative options, if any, to adopt, there are some policy questions you may want to consider.

First, tightening Medicaid laws regarding eligibility and asset transfers will likely deter people from deliberately manipulating the rules to qualify for Medicaid. Such changes, however, are likely to impose stricter penalties on people who made transfers without any intention of ever needing Medicaid's assistance. You may want to consider how you want the law to treat people in this latter group.

Second, who will actually pay for the care of elders when Medicaid won't? One possibility is that beneficiaries would pay for their own care during the penalty period by either recovering their transferred funds or liquidating any exempt assets they may have to pay for care. Another possibility is that providers, such as nursing homes, will assume more cases of uncompensated care, either reducing the profits of proprietary homes, or relying more heavily on the charitable donations of not-for-profit homes. Others may rely on informal caregivers to provide the care they need, and still others may forgo care altogether.

Third, you may want to consider the high costs of long-term care services, often reaching over $60,000 a year for a private stay in a nursing home. If changes to current law result in further restricting access to Medicaid's long-term care coverage, what, if anything, should be done to assist older persons with these costs?

Finally, it is unlikely that the adoption of just one or two of the policy options currently being discussed will lead to significant reductions in Medicaid estate planning. It is likely that narrow changes to current law will still allow people to find ways to divest assets. To achieve significant reductions in Medicaid estate planning, a package of changes is more likely needed. In designing such a package, you may consider measures to make transferring assets more difficult, measures to strengthen penalties for people who make inappropriate transfers, as well as measures that provide a safety net for applicants for whom the state determines that significant hardship could result without Medicaid's assistance.

At the request of the Committee, I have prepared some comments on some of the legislative options that have been proposed.

Changing the Penalty Period

One option is changing the beginning of the penalty period from the time the Medicaid applicant made the asset transfer to the time the applicant is determined eligible for Medicaid.

The proposal could increase the likelihood that people who improperly transfer assets will be penalized, possibly serving as a stronger deterrent to such transfers. Strengthening the penalty period could either delay or even prevent Medicaid from paying for care of certain individuals, thus potentially incurring savings to the Medicaid program. On the other hand, providers may end up paying for care not paid for by Medicaid and some people might not be able to obtain the care they need. These implications may have unintended consequences on provider budgets and access to care.

Extending the Look-Back Period

Another option would be to extend the look-back period for transferred assets beyond the three to five-year period in current law. This would require people who want to divest assets and avoid the penalty period to plan even earlier than they must under current law, making it more difficult. A longer look-back period could lead states to identify more transfers, and thus impose more penalties. Savings to Medicaid might be found.

However, the farther into the past the transfer was made, the less likely the applicant may be to recover the transferred funds to pay for care during the penalty period. Extending the look-back period could also place an additional administrative burden on eligibility workers, slowing down the process as workers review and try to obtain past financial documents from applicants.

Other legislative options include:

- Placing a universal cap on the value of all exempt assets;
- Counting assets not currently counted;
- Requiring applicants to apply a portion of their home equity to the cost of their care before Medicaid will pay for care; and
- Requiring an applicant to make the state the beneficiary of any remaining funds of an exempt asset after the beneficiary's death.

Each of these proposals could reduce the total amount of assets that could be protected either at the point of application to the Medicaid program or at the point of estate recovery upon a beneficiary's death. However, there would still be no guarantee that funds above the protected amounts would be used to pay for the cost of care.

Since each of these options would target a different method people might use to protect assets, together they represent a more comprehensive approach to addressing Medicaid estate recovery. On the other hand, without more information about which methods are most commonly used, we do not know which options would be most effective and which, if any, might have unintended implications on access to care.

Finally, there are insufficient data available to accurately estimate the prevalence of asset transfers today and none that can reasonably predict whether or how much this incidence might grow in the future. We do know that a significant amount of anecdotal evidence exists about persons engaging in Medicaid estate planning. We also know that an industry of elder lawyers specializing in Medicaid has developed across the nation. Court cases at federal and state levels also point toward the prevalence of transfers. In addition, we know that states have expressed a strong interest in curbing Medicaid estate planning and have taken a number of measures to try to do so.

Any protection of assets that results in Medicaid paying for care that would otherwise have been paid with private funds increases Medicaid's program costs. Unfortunately, without better data we cannot accurately estimate how much Medicaid estate planning costs the program now and how much savings could be generated from further restricting transfers in the future. Although changes to current law could deter people from transferring assets, strengthen penalties for doing so, and possibly increase the likelihood that private funds would be used to pay for care, it is still unclear how such changes might impact access to care for older persons with long-term care needs.

Senator KOHL. At this time we will take testimony from our third panel. We have with us today Mr. Vincent Russo, who is former President of the National Academy of Elder Law Attorneys. Mr. Russo is from Westbury, NY.

We have with us today Mark Gibson, deputy director, Center for Evidence-based Policy, Department of Public Health and Preventive Medicine of the Oregon Health and Science University out in Portland, OR.

We have with us Meg Murray, who is the executive director of the Association for Community Affiliated Plans, located here in Washington, DC.

Mr. Russo, we will take your testimony first, then Mr. Gibson, and then Ms. Murray.

STATEMENT OF VINCENT J. RUSSO, VINCENT J. RUSSO & ASSOCIATES, PC, WESTBURY, NY, AND PAST PRESIDENT, NATIONAL ACADEMY OF ELDER LAW ATTORNEYS, TUCSON, AZ

Mr. RUSSO. Good afternoon, Senator Kohl. My name is Vincent J. Russo. I have an elder law practice in New York and am a founding member and past president of the National Academy of Elder Law Attorneys. Today I welcome the opportunity to talk with you about ways Congress can achieve savings by eliminating aggressive Medicaid planning and loopholes in the rules. First, however, it is essential to respond to two ill-advised proposals that will harm countless number of older Americans who have worked all their lives, paid taxes, and have never been on public assistance.

One flawed proposal to make penalties harsher calls for changing the start of the penalty period from the date of transfers to the date one applies for Medicaid. The other proposal would increase the look-back period from 3 years to 5 years.

Senator Kohl, recognizing the harmful impact of these proposals on seniors and their families, aging advocacy organizations representing tens of millions of Americans, such as AARP, Alzheimer's Association, National Council on Aging, and the retired Officers Association, have consistently strongly opposed them. In fact, in the aftermath of opposition to these very changes, Governor Rell of Connecticut has since withdrawn the State's request to implement these ill-conceived policies.

To illustrate why those representing older Americans have rejected these policies, I would like to share three representative profiles of real clients whose stories are depicted on the charts to your left. The profiles are depicted on Chart 1.

We are using today the vertical line at July 20, 2005, as the date of Medicaid application. You will note that the line at July 20, 2002, represents the current look-back period, and the line at July 20, 2000, represents the proposed look-back period.

First, at the left of the chart, the story of Mary Richards, who has cared for her granddaughter since her daughter passed away. As noted on the chart, in July 2004, she pays her granddaughter's college tuition, $15,000. A year later, she suffers a stroke and requires nursing home care. Under the current law, since Mrs. Richards has spent down monies, she will be Medicaid eligible because the transfer penalty period has expired. Under the ill-conceived proposal to change the penalty start date, Mrs. Richard would be

denied Medicaid nursing home care because she helped her granddaughter. She will have no place to go. The hospital will want to discharge her, and the local nursing homes will be reluctant to take her. If she returns home, how will she be properly cared for?

Now let's turn to John Greer, who is a farmer in the Midwest. His farm has been in the Greer family for over 100 years. Mr. Greer transfers the farm worth $100,000 to his son, as noted on the chart. Unfortunately, 3 years later, he fractures his hip and requires nursing home care. Under today's law, Mr. Greer is eligible for Medicaid nursing home care, but under the proposal he would be denied care because he passed the family farm on to his son. What will happen to the Greer family and their farm?

My last story is about the Anderson family. In 2001, Steve Anderson, who controlled the family finances, made a series of withdrawals before he passed away from cancer. Mrs. Anderson had cared for him every step of the way. Since that time, Mrs. Anderson's health has declined. She has Alzheimer's and she needs nursing home care. As you can see on the chart, under the current law Mrs. Anderson can obtain Medicaid. If the look-back period were extended to 5 years, she will have to account for her husband's withdrawals, which were made over 4 years ago. She knows some money was spent on donations to the church and some on repairs to the house, but no records can be found. Under these proposals Mrs. Anderson would be denied Medicaid.

The combination of extending the look-back period and changing the penalty start date would create the harshest penalty of all on people like Mrs. Anderson, the most vulnerable members of our society.

Chart 2 represents additional common family situations where people will be hurt by the proposed changes. Senator Kohl, under these harmful proposals no one will be able to act with certainty because no one can predict the future. This will place an unfair burden on seniors.

Now I will focus on how we can eliminate aggressive Medicaid planning and loopholes in the rules. Over the last 6 months, I have been working with a group of Medicaid experts to develop proposals that would both close loopholes and achieve Federal and State Medicaid savings. I will now explain three of six solutions that we are proposing. The other three are in my written testimony for your full consideration.

First, balloon annuities should no longer be allowed as part of Medicaid planning. While annuities can be very helpful to some seniors, unfortunately they have been manipulated to be a Medicaid planning tool. Balloon annuities are structured with very small payments over the senior's lifetime which allows the senior to pass on the lion's share of the annuity to family while accessing Medicaid for nursing home care. The solution is to have balloon annuities treated as a transfer subject to the transfer penalty rules.

Second, self-canceling installment notes, referred to as "SCINs," should also be outlawed as a Medicaid planning tool and treated as an available asset to pay for long-term care.

Third, eliminate rounding down. Under current law in a rounding down State, each month one could transfer slightly less than two months of nursing home cost with only one month of penalty.

This allows people to transfer twice as much as is intended under the current Medicaid transfer penalty rules. By eliminating rounding down, transfers would result in partial month penalties and no doubling up of transfer amounts.

We welcome the opportunity to sit down with your staff to discuss six solutions in greater detail. I thank you for this opportunity. Since savings must be found in the Medicaid program, we believe strongly that closing loopholes is a better solution than creating a punitive and unworkable transfer penalties for our seniors, who have contributed so much to this Nation and now face chronic illness and the need for long-term care.

I would be happy to respond to any questions that you may have. It has been my privilege to testify before you.

[The prepared statement of Mr. Russo follows:]

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Statement of Vincent J. Russo, CELA

Vincent J. Russo & Associates, PC
Past President of the National Academy of Elder Law Attorneys

"Saving Money in Medicaid"

A hearing by the:

Special Committee on Aging

United States Senate

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"Saving Money in Medicaid"

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United States Senate Special Committee on Aging

Wednesday, July 20, 2005

Good afternoon. Chairman Smith and Ranking Minority Member Kohl, I congratulate you on calling for this hearing. I appreciate the opportunity to testify as a professional serving the elderly and individuals with disabilities and as a past president and one of the founders of the National Academy of Elder Law Attorneys (NAELA).

Thank you for your interest in our views regarding proposals to save money in Medicaid by changing the transfer of assets rules. Thank you also for your efforts during the budget process to protect Medicaid and your commitment now to minimizing the harm that is done to older Americans and individuals with disabilities as Congress cuts Medicaid spending.

NAELA

The National Academy of Elder Law Attorneys is a national, non-profit association composed of more than 4800 attorneys. NAELA provides information, education, networking, and assistance to lawyers, bar organizations, and others who deal with the many issues involved with legal services for the elderly and people with special needs.

Elder Law

Elder law is a specialized area of law that involves representing, counseling, and assisting the elderly and individuals with disabilities and their families in connection with a variety of legal issues. It is a holistic approach to the practice of law that focuses on the individual rather than a particular area of law. I have included at the end of my statement a list of the areas in which elder law attorneys provide support to older and disabled persons. I hope that it gives you a good picture of the range of concerns we help our clients work through, such as wills, advance directives, trusts, guardianships, government benefits, and long-term care insurance.

The Long-Term Care System

Mr. Chairman, Medicare remains an unfulfilled promise for many Americans with chronic illnesses. In the United States we discriminate in our delivery of health care based on the type of illness one has. If one has an illness like heart disease or cancer, Medicare provides comprehensive care. If one has a chronic illness like Alzheimer's disease, Parkinson's, ALS (otherwise known as Lou Gehrig's disease), or Multiple Sclerosis, the government doesn't help unless you are impoverished and qualify for Medicaid.

However, until a comprehensive long-term care system for all Americans is in place, it is essential for Medicaid to continue its role as a federal-state program and continue to help pay for the long-term care needs of low and middle-income older individuals and individuals with disabilities. It is in this context that families needing long-term care services engage in financial planning to pay for those services.

Most families needing long-term care feel defeated by having to apply for a "welfare" program after years of working and saving. A colleague of mine from Illinois recently stated that most middle-income seniors who turn to Medicaid for nursing home care are "people who are up against a wall because of a serious illness, who have never depended on a government handout in their lives." Many are children of the Great Depression and are World War II veterans, our so-called "greatest generation." Most of them are women, who, after losing their husbands to the devastation of chronic illness, have to suffer the indignity of impoverishment and financial dependence on family or the government.

Mr. Chairman, please keep in mind that when people do become eligible for Medicaid, regardless of whether they have engaged in long-term care planning, they must pay all but a small portion of their income each month for their care. Medicaid then pays whatever the difference is between that amount and the Medicaid rate. Thus, costs to Medicaid are always mitigated by the Medicaid recipient's monthly income.

The bottom line is that our health care system penalizes people who have pursued the American dream, saved for retirement, and then get the wrong disease.

What I Do - Who Comes to Me and Why

Saving money in Medicaid is the topic today, but as this committee in particular knows, real people who need care may be cut from this program as a result of these efforts. And, as I hope I make clear through my testimony, that these are not the type of Americans that anyone on this committee would conclude should be harmed by any Medicaid reform considered by the Congress this year.

Mr. Chairman, when I do long-term care planning, it is a part of a larger planning process that examines the full range of long-term care options, issues and costs relevant to the client's circumstances. Most often, the lawyer's help is sought when the need for long-term care has already arrived. It usually involves spouses and children of persons needing nursing home care who have already been heavily invested in providing care to the person for an extended period.

My clients' goals typically include finding the best quality of health care for their loved one, supplementing the Medicaid personal needs allowance (typically $30 to $50 per month), and

paying for non-covered Medicaid services and needs (e.g., dental care, hearing aides, eyeglasses, private duty nurse, clothing, books, flowers, etc.).

Who Doesn't Come to Me for Help with Medicaid and Why

Millionaires do not go on Medicaid. They don't need or want Medicaid. Most can afford the much-preferred home care, even on a 24-hour basis or nursing home care, if required. All would be vulnerable to large capital gains taxes, and gift taxes if they engaged in transfer strategies. Those with retirement plans often face significant taxes if they liquidate the plan prior to death.

I am not here today to present the evidence that there has been a myth created about millionaires on Medicaid, but I do want to call your attention to the June 29th testimony of Judith Feder of Georgetown University before the Senate Finance Committee. She clearly lays out the research on who uses nursing homes, how they pay for the care, what assets are transferred, and how Medicaid is affected. She thoroughly undercuts the myths that most elderly can afford to pay for extended nursing home stays and that they make significant transfers in order to become eligible for Medicaid.

SAVING MONEY IN MEDICAID

For various reasons the federal and state governments now are attempting to find savings in the Medicaid budget. Simply stated, some of those efforts and proposals are ill advised and will hurt the elderly and individuals with disabilities. Other more appropriate proposals would reduce the use of loopholes and aggressive Medicaid planning and preserve the dignity of our elderly citizens after years of working and saving. I will address both today.

Proposed Changes to Medicaid

Over the years, the Congress has enacted provisions to balance the welfare entitlement focus of the Medicaid program with the reality that middle-income Americans have few other options for long-term care. The transfer of assets rules are well designed for accomplishing a balance between the needs of individuals and families with that of fiscal responsibility. The transfer of asset rules include such provisions as:

- Individuals must postpone Medicaid eligibility if they give away assets;
- Only gifts from the recent past (3 years) are looked at, because they are the most likely to have been done with any thought of Medicaid eligibility;
- The penalty starts when the individual gave the money away because that is when the individual would have had it and could have used it for his or her care;
- Transfers of certain assets and transfers to certain individuals are protected from penalties because public policy should not promote or foster homelessness or financial dependency on the government by those whose loved ones need Medicaid; and
- Estate recovery exists so that states can be reimbursed for the monies they have spent to care for the individual on Medicaid in a nursing home.

We have adopted a national public policy to provide a modest degree of financial security to the spouse of an individual who requires long-term care. Through this policy, we have enabled the spouses of individuals who require long-term care services to continue their relationship rather

than be forced to choose between poverty and divorce. This will change with the proposals Congress is presently considering.

Making asset transfer penalties more punitive will mainly hurt seniors who are faced with horrific health and income security choices and who are acting in good faith. One proposal to make penalties harsher calls for changing the start of the penalty period from the date of transfers to the date one applies for Medicaid. This has the practical effect of extending the penalty period for years beyond what it is now. In addition, increasing the lookback period to five years would also punish seniors for everyday family transactions and poor recordkeeping.

I would like to note that prior to broad based opposition by aging advocacy organizations representing tens of millions of Americans, the state of Connecticut sought permission from CMS to impose a change in the start date for the penalty period and to increase the lookback period to five years. We were heartened to see that earlier this year Governor M. Jodi Rell (R) of Connecticut withdrew the state's request. Attached to my statement is a letter of opposition to these two ill-advised reforms from 36 aging groups who are part of the Leadership Council of Aging Organizations (LCAO), including such groups as AARP, Alzheimer's Association, National Committee to Preserve Social Security and Medicare, Catholic Heath Association of the United States, National Association for Home Care, Older Women's League, and The Retired Officers Association. I also want to mention that in testimony provided to the Finance Committee on June 15th, the nursing home industry specifically opposed changing the start date of the penalty period. This is because nursing homes well understand that such a shortsighted policy would leave them uncompensated for the care for tens of thousands of individuals.

A few of the likely victims of such measures are: the grandparent caring for a grandchild who provides savings to help pay for the grandchild's education; the devoted church supporter who donates personal assets to the church; the widow who lacks records of her now deceased husband's spending; the caring sister who uses savings to help a needy sister remain in her home. Under the proposals to close transfer of asset rules, each of these individuals will be cut off Medicaid if they subsequently get sick and need long-term care.

What Will Happen if You Change the Start Date of the Penalty Period and Extend the Lookback Period to Five Years?

I will use Chart One to provide examples of how three average Americans would be hurt by the proposed changes in the penalty period start date and extending the lookback period to five years. Chart Two lists the typical activities that are considered transfers that would be penalized under these proposals.

There are rules in place to deal with asset transfers under the Medicaid program. The current law provides that seniors must privately pay for care if significant transfers are made within a three-year lookback period.

Today, I would like to share with you three stories that reflect my more than 25 years of experience counseling thousands of seniors and the experiences of my colleagues around the country. These are representative profiles of real clients. I want to show you how the current rules work and what would happen under the two primary changes that the administration has suggested. Most of my clients desperately desire to take every possible step to maintain their independence and their dignity without help from the government.

RICHARDS STORY

First, I will tell the story of Mary Richards who is age 78. Mrs. Richards has helped her granddaughter since her daughter passed away. From her savings, she contributed $15,000 toward her granddaughter's college tuition in July 2004. At the same time, she continued to use her other monies for her living expenses. A year later she suffered a stroke and was in need of long term care in a nursing home.

Under the current law, if Mrs. Richards were to apply for Medicaid today, she will be Medicaid eligible because the transfer penalty period has expired. The penalty is 3 months from July of 2004 based on a $15,000 transfer and a State divisor of $5,000. The divisor varies from state to state, but is supposed to reflect the average private pay monthly cost of nursing home care.

Under the proposal to change the penalty start date, Mrs. Richards would be denied Medicaid eligibility, beginning today, the day she applies for Medicaid and is in medical need of long-term care. Because the tuition is paid, Mrs. Richards cannot get the money back. She will have trouble getting into the nursing home from the hospital because she will have no money available to pay the nursing home. The hospital would then look to discharge her to her home because Medicare will not pay them. But will it be safe for Mrs. Richards to return home when she cannot afford extensive home care? Her health and well-being would be jeopardized.

GREER STORY

Now, let's turn to John Greer who is a farmer in the Midwest. The farm has been in his family for over 100 hundred years. The plan is for his son to take over for Mr. Greer who is 80 years old.

Under the current law, when Mr. Greer transfers the farm worth $100,000 to his son, he is Medicaid ineligible for 20 months from September 2002.

The transfer was within the 3-year lookback, so it results in a period of Medicaid ineligibility for 20 months. If Mr. Greer needed long-term care during those 20 months, he would have to privately pay for his care.

Let us suppose that today Mr. Greer fractures his hip and requires nursing home care due to complications. He applies for Medicaid.

Under the proposal to change the Medicaid penalty period start date; he would be denied Medicaid because he tried to protect the family farm by transferring it to his son. Where will Mr. Greer get the money to pay for his long-term care? What will happen to him? What will happen to the farm? Will it have to be sold to take care of Mr. Greer? If sold, what will happen to Mr. Greer's son who has worked the farm his entire life and what will happen to his family?

ANDERSON STORY

My last story is about the Anderson family. Steve Anderson was a very private man and he controlled the family finances. In the year 2001, he made a series of withdrawals, which appear to include donations to his church. After fighting a battle with cancer, he died a year later. Mrs.

Anderson had cared for him every step of the way.

Since that time - over the past four years, Mrs. Anderson's health has declined. She has Alzheimer's disease. She has difficulty with paper work and her memory is failing her. Her children have determined that it is no longer safe for her to remain at home; she needs nursing home care.

Under the current law, Mrs. Anderson would be eligible for Medicaid because any transfers made beyond three years (the lookback period) would not be counted against her.

Under the proposal to extend the lookback period to 5 years, Mrs. Anderson, were she to apply for Medicaid today, would have to account for her husband's withdrawals of $25,000 made back in 2001 – more than 4 years ago.

Due to her condition, she would be unable to explain her husband's transfers. She knows some money was spent on donations to the church and some on repairs to the house but no records can be found.

But she would be denied Medicaid because she would be unable to document the $25,000 in withdrawals. In her time of greatest need, she would not able to obtain necessary care under the Medicaid program.

The combination of extending the lookback period and the penalty start date would create the harshest penalty of all on people like Mrs. Anderson. The most vulnerable people in our society will suffer the most.

These three stories are just the tip of the iceberg for the thousands of seniors that live lawful lives, productive lives who look to the government in their hour of need to pay for necessary long term care. This care allows them to live out their lives in dignity.

Members of the National Academy of Elder Law Attorneys with practices like mine counsel the Mrs. Andersons, the Mr. Greers, and the Mrs. Richards every day. Chart Two gives several examples of the kinds of everyday responsible family transactions that will be unfortunately penalized by the proposed changes in the penalty start date and lookback period.

The proposals that I have discussed are – frankly speaking – an attack on mothers and grandmothers who have given their lives and hard earned savings to help raise and support loved ones. They will create unacceptable new obstacles for vulnerable, frail elderly individuals and persons with disabilities to get care, partly because the proposals will require recordkeeping and documentation that is far beyond the normal practices of the elderly, especially poor and chronically ill elders. The harshest impact of these proposals will be on those applicants with Alzheimer's disease and other dementias, who will not be able to provide documentation or recollection for transfers, regardless of how small.

I have provided below additional examples of how these proposals will hurt the elderly and individuals with disabilities. At the end of my testimony I have provided an outline of the current transfer rule and additional analysis of how the changes would affect those that need Medicaid services.

Ways to Save Money in Medicaid by Changing the Asset Transfer Rules

Asset transfers have become a focus of cost cutting discussions. It is clear to me and my colleagues that there are loopholes and abuses under the asset transfer penalty rules. There are steps that can be taken to save the government money with the least amount of harm to seniors and people with disabilities.

These loopholes and abuses must be stopped because they unfairly characterize seniors as "gaming the system" when the vast majority of seniors look to Medicaid as a last resort to pay for long-term care.

Therefore, for several months I have been working with a group of Medicaid experts from around the country in the development of proposals that target the loopholes that have allowed for more aggressive protection of assets from the Medicaid program. It is our belief that these loopholes should be closed and the savings should be used to continue the good work of the Medicaid program.

I will take this opportunity to explain three of the six changes that we are proposing, and I have included the other three in my testimony for your full consideration.

BALLOON ANNUITIES

First, Balloon Annuities should no longer be allowed as a part of Medicaid planning. Seniors struggle to meet their living expenses from their fixed income and annuities can be very helpful in this regard. Unfortunately, annuities have been manipulated to be a Medicaid planning tool.

The abuse occurs with the use of Balloon Annuities. This abusive practice exists because of a loophole under the actuarially sound test. This loophole invites overly aggressive planning behavior and should be closed.

In short, it is now possible to structure a Balloon Annuity with very small payments over the senior's lifetime, which allows the senior to pass on the lion share of the annuity to family while accessing Medicaid for nursing home care. This is wrong because this loophole allows one to instantly convert an asset into an income stream for the sole purpose of taking advantage of the Medicaid program.

The solution is to have Balloon Annuities treated as a transfer subject to the transfer penalty rules. Self-canceling installments

SELF CANCELING INSTALLMENT NOTES

Second, Self Canceling Installment Notes (referred to as "SCINSs") should be outlawed as a Medicaid planning tool and treated as an available asset to pay for long-term care. SCINs work just like Balloon Annuities, which allow people to manipulate the system.

TRANSFER OF ASSETS, WHICH RESULT IN A PARTIAL MONTH PENALTY

Third, Rounding Down of the monthly transfer penalty should be eliminated.

Under the current transfer penalty rules, in some States, you can double the amount transferred while not creating a longer penalty period.

For example in a rounding down state, each month - one could transfer two months of nursing home cost with only one month of penalty. So, in a state with a Divisor of $5,000, transfers of $150,000 should create a penalty period of 30 months. Utilizing this aggressive strategy, the transfer penalty period will only be about 15 months. This was not intended when the laws were enacted under OBRA 1993.

The solution would be to eliminate the "rounding down." Therefore, transfers would result in partial month penalties.

I believe that these changes, if mandated by the federal government, could offer a significant savings to the government without harming average seniors.

Long-Term Care Insurance

Mr. Chairman, when a client comes to see me with significant resources, I suggest that he or she consider seeing a professional who is able to provide information on his or her long-term care insurance options or consider self-insuring.

NAELA and I also support the expansion of the Long-Term Care Insurance Partnership Program. I believe it is time to look carefully at this program and make any changes that are needed to make it a viable alternative in all states. The President has included this in his budget proposal and we believe that it should move forward this year. This proposal will also save Medicaid money in the future.

Medicaid Waivers

Mr. Chairman, as you consider the changes we have proposed, please consider the importance of rule consistency across the country. We understand the desire that states have for flexibility and it can lead to successful innovations, but allowing states to obtain a waiver to impose more restrictive transfer penalty rules will cause real problems. Seniors facing a long-term care crisis may be forced to move to other states to preserve assets for their spouse and heirs. Others may be forced to consider extreme options, such as divorce.

Conclusion

Mr. Chairman, I thank you for the opportunity to present testimony to this distinguished bipartisan committee that has done so much for the older Americans over the years.

As you can see from my remarks, one's life can truly end up on a Wheel of Fortune or misfortune. You spin the wheel and if it lands on heart disease or cancer, your costs are covered; if it lands on Lou Gehrig's disease, Multiple Sclerosis or Alzheimer's disease, you are on your own. If you get the right illness, the government will pay; if you get the wrong illness, they will not. Unfortunately, none of us has much control over which illnesses we contract.

Since savings must be found in the Medicaid program, we believe strongly that closing loopholes is a better solution than creating punitive and unworkable penalties for our seniors, who have contributed so much to our nation and now face chronic illness and the need for long-term care services.

We ask that even in these times of tight budgets that you continue the commitment that you have made to care for millions of Americans through the Medicaid program and that you work to ensure that the Congress does not inadvertently take actions that hurt the very people they want to help.

Mr. Chairman and Members of the Committee, I would be happy to respond to any questions you may have. Thank you.

Additional Examples of How the Proposed Legislation Will Affect the Elderly

Mr. Chairman, I have provided for the Committee's consideration additional "typical examples" of how these proposals will hurt real Americans and their families.

1. A church supporter

Mr. Banks was living independently and actively in Florida though he suffered from diabetes and heart disease. He sold his home for $135,000 and donated 10% of the proceeds, or $13,500, to his local church. Mr. Banks moved to assisted living and thereafter to a skilled nursing facility. Two years later, Mr. Banks had exhausted his funds and would otherwise be eligible for Medicaid but for this $13,500 gift to his church. Instead, Mr. Banks is ineligible for assistance for four months and has no resources to pay for his care during that period. Under existing law, Mr. Banks would have been penalized when he made the $13,500 gift and that penalty period would have elapsed long before his need for public assistance arose.

2. A grandparent caregiver

Mr. and Mrs. Brown are the primary caregivers for their 16-year-old grandchild. Over the last three years they have paid $20,000 for support of their grandchild. Mr. Brown suffers a stroke and needs long term care. Mrs. Brown has total liquid assets of $50,000. Mr. Brown is *otherwise eligible* but will not be approved for Medicaid because of the $20,000 expenditure for his grandchild. Instead, Mrs. Brown will be placed in the precarious position of paying privately for six months that will, at today's costs, totally exhaust her $50,000 nest egg.

3. A family emergency

Mrs. Jones' daughter loses her job due to chronic fatigue syndrome. The daughter is a single parent with two underage children. Mrs. Jones helps her daughter financially in amounts totaling $30,000. Six months later, Mrs. Jones suffers a heart attack and a debilitating stroke requiring long-term care. Two years later an impoverished Mrs. Jones applies for Medicaid and is denied because of the $30,000 gift made several years earlier.

4. Cash-based couple

Mr. and Mrs. Smith live in their own home and pay most of their day-to-day expenses with cash. Mr. Smith generally withdraws about $500 per month for food, gas, newspapers, house wares, car repairs, etc. Generally, he does not keep receipts, at least not in any organized way. Mrs. Smith has never handled their financial affairs and suffers from mild dementia. Unexpectedly, Mr. Smith suffers a stroke and now needs nursing home care. Their current assets and income would make him eligible for Medicaid coverage without difficulty under current law.

His withdrawals of $500 per month will result in a penalty period, unless they are accounted for. His withdrawals add up to $6000 per year in potentially disqualifying transfers, or $18,000 for the three-year lookback. Since Mrs. Smith cannot document the use of the withdrawn money, Mr. Smith will face a penalty period of approximately 4 months. ($18,000 ÷ $4,500/mo (average regional nursing home rate) = 4 month).

7. A helper through hard times

Mr. T, age 80, has been ill for several years since a stroke. His wife, age 75, has been caring for him at home. He became more seriously impaired this past summer when he contracted pneumonia. He was walking with assistance before the pneumonia, but increasing weakness has left him unable to walk. She is continuing to care for him at home, but nursing home placement looks imminent.

Mrs. T has a son from a previous marriage who lives in another state and is not well off. During the last half of 2001, Mrs. T paid his mortgage for him, at $850 per month ($5,100 total). In May of 2002, she gave him $2,200 to help him purchase an automobile so he could commute to and from a new job.

Thus, her total transfers were $7,300. Their own savings are now dwindling. Her husband will be otherwise eligible for Medicaid, but under the President's budget proposal, he will face a penalty period of one month and some days. Mrs. T will have to find a way to pay this out of pocket.

8. A caring sister

Two sisters, both in their 80s, have lived with each other in an apartment for several years. Both have reasonably sufficient assets to cover their anticipated needs. However, one sister has considerably more assets (about $250,000). She is concerned that if she were to become ill and leave the apartment to move into a nursing home, the sister with fewer assts would not be able to afford to remain in the apartment.

The sister with greater assets wishes to take steps to ensure that her sister will be able to continue living in the apartment, if possible, and so she funds an irrevocable trust with $48,000, intended to supplement the poorer sister's costs of living if the need arises.

Under current law and a regional monthly transfer rate of $4500, this transfer will result in a disqualifying period of a little over ten months ($48,000 ÷ $4500/mo = 10.67 months) from the date of transfer. But under the proposal, the caring sister, after spending down all her assets on nursing home care, would then face a penalty period of more than ten months before receiving Medicaid nursing home coverage. Alternatively, if she is aware of the penalty rules, she may be reluctant to help her less fortunate sister in the first place.

9. Helping family

A mother helps her two children - her daughter has medical problems and does not have insurance and her son's daughter (her grandchild) is in a college with expensive tuition. So she helps her daughter by paying $30,000 for health care and she helps her granddaughter by paying $50,000 in tuition. These are significant amounts paid almost five years before she was forced to go into a nursing home. With a five year lookback and a penalty period starting on the day of application, she will be ineligible for nursing home care for more than 17 months (depending upon the state's regional monthly transfer rate). Seniors will not be able to help family members because they will not be able to predict their circumstances.

10. A widow lacking records

Mrs. Waters was married for fifty years. Prior to his death, Mr. Waters handled all financial transactions. Mrs. Waters suffers from dementia and upon Mr. Waters' death is placed in a skilled nursing facility. Her resources are expended and she is applying for Medicaid. She has no knowledge or ability to explain the cash withdrawals totaling $50,000 during the five years preceding her husband's death. Nonetheless, Mrs. Waters is ineligible for Medicaid due to these inexplicable transfers.

11. A mother helping her daughter

Mr. and Mrs. G are in their late seventies and retired. Two and a half years ago, they were living independently and relatively healthy. At that point, one of their daughter's marriage ended and the daughter moved closer to her parents to be near them. She was unemployed at the time and needed to work. Her parents bought her a modest car for $18,000 so that she had transportation to get back and forth to work. The daughter then started working in a series of part-time jobs, which provided her just enough to meet her living expenses.

Two years after giving their daughter the car, Mr. G suffered a major stroke. He lost his ability to speak, walk and use his left arm. He received rehabilitation following the stroke but did not recover all of his abilities. Despite medical advice, his wife insisted on bringing him home. She cared for him herself and paid for services privately for one year. At that point, Mr. G's needs had increased and Mrs. G had become considerably weakened due to the demands of being the primary caregiver. They reluctantly decided that he would be best cared for in a skilled care facility. Mrs. G paid privately for this care for one year. By then, her assets were depleted and she had no more than the amount that would be protected for her as a community spouse. She applied for Medicaid benefits on behalf of her husband and was denied benefits due to the purchase of the car for their daughter.

Medicaid: Penalty Rule Computation

I. Current Law Concerning Penalty for Asset Transfers of Less than Fair Market Value:

The penalty period commences on the first day of the month following the month in which the transfer was made or the first day of the month in which the transfer is made, at the state's option.

II. Proposed Legislation:

Under the President's Proposed Budget, the penalty period would commence on the date of the transfer or the first day of the month during or after which a Medicaid application has been made, whichever is later.

III. Analysis and Issues

1. Under this proposal, seniors and people with disabilities denied Medicaid would, at the time of the denial, be impoverished, have physical and/or mental impairments so severe they could no longer care for themselves, be in need of nursing home or home care, and have no other means (private insurance or

Medicare) of paying for care.

2. The denial of long-term care will trigger adverse medical consequences. The absence of skilled nursing, physical, occupational and speech therapy and necessary assistance with medical care and activities of daily living will adversely affect seniors and people with disabilities who will be denied home care and nursing home admission under this proposal.

3. The harsh penalty that would be created by this proposal would be applied to all those who are unable to immediately recover the funds or the value of property alleged to have been improperly transferred prior to the Medicaid application. Most transferees will have no legal obligation to refund the transfer. In other cases, transferees will be financially unable to make any refund or there will be no transferee from whom to recover. For example, a senior with Alzheimer's who made a $3,000 withdrawal from her savings account thirty six (36) months prior to the Medicaid application would be ineligible for Medicaid long term care benefits for a portion of the month in which she applies. The nursing home or hospital will not be paid for care provided.

4. This proposal would discourage donations to charities, religious and political organizations and candidates for government office. Only those who can predict with absolute certainty that they will not need Medicaid for at least three years could safely make donations.

5. This proposal will harm families by inhibiting older members from providing financial assistance to younger members - with such things as down payments on homes and college tuition - out of fear that they may not qualify for Medicaid nursing home care if unforeseen events leave them unable to care for themselves.

6. In addition to the harm to seniors and those with disabilities, there would be considerable financial harm to health care providers. Hospitals and nursing homes are prohibited from discharging patients unless suitable alternative arrangements can be made, even if it means providing extended uncompensated care.

7. In cases where the nursing home admission has already occurred and the penalty is applied, nursing homes will be required to provide uncompensated care for the duration of the penalty period or until hospitalization. Nursing homes would become financially strapped - influencing staffing levels and the quality of care for all residents.

8. Those in hospitals at the time of the denial would be unable to leave since nursing homes and home care agencies will deny admission if there is no source of payment. Hospitals will become the default providers of care as access to nursing homes is barred during the penalty period. The cost of hospital care to the government will be far higher than it would have been in long-term care.

9. This proposal will most likely not harm those who set out to "game the system" because they most likely will be able to learn how to circumvent it, while those

who have no such intent will likely learn of the policy long after it is too late. In fact, this proposal may encourage more and earlier transfers, while it is unclear how this proposal encourages the purchase of long term care insurance, especially because some of those people are uninsurable.

10. Most long-term care is provided by informal caregivers (e.g. family members). This change could also have far-reaching economic effects if a family member has to leave his or her job to try to take care of a severely incapacitated elder.

Medicaid: Lookback Period

I. Current Law Concerning the Medicaid Lookback Period

Federal law (42U.S.C 1396p(c)) requires states to withhold payment for various long-term care services for individuals who dispose of assets for less than fair market value. The term assets includes both resources and income. The lookback period for both institutional care and home and community based waiver services is 36 months, except the lookback period for trust-related transfers is currently 60 months.

II. Proposed Legislation to Extend the Medicaid Lookback Period to Five Years

The budget bill may include a proposal to change the lookback period to 60 months for institutional care and home care, regardless of whether there have been trust-related transfers.

III. Analysis and Issues

1. The proposal will create unacceptable new obstacles for vulnerable, frail elderly individuals and persons with disabilities to get care, because the proposal will require record keeping and documentation that is far beyond the normal practices of the elderly, especially poor and chronically ill elders. Therefore, low-income elders would be denied admission to a nursing home because of inadequate record keeping.

2. Medicaid recipients who already receive home care services under the current law could lose eligibility under the proposed changes if they had made transfers within the past five years. Services could be abruptly terminated; thereby placing the elderly individual at risk of serious harm and inadequate or inappropriate care in the community.

3. The harshest impact of this proposal will be on those applicants with dementia, who will not be able to provide documentation or recollection for transfers, regardless of how small.

4. The extension of the lookback period is arbitrary and without sound reasoning, other than to look for transfers in order to keep seniors from accessing Medicaid for nursing home care (while increasing administrative costs). The current federal law uses three years, which is a sufficient and reasonable time period to assume that any transfers made were not in contemplation of a future event. The average stay in a nursing home is less than three years. Hence, under current law, most

seniors with more significant assets who transfer assets at the onset of needing long-term care in a nursing home will not receive Medicaid reimbursed nursing home care.

5. Any increase in the lookback period will have a significant impact on administrative overhead and be more burdensome on frail elderly, who must search and obtain records of proof for older transactions. How will the frail elderly (especially those with dementia) do this from a nursing home bed?

6. The proposal suggests that the elderly can predict their medical and financial circumstances five years into the future. An extended lookback coupled with a change in the transfer rules will punish unwitting elders who have helped their families with commonly made gifts and then experience medical events such as a stroke, hip fracture or Alzheimer's disease.

Transfer of Assets: Aggressive Practices and Solutions

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1. **TRANSFER OF ASSETS WHICH RESULTS IN A PARTIAL MONTH PENALTY**

Current Situation:

If an individual seeking Medicaid eligibility has made "uncompensated transfers"—i.e., gifts or other conveyances for which no goods or services were received in return—a "period of ineligibility" for Medicaid is imposed.

The length of the period of ineligibility depends on how much was transferred, when it was transferred, and a particular state's "Medicaid divisor". The Medicaid divisor is supposed to reflect the average cost of an average month in a nursing home in a particular state.

For example, if a state has a Medicaid divisor is $3,300 and an individual transfers a total of $13,000 in the month of December, applying this formula produces a quotient of 3.939 months.

Some states do not impose a fractional period of ineligibility, but instead, "round down" to the lowest whole number. Thus the 3.939 quotient becomes a 3 month period of ineligibility, making the individual ineligible for Medical Assistance through and including February 28th of the following year.

The imposition of a period of ineligibility by a state of an amount equal to the average cost of a nursing home in that state is logical. This logic is distorted, however, when the formula enables an amount equal to nearly the cost of two months in a nursing home to be transferred, yet resulting in only a one month period of ineligibility.

How does this work? Suppose our individual, instead of transferring a total of $13,000 in the month of December, transferred $6,500 in

each of the months of December, January. The period of each of these transfers would be $6,500/$3,300=1.969, rounded down to one month. Thus, the individual would receive an advantage due to the "rounding down" aspect of the formula, reducing the transfer penalty from 3.939 months to two months.

Solution

One of the reasons for the current "rounding down" is to avoid imposing a period of ineligibility for Medicaid based on relatively small transfers made for reasons other than securing Medicaid eligibility. For example, if an individual contributed $3,000 to a grandchild's college education in a state with a Medicaid divisor of $3,300, this would result in a quotient 0.909, or a zero month period of ineligibility for Medicaid.

As long as the transfer penalty is limited to transfers for the purpose of qualifying for Medicaid, then the solution would be to eliminate the "rounding down." Therefore, any transfer made for purposes of creating any period of ineligibility for Medicaid—even if less than one month—would result in a partial month of ineligibility.

2. NOTES AND LOANS (INCLUDING SELF CANCELING INSTALLMENT NOTES)

Current Situation

Non-negotiable promissory notes, loans and mortgages that cannot be converted to cash have no market value and according to SSI cash policy is not considered to be a countable resource.

Promissory notes and loans can be negotiated to provide that the loan is forgiven or terminates upon the death of the payee. A parent can thereby transfer considerable sums to children by casting the transfer as a *loan,* which disappears at the parent's death and amounts, in effect, as a disguised transfer. This problem is further compounded because the loan balance is not available for estate recovery.

Solution

Require that to be excluded as an available asset, a promissory note, loan or mortgage must: (1) have a repayment term that is actuarially sound; (2) provide for payments made in equal amounts during the term of the loan, with no deferral and no balloon payments made; and, (3) prohibit of the cancellation of the balance upon the death of the lender.

3. TREATMENT OF TRANSFERS FROM THE FIRST DAY OF THE FOLLOWING MONTH

Current Situation

Allows the States to have the option to either treat the transfer in the month made or as if made on the 1st day of the month following the month of the transfer.

Solution

Mandate the calculation of transfer penalty period beginning with the 1st day of the month following the month of the transfer.

4. ANNUITIES - BALLOON

Current Situation

Since OBRA '93, the transfer of funds to purchase an annuity has not been treated as a transfer of assets nor has the annuity been treated as an available asset if: (1) the annuity contract is irrevocable; (2) the payments are required to be fully made over the annuitant's actuarial life expectancy. Under federal law, there is no distinction between commercial and private annuities.

Certain annuities are designed to make final payment within the annuitant's actuarial life expectancy, but in small monthly amounts so that instead of the payments being made in equal monthly amounts, the bulk of the payments are deferred to the end of the annuity term,

resulting in insignificant amounts being made available to the annuitant and the bulk of the funds passing to their beneficiaries.

Why it works? The exclusion of annuities is based only on the total term of payment, i.e. actuarial life expectancy which is a life payout. The rules do not address the method of payout.

Solution

Require that an annuity which is not Qualified Retirement Plans and IRAs must be: (1) irrevocable and non-assignable, (2) actuarially sound; and, (3) provide for the payments to be in equal amounts during the term of the annuity, with no deferral and no balloon payments made.

5. PRIVATE ANNUITIES – ESTATE RECOVERY

Current Situation

Under a Private Annuity, a parent transfers assets to a child in exchange for the child's promise to pay to the parent a sum of money over the parent's actuarial life expectancy. For example, the promise from the child to the parent (the annuity) might be for small monthly payments of interest only, or even less, and a balloon payment at the time of death of the parent (to a designated beneficiary) in accordance with the actuarial tables. Since the parent is sick, it is not likely that they will live as long as the actuarial tables indicate. The payment is not subject to an estate recovery. Litigation around the country has held these transfers to be subject to the Medicaid transfer penalties.

Solution

To make the balance of Annuity payments based on life expectancy subject to an estate recovery.

6. PURCHASE OF A LIFE ESTATE INTEREST IN ANOTHER PERSON'S HOME WITH NO INTENTION OF LIVING IN IT.

Current Situation

A life estate is a property interest that provides that the owner of a "life estate" has the legal right to reside in a property or to the net rental income if that property is leased. Current law allows a parent to purchase a life estate interest in a child's home, and in many states that purchase is not considered a transfer.

For example: Parent age 85, and residing in an Assisted Living facility buys an interest in his son's home for $40,000, never resides in the home, and 90 days later, moves into a nursing home and applies for Medicaid.

Current law fails to require that the parent actually live in the residence. In some circumstances, the parent may have never intended to reside in the residence.

Solution

That the purchase of a life estate interest in a another individual's home be considered an improper transfer, if the purchaser does not reside in the home for a period of 30 days. If the purchaser resides in the home for period of 2 years or more, the purchaser should be permitted to transfer the life estate interest back to the seller, without a penalty being imposed.

LEADERSHIP COUNCIL
of
AGING ORGANIZATIONS

August 20, 2002

The Honorable Tommy Thompson, Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC, 20201

Dear Secretary Thompson:

The undersigned members of the Leadership Council of Aging Organizations (LCAO) strongly urge you to reject Connecticut's request for a waiver from Medicaid Transfer of Asset rules. The state is seeking two exemptions from 42 U.S.C. §1396p:

- To impose a penalty period beginning on the date when the applicant is otherwise eligible for Medicaid coverage, *i.e.,* when the individual needs long-term care (nursing home or home care) and lacks the income or resources to pay for that care, and,
- To permit a five-year look-back period for transfers of real property.

We understand the need to prevent individuals from illegally transferring assets in order to improperly qualify for Medicaid benefits. However, the Connecticut proposal would punish people who had never tried to cheat the system. It would be bad for consumers, families, and providers. It would cost, not save, money. Yet it would not likely affect those who try to illegally transfer assets.

In a June 2001 Special Session, the General Assembly authorized the Connecticut Commissioner of Social Services to seek a waiver of federal law from the existing transfer of assets rules under the Medicaid program, subject to the Commissioner submitting the waiver proposal to two committees of the Connecticut General Assembly -- the Human Services and Appropriations Committees -- for public hearing, after which the Committees may "...advise the commissioner of their approval, denial, or modifications, if any, of his application."

The Commissioner submitted the waiver proposal to the two committees in early 2002. The public comments received on the proposed waiver were uniformly negative. The Human Services Committee of the Connecticut General Assembly, after public hearing, unanimously rejected the waiver proposal. The Appropriations Committee failed to approve the proposed waiver by declining to act on it.

The Commissioner of Social Services ignored both the legislative process and the public hearings and submitted the waiver proposal to the Center for Medicare and Medicaid Services (CMS) for approval. Since its submission, both Senators Dodd and Lieberman, as well as all six members of the U.S. House of Representatives from Connecticut have voiced their opposition to the waiver, including Rep. Nancy Johnson, based upon their substantial concerns about the negative effect it would have on persons legitimately needing long-term care services under Medicaid.

Our opposition to the waiver proposal arises from our concern about the likely negative effects of the proposal:

- All of those affected by this waiver will unquestionably need long-term nursing home or home health care, yet be unable to pay for that care. Thus, the health and safety of older and disabled citizens will be seriously jeopardized.

- Those who need nursing home care would not be able to gain entry. Connecticut law allows facilities to deny admission when there is no payment source.

- In cases where nursing home admission has already occurred and the penalty is applied, nursing homes will be required to provide uncompensated care for the duration of the penalty period or until hospitalization.

- Those in a hospital at the time of denial would be unable to leave since nursing homes and home care agencies will deny admission if there is no payment source. Hospitals will become the default providers of care as access to nursing homes is barred during the penalty period.

- The waiver proposal suggests that the elderly can predict their medical and financial circumstances five years into the future. It punishes unwitting elders who have helped their families with commonly made gifts and then experience unforeseeable medical events such as stroke or Alzheimer's disease.

- The waiver proposal wrongly claims that it will expand the use of long-term care insurance. The cost of long-term care insurance is not affordable for many elders. It is definitely not available for many individuals who already have serious chronic illnesses.

- The harsh penalty of the proposed waiver would be applied to all those who are unable to immediately recover the funds or the value of property alleged to have been "improperly" transferred up to five years prior to the Medicaid application. Most transferees will have no legal obligation to refund the transfer (*e.g.*, charitable and religious donations, campaign contributions, etc.). In other cases, transferees will be financially unable to make any refund or there will be no transferee from whom to recover.

- The waiver will create unacceptable new obstacles for vulnerable, frail elderly and disabled persons to get care, because the waiver will require record keeping and documentation that is far beyond the normal practices of the elderly, especially poor and chronically ill elders. Therefore, low-income elders would be denied admission to a nursing home because of inadequate record keeping.

- The waiver will not save money nor encourage the sale of long-term care insurance. The persons most affected are those least able to obtain long-term care insurance.

- The waiver will generate unintended consequences. Rather than stopping asset transfers and encouraging the purchase of long-term care insurance, the proposal will encourage earlier and larger asset transfers by the elderly, discourage responsible decision-making, and ultimately add to Medicaid costs.

In addition, the waiver proposal appears to us to contravene federal law in the following respects:

- The proposed waiver fails to conform to the basic purpose of Section 1115 waivers, since it is devoid of any attempt to expand or improve services or service delivery under a bona fide research or demonstration program. Instead, it is a blatant eligibility restriction intended to cut expenditures.

- Federal law permits waivers of state plan requirements in section 1902 of the Medicaid statute, 42 U.S.C. §1396a. The transfer-of-asset rules created by Congress are not in this section and are not waiveable by CMS. Similar waiver requests by Minnesota and South Dakota were previously denied for this reason by HCFA (now CMS).

- The waiver would permit Connecticut to deny, rather than furnish, medical assistance to those who lack the income and resources to pay for medical care -- thus defeating, rather than promoting, Medicaid and waiver objectives.

For all the foregoing reasons, the LCAO respectfully requests that you reject the Connecticut Transfer of Asset Waiver Proposal. Thank you very much for your consideration of these comments.

Sincerely,

AARP
AFSCME Retirees
Alliance for Retired Americans
Alzheimer's Association
American Association for International Aging

American Association of Homes and Services for the Aging
American Foundation for the Blind
American Geriatrics Society
American Society of Consultant Pharmacists
Association for Gerontology and Human Development in Historically Black Colleges and Universities
B'nai B'rith International Center for Senior Services
Catholic Health Association of the United States
Eldercare America, Inc
Families USA
Gray Panthers
National Association for Hispanic Elderly
National Association for Home Care
National Academy of Elder Law Attorneys
National Association of Area Agencies on Aging
National Association of Nutrition and Aging Services Programs
National Association of Professional Geriatric Care Managers
National Association of Retired and Senior Volunteer Program Directors, Inc.
National Association of Retired Federal Employees
National Association of Senior Companion Project Directors
National Association of State Long-Term Care Ombudsman Programs
National Caucus and Center on Black Aged
National Committee to Preserve Social Security and Medicare
National Council on the Aging
National Hispanic Council on Aging
National Indian Council on Aging
National Senior Citizens Law Center
OWL, the voice of midlife and older women
The Retired Officers Association
United Auto Workers Retired Workers Department
United Jewish Communities
Volunteers of America

cc: The Honorable Tom Scully

NAELA Members as Resources: Issue List

The National Academy of Elder Law Attorneys' (NAELA) has members that are valuable public policy and substantive law resources. Within the membership we have expertise in almost all federal, state and local programs serving or affecting the elderly. Many are willing to be supportive of the work of legislators and regulators, and will provide expert opinions, testimony, articles, and other written materials upon request. Issue areas include, but are not limited to:

Alternative Dispute Resolution
Disability Law
Estate Planning
Health Care Decision Making and End of Life Issues
Health Care Advanced Directives
Long-Term Care Planning
Long-Term Care Insurance
Managed Care
Medicare
Medicare Appeals
Medicaid
Mental Capacity Issues
Nursing Home Care, Law, and Litigation
Public Interest Representation (including Legal Services Corporation and Older Americans Act delivery systems)
Retirement Housing
Retirement Planning
Guardianships, Conservatorships and other Surrogate Decision Making processes
Social Security
Supplemental Security Income
Tax Planning
Trusts and Wills

CHART 1

How the Transfer Penalty Works

And Who is Hurt by Proposed Changes

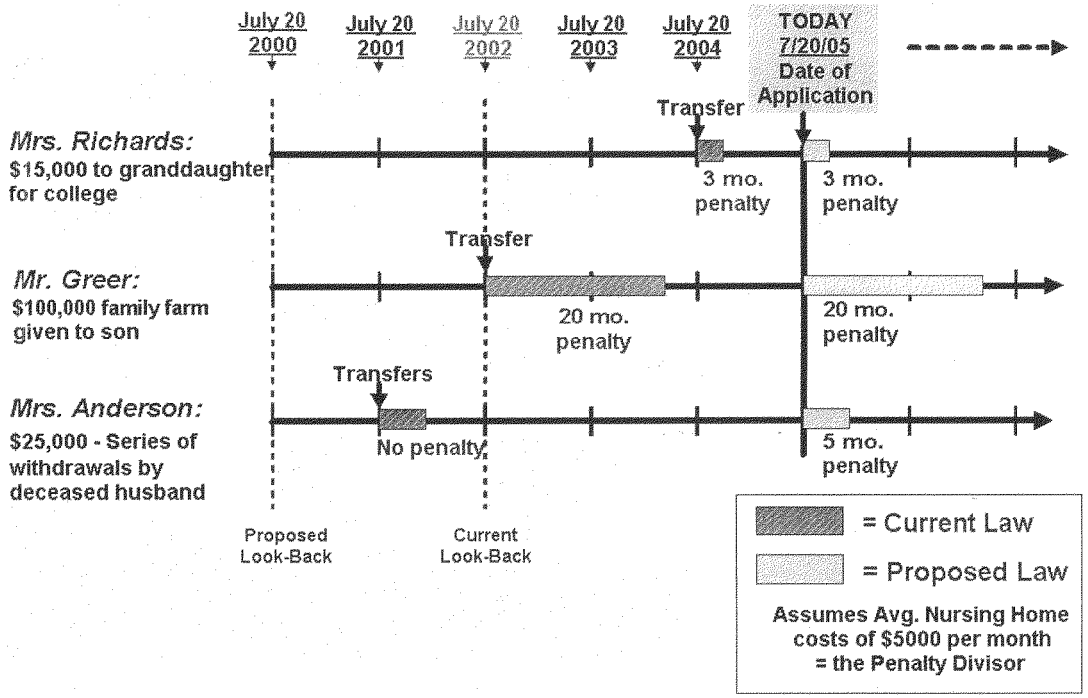

CHART 2

Who is Hurt by Proposed Changes
in Look-Back and Penalty Start Date

If you make any transfer to...

1. **Help a grandchild pay for education**
2. **Help a family member with medical expenses**
3. **Help a family member who is starting a business**
4. **Help a family member whose business is failing**
5. **Help with living expenses of a child**
6. **Help out a child who is caring for a parent in the parent's home**
7. **Contribute to your church, charity, high school or college**
8. **Convey the family farm to family members**

... then you will face a disqualification period at the time you apply for Medicaid.

Senator KOHL. Thank you, Mr. Russo.

Mr. Gibson.

STATEMENT OF MARK GIBSON, DEPUTY DIRECTOR, CENTER FOR EVIDENCE-BASED POLICY, DEPARTMENT OF PUBLIC HEALTH AND PREVENTIVE MEDICINE, OREGON HEALTH AND SCIENCE UNIVERSITY, PORTLAND, OR

Mr. GIBSON. Thank you, Senator. It is a pleasure to be here. I will give you a short overview of what come to be known as the Drug Effectiveness Review Project. This project had its beginnings when Oregon was faced with a projected 60-percent increase in its Medicaid drug spend over a 2-year budget cycle. However, the State did not want to reduce drug spending only to increase suffering and spending elsewhere in the budget as a result of using inferior medications. To avoid those unintended outcomes, we developed clinical information that did not previously exist, and once we had the information, we used it to guide our purchasing decisions.

This effort quickly grew into a collaboration among 14 States and two other organizations, pooling their resources to produce the best available evidence comparing drugs within classes. The research we perform is special because it consists of using what is called a systematic review of research evidence, and here is how it works.

First, research questions are crafted with care and specificity. We start with a general template that asks three questions: First, what is the comparative effectiveness of the drugs in this class? Second, what is the comparative risk profile of the drugs in this class? Third, what does the evidence tell us about any differential impact on subpopulations, be that in age, race, or ethnicity?

As the process proceeds, the questions are posted on our website and public comment is received and considered in preparing the final version. Once the questions are prepared, they are sent to all drug manufacturers in the U.S. and Canada with a request for any evidence that the manufacturers believe should be considered in the review.

Next, our researchers, who are all employees of evidence-based practice centers, as designed by the U.S. Agency for Healthcare Research and Quality, begin their search of the global evidence available. They search all of the major medical data bases, including EMBASE, Medline, and the Cochrane Registries of Systematic Reviews and Clinical Trials.

Studies that match the key questions are then read in detail, and the quality of the study is also evaluated. If the study is poorly designed or poorly executed, then it is removed from the ongoing analysis.

Once the high-quality studies are identified, they are synthesized. This synthesis combines the results of the studies in a way that allows us to have a view of what the entire body of good research says about the drugs that we are looking at. It takes into consideration the differences among the studies such as size and design, and then provides a detailed analysis of the cumulative evidence on the drugs.

Our work gives the highest grade to well-done, randomized, controlled trials that provide head-to-head comparisons of drugs with-

in a class. When those trials do not exist, we look for the next best available evidence. When assessing potential harms from drugs, we also use observational studies, which, though less rigorous than randomized, controlled trials, have longer timeframes that allow a more accurate view of risk.

When the synthesis is finished, a draft report is produced and sent to outside experts for peer review. In addition, we post a copy of the draft to our website and solicit comments on the draft from the public, from advocacy groups, and from the industry.

When the comment and peer review periods are complete, the legitimate criticisms brought to us are addressed in the final version of our report. The final versions are then posted to our website in the public domain.

In all, this process is more open and thorough than any other available to our knowledge. When a report is complete, one can identify every step that was taken, can review every report included or excluded, and know why that was done. We disclose on request public comments and the documents sent to us by the industry.

Our members use the information in different ways, including as an educational tool for prescribers, as an independent and transparent check against work done by commercial contractors, such as pharmacy benefits managers, as the primary information for use in evaluating drugs for inclusion or exclusion from a PDL, preferred drug list.

Depending on the methods used by our States, they report differing levels of savings. In general, States that have prior authorization processes realize greater savings than those who simply provide the information to prescribers or who have permissive exceptions processes. Some quick examples of savings realized by some of our States include one which shifted its use of the preferred drug in the opioids class—a pain-reliever class where there is no evidence of different effectiveness among the medications—from 33 percent use of the preferred drug to 69 percent use of the preferred drug. The savings were significant because the monthly cost for the preferred agent averaged $77 per patient and the nonpreferred agent averaged $331 per month.

The results of eight classes over a year, the results of using this process for eight classes over a year resulted in over $19 million in savings, and budget officials projected when the process was used on 16 classes, it would yield approximately $40 million in a year.

Another State reported approximately 5-percent savings in their overall drug spending with the adoption of a soft prior authorization process on four classes of drugs only: nonsteroidal anti-inflammatory agents, opioid analgesics, statins for cholesterol, and proton pump inhibitors for gastric conditions.

Our States also report that companies are now competing for market share based on price by offering States supplemental rebates so that their drug can be one of the lowest price in a class where the drugs are deemed to be equally effective. But the savings do not end there. As a result of our review of the nonsteroidal anti-inflammatory class and the fact that in 2002 it highlighted the potential cardiac risks associated with the use of Vioxx, with few ex-

ceptions our member States kept Vioxx off of their preferred drug lists and, arguably, not only prevented significant suffering and disability, but also saved the cost of treating cardiac problems that may have resulted from the widespread use of this medication by their Medicaid program.

We believe that the Drug Effectiveness Review Project demonstrates how good scientific inquiry can be used to build confidence in the clinical credibility of these purchasing decisions.

[The prepared statement of Mr. Gibson follows:]

Testimony
United States Senate
Special Committee on Aging

July 20, 2005

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I. Project Overview

While preparing the 2001 Medicaid budget for the state of Oregon, officials were shocked to see that analysts predicted a 60% increase in drug spending over the two year budget cycle. They immediately realized that something significant had to be done both from the standpoint of efficient use of tax dollars, and from the fact that rapidly increasing costs in Medicaid were constantly threatening the ability of the state to maintain Medicaid coverage for very low income Oregonians.

The state adopted a number of strategies to address this problem, one of which was to employ a preferred drug list (PDL). Preferred drug lists seek to create price competition among manufacturers by the state selecting the lowest cost drug in the class as its preferred drug and then giving providers incentives to prescribe that drug first. To the extent that the state can then shift usage to the lowest cost drug, the difference in price paid for the medications becomes savings that can be used to maintain access to the program for low income residents or to support other needed health services that would otherwise be dropped due to cost pressures in the program.

However, simply requiring doctors to prescribe the lowest cost drug in a given class of medications could be counter productive. Prescription drugs have changed over the years and in some cases, there have been significant improvements in the quality and effectiveness of some medicines. If insisting on the lowest cost drug caused doctors to prescribe inferior medications then not only would health outcomes be adversely affected, but other costs in the system could increase because patients might remain sicker longer, or have to use other health services more often.

The challenge facing Oregon was to create a clinically sound and effective PDL, based on the best possible assessment of the comparative effectiveness, safety, and effect on sub-populations of drugs within classes of medications. To get this information, the state partnered with the Evidence-based Practice Center (EPC) at Oregon Health and Science University in Portland. As a first step, the state commissioned the EPC to produce full systematic reviews of the global medical literature of four classes of drugs.

As the first four classes (Statins, NSAIDs, PPIs, and Opioid Pain Relievers) were completed, the information found its way to Medicaid officials in Washington and Idaho. Recognizing that these reports were more comprehensive and rigorous than what they were currently using they suggested that they join Oregon in an informal collaboration to fund studies of additional classes.

Soon additional studies were commissioned and the states began using them in their drug purchasing programs. However, because of its comprehensive nature, the process of doing systematic reviews is relatively expensive (approximately $130,000 per drug

class). In addition, it became clear that in some classes, frequent updates of the reviews would be required to stay abreast of the research taking place in the field.

As a result, the three Northwest states sought a broader collaboration with other states. The Center for Evidence-based Policy (Center) at OHSU with incubation support for the project from the Milbank Memorial Fund began working with a number of other states who had expressed an interest in gaining access to this high quality information and a larger collaboration quickly took shape.

This collaboration became known as the Drug Effectiveness Review Project (DERP). What had started out as one state working to bring the best clinical knowledge available to its Medicaid drug purchasing had become a broadly representative group of 14 states and two other organizations who would eventually commission systematic reviews of 26 classes of drugs, and routine updates of the classes once their original studies were completed.

Drug Effectiveness Review Project (DERP)

The Drug Effectiveness Review Project consists of the following elements:

- A collaboration of 16 participating organizations each contributing an equal amount to the financing of the project. The collaboration is producing systematic reviews of the comparative effectiveness, safety, and effect on sub-populations of drugs within 26 classes of drugs[1]. The participating organizations guide the operation of the DERP through a self-governing process in which each organization is equally represented. 14 of the 16 participating organizations are state Medicaid programs[2]. The other two participating organizations are the California Health Care Foundation and the Canadian Coordinating Office for Health Technology Assessment.
- The Center for Evidence-based Policy (Center), School of Public Health and Preventive Medicine, Oregon Health and Science University supports the collaboration, by executing the intergovernmental agreements and contracts required to finance the collaboration and by staffing the governance group that directs the Project. In addition, the Center supports communication between the

[1] Classes under review are: Proton Pump Inhibitors, Long-acting Opioids, Statins, Non-steroidal Anti-Inflammatory Drugs, Estrogens, Triptans, Skeletal Muscle Relaxants, Oral Hypoglycemics, Drugs to treat Urinary Incontinence, ACE Inhibitors, Beta Blockers, Calcium Channel Blockers, Angiotensin II Receptor Antagonists, 2nd Generation Antidepressants, Antiepileptic Drugs in Bipolar Mood Disorder and Neuropathic Pain, Newer Antihistamines, Atypical Antipsychotics, Inhaled Beta Agonists, Inhaled Corticosteroids, Drugs to treat ADHD and ADD, Drugs to treat Alzheimers, Anti-platelet Drugs, Thiazolidinedione, Newer Antemetics, Newer Sedative Hypnotics, Targeted Immune Modulators

[2] Alaska, Arkansas, California, Idaho, Kansas, Michigan, Minnesota, Missouri, Montana, North Carolina, Oregon, Washington, Wisconsin, Wyoming

participating organizations and the Evidence-based Practice Centers, provides technical assistance to participating organizations on the use of systematic reviews, ensures that timelines are met, and manages communication between pharmaceutical companies and the project.

- The Evidence-based Practice Centers (EPCs) perform the systematic reviews of medical evidence comparing the effectiveness of drugs within classes determined through the governance process of the Project. The EPCs are designated by the U.S. Agency for Healthcare Research and Quality as particularly well qualified to perform these evaluations of the medical literature.

The Project is based on the principle of "Globalizing Evidence and Localizing Decisions." The reports produced by the Project do not recommend a preferred drug nor do they consider the cost of the medications in question. They simple report on what the evidence shows about the comparative effectiveness, safety and effect on sub-populations of the medicines. This information is then taken by the states and incorporated into their local decision-making processes.

The Project's reports are created in a process that fully discloses each step taken, each source considered, and painstakingly describes the reasoning behind the analysis conducted. The process of producing the reports has numerous methods for soliciting comments and criticisms from the public, from advocacy groups, and the drug industry and this input is systematically used to improve the quality of the reports. Neither the researchers who produce the reports nor employees of the Center are allowed to have any economic interest in the drugs being investigated. The reports can be viewed at the Project's website at www.ohsu.edu/drugeffectiveness.

There are several ways in which the states use this information. In some cases they simply array it in formats readily useable by prescribers and distribute it as an educational service to practitioners serving Medicaid clients. In others it is used as a clinical check to analyses provided by commercial pharmacy benefit managers. In still others, the reports are the primary clinical information source for their PDL. However, all of the states using PDLs have processes for considering additional information including public testimony, review by local clinical experts, and incorporation of appropriate cost information.

Many of the states in the collaboration are experiencing significant savings in their drug expenditures. The clinical information provided by the DERP gives them clear indications of where they can aggressively bargain with drug companies for better prices and still maintain the quality of care provided in their Medicaid programs. Their savings vary according to the bargaining process they use, but virtually all that are using PDLs are experiencing savings as a result of higher utilization of equally effective lower cost drugs.

Many of the states are generating additional savings by coupling their PDL with a prior authorization process which requires doctors to give a clinical reason for not using the preferred drug before approval to purchase a higher cost drug is granted. This approach is so effective in moving usage to the preferred drug that manufacturers are willing to provide significant supplemental rebates to the states in order to ensure that their medications are included as first options in the PDL.

For example, one state reported that in a class where there was no evidence of any difference in effectiveness among the various medications available, their utilization of the preferred drug went from 33% of the drugs purchased in 2003 to 69% of the drugs purchased in the class in 2004. The savings were substantial because the monthly cost for the preferred drug was $77.61, and the average cost for the non-preferred drugs was $331.32 per month. This same state reports substantial supplemental rebates provided by providers wishing to ensure that their drugs are included in the PDL first option.

Moreover, using the best available clinical information can increase the quality of care in Medicaid and provide additional savings by ensuring that the best drug in a class is used. Here, the well known story of Vioxx provides a good example. In 2002, in the original report on Non-steroidal Anti-inflammatory drugs (NSAIDs), the EPC highlighted the potential cardiac risk associated with Vioxx. As a result, most states did not include Vioxx as a preferred drug. This not only saved the costs linked to purchasing Vioxx (typically one of the more expensive drugs in the class) but it also prevented the cardiac complications, suffering, disability and costs associated with the use of the drug before it was pulled from the market.

The DERP continues to evolve as more is learned about using systematic reviews to compare drugs. It has prompted significant discussions about the quality of evidence available on the effectiveness and safety of many drugs. The systematic approach has provided a clear view of the lack of information available on many subpopulations and has highlighted the need for either the industry or the public sector to fill in these gaps in much needed information.

The quality of the research provided by the DERP has generated significant interest in its products in groups outside of Medicaid. Presently, DERP reports are the foundation for the Consumer's Union Best Buy Drugs web site. This initiative takes the highly technical DERP documents and combines the findings with cost information then presents the information in language understandable to the public at large. This enables consumers to work with their physicians to ensure that they are receiving the best value for their prescription drug dollar. A similar approach has been undertaken by AARP, and its summaries of our reports are also posted on its web site providing consumers with access to this vital information.

The DERP is poised to provide constantly improving comparative information on drugs for the foreseeable future. It promises to be a continuing resource for public programs and private purchasers for years to come. More detailed information on the research process, the methods of communication with the pharmaceutical industry, specific elements of the program is attached.

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II. Systematic Reviews of Research and Evidence

The research produced by the project is the most rigorous and defensible clinical information for making drug purchasing decisions available today. The research consists of Systematic Reviews of the global medical literature. Well done systematic reviews are considered the gold standard for evaluating the whole of what research has to say on a given topic. The reports generated by the DERP compare the effectiveness, safety, and effect on subpopulations of drugs within therapeutic classes.

The reports generated by the DERP are also fully transparent. They fully disclose their methodology, sources, analysis, and conclusions. The final reports are posted in the public domain on the World Wide Web at www.ohsu.edu/drugeffectiveness.

The credibility of systematic reviews results from their painstaking research process. The following are the key elements of the systematic review process conducted by Evidence-based Practice Centers used in the collaborative effort:

- Formulating key questions;
- Finding evidence;
- Selecting and evaluating evidence;
- Synthesizing and presenting evidence;
- Conducting peer review;
- Revising draft documents into final systematic reviews; and
- Maintaining and updating reviews.

Each step of this process is important to producing the highest possible quality reports and in providing decision makers with relevant, reliable information as they address coverage, reimbursement and other decisions concerning pharmaceutical products. A greater understanding of the research process will demonstrate why policy makers can trust the information in a well done systematic review.

Formulating Key Questions

The most important and sometimes the most difficult steps in starting the systematic review process are to establish the questions that the review of research literature is to answer. Clearly, top quality research that answers an irrelevant question is useless to policy makers and wasteful of resources.

It is important to spend the time needed to engage fully in the process of identifying key questions. This step cannot be left to one party. Policymakers need advice on exactly how to

phrase questions clearly, and in ways suitable for an evidence-based process, so that they can obtain the information they need for policy formulation. Researchers need this dialogue to ensure that the work they are doing is relevant to the policies being developed.

In the Drug Effectiveness Review Project, the Center convenes a dialogue between the participating organizations and the researchers assigned to the class of drugs under review. This dialogue carefully specifies the populations to be addressed, the interventions to be studied, and the health or other outcomes (both positive and negative) to be evaluated.

The DERP usually starts with the following general template and then adds details to the template until it defines the scope of the research:

1. What is the comparative efficacy of different (name drug class) in improving (name the outcome desired) for (name type of patients by symptoms, disease etc.)?

2. What are the comparative incidence and nature of complications (serious or life threatening, or those that may adversely affect compliance of different (name the drug class) for patients being treated for (name the type of patients by symptoms, disease, etc.)?

3. Are there subgroups of patients based on demographics (age, racial/ethnic groups, and gender), other medications or co-morbidities (obesity for example) for which one or more medications or preparations are more effective or associated with fewer adverse effects?

Participating organizations have time to gather input from parties that will be affected by the policies in question, including among others, patients, pharmacists, and physicians. This feedback helps ensure that the concerns of patients and practitioners are thoroughly considered. In addition, draft key questions are posted to the project's web site and comments on the questions are solicited from the public, advocacy organizations, and the industry. Specifying clear and appropriate key questions *in advance* helps ensure that evaluations of the evidence are not biased and that the evidence is interpreted without regard for pre-existing opinions.

When the dialogue is completed, the key questions:

- Specify the clinical conditions (diagnoses, diseases) to be included in the review;
- Define the populations, interventions, and outcomes (expected benefits, potential risks or harms) of interest for the review.

Finding Evidence

In an electronically connected world, finding all the information needed to make good decisions sounds easy. Although finding some information is easier than ever, the diversity of sources for information pertinent to the types of decisions under consideration by states and other purchasers, requires knowledgeable and skilled personnel as well as access to a wide array of computer-based and hard copy sources of research literature. Using all available information sources ensures that the greatest possible amount of relevant information is obtained and analyzed.

The Evidence-based Practice Centers (EPCs) specialize in using multiple search techniques. These technologies are focused on major databases of the world's medical literature and other resources such as systematic reviews and clinical trials found in the Cochrane Collaboration Library. In addition, the Centers can accept published or unpublished information from all reasonable sources, if the party submitting the information allows the information to be made public so that it can be openly compared to other information acquired by more traditional methods.

After searching these data bases, the bibliographies of relevant studies are also searched for any citations that have otherwise been missed.

Finally, all U.S. and Canadian drug manufacturers are provided the key questions and are asked to provide a dossier containing any evidence they believe is useful in answering the questions posed.

Selecting Evidence

Sometimes the known or expected volume of information is overwhelming. Moreover, Separating information expected to be useful from potentially irrelevant or misleading data is a special challenge, even when key questions have been well specified. Thus, an important step is to specify, in advance, the sources of "admissible" evidence related to the key questions. This is referred to as "stating the eligibility criteria" for material that will be included or excluded from consideration in the review process. The evidence-based process calls for EPCs to take the following factors into account in describing evidence to be selected and retained:

- Which databases or other sources and information to include;
- What factors relating to language, year of publication, and similar details should be considered;
- What types of publications to include; and
- What types of research studies to include.

When considering the types of research that will be accepted, although randomized controlled trials (RCTs) involving head-to-head comparisons of drugs may be the optimal

design for this process, they are not the only evidence that may be valuable to or necessary for decision makers. RCTs with placebo controls, for example, may be important as well. Moreover, large, well designed studies other than RCTs are often critical sources of data on populations not typically included in RCTs, on longer-term outcomes, and on potential adverse events.

Once the eligibility criteria have been identified, the process of searching for relevant evidence begins by reviewing titles and abstracts of research studies, or entire articles reporting on such investigations, against the eligibility criteria already stipulated, and deciding which items to use and which to set aside. If an article or study is excluded from consideration, the reason for doing so is recorded as part of the final documentation.

Once the acceptable sources of information have been identified, the information in them is abstracted into detailed "evidence tables" that provide crucial information on study purpose and design, populations, diagnoses or conditions, interventions, outcomes, and other data.

Synthesizing and Presenting Evidence

Synthesis of evidence is the process of analyzing and combining all good information gleaned from the review of research studies and findings relevant to the key questions formulated at the outset. Analysts typically rely heavily on information from evidence tables for this task. This step, and the overall presentation of evidence, can be done in qualitative terms, through text discussion of the evidence, and in quantitative terms, through statistical combination of information in a technique known as meta-analysis.

A critical element of the evaluation of the evidence involves two related steps: grading the quality of individual studies and rating the strength of the overall body of evidence. These are formal steps for which well-recognized methods exist. For a systematic review to be defensible it is imperative that both of these judgments be made in a clear and consistent manner.

Review of the quality of individual studies relies on study design *and* conduct. Study design alone is insufficient. The best-designed study can provide poor evidence if the conduct of the study does not rigorously follow good research practice. The quality of a study is often summarized as providing good, fair, or poor evidence, and reviewers must clearly state how the review uses each category of evidence. For example, does the review consider (but down-weigh) poorly designed or conducted studies or exclude them altogether. This may be particularly important when quantitative syntheses are performed. Another consideration is that study quality may not, by itself, be sufficient. A very good study that has only limited applicability to a key question may not be as helpful as a fair study that is directly related to the question at hand. Often, systematic reviews will focus particular attention on a limited number of high-quality, critical studies, from which key evidence can be highlighted in more detail

Evidence tables are always created to allow those decision makers the opportunity to examine the entirety of the evidence. For ease of presentation, summary tables derived from detailed evidence tables may also be desirable or other approaches to presenting information about the magnitude of benefits and harms such as "balance sheets" that provide results in terms of the number of patients who would benefit or be harmed by undergoing a particular intervention can be used. The Center works with the participating organizations and the researchers to make certain that the information provided is arrayed in ways that are most useful to the policy makers that will use it.

As all the evidence is organized into evidence tables, summary tables, and text, reviewers then need to make some assessment of the overall quality and applicability of the evidence. The questions at this stage involve the cumulative quality of the studies (are studies mostly of good quality, mostly of fair or only poor quality, or a mix), the quantity of the data (e.g., numbers of studies and aggregate sample sizes), and consistency (e.g., do the studies show consistent results or are some clearly negative and some positive). Again, the entire body of evidence is often characterized as good, fair, or poor, and typically the limitations of the literature are discussed.

In synthesizing all this information, reviewers may also address a variety of other questions of concern to policymakers. These include but are not limited to:

- What do the largest studies show compared to smaller ones?
- What populations have been studied and are those populations relevant to the question at hand? What critical populations have been excluded or ignored?
- Have "real life" outcomes of concern to patients been studied, or have outcomes been limited largely to biologic or physiologic measures?
- Have risks and harms been reported as thoroughly as benefits?

All these preceding steps will then be assembled into a draft systematic review, complete with background, methods, results, discussion, evidence tables, summary tables, and citations (references). This draft is then subjected to external peer review.

Conducting Peer Review and Revising the Draft into a Final Systematic Review

Peer review is the act of soliciting critiques from national and international experts and potential users of the systematic review. Peer reviewers are asked to comment on factual matters, presentation, interpretation, missing information, readability/usability, and similar matters. The aim is to identify omissions, unwarranted conclusions or inferences, unintentional bias, inadvertent over- or under-emphasis, and unnecessarily tedious, obscure, or misleading writing. Peer review is an integral part of the standards required by the Agency for Healthcare Research and Quality for developing systematic reviews. Comments from reviewers are all given serious consideration.

Peer reviews are solicited through distribution of the draft review to reviewers with expertise in the relevant clinical area outside of the EPC. The draft is also placed on the DERP website to obtain reactions from the public, advocacy organizations, and the industry.

Following peer review the authors of the systematic review begin necessary revisions. All legitimate points raised by the peer review are addressed in the final draft of the systematic review. For example, if reviewers note important missing data or studies, these are obtained and data from them are added to evidence tables and text, as appropriate.

Once the authors have completed the final evidence report, they will then make it available for dissemination as determined by the participating organizations. The authors of the report may also submit the report, or a shorter article summarizing it, for publication in a scientific journal. These journal publications further enhance the credibility and impact of the reports and of the evidence-based process within the scientific community.

Maintaining and Updating Reviews

Even the best information can become outdated, sometimes quickly (within months) and, sometimes, over a longer period (two to three years). The Drug Effectiveness Review Project updates reviews as appropriate given the amount of research being done on the given class. For classes that are experiencing a large amount of research, the updates occur every 6-8 months. Classes with little research taking place may wait for two years to be updated. Each update will consist of a new literature search that seeks additional data or analysis from studies published in the interim; of particular significance will be newly published systematic reviews on the same or a related topic and results from clinical trials or large observational studies.

III. Evidence-Based Practice Centers

Overview

Evidence-based Practice Centers (EPCs) offer a perfect resource for answering complex clinical questions. The EPCs are experienced at the task of evidence-based systematic reviews. They are part of a larger effort devoted to evidence-based analysis overseen by the Agency for Healthcare Research and Quality (AHRQ). As a result, they have access to researchers, peer reviewers, and database searching resources throughout the world.

Considerations that support the use of EPCs in the Drug Effectiveness Review Project include:

- EPCs realize the importance of getting the question right – making sure that research is relevant and properly focused for use in policymaking.
- EPCs have access to extensive peer review resources.
- EPCs are experienced in working with both public and private customers.
- EPCs have experience working in public settings. Their work is virtually always used and reviewed in public settings.
- EPCs have a proven record of performing to contract requirements.
- EPCs have high standards regarding conflict of interest. They strive to avoid even the appearance of conflicts of interest.
- EPCs have experience helping local decision-making groups understand the research process and assisting these groups in appropriately using research products.
- EPCs have the flexibility to produce the type of report needed—from Cochrane-type reports to technology assessments, systematic reviews, and other decision aids.

EPC Background and History

In 1997, the Agency for Healthcare Research and Quality (AHRQ, known previously as the Agency for Health Care Policy and Research) launched its initiative to promote evidence-based practice in everyday health care through establishment of 12 Evidence-based Practice Centers (EPCs). The EPCs develop evidence reports and technology assessments on clinical topics involving conditions or health services that are common, expensive, and/or are significant for the Medicare and Medicaid populations. With this program, AHRQ became a "science partner" with private and public organizations in their efforts to improve the quality, effectiveness, and appropriateness of health care by facilitating the translation of evidence-based research findings into clinical practice.

AHRQ is the lead federal agency for enhancing the quality, appropriateness, and effectiveness of health care services and access to such services. In carrying out this mission, AHRQ conducts and funds research that develops and presents evidence-based information on health care outcomes, quality, cost, use and access. Included in AHRQ's legislative mandate is support of syntheses and widespread dissemination of scientific evidence, including dissemination of methods or systems for rating the strength of scientific evidence. These research findings and syntheses assist providers, clinicians, payers, patients, and policymakers in making evidence-based decisions regarding the quality and effectiveness of health care.

Since 1997, the EPCs have conducted more than 100 systematic reviews and analyses of scientific literature on a wide spectrum of topics. Summaries of EPC reports may be reviewed by visiting AHRQ's website, www.ahrq.gov. EPC evidence reports and technology assessments have been used by systems of care, professional societies, health plans, public and private purchasers, states, and other entities, as a scientific foundation for developing and implementing their own clinical practice guidelines, clinical pathways, review criteria, performance measures, and other clinical quality improvement tools, as well as for formulating evidence-based policies related to specific health care technologies.

The EPC Program is an essential component of AHRQ's support for evidence-based systematic reviews, analyses, and research. AHRQ intends that evidence reports, technology assessments, and research flowing from EPCs will be useful to a broad array of stakeholders— consumers, providers, employers, policymakers—and be more rapidly available than previous evidence-based efforts.

In June 2002, AHRQ announced the award of new five-year contracts for EPC II to 13 Centers in the US and Canada to continue and expand the work performed by the original EPCs.

Development of Reports

The EPCs develop evidence reports and technology assessments based on rigorous, comprehensive syntheses and analyses of relevant scientific literature on clinical, behavioral, organizational, and financing topics, emphasizing explicit and detailed documentation of methods, rationale, and assumptions. These scientific syntheses may include meta-analyses and cost analyses. All EPCs collaborate with other medical and research organizations so that a broad range of experts participates in the development process.

The resulting evidence reports and technology assessments are used by federal and state agencies, private sector professional societies, health delivery systems, providers, payers, and others committed to evidence-based health care. In addition, the EPCs:

- Update existing reports;
- Provide technical assistance to professional organizations, employers, providers, policymakers, and others to facilitate translation of the reports into quality improvement tools, evidence-based curricula, and reimbursement policies; and
- Undertake methods research by comparing and studying the outcomes of various research methodologies. Profiles of Evidence-based Practice Centers Likely to be used in Project

The following are profiles of the three EPCs that produce systematic reviews for the DERP.

PROFILE - Oregon Evidence-based Practice Center

The Oregon Evidence-based Practice Center based at Oregon Health & Science University, (OHSU) in Portland, Oregon, serves as a resource center for the production of systematic reviews and related projects in evidence-based medicine for federal and state agencies and private foundations. These reviews report the evidence from clinical research studies and the quality of that evidence for use by policymakers in decisions on guidelines and coverage issues.

Capabilities

Mark Helfand, MD, MS, MPH, associate professor of medicine and medical informatics & clinical epidemiology, directs the Oregon EPC; Heidi D. Nelson, MD, MPH, associate professor of medical informatics & clinical epidemiology and medicine, serves as co-director. Associate Director Merwyn Greenlick, PhD, is professor and chair emeritus of the Department of Public Health and Preventive Medicine and was the former director of the Kaiser Permanente Center for Health Research. EPC Associate Director William Hersh, MD, chair of the Department of Medical Informatics & Clinical Epidemiology, is one of several OHSU faculty involved with the Cochrane Collaboration.

Oregon EPC investigators have a particular interest in diagnostic technology assessment, prevention effectiveness, women's health issues, Medicare coverage, evidence-based informatics, systematic drug class reviews, patient safety, and behavioral counseling in the primary care setting. Since 1998, the Oregon EPC has produced systematic reviews of prevention, screening, and behavioral counseling topics to inform recommendations of the US Preventive Services Task Force.

Collaboration

The Oregon EPC is collaboration between Oregon Health & Science University, the Kaiser Permanente Center for Health Research, which has strong expertise in the areas of prevention effectiveness, health economics, and managed care, and the Portland Veterans Affairs Medical Center. Investigators at OHSU come from a wide variety of disciplines within the Schools of Medicine and Nursing. The EPC has also worked with investigators

from the University of Washington, the University of Colorado Health Sciences Center, the Portland Shriners Hospital, and Griffith University in Queensland, Australia.

Additional Information

All inquiries related to the Evidence-based Practice Center at Oregon Health & Science University should be directed to e-mail address: epc@oshu.edu. The Center's Web site is http://www.ohsu.edu/epc, or contact:

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PROFILE - Research Triangle Institute and University of North Carolina at Chapel Hill Evidence-based Practice Center

Research Triangle Institute, in collaboration with the five health professions schools and the Cecil G. Sheps Center for Health Services Research at the University of North Carolina at Chapel Hill, operates the RTI International*-University of North Carolina at Chapel Hill (RTIUNC) Evidence-based Practice Center for the Agency for Healthcare Research and Quality. The RTI-UNC EPC is headquartered at the North Carolina campus of Research Triangle Institute, a short distance from the UNC-Chapel Hill campus.

The RTI-UNC EPC will:

- Foster the development and dissemination of systematically developed, authoritative evidence reports (or technology assessments) on critical health care topics affecting all population groups.
- Work with science partners in the public and private sector, which will use these reports to improve clinical practice; help clinicians, patients and their families, payers and purchasers, and policymakers and to make better decisions and choices of effective and appropriate health care technologies; and improve patient and population health and well-being.
- Enhance methodologies for evidence reports and technology assessments.

- Determine the effects of such materials on health care practices and patient outcomes.

Capabilities

The RTI-UNC EPC brings extensive assets from five significant clinical and public health areas: dentistry, medicine, nursing, pharmacy, and public health. It also combines expertise in health services research and policy analysis with depth of technical skills in all forms of quantitative, qualitative, and social sciences methodology. The RTI-UNC Center can marshal appropriate and appreciable resources to study issues on a full range of clinical topics, from prevention and screening through diagnostic testing to therapy, rehabilitation, counseling, and palliative care.

The EPC is prepared to:

- Carry out rigorous review and critique of the clinical and biomedical research literature in a timely and efficient way.
- Conduct all forms of relevant analysis (such as meta-analysis or cost-effectiveness analysis).
- Produce useful materials for and provide technical assistance to all interested parties and provider, patient, and consumer groups.
- Perform small or large projects to evaluate the use, implementation, and impact of evidence reports and similar tools and products on the delivery, costs, quality, and outcomes of health care in the United States and elsewhere.

The RTI-UNC Center can call on up to 450 clinical, substantive, and methodologic experts for studies and activities done for the AHRQ evidence-based practice program, for other public sector agencies at both the Federal and State levels, and for an array of private sector organizations such as professional societies and associations, patient and consumer groups, managed care organizations and insurers, and pharmaceutical firms.

Its Co-Directors are Kathleen Lohr, PhD, of RTI and Timothy S. Carey, MD, MPH, of the Sheps Center at UNC-CH.,

The RTI-UNC Center has numerous collaborators representing important constituencies, populations, and perspectives on health care. An initial list includes: the American Pharmaceutical Association; American Society of Health-System Pharmacists; Center for Clinical Quality Evaluation; Center for Health Services Research in Primary Care, Department of Veterans Affairs Medical Center (Durham VAMC); Center for Quality of Care Research and Education at Harvard; IMCARE (the Internal Medicine Center to Advance Research and Education); Kaiser Foundation Hospitals; Morehouse University Medical Treatment Effectiveness Center; Paralyzed Veterans of America; The Permanente Medical Group Research Institute, and Urban Health Institute at Harlem Hospital Center and Columbia College of Physicians and Surgeons.

*RTI International is a trade name of Research Triangle Institute. *Southern California-RAND*

PROFILE - Southern California Rand Evidence-based Practice Center

The Southern California Evidence-based Practice Center conducts systematic reviews and technology assessments of all aspects of health care, performs research on improving the methods of synthesizing the scientific evidence and developing evidence reports and technology assessments, and provides technical assistance to other organizations in their efforts to translate evidence reports and technology assessments into guidelines, performance measures, and other quality-improvement tools.

Capabilities

The Southern California EPC brings together a breadth and depth of methodological and clinical expertise and can staff multiple simultaneous task orders. The EPC is also the natural progression of more than 20 years of work (dating back to 1972 and the beginning of the RAND Health Insurance Experiment) by RAND and its affiliated institutions in reviewing the biomedical literature for evidence of benefits, harms, and costs; using meta-analysis, decision analysis, and cost-effectiveness analysis to synthesize the literature; developing measures of clinical appropriateness and practice guidelines; developing and assessing medical review criteria; and developing and assessing performance measures and other tools for translating evidence-based knowledge into clinical practice. The hallmark of this work has been: (1) its multi-disciplinary nature: RAND and its affiliated institutions combine the talents of clinicians, health services researchers, epidemiologists, statisticians, economists, and advanced methods experts in meta-analysis and decision analysis; (2) the advancement of knowledge about the methods for performing literature reviews, synthesizing evidence, and developing practice guidelines or review criteria; and (3) the emphasis on developing and evaluating products for use in the real world of health care delivery.

Collaboration

The Center combines the talents of RAND and its five affiliated regional health care institutions:

- University of California, Los Angeles
- University of California, San Diego
- Cedars-Sinai Medical Center/ZYNX Health
- University of Southern California
- Children's Hospital Los Angeles.

In addition, through the VA/RAND/UC Field Program "Center for the Study of Health Care Provider Behavior," two Department of Veterans Affairs (DVA) Healthcare Systems collaborate with the Center:

- Greater Los Angeles VA Healthcare System
- San Diego VA Healthcare System

The Center is also affiliated with five health services research training programs, and the International Cochrane Collaboration.

Center for Evidence-based Policy
Department of Public Health and Preventive Medicine
Oregon Health and Science University

2611 SW Third Avenue, Marquam II, Suite MQ280
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IV. Pharmaceutical Companies: Communication and Involvement

The Center for Evidence-based Policy (Center) and the Evidence-based Practice Centers (EPCs) seek a fair and constructive relationship with the pharmaceutical industry. This document outlines the methods available to the pharmaceutical industry to inform the process of the Drug Effectiveness Review Project. The goals of the Center in relating to the industry include:

1. Obtaining the best evidence relevant to the key questions identified by the participating organizations for each drug class chosen.
2. Obtaining this evidence in a timely fashion.
3. Giving pharmaceutical companies an equal opportunity to provide evidence to the systematic review process.
4. Providing to participating organizations, policy makers, the public and pharmaceutical companies full disclosure of the source and content of all evidence considered in the systematic review process.
5. Providing a standardized, efficient, and open process for pharmaceutical company submission of evidence.

Note: All information submitted to the center will be available to the public at cost upon the release of the related draft systematic review or draft update.

The DERP provides the following opportunities for the pharmaceutical industry interaction with the Project.

- The primary process for pharmaceutical companies to transfer evidence to the Project will be by dossier submission. Submitting a correctly completed dossier will ensure that the evidence submitted by a company will be fully reviewed. Good quality evidence that is relevant to the key questions will be integrated into the Project reports and updates. Local decision makers will have the benefit of considering dossier information in the full context of other evidence.
- The Center will make available, at cost, copies of any evidence submitted in the Project dossier process at the time of release of the relevant draft report or update. This will enable all interested parties to assess the evidence submitted and its use in the systematic review process.
- The Center and the EPC will make every effort to ensure that all relevant evidence is considered in the systematic review process by conducting thorough searches of

the appropriate databases, review of dossiers, and any other appropriate sources of evidence. The Center and the EPC cannot ensure that evidence submitted by pharmaceutical manufacturers outside the dossier format will be included in the systematic review process. The Center will adhere to the timelines articulated in the initial report and update processes in order to provide an efficient and predictable product to local decision makers. Questions regarding the Project, any specific report, or update should be addressed to the Center for Evidence-based Policy as outlined below. Substantive communication will be scheduled in sessions open to the public. EPC staff will not meet with industry representatives regarding substantive issues outside of these public sessions.

- The Center and the Evidence Based Practice Centers host an annual conference for industry representatives to discuss the process, answer questions, and receive input on how to improve the dossier process.

Dossier Submission

Note: Any information submitted as confidential will be rejected. The Dossier submission process includes the following steps:

- A description of the Drug Effectiveness Review Project dossier submission process is provided to all pharmaceutical companies licensed to do business in the United States and Canada.
- The Center notifies pharmaceutical companies of the initiation of an evidence-based report or an update by certified mail. Notice is sent to the company CEO. Key questions in the initial systematic review or update are provided in the notice.
- Companies have eight weeks from the date notification is mailed to submit a dossier for an initial systematic review. Deadline for submission of a dossier for an update is four weeks from the date notice is mailed.
- To be considered, dossiers must be sent to the Center for Evidence-Based Policy, Oregon Health & Science University, 2611 SW 3rd Ave, MQ280, Portland, Oregon 97201-4950.
- Notice of this process is also provided on the Project web site.
- Only evidence relevant to the key questions is considered.
- To ensure that their evidence is considered, companies must submit evidence in the format provided by the Center including:
    - Indicating whether the company asserts their product is superior, equivalent or has unknown performance compared to other products in the class for the issues identified by the key questions contained in the initial systematic review or the update
    - Providing the current label for their product.

- Summarizing the submitted evidence in a table that includes study name/number, indication, population, and duration of exposure, endpoints, location, key results, and publication.
- Submitting electronic copies of the full text of any studies referred to in their dossier. An electronic copy of the bibliography for the dossier is also required. Illegible submissions will be rejected.

Center Submission to EPCs

The Center for Evidence-based Policy:

- Notifies pharmaceutical companies as described above.
- Receives dossiers, log their receipt, and distribute them as outlined below.
- Screens for required elements and legibility, and inform companies of dossiers not meeting these requirements.
- On the business day, following the dossier submission deadline provides 2 copies of each dossier to the EPC assigned to the initial report or update and a single copy to the coordinating EPC.
- Retain the master copy.
- Logs all dossier submissions by class, creating a specific entry for each submission that includes date received, company, whether the dossier complied with requirements, and any follow up communication with company.
- Coordinates the entry system with the coordinating EPC using EndNote software.
- Holds information submitted after the deadline for consideration in the update process.

Center Process for Release of Evidence

All materials submitted to the Center are available to the public upon the release of a draft systematic review or update. All evidence included in the report or update is listed in the report.

The Center for Evidence-based Policy:

- Maintains a file of all accepted dossiers.
- Maintains a master copy of all dossiers.
- Makes copies of dossiers available at cost and upon request at the time of release of the related draft initial report (16 weeks after dossier submission due) or draft update (13 weeks after dossier submission due).

- Notifies the requesting party of the cost of the request within 3 business days of the request. Cost will include a flat charge, a per-page copying fee and a shipping charge.
- Ships dossiers to the requesting party within three business days of receipt of payment.

Note: The Center will release only the full set of dossiers submitted for a drug class. Individual dossiers will not be copied and released.

Evidence Submitted to Local Decision Making Processes

When information is submitted to the local decision-making process, neither the Center nor the EPCs can ensure that the information will be considered in the relevant systematic review or update. The Center will:

- Inform all participating organizations of the process for submitting evidence to the Center and provide the participating organization with written instructions to give to pharmaceutical companies desiring to have their information considered.
- Encourage participating organizations to ask pharmaceutical companies to submit a dossier to the Center for inclusion in the review process and to give them the written instructions on how to do so.
- Review requests from participating organizations to review information submitted in local decision making processes, and determine whether the information has already been considered in the systematic review, and if not, the best way for that information to be reviewed.
- Track requests for review of additional information from participating organizations, the disposition of those requests.
- Notify all participating organizations of requests for additional information and the disposition of those requests.
- When appropriate, refer the additional information to relevant EPC to determine if the information meets the inclusion criteria for the related systematic review. If deemed not relevant the Center will inform the local decision maker within ten business days of receiving the information.
- If information is relevant to the key questions, the Center will forward the information to the appropriate EPC.
- If the information is relevant, submitted prior to the due date for the dossier submission, and submitted in the required dossier format, the evidence will be included as a dossier.

- If the information is relevant, submitted in the required dossier format, but submitted after the due date of the dossier process, the dossier will be included in the next update process.
- If the information is related to adding to or otherwise modifying the key questions, the evidence will be referred to the next governance group discussion regarding key questions for the update of the class.
- The Center will provide copies of evidence submitted in any local decision making process to any interested party upon their request following the same procedure as outlined for dossiers.

Note: All information submitted to the Center via a localized decision-making process will be available to the public on request.

Yearly Conference for Pharmaceutical Companies

The Center and EPCs will organize a conference on an annual basis for pharmaceutical companies and other interested parties. The conference goals will be to describe the current processes related to the Project, answer questions regarding these processes and provide a venue for industry participants to suggest improvements.

The conference will be held at a time and place designated by the Center and EPCs. The Center will notify pharmaceutical companies licensed to do business in the US and Canada 12 weeks prior to the conference of the time, place, cost and registration process. The Conference will be open to the public. The cost of the conference will be covered solely by registration fees. Any significant balance remaining in the conference account will be returned to participants on a pro rata basis. Center and EPC staff will be compensated for their time related to the conference from Center and EPC operating budgets, not the conference budget. Center and EPC support staff with dedicated time to the Conference will be compensated for that time from the Conference budget. Any travel expenses for Center and EPC staff related to the conference will come from the conference budget rather than operating expenses. The Center and EPCs reserve the right to cancel the conference if there is not sufficient registration to cover the cost of the conference. Participating organizations will be invited to attend the conference at their expense.

Ad Hoc Communication with the Center and EPCs

Pharmaceutical companies desiring to communicate with the Center and EPCs regarding the Project should contact the Center first. The Center will determine the nature of the inquiry and the appropriate next steps. If the contact involves the submission of evidence, the Center will provide the information required to integrate that submission into the dossier process. Any contact with the EPCs attempting to communicate or commenting on evidence will be made public. EPC staff will direct pharmaceutical inquiries to the Center.

John Santa MD will be responsible for responding to inquiries from scientific staff. Mark Gibson will be responsible for responding to inquiries from governmental affairs staff.

Note: Those wishing to have input into the Project cannot be assured their information will be included unless it is submitted according to the processes and guidelines outlined above.

Web Site

The Center and EPCs will maintain a web site for the Project. The web site will be updated on a regular basis regarding the Project including timelines, status reports, draft reports, updates, and key questions. If the web site is not available, the Project will make Center staff available by phone to answer questions.

www.ohsu.edu/drugeffectiveness

The CHAIRMAN. On that point, I am going to come back to questions, but, Mark, did you do the testing on it that revealed the problems with Vioxx ahead of time? Did you know that ahead of time before FDA revealed it?

Mr. GIBSON. Chairman Smith, our report that was published in 2002 highlighted the potential cardiac risk.

The CHAIRMAN. Very interesting.

Mr. GIBSON. It was in the evidence. We did no specific—we did not do trials, but we did find in the trials that existed clear indication that there was a hazard there.

The CHAIRMAN. Very interesting.

Meg Murray.

STATEMENT OF MARGARET A. MURRAY, EXECUTIVE DIRECTOR, ASSOCIATION FOR COMMUNITY AFFILIATED PLANS, WASHINGTON, DC

Ms. MURRAY. Thank you, Senator Smith, and welcome back. My name is Meg Murray, and I am the executive director of the Association for Community Affiliated Plans and a former Medicaid director in New Jersey.

The Association for Community Affiliated Plans seeks to offer a positive contribution to the national discussion over Medicaid. We believe Medicaid is a critical component of the safety net. However, we agree with you that certain aspects of the 40-year-old program need modernizing, and for that reason we have brought today to you a simple proposal which would equalize access to the Medicaid drug rebate between fee-for-service and the capitated managed care program. This would provide the Federal Government with significant savings by lowering the prices paid for individual drugs by the health plans. This would lead then to lower capitation rates, which is how the Federal and State governments save money from the proposal.

Just as background on who ACAP is, we are a national trade association of health plans focused primarily on Medicaid. Most of the plans are not-for-profit or owned by a not-for-profit, such as community health centers. We have 19 plans, including Care Oregon in Oregon, and we serve over 2 million Medicaid beneficiaries, and I am accompanied today by the Chairman of ACAP, Jim Hooley, who is the CEO of Neighborhood Health Plan in Massachusetts.

Just to give you an overview, Medicaid plans currently pay less for drugs on a per member per month basis than the States. This is true despite the fact that plans pay a higher price for drugs because they do not have access to the Federal rebate, which guarantees that the States will get the best and lowest price.

Plans offset this price disadvantage through more efficient use of utilization management techniques, which I will talk about in a few minutes.

The Center for Health Care Strategies sponsored a study by the Lewin Group which found that Medicaid plans were paying on average $17.36 per member per month for TANF enrollees for their drug costs. States, on the other hand, were paying over $20 per member per month. In other words, States were paying about 18 percent more for drugs than health plans.

We believe that allowing plans to have access to the Federal drug rebate could further lower per member per month cost for drugs. This would save the Federal and State governments significant dollars through lower capitation rates to the plan.

Plans have been excluded from the Federal drug rebate program since the program was enacted in 1990, and instead the plans receive rebates from the manufacturers on their own, typically through pharmacy benefits managers. States, on the other hand, receive a statutorily required rebate of at least 15 percent of average manufacturer's price for brand name drugs and 11 percent of AMP for generic drugs, as was talked about in the first panel.

Medicaid health plans, on the other hand, average only about 6-percent rebate on brand drugs compared to at least 15 and more like 30 percent for the States, and they usually receive 0-percent rebate on generics; whereas, the States are getting about 11 percent.

Because the fee-for-service program is required by law to get the best price, Medicaid plans serving the exact same clients end up paying a higher price for individual drugs.

As I said before, although they pay a higher price for individual drugs, plans are able to offset the price disadvantage by more efficient use of utilization management tools. These tools both reduce the total cost of drugs and improve the quality of care to our Medicaid beneficiaries.

The range of tools include things such as using drug data to identify pregnant women or people with HIV and diabetes, or beneficiaries who might be using drugs inappropriately, either too many or too few.

Other tools, such as greater use of generics and greater use of lower-cost drugs, lead to the lower per member per month cost than in the State fee-for-service program.

Equalizing the Federal drug rebate program by giving both plans and the States access to the higher Federal rebate would allow the plans to lower prices paid for individual drugs, thereby further decreasing the already lower per member per month payment. This savings in turn would be passed on to the States and the Federal Government through lower capitation rates.

As you may know, several States have considered carving drugs out of the capitation to take advantage of the Federal rebate. The Lewin Group estimated that carving drugs out of the capitation in Arizona would actually cost the State $4 million because of the State's inability to manage utilization as efficiently as the States have.

ACAP is suggesting that a better policy would be to instead equalize the plans' access to the Federal rebate. The Lewin Group has estimated that there are potential savings of over $2 billion over 10 years.

ACAP has been very active in discussing this proposal with other Medicaid stakeholders. It has recently been endorsed by the National Governors Association as well as the National Association of State Medicaid Directors, the Medicaid Health Plans of America, and the National Association of Community Health Centers.

In conclusion, at a time when Congress must make tough decisions, we believe that equalizing the drug rebate makes sense. It

will modernize the program, save billions of dollars, not reduce any benefits, or force any beneficiary off the rolls. We urge you to consider this provision in any Medicaid reform proposal produced by the Senate.

Thank you.

[The prepared statement of Ms. Murray follows:]

ACAP

Association for Community Affiliated Plans

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James Hooley, Chairman · Margaret A. Murray, Executive Director

Statement of
Margaret A. Murray, Executive Director
Association for Community Affiliated Plans (ACAP)
to the
Senate Special Committee on Aging

On Equalizing the Medicaid Drug Rebate Between Medicaid Fee-for-Service and Medicaid Managed Care

July 20, 2005

ACAP Mission: To improve the health of vulnerable populations through the support of Medicaid-focused community affiliated health plans committed to these populations and the providers who serve them.

Introduction

Chairman Smith, Senator Kohl, members of the Committee, thank you for the opportunity to testify today before the Senate Special Committee on Aging. My name is Meg Murray and I am the Executive Director of the Association for Community Affiliated Plans (ACAP). Before I begin, I want to thank you for holding this hearing. The Medicaid program is a vital source of care for more than 40 million Americans and it is important that Congress do everything it can to properly understand its complexities and nuances as it looks to change the program. Hearings like this go a long way in fostering a greater understanding of Medicaid.

Thank you.

ACAP seeks to offer a positive contribution to the national discussion over reforming the Medicaid program. ACAP believes that Medicaid is a critical component of America's health care safety net. However, we also recognize that certain aspects of the 40-year-old program are in need of modernization. As a result, ACAP brings to Congress a proposal that would change Federal law to equalize access to the Medicaid drug rebate between fee-for-service and managed care, thereby modernizing the program and providing State and Federal governments with substantial savings.

About ACAP and Safety Net Health Plans

ACAP is a national trade association representing "safety net health plans" that are Medicaid-focused (75% of the plans' enrollees have Medicaid or SCHIP coverage) and are non-profit or owned by non-profit entities like public hospitals or community health centers. ACAP's mission is to improve the health of vulnerable populations through the support of Medicaid-focused community affiliated health plans committed to these populations and the providers who serve them.

As of July 2005, ACAP represents 19 plans serving 2.1 million Medicaid beneficiaries in 12 states. ACAP plans serve one of every six Medicaid managed care enrollees. I have included a list of ACAP's member health plans at the end of my written statement for your review.

Support for Common Sense Medicaid Reform

ACAP has taken a strong and consistent position in discussions on Medicaid that the 40 year old program is in need of reform and improvement, but the essential elements of Medicaid must be maintained – coverage of comprehensive health care services, the entitlement to coverage for those categorically and income needy, and the essential oversight and partnership role that the Federal government shares with the States.

In addition, ACAP has consistently opposed making changes in Medicaid solely to meet arbitrary budget targets. Although ACAP understands the need for and

supports fiscal responsibility, we also understand that Medicaid provides essential services for the most needy Americans – most of whom would otherwise have little access to health care coverage if not for Medicaid. In this case, cuts in the program mean cuts to people. ACAP has always supported a discussion of Medicaid reform outside the scope of the budget process (or at least that was not driven by the budget process) and will continue to believe that changes in the program should be made in the best interest of the people who need its services.

How Safety Net Plans Manage Drug Costs While Maintaining Quality of Care

Prescription drug utilization management is an important tool plans use to improve the quality of care to beneficiaries and control costs. Plans employ a range of drug management tools that allow them to coordinate and fully manage all aspects of beneficiaries' care. For example, drug utilization management allows plans to identify who may need prenatal services and to track use by disease or high use so plans can assist beneficiaries in managing chronic conditions such as diabetes or HIV. It also provides plans with a way to identify potential problems such as drug interactions. Plans are able to strike the right balance between appropriate use of generics and situations where brand prescription drugs are medically appropriate.

In January 2003, the Center for Health Care Strategies (CHCS) published a report entitled *Comparisons of Medicaid Pharmacy Costs and Usage between the Fee-for-Service and Capitated Setting*[1]. The report concludes that the MCOs are able to reduce their average per member per month (PMPM) drug costs for families in Medicaid managed care to $17.36 compared to $20.46 in the state fee-for-service programs. The report postulates that although the MCOs are at a price disadvantage due to the their inability to access the federal Medicaid drug rebate program, they make up the price disadvantage by paying less in dispensing fees, using more generics and other lower cost drugs, and lowering the number of prescriptions per month. These figures suggest that pharmacy costs in the FFS Medicaid setting end up 18 percent higher than in the managed care setting even though plans are at a disadvantage with respect to the federal rebate.

In addition, the report also made the following findings with respect to Medicaid managed care and prescription drugs:

- The pre-rebate ingredient prices paid for medications are similar in both FFS and managed care settings. Due to federal rebate that is triple those received by the health plans, the average post-rebate price of a given drug in the FFS setting is 16 percent lower than the same drug in the managed Medicaid setting.

[1] http://www.chcs.org/grants_info3963/grants_info_show.htm?doc_id=206522

- Managed care organizations (MCOs) typically pay much lower dispensing fees to pharmacies than do state Medicaid agencies. This lowers the FFS price advantage from 16 percent to 12 percent.

- MCOs further lower the average price paid for prescription drugs by influencing the mix of drugs vis-à-vis the mix that occurs in FFS. For example, 59 percent of MCO TANF prescriptions were for generic products, versus 50 percent of FFS prescriptions. Once the mix of drugs is taken into account, the overall price advantage of the FFS setting is only six percent.

- The TANF usage rate of drugs is 15-20 percent lower in the managed Medicaid setting than in FFS Medicaid.

- Overall TANF per member per month costs of the pharmacy benefit are 10 to 15 percent lower in the capitated (Medicaid MCO) setting than in FFS Medicaid. Thus, while health plans start out roughly at a price disadvantage of 15 percentage points due to the rebate differential, health plan benefits management efforts completely turn the equation around. The MCOs end up paying significantly less than FFS in terms of final PMPM pharmacy costs.

CHCS concluded that these findings may have several policy implications. For example, the findings appear to support including – rather than carving out – pharmacy in the MCOs' capitation rates. The findings also can serve as a starting point in quantifying the level of system savings that might be achieved by extending the FFS rebate to MCOs, as well as the level of FFS savings that might be achieved if states adopt some of the pharmacy benefits management techniques that are proving effective in the capitated Medicaid setting.

Congress Should Equalize the Medicaid Drug Rebates Between Medicaid Fee-for-Service and Managed Care

Created by OBRA 1990, the Medicaid Drug Rebate Program requires drug manufacturers to have rebate agreements with the Secretary of Health and Human Services for States to receive federal funding for outpatient drugs dispensed to Medicaid patients as part of their fee-for-service programs. At the time the law was enacted, health plans were excluded from access to the drug rebate program. In 1990, only 2.8 million people were enrolled in Medicaid health plans and so the savings lost by the exclusion were relatively small. Today, *12 million people are enrolled in capitated health plans.* Even though managed care plans pay higher prices for drugs due to the inequities of the drug rebate, they still pay less on a PMPM basis because of their better utilization management techniques. Equalizing access to the drug rebate would allow plan to pay even less for drugs on a PMPM basis.

Through the drug rebate, States receive between an 18 and 20% discount on brand name drug prices and between 10 and 11% for generic drug prices. According to a study by the Lewin Group for ACAP and other Medicaid-focused health plans, Medicaid-focused MCOs typically only receive about a 6% discount on brand name drugs and no discount on generics[2]. Because the Medicaid fee-for-service program is required by law to get the best and lowest price via the drug rebate mechanism, Medicaid managed care plans end up paying higher prices for the drugs even though they are also serving Medicaid beneficiaries. That is why ACAP believes that equalizing the drug rebate program between fee-for-service and managed care provides States with the best of both worlds – allowing plans to continue managing drug utilization while also obtaining access to the lower costs drugs through the drug rebate.

MCOs' Lack of Access to Medicaid Drug Rebate May Force States to Make Bad Long Term Budget Decisions

The inability of health plans to access the Medicaid drug rebate has caused some states to carve prescription drugs out of the capitated payments to the plans to retain access to the drug rebate – thereby eliminating the ability of health plans to engage many of the innovative drug utilization programs that maintain continuity and appropriateness of care and control drug costs. Currently 12 states[3] with a combined Medicaid managed care population just below three million carve drugs out of their capitation payments.

In November 2003, the Lewin Group issued a report entitled *Analysis of Pharmacy Carve-Out Option for the Arizona Health Care Cost Containment System* for

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[2]http://www.communityplans.net/publications/Working%20Papers/Lewin%20II%20report%20FINAL%20REPORT.pdf

[3] Those states are Delaware, Iowa, Maine, Nebraska, New Hampshire, New York, North Carolina, North Dakota, Tennessee, Texas, Utah, and West Virginia.

the Center for Health Care Strategies.[4] In their report, Lewin found that "Pharmacy costs in the AHCCCS program are the lowest that have been achieved in the Medicaid setting. Arizona's PMPM costs for aged, blind, and disabled eligibles were found to be the lowest in the nation, 38 percent below the national Medicaid average (after taking into consideration the large rebates other states receive)...Based on our qualitative and quantitative research, **we attribute this performance to the AHCCCS health plans**."

At the time of the report, Arizona had been considering carving prescription drugs out of the control of the Medicaid health plans in an effort to generate savings from the Medicaid drug rebate. Lewin addresses this in their report...

> *"In modeling the impacts of a carve-out, we estimated the incremental value of the federal rebates under a carve-out to be approximately $40 million annually. (This incremental value is the amount by which the federal rebate revenue would exceed the rebate revenues obtained by the health plans in FFY 2002.)...Our best estimate is that offsetting costs (including administrative costs and costs associated with a changing drug mix and volume) will exceed the $40 million in rebate savings,* ***resulting in net annual costs of a carve-out of approximately $3.7 million in state funds****. At a projected $7 million, net administrative costs are significant but not the driving cost factor associated with a carve-out. The key costs projected are those associated with a more expensive volume and mix of drugs that are likely to result under a carve-out."*

In short, Lewin found that Arizona would actually have lost money if it had carved prescription drugs out of the capitated payments to the plans because the State would have removed beneficiaries from the health plans' drug management programs and exposed them to less coordinated and managed systems of care.

Opportunity to Save Federal and State Governments Medicaid Dollars

We also believe that this proposal will generate savings for Federal and State governments. The Lewin study found that giving health plans access to the drug rebate could save Federal and State governments up to $2 billion in Medicaid savings over 10 years. ACAP actually believes that the savings could exceed $2 billion because more states are turning to managed care in their states and the report is several years old. We are prepared to continue working with the Congressional Budget Office to identify the scorable savings from the proposal.

As such, we believe that this drug rebate proposal can play an important role in the discussions that are currently being had in Congress about how to arrive at the $10 billion in savings that must be produced as a result of budget reconciliation. Although this proposal will not generate all of the savings, we believe that it can contribute to the savings or offset the costs of new Medicaid spending that may be included in the reconciliation package. Ultimately, we hope that this proposal will provide some relief to

[4] http://www.chcs.org/publications3960/publications_show.htm?doc_id=211308

Federal policymakers who are forced to make tough decisions about where to save money in Medicaid.

We also want to reiterate that there is no guaranteed benefit to the Medicaid health plans. In the most likely scenario, States will reduce the capitated payments to the plans to take advantage of the savings generated by the rebate. While we recognize this, we also hope that states will reinvest a portion of the savings generated under this policy change to provide for quality improvement initiatives to beneficiaries enrolled in Medicaid managed care plans. As partners with the States, we believe that this is a reasonable (although not mandated) position that will continue to help strengthen the Medicaid health plan delivery system.

Support Among State Policymakers and the Medicaid Managed Care Industry

In an effort to raise awareness of this proposal, ACAP has been very active in talking to Medicaid stakeholders about this proposal. We are very pleased with how well this proposal has been received. It has been endorsed by organizations representing both state government and the managed care industry, including the:

- National Governors' Association;
- National Association of State Medicaid Directors;
- Medicaid Health Plans of America;
- Association for Community Affiliated Plans; and
- National Association of Community Health Centers.

I have included several of these endorsement letters and policies at the conclusion of this statement. In short, we believe that this widespread support demonstrates that this drug rebate proposal is a common-sense idea that will modernize the program and help policymakers generating Medicaid savings without being divisive or threatening critical health care services.

Conclusion

At this time when Congress is forced to make tough decisions to identify savings in the Medicaid program, ACAP believes that this proposal to equalize Medicaid health plans' access to the drug rebate makes sense. This proposal will modernize the program, save billions of dollars in Federal and State Medicaid expenditures, and will not force the elimination of needed benefits or force beneficiaries off the rolls. Because of this, we urge the inclusion of this provision in any Medicaid reform or reconciliation language produced by the Senate.

This concludes my statement and I would be happy to answer any questions the Committee may have. Thank you.

Short Biography for Meg Murray, Executive Director
Association for Community Affiliated Plans (ACAP)

Margaret A. Murray, MPA, Meg Murray is the Executive Director of the Association for Community Affiliated Plans. Her previous experience with healthcare finance includes serving as the Medicaid Director for the New Jersey Department of Human Services, as the Senior Program Examiner for the Office of Management and Budget, and as the Senior Associate at the Alpha Center. She has also held public finance positions including Tax Legislative Analyst for Senator Bill Bradley and Revenue Director for the Massachusetts House Ways and Means Committee. She received her MPA from the Woodrow Wilson School of Public and International Affairs at Princeton University and her BA from Wellesley College.

ACAP Member Plans as of May 2005

Affinity Health Plan Ms. Maura Bluestone 2500 Halsey Street Bronx, NY 10461	Commonwealth Care Alliance Dr. Robert Master 30 Winter Street, 9th Floor Boston, MA 02108
Alameda Alliance for Health Ms. Ingrid Lamirault 1240 South Loop Road Alameda, CA 94502	Community Choice Health Plan Ms. Le'Dice Murphy 30 South Broadway Yonkers, NY 10701
AlohaCare Mr. John McComas 1357 Kapiolani Boulevard, Suite 1250 Honolulu, HI 96814	Community Health Network of Connecticut Ms. Sylvia Kelly 11 Fairfield Blvd. Wallingford, CT 06492
CareOregon Mr. David Ford 522 SW Fifth Avenue, Suite 200 Portland, OR 97204	Community Health Plan of Washington Mr. Darnell Dent 720 Olive Way, Suite 300 Seattle, WA 98101-9619
CareSource Ms. Pam B. Morris One S. Main Street Dayton, OH 45402-2016	Health Plus Prepaid Health Systems Mr. Tom Early 335 Adams Street, 26th Floor Brooklyn, NY 11201
Colorado Access Mr. Donald Hall 10065 East Harvard Street Denver, CO 80231	Health Right, Inc Ms. Patrina Fowler 1101 14th Street, NW Suite #900 Washington, DC 20005
Monroe Plan for Medical Care, Inc. Mr. Bob Thompson 2700 Elmwood Avenue Rochester, NY 14618	Hudson Health Plan Ms. Georganne Chapin 303 South Broadway, Suite 321 Tarrytown, NY 10591
Network Health Allan Kornberg 432 Columbia Street, Suite 23 Cambridge, MA 02141	Neighborhood Health Plan of Massachusetts Mr. James Hooley 253 Summer Street Boston, MA 02210
Total Care Mr. Ruben Cowart 819 South Salina Street Syracuse, NY 13202	Neighborhood Health Plan of Rhode Island Mr. Ernest Balasco, Interim 299 Promenade Street, Providence, RI 02908
Virginia Premier Health Plan, Inc. Mr. James Parrott P.O. Box 5307 Richmond, VA 23220-0307	

National Association of State Medicaid Directors

Policy Statement:
MCO Access to the Medicaid Pharmacy Rebate Program

Background

The Omnibus Budget Reconciliation Act of 1990 (OBRA '90) established a Medicaid drug rebate program that requires pharmaceutical manufacturers to provide a rebate to participating state Medicaid agencies. In return, states must cover all prescription drugs manufactured by a company that participates in the rebate program. At the time of this legislation, only a small percentage of Medicaid beneficiaries were enrolled in capitated managed care plans and were primarily served by plans that also had commercial lines of business. These plans requested to be excluded from the drug rebate program as it was assumed that they would be able to secure a better rebate on their own. Though regulations have not yet been promulgated, federal interpretation to date has excluded Medicaid managed care organizations from participating in the federal rebate program.

Today, the situation is quite different. 58% of all Medicaid beneficiaries are enrolled in some type of managed care delivery system, many in capitated health plans. Some managed care plans, especially Medicaid-dominated plans that make up a growing percentage of the Medicaid marketplace, are looking at the feasibility of gaining access to the Medicaid pharmacy rebate. However, a number of commercial plans remain content to negotiate their own pharmacy rates and are not interested in pursuing the Medicaid rebate.

Policy Statement

The National Association of State Medicaid Directors is supportive of Medicaid managed care organizations (MCOs), in their capacity as an agent of the state, being able to participate fully in the federal Medicaid rebate program. To do so, the MCO must adhere to all of the federal rebate rules set forth in OBRA '90 and follow essentially the same ingredient cost payment methodology used by the state. The state will have the ability to make a downward adjustment in the MCO's capitation rate based on the assumption that the MCO will collect the full rebate instead of the state. Finally, if a pharmacy benefit manager (PBM) is under contract with an MCO to administer the Medicaid pharmacy benefit for them, then the same principal shall apply, but in no way should both the MCO and the PBM be allowed to claim the rebate.

Approved by NASMD June 24, 2002

Ensuring Access to Better Healthcare

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April 7, 2005

Margaret A. Murray, Executive Director
Association for Community Affiliated Plans
2001 L Street, NW Suite 200
Washington, DC 20036

Dear Ms. Murray:

The Medicaid Health Plans of America (MHPOA) supports your proposed initiative to provide Medicaid managed care organizations with access to the Medicaid drug rebate found in Section 1927 of the Social Security Act. We support this effort and urge Congress to enact this common sense provision.

Medicaid Health Plans of America, formed in 1993 and incorporated in 1995, is a trade association representing health plans and other entities participating in Medicaid managed care throughout the country It's primary focus is to provide research, advocacy, analysis, and organized forums that support the development of effective policy solutions to promote and enhance the delivery of quality healthcare. The Association initially coalesced around the issue of national healthcare reform, and as the policy debate changed from national healthcare reform to national managed care reform, the areas of focus shifted to the changes in Medicaid managed care.

Your proposal to allow Medicaid managed care organizations access to the Medicaid drug rebate makes sense given the migration of Medicaid beneficiaries from fee-for-service to managed care since 1990. Increasingly, states have not been able to take advantage of the drug rebate for those enrollees in managed care, thus driving up federal and state Medicaid costs. The savings estimated in the Lewin Group study are significant and may help to mitigate the needs for other cuts in the program. In addition, it demonstrates a proactive effort to offer solutions to improving the Medicaid program. We applaud this effort.

MHPOA is proud to support this legislative proposal and will endorse any legislation in Congress to enact this proposal.

Sincerely,

Thomas Johnson
Executive Director

Excerpt from National Governors Association's June 15, 2005
***Medicaid Reform: A Preliminary Report* (pages 3 – 4):**

"*Governors believe that the burden of reducing Medicaid expenditures for prescription drugs will require a multi-prong approach and should include savings proposals that affect both drug manufacturers and retail pharmacists, as well as increase state utilization management tools that decrease inappropriate prescribing and utilization. It is critical that states maintain and enhance their ability to negotiate the best possible prices with the industry.*

There may be benefits of using ASP or other calculations as a reference price, because increased transparency of drug costs can serve to decrease total costs, especially if there is more flexibility with respect to dispensing fees (they should not be tied to a percentage of the cost of the drug dispensed, for example.)

This proposal should be modified in several ways…

- *Allowing managed care organizations to access Medicaid rebates directly for the Medicaid populations that they serve.*"

The CHAIRMAN. Thank you very, very much.

I apologize, Mr. Russo, that I was away during your testimony. I truly want to express to all of you how much I value your being here and your contribution to the Senate record. I hate being pulled away from these because I do gain much from it and you add much to it. So to all of you for your sacrifices in being here, we are very thankful. Because I missed yours, I may ask you questions you already answered in your testimony. But you have identified a number of loopholes in Medicaid that have allowed individuals to transfer assets to achieve premature Medicaid eligibility with limited risk of penalty. In your experience, how prevalent are these practices?

Mr. RUSSO. Chairman, first I would like to say on this issue that elder law attorneys are charged with an ethical duty to advise clients in their best interests. In fact, it would be malpractice not to.

Aggressive Medicaid planning occurs when one uses loopholes. In order to save money, these loopholes need to be closed. We have not had a chance to score the six solutions that we are proposing, but we are confident that they would result in savings that would be a much better approach than creating these much harsher changes that truly will harm seniors if we were to change the look-back period to 5 years or to change the penalty start date to the date of application.

The CHAIRMAN. Your testimony had these six loophole closures in them?

Mr. RUSSO. Yes, in the written testimony, Chairman, we have the six. I mentioned three in my oral testimony, which were balloon annuities, self-canceling installment notes, and changing down the rounding-down rule consistently throughout the United States.

The CHAIRMAN. OK. What are the other three?

Mr. RUSSO. The other three would deal with the State recoveries on annuities, would deal with changing the treatment of when a transfer penalty starts, so it would be from the first day of the following month rather than in the month in which the transfer were made, so that is right now a State option that is available. Let's see, the sixth one—it will take a moment.

The CHAIRMAN. That is OK. We will find it. But in your experience—I do not want you to rat on your colleagues, but do attorneys widely employ these loopholes that you think are—

Mr. RUSSO. Well, Chairman, I do not think it is ratting out other attorneys. Attorneys are good people who do good work. We serve our clients. We provide a holistic approach to planning. It is not simply about Medicaid. Most seniors, if not all seniors, who come into our offices—and I am speaking from my own practical experiences—come in out of fear, in crisis, concerned that they are going to lose their autonomy, their independence, that they are going to be pushed into a nursing home with no options, that there will be no one to care for them. They have loved ones that they care about. How will money be used for them if it is gone? How do we take care of a spouse or a child who is disabled? How do we get quality care?

So people are coming in because we have pushed them into a corner where they have no choice but to look at this Medicaid program to help them get through this very difficult time in their lives.

The CHAIRMAN. What is the loophole that is most commonly abused?

Mr. RUSSO. Well, I think loopholes result in aggressive planning. "Abuse" is a pretty strong word, but I appreciate that that is the term you are using. When we look at these balloon annuities and the self-canceling installment notes, they are simply inappropriate for seniors to be engaging in utilizing those planning tools. Annuities now are marketed as the answer to how to get onto Medicaid. That is really inappropriate.

I think we can change some of the existing rules that allow for aggressive planning, like changing the rule on rounding down so we can round down a partial transfer, which is the current rule. For example, if someone transferred $9,999 in a State with a $5,000 regional rate or divisor, that results in a penalty period of 1.99. In a State that rounds down, it becomes 1 month. So, in effect, you were able to double up how much you transferred with only 1 month of penalty.

The penalty should stand at 1.99. It should not be rounded down. States have the option. I think the Federal Government should mandate that change.

The CHAIRMAN. OK.

Mr. RUSSO. We also look at—the sixth solution we suggested was to outlaw one from being able to purchase a life estate, the right to live in a house, for example. When someone purchases a life estate, a parent, let's say, purchases a life estate in the child's home but has no intention of living there, it makes the asset disappear, and that is not what was intended here.

The CHAIRMAN. Right.

Mr. RUSSO. We need to be fair to seniors in this program. We need to be clear about what the rules are. But we should not penalize them any further because right now we discriminate against them because they happen to have the wrong disease.

The CHAIRMAN. I think you told me. Are you from New York?

Mr. RUSSO. Yes, I am.

The CHAIRMAN. My question has nothing to do with the New York Times article, but I assume you saw those.

Mr. RUSSO. Yes.

The CHAIRMAN. I hold up my own State as a great example on home and community care options that are much less expensive. Does New York have such a thing?

Mr. RUSSO. Chairman, we have the best home care program in the country through a non-waiver program, which actually provides home care to thousands and thousands of seniors. We think it is a terrific idea.

As we look at the Medicaid program as a whole, it would be terrific to start looking at alternatives that focus on keeping people at home. That is where they want to be. No one comes into my office and says, "I want to go to a nursing home." Every person in a nursing home wants to get out of that nursing home. They really want to be home and in the community and independent.

The CHAIRMAN. The next panel are the nursing home people, by the way. No, I am kidding. [Laughter.]

Your point is very well taken. Are you familiar with reverse mortgages? What do you think of the impact of those?

Mr. RUSSO. Chairman, I think reverse mortgages can be very helpful in terms of allowing people to stay at home while tapping the equity in their home, using that money for care that they otherwise could not afford. But there is a concern, and the concern is that, No. 1, they are very expensive. To obtain a reverse mortgage, the costs are very high. Also, when you are no longer living in the home, the reverse mortgage is called in. So if an individual went to a nursing home, it would automatically force a sale of that home to pay back the reverse mortgage, and that is particularly upsetting to people because people feel, seniors feel that if they fracture a hip and they go to the hospital and then they enter a nursing home for rehab, their goal is to come home.

The CHAIRMAN. Sure.

Mr. RUSSO. Where are they going to go to if they have to sell their house when the reverse mortgage is called in?

The CHAIRMAN. If they lose their house, they kind of lose hope, don't they?

Mr. RUSSO. Yes, they do.

The CHAIRMAN. So that is not an option you would recommend that Congress consider?

Mr. RUSSO. Absolutely not to mandate that.

The CHAIRMAN. You have spoken critically now—and I am sure you did in your testimony; again, I apologize I was not here for it. But you think that the look-back provision is just unduly arbitrary and quite harsh?

Mr. RUSSO. Yes, the example I would give there—and it was Mrs. Anderson in my example—she was in a situation where her husband controlled the finances and transferred $25,000 4 years before she later needed to apply for Medicaid. She cared for him. He passes away. She has Alzheimer's. She knows that the money went to various causes, like paying for repairs on the house or a donation to the church capital campaign. But she has no records. She has no ability to know what exactly happened. She is going to be denied Medicaid if that look-back period is extended to 5 years.

I challenge anyone in this room to come back tomorrow and report to you every transaction that they have made in the last 3 years. It is difficult now for seniors. Five years is a burden that should not be placed on them.

The CHAIRMAN. Can you speak to asset caps or did you speak to that in your testimony?

Mr. RUSSO. The proposal by the National Governors Association?

The CHAIRMAN. Yes, it is another option that would make all assets countable for purposes of determining Medicaid eligibility and would set a limit on the total value such that assets in excess of that amount must be liquidated and applied toward health care services.

Mr. RUSSO. I think that any alternatives we can look at are helpful. I have real concerns here with this one because this is part of a bigger package; that proposal also deals with changing the penalty start date and also deals with extending the look-back period, which we oppose. So I am a little apprehensive about it.

One size does not fit all around the country. Nursing homes in New York cost between $120,000 and $150,000 in the area where I practice. So—

The CHAIRMAN. That is about double the rest of the country.

Mr. RUSSO. Right. So we need to have a program that allows us to take into account the differences around the country in the cost of care and people's situations. At this point the National Academy of Elder Law Attorneys has not had a chance to analyze it for me to be able to speak in more detail about it, but I am sure we will be doing that, and we welcome the opportunity to give you our thoughts.

The CHAIRMAN. Fair enough. Thank you very, very much.

Mark, thank you for coming. It is good to see you. I came in in the middle of your testimony, and a question I have—I was not in the legislature when Governor Kitzhaber passed this proposal on testing drugs and greater State control over their acquisition for Medicaid. But I understand subsequent to his administration that it was changed. Is that correct? If it was changed, did it improve care and did it reduce savings?

Mr. GIBSON. Mr. Chairman, you are correct, it did change—before I go into that, just it is a pleasure to be here, and I appreciate the invitation.

The CHAIRMAN. I only ask this for my own edification because I am interested from your perspective, and perhaps Governor Kitzhaber's; what has been the result of that change?

Mr. GIBSON. Right. The change was to repeal the State's ability to have prior authorization for its preferred drug list. The prior authorization process the State ultimately adopted, which resulted in a significant increase in the savings realized, was when a physician wanted to prescribe a drug that was not the preferred drug in the class, they or a member of their staff simply had to call a number and listen to a message about the evidence relative to the drugs in that class.

As a result of that simple intervention, Oregon was the State that I mentioned that experienced about a 5-percent drop over the period of time that that prior authorization was in place, about a 5-percent drop in its overall drug spend, by just applying that prior authorization process to four drug classes.

The CHAIRMAN. Just the education.

Mr. GIBSON. Just the education and just the requirement that there be contact with that education.

The CHAIRMAN. So the change then really didn't reduce much in terms of what the State has been saving on drugs.

Mr. GIBSON. The change did reduce what the State has been saving because that is no longer—the State is no longer able to require the physician to call and get that information prior to receiving an exception from the preferred drug list. So we typically see about a 30-percent use of preferred drug when there is not an intervention such as a prior authorization.

The CHAIRMAN. The total drug savings from this program, what did you lose from the change?

Mr. GIBSON. I have not seen exact figures on the reduction of savings from the change, although the internal research that the agency is doing and the folks that I had contact with there—I would be happy to put you in touch with them—have said that immediately upon suspension of the prior authorization, the trends

began to go back the other way. I do not have a firm number at that point.

The CHAIRMAN. So you would not recommend that change then to other States?

Mr. GIBSON. I would not, no.

The CHAIRMAN. OK. I was very intrigued by your comment, your answer to the Vioxx question, but what I think I heard you say is that you did not have to do any trials on it, you did not have to do any tests on it; you just read the material and it reflected the downstream difficulties in health and saved a whole lot of people a whole lot of grief.

Mr. GIBSON. That is correct, Mr. Chairman. The study in question is called the VIGOR Trial, and within that there was an unexplained increase in adverse cardiac events among people who were taking Vioxx.

Now, when we looked at this information, at this evidence, and we looked at the size of the trial, the design of the trial, and the results, it was a well-done, well-randomized, well-reported, double-blind trial, and it came out with this unexplained increase in cardiac adverse events. As a result of highlighting that to our States, even though we did not—our process, our research process, does not recommend a drug, we did highlight this risk in the report, and most but not all of our States said that this is too much a risk for us, we are not going to include Vioxx as one of our preferred drugs.

The CHAIRMAN. Mark, since, you know, Oregon has had such, frankly, a positive result with the Drug Effectiveness Review Project, do you think Congress should leave this up to the States, or as part of Medicaid reform, should we be mandating this kind of a thing?

Mr. GIBSON. Mr. Chairman, I think that is a great question. I think that the States have done a terrific job of blazing a trail here. As we learn more about doing systematic reviews of drugs within classes, we recognize that there are ways to continually improve this work, which ultimately becomes a bit of a resource issue.

Now, resource in terms of getting the right research done is modest compared to the expenditures. In our home State, we spend in the neighborhood of $480 million in Medicaid on drugs—or excuse me, in a biennium on drugs, and the entire cost of the Drug Effectiveness Review Project was $4.2 million over 3 years, and shared among 16 organizations that comes out to be a fairly nominal investment in getting good evidence.

On the other hand, these organizations all faced their resource constraints. They are primarily Medicaid programs. So to continue to improve this and to continue to address some of the criticisms that come out of what we have done, I think there is a resource issue that the Federal Government could be helpful on.

On the other hand, I would say that I think the States have done a terrific job, and, you know, some very close collaboration between the two that maintains the autonomy of the process could be very useful.

The CHAIRMAN. How many States are in your program?

Mr. GIBSON. There are currently 14 States.

The CHAIRMAN. They have all enjoyed the same benefit that Oregon has seen?

Mr. GIBSON. Mr. Chairman, they use the information in different ways, so their benefits change from State to State. North Carolina, for example, uses the information to inform and educate their practitioners about the relative effectiveness and risk profile of drugs within these various classes. So they use it primarily as a prescriber education process. They couple that up with cost information so that their prescribers can then consider cost as they make these decisions. But they start out knowing what the relative or the comparative benefit is, too. Other States already had prior authorization processes run by commercial firms, but their concern was that they might not be getting the depth of analysis around these drugs that they really needed to ensure that they were not making a penny-wise, pound-foolish decision. So they have come into the project from the standpoint of saying let's go to a more thorough, more transparent, and more open process, one that we can go to our medical community or we can take to our advocacy community and say here are the steps that we went through to analyze these drugs, this is what we are basing our determination of their effectiveness on, where you do not have that kind of transparency with commercial products.

The CHAIRMAN. These are States outside of the 14 that are part of your group?

Mr. GIBSON. Well, there are States outside of the 14 that are in the group that are using the information because it is in the public domain, and we have had several States come up and say, "Gosh, you guys are doing a great job, thanks a lot."

The CHAIRMAN. Are there any States outside your group who are doing anything different that is showing to be effective in savings and in efficiency?

Mr. GIBSON. Yes, but they do not have the transparent clinical perspective that we are able to bring to it.

The CHAIRMAN. Because they rely on commercial sources.

Mr. GIBSON. Yes.

The CHAIRMAN. OK.

Mr. GIBSON. Mr. Chairman, I would just add, to clarify my comments, that if it is simply about money, then you do not need our product. If you really want clinical certainty, if you want the best analysis of the cumulative evidence around these drugs, then I think you should participate or at least utilize the information that the collaboration brings forward.

The CHAIRMAN. Why do you think the FDA and CMS perhaps were so late on the Vioxx issue?

Mr. GIBSON. Mr. Chairman, there is a lot of ground to cover there.

The CHAIRMAN. I am getting you in trouble here, Mark.

Mr. GIBSON. Yes, well, I would just say that I think one of the things that sets our process aside from others is that there is a real firewall between our researchers and the industry. That is not to say that we do not utilize the best evidence the industry can give us. We reach out to the industry. We solicit any evidence they believe pertains to the questions that we are researching. They provided us with hundreds of dossiers on these drugs and thousands of pages of research information that we analyzed, just as we do any information we find on our own.

But we do not have an ongoing intimate dialog between the folks that are doing the research and the industry, and we do not receive support from the industry. I think there are a number of things that have happened over the years with the FDA that may have—

The CHAIRMAN. Makes them a little slower on the trigger?

Mr. GIBSON. Yes, just—yes.

The CHAIRMAN. I understand what you are saying. Thank you very much.

Meg Murray, as I understand your testimony, you have spoken between Medicaid managed care plans and fee-for-service plans and that there are some savings in managed care that are not being realized in fee-for-service. Can you discuss some of the things that your health plans do to manage drug utilization compared to State fee-for-service plans? What would you have us take into this budget reconciliation when we focus on that area for savings?

Ms. MURRAY. In many cases, what our plans are doing is just more aggressive use of what States can do under the drug rebate law. So our plans are much more aggressive on generic utilization. For instance, our plans have almost 60 percent of their prescriptions are generic, compared to only about 50 percent by the State programs.

More specific examples are our plans do require—they promote first-line antibiotic use more often than the States do. They note through the data excessive use of inhaler medications for asthmatics instead of the controller medications. So a lot of what they are doing is what States can do, but just they are much more aggressive about it.

The CHAIRMAN. Perhaps you heard that CBO expresses concern that health plans already have access to the drug rebate. Can you address that issue a little bit more?

Ms. MURRAY. Sure. Our health plans do get a rebate. Many of them contract with pharmacy benefits managers who in turn contract with manufacturers to get a rebate. So, yes, our plans do have access to a drug rebate, but they do not have access to the Federal rebate, which, I was pointing out, is much more—almost three times better than what they can get on their own through private contracts with the manufacturers.

The CHAIRMAN. Since managed care plans are already operating at a lower cost than fee-for-service programs, would access to the Medicaid drug rebate provide your plans with even greater savings, in your view?

Ms. MURRAY. Yes. By increasing the rebate, that effectively lowers the price of individual drugs to our health plans, thereby further lowering the per member per month cost. This, as I said, will be passed on to the States through the lower capitation rates.

The CHAIRMAN. Then that savings is what, 16 percent?

Ms. MURRAY. The net savings would be the difference—well, in terms of gross dollars, it is potentially up to $2 billion over 10 years.

The CHAIRMAN. You are starting to talk real money.

Ms. MURRAY. That would be split between the States and the Feds.

The CHAIRMAN. The Fed.

I think I have asked my questions. Meg and Mark and Vincent, thank you so very, very much. This has been a helpful hearing for me, and we are grateful for your time, and to our audience, we appreciate your patience with the Senate schedule.

We are adjourned.

[Whereupon, at 4:50 p.m., the committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR SUSAN COLLINS

Mr. Chairman, the FY 2006 budget resolution includes $10 billion in reconciliation instructions for the Finance Committee. I therefore want to thank you for holding this hearing to examine options for meeting those instructions, while still preserving the critical Medicaid safety net that keeps 54 million of the most vulnerable Americans from falling through the cracks of our nation's health care system.

Medicaid is the sole source of health insurance coverage for 40 percent of our nation's poor, including one in four American children. It also finances the health and long-term care needs for about 20 percent of individuals with serious disabilities and helps pay for the care of 60 percent of our nation's nursing home residents. Financed jointly by the federal and State governments, Medicaid is now the nation's largest health care program, with annual costs exceeding $300 billion.

Medicaid is costly because it serves those citizens with the most complex care needs and chronic problems requiring long-term care. Moreover, it is not just our most expensive health care program. It is also the most complex because it is structured and administered differently in each of the 50 states and the District of Columbia. In fact, there is an old saying among policymakers: "If you've seen one Medicaid program, you've seen one Medicaid program."

Medicaid is also one of our fastest growing programs, putting substantial pressure on both State and federal budgets. Moreover, with the aging of the baby boomers, those costs are certain to rise even more rapidly, threatening the long-term financial sustainability of the program. It is therefore important that we begin now to work to identify ways to stabilize and strengthen Medicaid.

As part of that process, it is critical that we take the time to learn how the current Medicaid program works and to examine thoroughly the various options for reform. Today's hearing gives us an opportunity to focus on two specific components of the program: how Medicaid pays for prescription drugs and considers assets in determining eligibility.

Again, Mr. Chairman, thank you for calling this hearing, and I look forward to working with you on a plan to ensure that Medicaid can continue to fulfill its commitment to providing quality care to poor, elderly, and disabled Americans in a way that is financially sustainable.

American Health Care Association

WRITTEN STATEMENT
Of
HAL DAUB
President and CEO of the American Health Care Association (AHCA) &
The National Center for Assisted Living (NCAL)

For the U.S. Senate Special Committee on Aging

July 20, 2005

"Sound Policy, Smart Solutions: Saving Money in Medicaid"

On behalf of the American Health Care Association (AHCA) and National Center for Assisted Living (NCAL), we thank Chairman Smith and Ranking Member Kohl – and every member of the Senate Special Committee on Aging – for conducting this hearing on the importance of saving Medicaid resources, utilizing our resources in the most efficient, effective manner possible, and how, ultimately, we can help strengthen the healthcare safety net for our nation's frail, elderly, and disabled seniors and people with disabilities.

This hearing is important and timely – not just because of the budget and healthcare policy implications, but because of the decisions that are ultimately made regarding necessary, comprehensive reform that will have far-reaching implications on the lives of nearly every American.

In evaluating the means, methods, and concepts we can employ to save Medicaid resources – and to use them in the manner intended for our most vulnerable citizens – we see three primary areas of opportunity: Medicaid estate planning, tax incentives to encourage the purchase of long term care insurance, and home equity conversion concepts.

Medicaid Estate Planning

Medicaid was never intended to become the nation's primary long term care financing program and is not sustainable if the baby boom generation uses it as such. While we must preserve Medicaid as a safety net program, we must also take steps to encourage people who are able to otherwise fund their own long term care.

Medicaid is a means-tested public assistance program. However, the eligibility rules and the statutory prohibition on asset transfer have not apparently achieved the desired end of care for the truly eligible for at least two major reasons: first, the prohibition itself is not adequate; and, second, the apparent proliferation of Medicaid estate planning techniques that circumvent the prohibition.

The situation results in the inappropriate use of state Medicaid funds for individuals who should not qualify for such public assistance and the concomitant lack of funds for appropriate reimbursement to providers for care of the truly needy. Thus, both the state and Medicaid providers such as nursing facilities are negatively impacted.

The problem for nursing facilities is exacerbated by state rules that delay and then often deny payment to nursing facilities – due to various reasons, including asset transfers that have violated the Medicaid statute, until the state process – often long and drawn out – for determining an individual's eligibility has been completed. Some states have sought to change the date on which penalty periods resulting from improper asset transfer begin. In these cases, a nursing home may admit an individual as a private paying resident, will receive private funds for the cost of care until such funds run out and the penalty period begins, and then will continue caring for the individual when there is no source of payment. Such a period could last many months. Nursing homes will have no option due to a combination of law and reality other than to absorb the cost of care of these residents. Federal law prohibits nursing homes from requiring a third-party guarantee of payment upon admission; thus, there is no other party to which to turn. Surely, nursing homes were not intended to provide the entire cost of care while this is settled.

AHCA/NCAL supports additional policy and efforts that both help states retain Medicaid funds for the truly needy and help providers to receive reimbursement for care that has been provided.

On the state level, the look back period is one of the weakest links in the asset transfer law and should be lengthened. In addition, a variety of Medicaid estate planning mechanisms – trusts and annuities, for example – have been developed to circumvent the legislative asset transfer rules. These permit middle to higher income individuals to make funds disappear through asset transfer and conversion, which could and should be used to support them when they need long term care services.

Thus, AHCA/NCAL supports the following policy positions aimed at assisting states and providers to preserve Medicaid funds for those truly in need:

- Support Section 1115 waiver applications to increase the look back period from 3 to 5 years, but leave the starting date of the penalty period as currently provided in law, and close the loopholes in law that enable individuals to use Medicaid estate planning techniques to circumvent asset transfer prohibition and eligibility rules;

- Eliminate the regulatory prohibition on a third party guarantee of payment to the facility as a condition of admission or expedited admission, or continued stay in the facility; and,

- Change the state policy and process for determining eligibility of individuals for Medicaid so that exposure to inappropriate loss of payment for the facility is eliminated or minimized. The President's FY 2005 budget included a proposal to establish a State Medicaid option allowing presumptive eligibility for institutionally-qualified individuals who are discharged from hospitals into the community.

We argue that presumptive eligibility should apply to all provider categories so that availability of the presumption would not skew an individual's choice of care site, which should be driven by clinical considerations.

However, at a minimum, the facility provider should be held harmless in the event that Medicaid eligibility is denied due to an asset transfer that violates Medicaid law, i.e., there is no ability to recoup a state payment made to the provider by the state.

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The state, in effect, pays the provider and assumes responsibility for recouping the money from the beneficiary; and the state must make an eligibility decision within 30 days of the application of the resident and facilitate discharge and relocation of the individual if reimbursement is denied.

If the state takes longer than 30 days to make a decision, payment is guaranteed to the provider so long as the provider must furnish services to the individual.

Tax Incentives to Encourage the Purchase of Long Term Care Insurance

In recent congressional sessions, legislative efforts to expand the utilization of insurance through tax incentives have found growing support. In addition to tax credits, AHCA/NCAL has supported an "above-the-line" deduction to make the deduction available to a maximum number of Americans.

We continue to support such measures today but recognize that the cost to the federal government has been a hurdle for congressional passage of the legislation. Although he has supported it in the past, we were disappointed that the President did not include a similar provision in this year's budget. Such solutions must allow the nation and its citizens' to move beyond today's pay-as-you-go financing system to one that encourages, supports, and protects individuals who choose to plan for their own long term care needs through private insurance and other financial means, while preserving Medicaid as a safety net program.

Home Equity Conversion and Other Resources

Other proposals being advanced involve home equity conversion, long term care annuities, and inclusion of long term care policies in cafeteria plans. While encouraging citizens to utilize long term care insurance alone won't save the Medicaid program from collapse – these and family caregiver exemptions and credits are all elements that could be combined with the Long Term Care Partnership Plan into a comprehensive national long term care policy.

Home equity conversions such as reverse mortgages are particularly intriguing. According to the National Council on the Aging, 48% of America's 13.2 million households age 62 and older could utilize $72,128 on average from reverse mortgages. The value is that these funds are available immediately and could go a long way to pay for help at home and for retrofitting the home to make it safer and more comfortable. These funds could also be used to purchase long term care insurance, or for assisted living or nursing home care for an ill spouse while the well spouse remained in the family home. We are aware of the limitations in utilizing reverse mortgages to fund long term care expenses. Despite the current limitations, the equity that many seniors possess could help them tremendously with their needs and their desire to remain in their homes. We would like to work with Congress to find creative ways to help seniors tap into this resource.

Mr. Chairman, in any discussion on how to go about saving Medicaid resources, it is essential to discuss the growing importance and utilization of home and community based care services (HCBS) throughout America. At the state level, expansion of HCBS care is among the most significant developments in the context of budgets as well as overall policy.

In an attempt to grant more flexibility to states, President Bush has proposed decreasing or eliminating hurdles that states currently face in obtaining approval for their home and community based services

(HCBS) waivers. The stated purpose of the waiver is to help curb state spending, while also providing more choices to seniors and people with disabilities. Similarly, the National Governor's Association (NGA) also supports improving access to home and community based care, both for better outcomes and for greater efficiencies.

Obviously, this has enormous appeal for state policy makers of both parties attempting to reign in Medicaid costs while simultaneously improving seniors' and people with disabilities' quality of life. Every one of us today can agree we would prefer to reside in our homes for the rest of our lives – and forego a move to a long term care facility.

But we are troubled by the development of a well-meaning, yet factually unfounded, mindset among elected officials, seniors' and disability advocacy groups, and the media that the simple answer to lower Medicaid costs and higher care quality will be found by rapidly shifting a significant population of seniors and people with disabilities out of facilities like nursing homes and intermediate care facilities for persons with mental retardation to home and community care settings.

While AHCA/NCAL always has, and always will favor individuals being able to receive necessary long term care services in the most appropriate setting, we are concerned that efforts to ostensibly "save" money may not serve that purpose and may drain essential funds away from care to seniors and persons with disabilities who require the services provided in nursing home settings.

Moreover, as the fastest growing population of seniors is those eighty and older, now is the time to be *strengthening* our facility-based care infrastructure – not *divesting* in our capacity to care for patients who will live longer and require higher acuity care. The nursing home of today is treating higher acuity individuals and the infrastructure has not kept up with that demand.

Most nursing homes around the country have aging buildings and infrastructure – and need upgrades to keep up with technology and the needs and choices of today's patients, such as private rooms. We may need less nursing home beds in the future, but we need more technology and physical plant changes to ensure the safest environment and the highest quality of life for patients and residents. Now is not the time to divert funds from facility care. Rather we should provide incentives to make changes that better serve seniors and people with disabilities who need 24–hour care in a facility.

AHCA/NCAL commends Chairman Smith and Ranking Member Kohl for their staunch support of a viable, effective Medicaid program, and we thank them for their leadership. We intend to continue offering positive solutions to reforming our nation's Medicaid long term care system – and we seek to work with you to help establish more choice for seniors and people with disabilities, and that injects more private dollars into the long term care system.

Demographic realities require a change in policy and a transformation in thinking. We must fundamentally shift the role of government – from government simply paying for services to government helping individuals save and plan for their own long term care needs, while still preserving the Medicaid program as a safety net for those who truly need it.

As we work to strengthen every citizen's future ability to prepare for their retirement, we urge this Committee to further investigate and address the issues we have discussed today. Thank you, Mr.

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Chairman, for the opportunity to submit our testimony, and we look forward to working productively and cooperatively with this Committee to help strengthen retirement security for every American.

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