MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Thursday, March 10, 2005
10:03 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
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P R O C E E D I N G S

MR. HACKBARTH: Good morning. Before we begin let me just talk about the agenda of bit for the morning and immediately after lunch. We've done a little bit of rejuggling of the agenda.

On the published agenda the first item is Medicare Part D: Access, cost and quality issues. And then we move to Medicare Advantage issues. What we're going to do is take up a piece of the Part D discussion, namely the piece related to the premium setting process.

And then we will move the other Part D issues to immediately after lunch, for example, the discussion of the grievance and appeals issues.

The reason for splitting them that way is that we thought that the premium setting issues conceptually were linked to some of the Medicare Advantage issues that we're going to take up about how to establish appropriate payments for private plans. And so we thought it might be helpful and clearer if we proceeded that way.

So Part D premium setting issues and then Medicare Advantage premium setting issues and so on, with the remainder of the Part D issues immediately after lunch.

With that preface, Rachel.

DR. SCHMIDT: Good morning.

As one of our chapters in the June report to Congress, we're looking at several aspects of implementation of Medicare's new outpatient prescription drug benefit. As Glenn mentioned, Joan is going to discuss formulary exceptions, grievance and appeals issues later today. But right now I'm going to describe our ongoing work on geographic variation in drug spending and the process by which Part D premiums will be set.

The motivation behind this work really stems from the same sorts of issues we've talked about with respect to regional variation in Medicare's medical benefits under Parts A and B. We know that program spending for Parts A and B varies quite around the country and that higher spending regions do not necessarily have higher quality or better outcomes. However, we don't as much about those questions when it comes to prescription drug spending by the Medicare population.

For our longer term research agenda, we hope to address question such as those on the slide as they relate to Medicare beneficiaries. Obviously, we can't answer these

difficult question in much detail by June. However, we do plan to at least begin addressing the first and last bullets on the slide that are highlighted, and I'm going to walk you through some preliminary work toward that end.

Has everybody found the paperwork? It's kind of midway through the group on Part D at this point.

Our approach for this research is as follows. First, we looked at how the MMA envisions using private plans to deliver the Part D drug benefit. We also looked at how CMS will pay plans and the methods that the MMA calls for in calculating enrollee premiums. In this presentation, I will show you some publicly available data to look for evidence of geographic variation in drug spending for the Medicare population. For the future, we may also analyze some variation in drug spending for a sample of privately insured Medicare beneficiaries.

First, let's talk about Part D's approach to delivering an outpatient prescription drug benefit. It will rely on private plans, that includes stand-alone plans and Medicare Advantage prescription drug plans, to deliver benefits in 34 different regions around the country. Those plans will be at risk for the benefit spending of their

enrollees.

The MMA used this approach in order to give plans incentive to control growth in prescription drug spending. Private plans must offer a standard benefit or one that is actuarially equivalent to it within some specific constraints and Medicare will subsidize nearly 75 percent of the cost of that standard benefit. Plans can also offer supplemental drug coverage but enrollees have to pay the full premium of that.

The MMA provides for several different kinds of subsidies under Part D to serve the purposes that are shown on this slide. Direct premium subsidies, individual reinsurance and risk corridors are aimed at encouraging beneficiaries to enroll in Part D and encouraging private plans to participate. In addition, Part D has subsidies that will pay for some of the cost sharing and premiums for individuals with low incomes and low assets.

As I mentioned, private plans, both stand-alone and MA, will be at risk for the Part D benefit spending of their enrollees, but there's still a lot of uncertainty as to how many Medicare beneficiaries will enroll and how many plans will enter the market and where.

The MMA specifies that in the event that beneficiaries do not have a choice of two plans, CMS must contract with a fall back plan that will not be at risk for the benefit spending of its enrollees.

This is just a reminder of the structure of the Part D benefits with its doughnut hole in the middle, where the enrollee pays 100 percent cost sharing. And also remember that the catastrophic coverage of the standard Part D benefit kicks in after the enrollee has paid, in 2006, $3,600 out of his or her own pocket with a few exceptions. That's called the true out-of-pocket provision.

Here's our nice color graphic showing you the 34 PDP regions that CMS announced at the end of last year. Many regions are made up of single states but a few states are grouped together into a single region, most notably a seven state region in the upper Midwest. CMS picked these groupings for some specific reasons. One overarching goal of the Agency was to minimize their need for fall back plans. CMS wanted to have enough Medicare beneficiaries in each region to make it economically viable for two PDPs to enter each market. That logic might argue for lots of grouping of states into single regions, but after it spoke

with potential plans CMS decided that it would use a larger number of regions because stakeholders were concerned that they could be exposed to too much financial risk if regions included too many people.

CMS also tried to group states that had similar levels of average drug spending.

Let's talk a bit about the bidding process and how that will work. Risk-bearing plans are to submit bids to CMS by the first Monday in June, which this year is June 6. To submit a bid, plans will have to estimate what monthly costs of standard benefits and plan administration will be for a standard beneficiary. That means one of average health.

Here's the way that CMS will make payments to plans. Plans will get three types of prospective payments each month. They'll get paid their risk adjusted bid amounts, minus the premium that their enrollees pay. They will also get an estimated amount of individual reinsurance for very high cost enrollees who have drug spending above the catastrophic threshold. And they'll get low income subsidies for those plan enrollees who are in Part D's low income subsidy program.

After the end of the year, CMS and the plan will then have to reconcile those payments with actual enrollment, actual spending above the stop loss, and so on. As you can imagine, that process is going to be very complex.

Now let me describe how enrollee premiums will be set. First, CMS will take most of the bids from the risk-bearing plans and calculate a national average bid where the average is weighted by each plan's projected enrollment. Enrollees will have to pay a percentage of that nationwide average bid. But in addition, if their plan happened to bid more than the nationwide average the enrollee must also pay the full difference between the two. Likewise, if their plan bids under the nationwide average, the enrollee gets credited with the full difference between the two. This is the basic reason why we may see different levels of premiums under Part D.

This approach to setting premiums means that Medicare will basically pay the same direct premium subsidy for each enrollee with the caveat that it will be risk adjusted.

Under the MMA, CMS has the authority to adjust for

geographic differences in drug prices. But at least for 2006, the Agency doesn't plan to make such an adjustment. Some analysts think that since many drug manufacturers, pharmacies and PBMs operate under national contracts, there's reason to believe that the underlying prices for the same drugs may not vary that much in different parts of the country.

The MMA does not allow for any kind of geographic adjustment related to differences in typical prescription drug use around the country. This means that people who live in parts of the country that tend to use more prescription drugs than average could pay higher Part D premiums than those who live in areas that use fewer prescription drugs.

Here is the same numerical example of premiums that I put into a text box that's in your mailing materials. Here we have three plans. Let's think of them as being in three different parts of the country. Look first at plan two. The yellow bar shows plan two's bid for the standard benefit and for a standard beneficiary. Notice that the bid, the yellow bar, is the same height as the dark line across the top. That line represents the national average

across all three of these bids. So when CMS does the math and calculates a base level enrollee premium from the national average of bids, it turns out that the enrollees in plan two just paid that base enrollee premium. That is why their pink bar, their enrollee premium, is the same height as the gray bar, the base enrollee premium.

Now look at plan one, which has a bid that's higher than the national average. In addition to the base enrollee premium, enrollees in that plan also would have to pay the full difference between the height of plan one's yellow bar and the thick white line on the slide. Notice that plan one's pink bar, it's enrollee premium, includes that full difference.

Similarly plan three has a bid that's lower than average. It's enrollee premium, the pink bar, is lower than the base enrollee premium by the same amount that plan three's bid is below the national average bid.

A key thing to take away here is that enrollee premiums across these three plans, the pink bars, could vary more in percentage terms than the plan bids, the yellow bars. That's because most enrollee premiums include the full difference between plan bids and the national average

added to a base enrollee premium that's relatively smaller because it's subsidized.

Publicly available data suggests that there is geographic variation in drug spending but patterns in that variation depend on the data source you use. This slide divides the country into four areas. Each bar reflects a different data set. Let me warn you that each of these data sets is a little different from the others in the years that it covers or the age of the populations that are covered. So the bars are indexes where the overall average of per capita drug spending in each data set has a value of 1.0.

Although they each show some geographic variation, the data sets don't tell precisely the same story. They generally suggest that drug spending is a little higher than average in the South and lower than average in the West. But one data set tells us that people in the Northeast have the highest spending per person while other data sets suggest the people in the Midwest or South have higher spending.

There is no gold standard among data sets for telling us how much geographic variation in drug spending we should expect to see for the Medicare population and for

Part D. In your mailing materials I talk about some of the problems with using available data to look at Medicare beneficiaries. But a key point here is that plans are also going to have a hard time estimating what their Part D spending will look like and therefore what their bids should be. It may take a few years of collecting real claims information to reduce uncertainty in setting premiums.

This work starts to explore the degree to which drug spending varies around the country. We intend for this research to help us think about how Part D premiums may vary geographically and help us to examine an issue that the Commission might want to monitor. But it also raises some other issues.

For example, will beneficiaries who live in some of the higher cost regions be less likely to enroll because their premiums will be higher? On the one hand, it may seem like a relatively high expense. But on the other hand, maybe people in those areas value prescription drug spending more and would be willing to sign up anyway.

A related issue is how plans will perceive the situation. If it looks like relatively high enrollee premiums in some parts of the country will affect take up

rates, will risk plans be less inclined to enter those markets? It will be interesting to see what effects geographic variation in Part D premiums have over time. For example, some analysts believe that within a given region competition among plans that is based at least in part on the price of the premiums could encourage higher cost plans to apply some of the management tools of their competitors and lower their costs. It's less clear, though, what effects would result from having different levels of premiums across geographic regions.

Of course, how you think about these and other issues related to geographic variation in drug spending depends on what you think is equitable. Some people believe it is more equitable for beneficiaries everywhere to pay the same amount, while others believe it is more equitable for Medicare to pay the same subsidy per beneficiary.

That concludes my presentation and I'm happy to take your questions.

MR. BERTKO: Rachel, could you go back to the bar graph with all that data on it. I would just make a comment that Bill and I observed in our other panel, the Trustees panel report. I believe you have the FEHBP data on their in

the middle bar, which I'll let you call it, but I think it's the pink one.

DR. SCHMIDT: Yes.

MR. BERTKO: There are, as you pointed out, lots and lots of limitations on the data quality here. I would suggest, partly from our discussions but also from other stuff, that this federal retirees and spouses from the FEHBP program may be the best we have in terms of going across regions.

Is this simply the BCBSA part of the data?

DR. SCHMIDT: That's what they refer to on the CMS web site.

DR. BERTKO: And so, in this sense, if you're trying to compare these across there, this might be the best one across because it's got similar kinds of people across regions. And as one of the other points then that to make is out of the amounts of variation there I think you'd note that maybe this one has the least -- among the lesser amounts of variation on there if you're just trying to observe something. That would be the first point.

A second point, and this is to address your comment about both competition, both in the region and

across regions, already there have been announced a couple of insurance carriers who say that they may be national players, that is offered in every state, thus bringing those utilization management tools across all.

First of all, I will again completely agree with you that we don't know enough about this. But the second part, the competition in these national players, may very well serve to reduce the current differences that might be observed in a graph like this. But again, we won't know until sometime late in 2006 how this all plays out.

DR. REISCHAUER: When we were discussing this yesterday, we didn't know the answer to the question on whether the national plan has to have a single premium across the country or can it go region by region?

DR. BERTKO: My understanding would be the bidding would be regionally but the plan is --

DR. REISCHAUER: But the plan's dimensions would be national.

DR. BERTKO: Yes. It's likely the formulary would be the same. It's very likely the drug utilization management would all be the same.

MR. HACKBARTH: Other questions, comments on Part

D premiums?

You were so clear, Rachel. No questions left unanswered. Thank you very much.

Next, we'll move to Medicare Advantage premium setting.

DR. HARRISON: Now let us discuss how MMA changes in the method for paying plans, particularly the introduction of bidding, might raise issues in our previous support for Medicare's financial neutrality.

MS. THOMAS: This is about halfway through your Medicare Advantage package.

DR. HARRISON: The Commission has supported the concept that private plans can offer beneficiaries an important choice of health care delivery systems. At the same time, beneficiaries' choice of delivery systems should not be influenced by differing levels of Medicare payment, depending on which choice the beneficiary makes.

MR. HACKBARTH: It's page 11, to help people find it.

DR. HARRISON: We have stated that the Medicare program should be financially neutral in the beneficiaries' choice. In other words, the Medicare program should spend

the same for a beneficiary who chooses any private plan as it would spend for that beneficiary to remain in fee-for-service Medicare. If payments for all beneficiary choices were equal in the local area, then competition for enrollment among the plans and between plans in fee-for-service Medicare would be based on the efficiency of each delivery system and the perceived quality of care they provide. Hopefully, this competition would result in increased efficiency and quality for Medicare services in the long run.

Under current conditions, paying the private plans at the same level as local fee-for-service spending would result in savings to the Medicare program. And I'll get into that a little more shortly.

We have made formal recommendations regarding financial neutrality in our past reports. In 2001 we recommended that Congress pay plans at risk adjusted rates similar to the cost those beneficiaries would have in fee-for-service Medicare. And we made a more precise recommendation in our 2002 report, recommending that Medicare+Choice payment rates should be set equal to risk adjusted local spending under fee-for-service Medicare.

When we made that recommendation there were some concerns about the adequacy of the risk adjustment mechanism and Dan will now talk briefly about the state of risk adjustment.

DR. ZABINSKI: Actually, what I'm going to discuss is quality of the risk adjustment that we have right now.

As part of the larger study mandated by the MMA, MedPAC is required to assess the predictive accuracy of the CMS-HCC risk adjustment model, which is current used to risk adjust payments for Medicare Advantage plans. This model uses administrative data, as well as beneficiaries' conditions diagnosed in the previous year to predict their costliness in the current year.

The analysis we performed consists of grouping beneficiaries by indicators of health status, including diseases diagnosed, program spending, and number of inpatient stays in the previous year.

DR. MILLER: Dan, since we've changed some of the order around, can you just be sure to point everybody to which hand out you're looking at?

MS. THOMAS: We added these. These were added, so you don't have them in your handouts.

DR. MILLER: In each instance, if you can make sure they know where they are.

DR. ZABINSKI: For each of those groups we compared predictive ratios from the CMS-HCC to predict the ratios from a model that uses only beneficiaries' age and sex to predict costliness. Where a predictive ratio is simply the mean of a group's costs as predicted by a risk adjustment model divided by the mean of their actual cost. The age/sex model that we used has been used in several studies as a point of comparison for other risk adjustment models. It is similar to the demographic model that CMS currently uses to adjust 50 percent of Medicare Advantage payments.

In our analysis we found that in each group that the predictive ratios from the CMS-HCC are closer to one than are the predictive ratios from the age/sex model. What that indicates is that the CMS-HCC does a better job than the age/sex model.

For example, on this diagram we divided beneficiaries by conditions diagnosed in the year 2001 and compared it to their costs for 2002. And as you can see for each condition, the predictive ratio is closer to one and

generally much closer to one under the CMS-HCC than under age/sex model. And as I just mentioned, that means the CMS-HCC is doing a better job of predicting costs.

I'll turn it back over to Scott and he'll complete the presentation.

DR. HARRISON: So I think we must now be on slide 13. Mine, of course, are numbered differently.

The system used to pay Medicare Advantage plans this year is not financially neutral. Plans are paid based on administratively set county rates. However, the formulas that have set the rates are only partially based on county fee-for-service costs. While the formulas ensure that plan payment rates will not be lower than fee-for-service costs, rates are often well above the local fee-for-service.

Our analysis of the 2005 payment rates finds that they average 107 percent of fee-for-service currently. Some in the industry would disagree with some of the calculations, but even if we accepted their arguments the average would still be 105 percent.

The rates are above fee-for-service for two primary reasons. First, Congress wanted to encourage plans to go to low payment areas, so it guaranteed that no county

would have payment rates below the so-called floor rates. In many areas, the floor rate was well above the county's fee-for-service Medicare cost.

The second reason is the treatment of indirect medical education or IME payments. When a fee-for-service Medicare patient is treated in a teaching hospital, the DRG payment to the hospital includes an extra amount for medical education. Recall that I said plan payment rates are not allowed to fall below fee-for-service costs. Well, the measure of fee-for-service costs used to support the payment rates includes the fee-for-service IME payments.

The problem is that when a Medicare Advantage enrollee is treated in a teaching hospital, the plan pays the hospital a negotiated rate. And in addition, the Medicare program makes a payment to the hospital equal to what the IME payment would have been if the beneficiary had been in fee-for-service.

Thus, the Medicare program pays the plans the rates that include the expected cost of IME payments and also pays those same amounts directly to the hospital.

We have prepared a draft recommendation on IME for you to consider at the end of this. As the recommendation

is currently stated, the Congress could follow it by either removing expected IME payments from the measure of fee-for-service costs or by discontinuing IME payments to hospitals on behalf of Medicare Advantage patients. In your discussion later you might consider whether one of these actions is preferable to the other.

MR. HACKBARTH: Scott, let me just leap in for a second and clarify for the audience that we will be taking no votes at this meeting. All votes on recommendations will occur at the April meeting.

DR. HARRISON: The current system that I just talked about ends this year and next year a bidding process will determine Medicare's payments to plans. However, the current payment rates are still used in the process. Under the new process, plans will submit a formal set of bids to participate in Medicare Advantage. Each bid will consist of up to three separate components. However, the payments are based on only one component, which is the bid for the standard Medicare Parts A and B benefits. For this presentation the term bid will mean the A/B bid.

Payments to the plans are determined by the plan's bid and the payment area's benchmark. The benchmarks for

2006 are the 2005 county payment rates updated by a national growth rate. A plan's bid will be compared with the benchmark. If the bid is below the benchmark, the plan is paid its bid plus 75 percent of the difference, known as the savings -- I'm sorry, the difference is known as the savings. So 75 percent of the savings go to the plan. And the remaining 25 percent of the savings is retained by Medicare. The plan is then obligated to return its share of the savings, and that's called the rebate, to its members in the form of supplemental benefits or reduced cost sharing or a reduction in premiums.

If for some reason a plan bids higher than the benchmark, the plan is paid just the benchmark and the plan enrollees would have to make up the difference with a premium.

This process probably will not produce financially neutral payments as I'll show in the following example of how the plan bids will affect Medicare payments to plans as well as beneficiary premiums.

For this example, let's assume the national Part B premium which all beneficiaries, even plan members, are responsible for paying, is $100 per month. And we are in a

county with average fee-for-service costs of $1,000 a month. Just for illustration purposes I assumed that the benchmark was also $1,000, even though I know benchmarks are likely to be above fee-for-service costs.

Two plans bid here, one at $950 and the other at $900. Beneficiaries in fee-for-service Medicare are unaffected by the bidding process and they continue to pay the Part B premium.

Now let's look at plan two, and we'll look at two because the math is easier. Plan two bids $100 below the benchmark so it is paid its bid of $900 plus 75 percent of the $100 difference for a total of $975. The enrollees in plan two will receive a reduction in their premium of the $75 rebate because for the illustration here I have assumed that the rebate would all be returned to the beneficiary in the form of a premium reduction. As a result, plan two enrollees would pay an adjusted premium of $25 for the Medicare package of benefits.

Sparing you the math, plan one would receive payments from the Medicare program of $987.50 and its enrollees would pay an adjusted premium of $62.50.

Because part of the difference between the bid and

the benchmark is retained by the Medicare program, plans may receive different payments than each other as in this example and payments different than Medicare's cost for covering beneficiaries in fee-for-service.

Of course, I should note that currently benchmarks are above fee-for-service Medicare costs and some plans will likely receive payments higher than fee-for-service costs. But this example illustrates that the bidding process is not financially neutral even when the benchmark is lowered to be equal to the fee-for-service Medicare cost.

This shows that we can't get financially neutral payments from a bidding process where a plan's bid determines its payment unless we restate our financially neutral recommendation to say that plan's should be paid no more than local fee-for-service costs rather than equal to fee-for-service costs. However, if we set the benchmarks at 100 percent of local fee-for-service costs and redistribute Medicare's share of the savings back to the plans in the form of quality payments, we would have a financially neutral system that would not discourage plan participation in enrollment by reducing payments below fee-for-service. And we might further encourage quality in the plans.

It is also possible to create a bidding system that is financially neutral another way. We have created one here to illustrate some of the potential implications of such a system. Under this illustrative full competition system, plans would submit bids. The fee-for-service system would also be considered a plan and its bid would be considered to be the area's fee-for-service cost.

The area's benchmark would be the average of all bids, including the fee-for-service system. And all plans would be paid at the benchmark. Beneficiaries enrolling in plans with bids above the benchmark pay a premium equal to the difference. And beneficiaries enrolling in plans with bids below the benchmark would receive a rebate equal to the full difference between the benchmark and the bid.

So here we are again in a county with average fee-for-service costs of $1,000 and two plans bidding $950 and $900 respectively. For this example, let's assume a benchmark of $982.50.

Under this illustrative system, beneficiaries in the fee-for-service Medicare system in the market would pay an extra $17.50 above the usual Part B premium. Meanwhile, enrollees in plan two would receive a rebate of $82.50. The

Medicare program would make the same financially neutral payment equal to the benchmark on behalf of each beneficiary regardless of the beneficiary's choice of plan. Beneficiaries, on the other hand, would face the full cost difference in their enrollment decision shown here as $100 difference in premium between fee-for-service Medicare and plan two which bid $100 less than the fee-for-service cost.

In addition to advocating a payment policy that supports risk adjusted financial neutrality for all types of plans, we recognize that there may be other considerations that should affect payment policy design. We recognize that some policymakers have increased plan participation as a goal. We also recognize that some policymakers are concerned about the geographic variation in the Medicare program and about the overall cost of the Medicare program and about protecting low income beneficiaries by providing low-cost options.

I'm using this chart to try and explain why Medicare has always had trouble attracting plans to many low cost areas, particularly rural parts of the country, and why plans have gravitated to the higher urban markets. The bottom axis shows the level of fee-for-service Medicare

costs in a local market. The height along the side axis shows the cost of delivering the Medicare benefit package in the local area, either by the fee-for-service program represented by the dotted orange line, or by private plans represented by the solid red line.

The chart illustrates our hypothesis of the relationship between managed-care plan costs and fee-for-service costs. The thought is that plans have some fixed administrative costs and can reduce costs from fee-for-service levels by managing care more efficiently and/or by reducing payment rates paid to providers. Regardless of the technique that the plan uses, they can reduce spending more where there are higher levels of fee-for-service spending.

Our quantitative analysis confirmed the general shape of this relationship and our analysis suggests that the initial costs to administer plan systems can best be offset in higher cost areas or in areas where they can attract large membership. In many low cost areas plans are likely to have higher total costs than fee-for-service Medicare.

This may help explain why managed care plans were not attracted to many lower cost areas even when legislation

raised payments in those areas.

Financially neutral payment systems are unlikely to attract plans to low cost areas because really the only way to attract plans to those areas is to pay more than the cost of fee-for-service there.

However, in areas where plans have been able to compete successfully with fee-for-service Medicare, plan participation would be likely to increase under this illustrative competition system. In these areas, beneficiaries would have to pay higher premiums to stay in fee-for-service Medicare and some beneficiaries are likely to switch to private plans to avoid these higher premiums. Therefore, plans are likely to enter these higher payment areas to meet the increased demand for low premium options.

This table shows what might happen under the illustrative competition model in three different types of areas and serves to illustrate some of the competing views of geographic equity that we might wish to consider. Area one is a low-cost area that does not have any private plans. Area two is a medium cost area with some private plans that are competitive with fee-for-service Medicare. And area three is a high cost area with plans that are much less

costly than fee-for-service Medicare.

The first column shows the fee-for-service costs in each area and illustrates one view of geographic equity or inequity that beneficiaries in different parts of the country have different amounts spent on them under fee-for-service Medicare. Plans in those areas are also currently paid different amounts, often reflecting those differences. Currently, however, beneficiaries in all three areas can participate in fee-for-service Medicare for the same Part B premium.

The second column shows the benchmark that results from bidding under this illustrative system. Because the benchmark is the average bid in the area, it is guaranteed there will be at least one option available in each area that bid at or below the benchmark, meaning that there would be at least one option available at or below the premium benchmark, the benchmark premium which is $100 in this case.

MS. BURKE: I'm sorry, would you step back two steps and say that again? I'm trying to figure out -- is the benchmark here the average of the three where the benchmark is the fee-for-service in the first but not in the second?

DR. HARRISON: The benchmarks are area specific. They are calculated, created, whatever as an average of the bids in those areas.

MS. BURKE: The bids, including fee-for-service.

DR. HARRISON: Including fee-for-service.

MS. BURKE: I got it.

DR. MILLER: So the reason it equals in the first area is because there's no plan to bid it down; right?

DR. HARRISON: Right.

In fact, that was my next sentence.

The Medicare program pays the benchmark to all options in each market so that Medicare would continue to pay more in area three but the difference in payments between markets would decrease from the current situation.

The fee-for-service premium is equal to $100 plus the difference between the fee-for-service costs and the benchmark in each market. For example, in area two the fee-for-service premium would be $100 plus the $10 difference between the $800 fee-for-service costs and the $790 benchmark. Looking down that column, you will notice that the fee-for-service premium can vary significantly with beneficiaries in area one paying $100 and beneficiaries in

area three paying $200. This difference in premium for fee-for-service Medicare may be viewed as an inequitable by some. And bear in mind this is the type of system that we are going to have for the setting of Part D premiums.

The last column, however, shows that beneficiaries in all markets can get the Medicare benefit package delivered by a choice. One option that bid at the benchmark for the same $100 across the country. Only in area one would that the benefit package be delivered through the fee-for-service Medicare system. In areas two and three, beneficiaries would have to pick a plan that had bid at or below the benchmark in order to pay the $100 or lower premium.

Now let me just quickly summarize what I've talked about about financial neutrality.

DR. MILLER: Scott, why don't you back up to that slide just for a second to make sure that we have everybody.

What's going on here is that if you stayed in fee-for-service you would either pay $100 in area one or area two you would pay $110. That $10 is arrived at -- the $100 everybody pays. The $10 difference is the difference between $790 and $800. What the last column is saying is

that plans in an area who underbid the benchmark can still deliver the benefit at $100.

So what this illustrates is two things. Number one, if you choose to stay in fee-for-service in this illustrative example, you would pay more out-of-pocket. Alternatively, you could get the A/B benefit by moving to a plan at $100. That's the point of the illustration and how you can think about geographic equity in a couple of different ways.

MR. HACKBARTH: Everybody have that? This is an important basic foundation point. Any questions about it?

DR. BERTKO: Just to make a point that as an illustration of how Part D works with the wrong number of zeros, it's accurate, and but it does not exist in law today.

MR. HACKBARTH: Explain that, John.

DR. BERTKO: The illustration is good but this is not how the MMA works today. This is just an illustration of a fully competitive system and we today, on the A/B benefits have, for lack of a better term, a semi-competitive system.

DR. MILLER: That's absolutely correct. We're

trying to just illustrate how a pure competitive model might work across geographic areas to illustrate these two different points about how a beneficiary could choose, on the one hand to pay more out-of-pocket, or alternatively move to a plan. This does not exist under MMA. This is a different way of thinking about how to pay plans. That's correct.

MS. BURKE: Is the presumption that the fee-for-service premium is still calculated on a 25/75 basis? So that -- in terms of the program's costs.

DR. HARRISON: Yes, it's just fixed across the country.

MS. BURKE: It's just fixed. So query how that relationship changes, I mean what the general revenue contribution becomes over time, what that ratio looks like.

MR. HACKBARTH: But that's an independent variable that could be altered by different forces.

MS. BURKE: I understand. I'm just trying to understand politically when you go down this road what does it mean about the ratios, what the general revenue expectations is in terms of the support of the program going forward, how that begins to alter.

MR. HACKBARTH: So if I'm following, there's always a reaction to the action. So if such a system were in place and it meant substantial increases in premiums to stay in traditional fee-for-service in some markets, another variable that the political process might turn to is the 25/75 split.

MS. BURKE: Right. And the basis upon which it's calculated, which would change.

MS. RAPHAEL: Just a point of information. This, I assume, is predicated on having a full risk adjuster?

DR. HARRISON: Yes.

MR. HACKBARTH: So these numbers are all caring for the same level risk person and equal level of risk assumed.

MS. RAPHAEL: That we don't have a different population in fee-for-service.

DR. REISCHAUER: You said that you can get the Medicare A/B benefit package for paying the same premium. But I mean, in all these examples, you could get it for even less; right?

DR. HARRISON: Most likely you'd have some bids below the benchmark, yes. In area one, you wouldn't --

DR. REISCHAUER: I mean, you'd have to have some below the benchmark, arithmetically.

DR. HARRISON: It would depend on how you actually set that average.

MR. HACKBARTH: Let me just go back to Carol's question about risk adjustment. That really explains why we had Dan's presentation on the risk adjustment system inserted in here.

When MedPAC last looked at this issue of competitive bidding for private plans we said that it has positive attributes but also some areas of concern. One is on the impact on beneficiaries that remain in fee-for-service. In particular related to that is if you don't have a good risk adjustment system and there's adverse selection against the traditional fee-for-service program the premiums for staying in that option could spiral dramatically.

So this was March 2001 when we were still using a demographic based model. As Dan described in his presentation, the new risk adjustment system is quite significantly better than the old demographic model. So that raises the question well, is that enough of an improvement to offer a more stable competition, a fairer

competition between traditional fee-for-service and private plans?

Other questions or comments on this?

MS. DePARLE: Are you done, Scott?

DR. HARRISON: I was just going to summarize. I'd just as soon not interrupt the flow of the conversation.

MS. DePARLE: So John just made the point that this isn't what the law is but chart 15, I think, is the one that reflects current law under the MMA?

DR. HARRISON: I'm not sure what your numbers are.

MS. DePARLE: Just to follow through on one of the points you made --

MR. HACKBARTH: Yes, that's right. Page 15 is the description of current law under MMA.

MS. DePARLE: I just want to understand one point that Scott made. You make the point, Scott, on plan number two that you've treated the premium adjustment as though it were being fully given back to beneficiaries. In fact, isn't it the case that the plan could be getting a payment of $975 plus $75? There's nothing in the law that requires them to give it all back is there?

DR. HARRISON: Yes, there is something in the law

that requires them to give it back. The reason I made that assumption, what really I would expect to happen is that the plan would take this $975 and provide a package probably richer than the Medicare benefit package and either give some premium rebate to the beneficiaries or not.

MS. DePARLE: The thing that would enforce that which hasn't been there before is what?

DR. BERTKO: The law.

MS. DePARLE: The law has said that before, too. So what is the mechanism?

DR. HARRISON: It's the bidding process. The bidding processes says you're going to submit a bid for the basic benefit package, a second component for any supplemental including lower cost sharing. And then the third would be for the Part D but I didn't want to confuse us with the Part D.

MS. DePARLE: But the idea is supposed to be that CMS and the actuaries will have more time and more energy devoted to assessing this to make sure that the savings are really returned both to the program and the beneficiaries?

DR. HARRISON: Yes.

DR. BERTKO: I'll make one comment now and maybe a

couple later. On this slide, in particular, let me point out here that if the benchmark were actually the fee-for-service prong exactly --

DR. HARRISON: Which it is here.

DR. BERTKO: Yes, which it is here, that the payments here, because of the competition to plans, will actually turn out to be under the fee-for-service benchmark because of the recapture of the 25 percent, namely $12.50 from plan one and $25 from plan two.

Scott made a comment here that this could be recycled. That, again, is not in law either.

MR. HACKBARTH: I want to come back to the recycling point in a minute but let's get some other comments on the table. Alan and then Dave. Was it on this particular point? Go ahead.

MR. SMITH: Scott, we could add to the chart on page 15 plan four or plan three, which bid at higher than the benchmark; right? The law would provide for an option which had a beneficiary choosing to pay a higher premium equal in the other direction?

DR. HARRISON: Yes.

MR. SMITH: And again, would be free to modify the

benefit package above the A/B combined in order to try to --

DR. HARRISON: Yes, but you need to charge an extra premium for the A/B part and then you need to charge the full additional premium for any supplemental package you offer.

MR. SMITH: So you couldn't take your higher premium and use that as the resources to underwrite a richer benefit package?

DR. ZABINSKI: And these bids are strictly for the A/B benefit package.

MR. SMITH: Strictly for what's paid for by the benchmark number?

DR. HARRISON: Right.

MR. SMITH: Thanks.

DR. NELSON: With respect to the subsequent slide to this, the one that shows the $200 premium, I think it's on page 20 of what we've got. This model makes sense looking at it from the side of the payer who is trying to achieve some sort of neutral impartial treatment of the various delivery products. But from the standpoint of the beneficiary, it's patently unfair because the fee-for-service beneficiary in a high cost area gets whacked with a

higher premium even though it's the provider of care that orders the services that set the higher levels of utilization within the area.

DR. BERTKO: That's actually not necessarily true.

DR. NELSON: If I were a beneficiary in Florida and I got whacked a higher premium, I would argue that it's not my fault. I didn't do it. It's the practice style or whatever those causes are.

DR. REISCHAUER: You're a parsimonious user of services would be the argument. I'm not the average of Miami.

MR. HACKBARTH: Let me just amend that. There are two different ways basically, and a very simple way of thinking about this, is setting the benchmark. One is the national average benchmark, in which case if you live in a very high cost area as a beneficiary you could get nailed due to the practice patterns that prevail in your part of the country versus the national average.

Another model is to have the benchmarks based on local markets. In that case it wouldn't be the prevailing practice pattern in the community that results in your paying the higher premium because there are other lower cost

options available in that market. The logic would be that it's because you elected a relatively unconstrained open system, fee-for-service system, that is increasing your premium, not the prevailing practice pattern in the community.

So the model that we're talking about, at least as I see it, is the second model with locally set benchmarks which obviate the problem of getting whacked just because of the regional differences.

DR. CROSSON: I'd like to back off from the numbers for a minute and talk for a few minutes about the financial neutrality idea itself. It seems to me, just from this discussion, and I hope over the next month or so we have more discussion about what we actually mean by that and what values we're talking about and then some of the derivative consequences of picking one interpretation of financial neutrality or the other. I'd like to just talk about two things.

One, I think, was mentioned in the report and it has to do with the real life consequences of changing the payment system, changing the proposed basis for the benchmark on low income seniors. I think it's certainly

been our impression, in our own program, that a significant number of Medicare Advantage beneficiaries are low income seniors. I don't know what the proportion is but it's a fairly significant. And that, in fact, one value of the Medicare Advantage program as it currently set up, rightly or wrongly, is that it results in lower out-of-pocket costs to those same low income seniors.

Not that is a value. It's not the value of financial neutrality but it has a real life value.

I would hope, as we work this through, that we focus our analysis, at least in part, on that question because that's a very real world -- will be or could be a very real world consequence of changing.

The second one has to do with the fact that again -- and this is not to suggest that the way we've gotten here in terms of the payment structure was good or even thoughtfully constructed. But it seems to me, as I look at what the Congress is trying to do here, is that there's a suggestion that Medicare Advantage or private plans or whatever you want to call it has a potential value in the future.

Could we return to slide 12 for a second? If we

were to just change the basis for the -- no, your slide 12, I'm sorry.

If we were just to change the horizontal axis there and suggest that was time, I think there's a suggestion -- and this is something that I believe that in order to get to that world that some believe we could be in, which is that private plans, if you will, result in higher quality and lower cost through the inherent efficiencies of the private market and whatever. You may disagree with that but others believe that.

Then it would suggest that to fill in that area under the curve at the beginning of that line, there is the need for some investment.

I think that some believe that that investment is, in fact, what's intended even though, as I said, the way we got there may not have been a kind of sausage making that any of us would like to have seen.

So I just hope that as we go through this we take that into consideration and we kind of analyze the real world necessity, if you will, for an investment over a period of time and how that relates to the underlying value of financial neutrality. Because I think, again, if it's

true -- let's just take the pay for performance for the moment. Let's assume that we weren't under the constraints that we had in terms of the budget deficit and concerns about Medicare costs and we wanted to pursue pay for performance more aggressively, as some commissioners have argued.

We might have decided in a different environment that additional money needed to be put in there in order to aggressively move that forward. I think some proponents of the payment system as it exists and of potential ways that it could exist, their arguments are predicated on the idea that over some period of time investment is needed in order to get to that better world. Some may not agree with that but I think it's a legitimate issue.

MR. HACKBARTH: Let me go to your initial statement about we need to think through carefully the implications of neutrality. And that's the very purpose of this. There have been important changes in the rules of the game. And so I envision this as our thinking about what does, in fact, neutrality mean? That's abstract. Let's get more concrete and apply it to particular models and see whether we can come up and either endorse existing models

that are in MMA or refinements of them that get us closer to where we want to be, not just on neutrality but on a number of other goals.

My personal list is I'd like to have a system that's neutral. I would like to encourage participation by plans so that beneficiaries have more options. I would like to have a system that better matches payments to cost then pure administered prices systems do. This is the standard MedPAC thinking. Let's try to get our payments so that they better reflect the costs of high quality, risk adjusted care.

I'd like a system that also helps reduce federal expenditures given the pressing problems that the program faces and a pure administered price system does not do that. The money goes back to the plans and beneficiaries exclusively.

And I'd like to reward quality. Those are all goals that I have. And how we achieve them is the trick.

I would also endorse what you say about making sure that we protect low income beneficiaries. And with some modification, I could even agree to encouraging investment in good things.

My concern about the existing policies on those two points is that they are indiscriminate. The extra dollars do not just go to support care for low income beneficiaries. And the dollars do not just flow to organizations investing in improving care. They are just spewed out in every direction. But I think that those are also important values.

So where I had hoped that this conversation might go, and then I'll let you folks take over, is that we try to match up where we are and MMA as the system will work in 2006 with goals like that and see if we can suggest ways that the system might be tweaked, amended so that it will move us more closely towards maximizing those kinds of values.

DR. MILSTEIN: Given the goals that Glenn outlined, I would hope that our future analyses and discussions might also begin to look at benchmarks that include disaggregated performance units within Medicare fee-for-service. More recent publications from the Dartmouth research team are beginning to tell us a couple of things, including the fact that by and large Medicare patients in the fee-for-service program tend to stay loyal to a

particular hospital and their associated medical staff.

Everything I'm saying now is pertinent to urban areas -- I'm not talking about rural areas -- where by and large beneficiaries do have pretty good choice and ability to shop among hospitals and their affiliated medical staffs.

And so what the more recent Dartmouth research is telling us is that within urban areas hospitals and their affiliated medical staffs in the Medicare fee-for-service program vary dramatically with respect to total resources consumed, and in some cases quality of care.

So I hope that as we begin to explore various frames of reference for deciding what really constitutes benchmark performance in a geography, we don't limit our evaluation of the fee-for-service program to all hospitals and all doctors in a geography as a lump, but rather begin to build on some of the analytic insights coming out of the Dartmouth group and begin to, in urban areas, look at hospitals and their affiliated medical staffs as one source of fee-for-service benchmark.

DR. SCANLON: To echo Jay's comment about the need to define what we mean by neutrality. And part of it is

reinforced by what you said in terms of the list of objectives that you have, and I wouldn't disagree with them in most senses of them.

But for me they almost come ahead of the issue of neutrality. I'm not only concerned about having -- or primarily concerned about having Medicare neutral in terms of how it pays, but having Medicare be efficient, buying quality, encouraging a change in the system that makes it more sustainable over time. Those are kinds of things that take preeminence.

Then the question is if I think of them as my primary goals and I want to think about how I use plans and the fee-for-service system to achieve those goals, how would I define neutrality when I'm done thinking about those prior questions. I think it may be different than where we are today in terms of this discussion because this discussion is assuming they we're bidding on a Part A and a Part B benefit by all these different plans and it's all the same. I think potentially it's not.

What Arnie just said about trying to influence the choices of providers. It's different, what plans are trying to do versus what the fee-for-service system tries to do.

We may want to reward that difference.

We may think that we don't want to over reward it, and maybe neutrality is defined in that sense, that we don't sort of pay more for this management than we should.

I'd like to go down the path of the objectives that you have and think about how we would structure use of private plans in Medicare and in their relationship to fee-for-service and develop sort of the definition or we think about neutrality or how the word neutrality fits into that context after we've done that, as opposed to starting with it and thinking that we can look at the current system and say we can revise it to be more neutral. Because these other objectives are more critical in my mind.

The other thing I think that's important, and Jay brought it up to an extent, is this issue of there are people that believe that we are making an investment and we're going to get plans to participate and we're going to see the benefits of that, the beneficiaries are going to see the benefits of that, and we're going to transform the system with that respect.

It's, I think, important to test some of these ideas including what you brought up a little bit earlier

about risk adjustment. I'm not sure if the risk adjustment assessment that we've done is based upon enrollees in plans or is it based upon fee-for-service beneficiaries

DR. ZABINSKI: Fee-for-service only.

DR. SCANLON: The issue is going to be how good is that risk adjuster after we see who actually enrolls. Because that's the test that we used before. Clearly, it's doing better than the demographic model. But is it going to do well enough when we actually experience in the real world?

So we need more information and we need a broader context, I think, to have this discussion.

MR. MULLER: I think the themes of looking at how we get better care through long term effective management of care for the population is one that we've been suppressing all year.

My reading of the background that we had on the payment though in the material that was sent to us is that the payments, in fact, unlike the ones up on the screen, will be higher than the fee-for-service during this transition period.

I'm concerned that some of the evidence we saw in

Medicare+Choice seven or 10 years ago, where plans come in when the payments are better and exhibit pretty fast when the payments get reduced, as they seem inevitably to get reduced when there's budget crunches going on and so forth, that we not have a lot of people coming into this for short-term advantage, financial advantage and not for the long-term advantage of the beneficiaries.

Obviously, institutions such as Jays, that have been around for 50 years or more don't come in and out of this but others might. I think one of the things we need to be looking at is if the payment incentive is concerned enough about fee-for-service that, in fact, we are violating at least my understanding of payment neutrality that may encourage that kind of behavior rather than that kind of long-term behavior that Bill and others in the previous comments have asked for.

Because obviously if one thinks of investment and investing in the kind of case management and disease management and other kind of performance-enhancing measures that we all want to encourage, that requires a kind of constancy of approach to working with the population over a period of time.

That could be mitigated if, in fact, people come in and come out of this program once the financial advantage is not as great.

Therefore also, I think these examples, perhaps Scott and Dan could share some of the examples of not the competitive modeling in theory but what, in fact, we are paying right now, which is different than I take it we're showing on the sheets. I want to make sure I understand.

If the payments are above the fee-for-service plan where, in fact, does that extra go? Does it go necessarily to the beneficiary through enhanced services? To use this chart, let's say if we put $1,100 in there, just for the heck of keeping in round $100 numbers. How would roughly this chart read if it was an $1,100 payment and the fee-for-service in this example were $1,000? Where would the extra money go?

DR. HARRISON: On this chart, let's say you had a plan that -- I'm sorry, the benchmark was set at $1,100. Let's look at plan two. Plan two would get $900 plus 75 percent of the $200 different. So $150. They'd get $1,050. They would need to give back $150 in benefits to the enrollee.

DR. BERTKO: Yes.

MR. MULLER: But they're not obligated to give $150 in benefits back?

DR. BERTKO: Yes, they are. It's in the law.

MR. MULLER: Okay.

DR. MILLER: To just one other point that you were saying, at least in the 2006 bidding process you have the benchmarks that are set above fee-for-service. And then you have the requirement that 25 percent of the savings go back to the government. We're not saying definitively that the plans will be paid above fee-for-service. I don't think we know because we have to see how the bids come in.

It's just with the benchmark where it is and 25 percent, between that arithmetic it's not exactly clear where we would end up paying.

DR. HARRISON: Yes, that's correct.

MR. SMITH: Thanks Glenn. Arnie and Bill and Ralph have raised a lot of what I wanted to, but three thoughts.

Jay, you talked about changing the horizontal axis on the chart on page 18 to a time axis. When Scott described what might explain this changing production

function, he offered two hypotheses. Neither was time. One was volume and one was the cost of providing services in an area. A high-cost high-volume area would show the dotted line exceeding the solid line sooner.

In our experience, as Ralph described, with time and Medicare+Choice is we got less of it over time, not that we got more of it. Not only did we get less participation but we got less services provided as plans cut those over time. So we ought to be careful hypothesizing that time here produces more investment and higher quality.

I'm concerned, too, Glenn, and I don't fully know how to think about this. A lot of the discussion has been helpful. But I suspect, as Bill argued, we need months of it, not hours of it.

When we started to talk about neutrality we had two notions in mind. It is interesting that the word choice has slipped out of the vocabulary here. We had a neutrality notion with respect to choice, that if Bill chose to participate in the fee-for-service system or chose to participate in a managed-care plan that his choice ought to be neutral with respect to the impact on him financially.

Now we've reduced the neutrality notion simply to

a taxpayer notion, that taxpayers ought to be indifferent as to what choice Bill makes. It's a huge difference, obviously, between a $100 premium and a $200 premium with no assurance at all that if I make the rational financial choice I'm actually getting the same service or the same quality of service -- Arnie's question -- that I'd be getting if I made the $200 choice. And no assurance at all, and in fact some reason to be quite suspicious, that making the financially sensible choice is something which will meet my long-term needs for stable care and a stable situation with continuity of providers because our experience is, the last time he went down this route, that didn't happen.

This is both more complex in vocabulary terms, but I do find it interesting that we've now reduced neutrality to only one of the two dimensions that we thought was important 24 months ago.

MR. HACKBARTH: I think you've given a very concise clear summary of some of the most important concerns of those people who argue against the pure competitive bidding model where beneficiaries remaining in traditional fee-for-service would face a potentially larger premium to stay. Those are the sort of issues that I often hear in

talking to people about this on the Hill. And those are the sort of issues, I think, that made this such a matter of controversy during MMA.

From my perspective the pure competitive bidding model has a lot of positive attributes. These issues that you identify, though, are so important, and the difference of opinions on them so great, I'm not sure -- it would be presumptuous to think that an opinion from MedPAC would materially alter where people come down on that.

And so whatever its conceptual merit, I'm not sure that we could have a big breakthrough there. But even if we can't do that, my hope is not to avoid the months long discussion. I think that we can, maybe more quickly, focus in on some potential improvements in MMA 2006 that would be in accord with the sort of values that I've outlined.

Scott alluded in his presentation, just in passing, to one variation which would be to say let's have bidding. Fee-for-service beneficiaries are not expected to pay more if that's their option. So we have private plans bidding perhaps below the benchmark.

But as opposed to taking 25 percent of the savings out and putting it in the federal treasury, maybe what we

ought to do is take that money and recycle it into productive investment if it improves the quality of care, reward excellent performance where it exists, as opposed to spreading the money indiscriminately across anything that is called private.

That's a relatively modest change in the framework. It would be in accord with the most basic notion of neutrality in that the total payments going out would be benchmarked to 100 percent of fee-for-service. It would help us get some competitive forces determining in each market what an efficient level of cost is with an opportunity for the beneficiaries in the program to benefit from moving away from a pure administrative price.

That's an idea that I'd like to see us talk about as an incremental change short of engaging in the months long philosophical discussion.

DR. REISCHAUER: I might be looking at this a little simplistically, but I don't have the problem that Bill raised. He was saying that here we're looking at financial neutrality and there are other objectives that trump, in a sense, financial neutrality in his mind, quality, efficiency, protecting low income people. I guess

I looked at financial neutrality holding everything else constant.

First of all, efficiency should be caught up really in financial neutrality because if you're more efficient there is value that is being captured somewhere, maybe incorrectly, in the system we're having.

But I don't see why quality, in a sense, isn't completely separable from financial neutrality. You're talking about financial neutrality of situations where you have the same quality and we want to reward good quality and penalize bad quality. There are other various other mechanisms that we try and use to help low income people to make sure that they can pay the copayments, premiums or whatever. And maybe they aren't as extensive as they should be. But we shouldn't try and mesh that in somehow with the plan kind of system.

Jay raised the issue of looking at the chart with a different label on the X axis, that being time, and suggesting that there was an investment aspect to this. I wasn't sure if you were talking about the investment in creating a different system or you were speaking -- this is what I thought you were speaking about -- that the longer an

individual remains in a managed-care type of structure the greater the payoff down the line. I believe that to be true.

But if you're tying payments to fee-for-service, which gets none of that, presumably we're already paying for it in a sense and paying for it more and more over time. And alternatively you could change the capitation such that it was not only risk adjusted but length of time in other system adjusted, as well, if you really thought this were great.

But I don't see why necessarily, for an entity like yours, which has sort of a mature profile of participants, you aren't already capturing that. We're overpaying people who have been in there a long time, in some sense, if these benefits are there and underpaying those who just joined.

DR. CROSSON: Thanks, Bob. Just to clarify, I actually was talk about the former concept, not the latter concept.

DR. REISCHAUER: But the problem --

DR. CROSSON: Let me finish. Specifically, the time for organizations, and I can't speak for all

organizations, I have to say that. But specifically the time for organizations to implement oddly the same kinds of process we've been talking about in Medicare fee-for-service, for example effective profiling, pay for performance, disease management programs, and the utility, attaining the utility of clinical information technology in the managed-care environment.

Now some organizations use those effectively. Others are still trying to figure out how to use those. These are, for the most part, newer techniques than I think what we saw to some degree in the 1990s. Again, I can't defend all situations but I'm just saying that there's an argument to be made here that if we want to get to the right side of that curve there is a justification for making investments.

To the extent that those need to be made budget neutral, as we had to do with pay for performance, I can understand that. But I can also understand advocates who would say that we need to make an absolute investment in this, because of the complexity of that, to get to where we want to be.

DR. WOLTER: Glenn, for those of you that have

been thinking about this, if our page 20 is a potential policy direction or some version of it to create more competition that would have more effective results, what thoughts have you had about rural areas? Is this intended to be an urban sort of focused program? Is there a way for rural areas to be considered in all this? Or is the thought that more likely under a scenario like page 20, rural areas would just stay with fee-for-service?

DR. MILLER: One thought is by moving off of a national benchmark and going to a local area benchmark you have some greater possibility for that happening. But I also don't want to overstate it.

Given the cost function illustration that Scott has there, there is sort of a systematic problem with rural areas that you have this fixed cost barrier that you have to get over before you can get the plan.

MR. HACKBARTH: My thought on it is, of course we want quality of care to improve in rural areas as well as urban. The tool of competition among private plans, however, may be less applicable given lower population levels, pure providers, less opportunity for meaningful competition. And therefore, we may have to look at other

devices to achieve the same results in very different market circumstances.

To pretend that rural markets are like urban markets, I think is folly. All we do is we throw in more money until we get private competition. We're going to have to throw a lot of money into the pot.

I think what I just described is one of the reasons why some people inserted regional PPOs in MMA. I'm not sure that I agree with all of the elements of the logic, but the logic was okay, let's not depend on competition among local private plans. Let's set up a regional PPO and effectively require participation in broad geographic areas that also include rural areas. So just throwing money at private plans and keep upping the amount until we get enough private plans in is not a very appealing option to me.

Now whether I endorse the regional PPO, that's sort of a separate discussion, but we need to look at alternative paths as opposed to just increasing payments, is my take on your question.

DR. WOLTER: I certainly wouldn't suggest that we just throw more money in hopes that lots of plans would come into Montana and North Dakota.

MR. HACKBARTH: I think that that's what we've been doing.

DR. WOLTER: But I do think that some of the opportunities created that allow benefit structures to be richer for beneficiaries or allow investment in chronic disease management or whatever, it would be wise to look at what ways can we approach that for rural areas, as well. And there might be different tools.

MR. HACKBARTH: I agree with that. What I don't want is the need to have private plans in rural areas become a fundamental design constraint on developing a system that applies to every place else in the country. I think that's just misplaced emphasis.

DR. BERTKO: Scott, could you put up one of your recommendation slides because I'd like to now talk about offsetting technical fouls, if I can use one of Bob's favorite metaphors.

Given that there are two parts here, possibly, to the payment question, the IME part is one you're suggesting we make a specific recommendation on. And for another time, I will again remind the Commission that missing from the payment mechanism today is, I think, an agreed upon

technical flaw which is that anybody in that VA/DOD system who receives care doesn't have the cost of that care counted in the way the calculation is done.

So if there are 20 of us around the table who are all Medicare eligible, and 19 of us get paid through the fee-for-service system and one gets their total care from say the VA system, the calculation shows 20 people in the denominator and 19 cost of care in the numerator.

From the background reading and from ancient gossip, the magnitude of those two things appear to be roughly offsetting technical fouls.

The MMA actually, I believe, instructs CMS to put the money back in and CMS has declined to do it in this year once again because it is a difficult number to calculate. I accept that completely. But it's out there and it's missing and it's a technical flaw that is of the same nature as this technical flaw.

DR. REISCHAUER: But with a very different geographic distribution.

DR. BERTKO: Agreed. It varies by where the people are but across the country it is, I think, rumored to be in the same kind of rough size range.

DR. HARRISON: CMS has had a lot of trouble getting the data to do that adjustment. There is a theoretical difference too, in that VA people who join plans can still use VA facilities. And so the cost to plans may also be a lot lower.

DR. BERTKO: Yes, and I would suggest that that is de minimus for most plans today.

MR. MULLER: I thought I could get through a year without an IME discussion.

That this was incorporated in the BBA in '97, as well, and the '99 and 2000 amendments, they averaged the IME in and they took it back out. I think we should continue our discussion about how a very complicated system ensues. I think throwing this IME recommendation here, it's not quite clear to me why we're putting it up at this time, in part because we dealt with it once in policy and took it back out and we now make direct payments to the hospitals for the IME that's included in the Medicare plans.

MR. HACKBARTH: That's not the issue that's raised by the draft recommendation. What we're getting at in the draft recommendation is that the separate payments are made to the teaching hospitals. But then the money is also

included in the payments to the private plans.

MR. MULLER: I understand that and there are at least two ways, if not more ways to fix that. One is, and I heard John speaking about if you take it out of the plan payments you have to then also take into account these VA payments that aren't in. So the alternative then is to take them out of the hospital payments.

My point is those IME payments are targeted in public policy, and we've had this discussion many times, for very specific purposes. Why we should then leave it to the plans to distribute them to hospitals when they might feel this is a make up for VA payments or something else, I'm not sure it's the right time to take that kind of issue on.

I'm a little hesitant to start going down the course of making this the one recommendation that we focus on out of this whole fairly contemplated policy area.

MR. HACKBARTH: Bill wants to go, but just again about what's shown up as a draft recommendation versus what has not. That one was put up as a draft recommendation because it seemed like it was pretty straightforward based on previous MedPAC discussion. I would not envision that that would be the sole recommendation. We're trying to see

if there are some additional elements. And when we switch the presenters here in a minute, you'll some other draft recommendations, as well. So it's not going to be considered in isolation.

DR. SCANLON: I would just respond a little bit to Bob. You started off by saying that things seemed more simple then. Maybe it was portraying them. But I think as you went on you kind of introduced some of the complexity in it.

I think that some of our differences in terms of how complex this is maybe goes to the issue of what are the assumptions that lead us to be able to evaluate whether something is neutral. My sense is we need to be explicit about what those assumptions are and then we need to determine whether or not they're truly valid.

Glenn earlier talked about the issue of risk adjustment in the past slowing or deterring MedPAC from thinking that a simple comparison should be made. I again raise the issue that we don't have the experience with risk adjustment.

You introduced trying to protect low income individuals. Just on that alone, thinking that we heard

that the proposal in the President's budget for Medicaid is to extend the Q1 program for one year. But it's denominated in terms of a national poverty level. So we've introduced geographic variation here. Again, the complexity needs to be explored. I understand fully what the impact is going to be.

We've also been talking about MA as a single entity. We should be thinking potentially about the fact that there are multiple types of plans within MA. Do we want to encourage them all? Or do we want to encourage some of them more than others?

That's the kind of discussion I think we need to have as part of this idea of neutrality.

DR. MILLER: That's an excellent segue.

MR. HACKBARTH: So we're going to switch gears now and move from the premium setting financial issues to some other issues, one of which is regional PPOs.

DR. MILLER: Sarah, if you can tell them what handout they'll be working in and all that.

MS. THOMAS: You should go to the first half of your MA package. And then after I go through some of the perhaps less complicated issues in MA, then Dan is going to

talk a little bit about the mandated report payment areas and some other aspects of risk adjustment other than the ones he just covered.

I'm going to talk about types of plans, quality, enrollment provisions and benefits.

This chart, I will be real quick. It just summarizes some of the key changes to the program for private plans. Scott has talked to you in depth about the last block but I also wanted to mention types of plans, added regional PPOs and specialized plans. It's shifted enrollment from a month to month process to an annual one. And of course, the law added outpatient drug benefits to Medicare. And some types of plans, but not all, must offer this coverage to their enrollees. I'm going to hit one issue here that's listed on this chart under benefits that's really a carryover from the earlier law.

Regional PPOs. Legislators, as we discussed earlier, hope that requiring plans to serve larger regions will bring them to more parts of the country. The logic will be that in order to serve the urban areas of the regions, that plans will agree to serve rural ones as well. PPOs are very popular in the non-Medicare populations so the

hope is that they will attract Medicare beneficiaries, as well.

Much as it did for the drug plans, CMS defined 26 regions for these regional PPOs following a market analysis. The drug regions are nested within these 26 regions. The key factors it looked at, very similar to the drug situation, were population size, at least 200,000 eligible beneficiaries but no more than 3 million, sufficient number of existing competitors, limited variation in payments within regions, and grouping states where beneficiaries typically receive care across state borders.

PPOs main tool to get enrollees to use their preferred providers is to offer different cost sharing, lower cost sharing to use in-network providers and higher cost sharing when you go out of network. It is the case that for most Medicare local plans that they much show that the overall cost sharing for their benefit package is no more than the fee-for-service program. For regional PPOs this is only true for in-network services.

Regional PPOs must have a combined deductible for Part A and B services and cap beneficiaries' total out of pocket liability for these services. The cap may differ for

in-network and out-of-network services. Neither the law nor regulations sets a level for these benefit parameters.

Regional PPOs can contract with CMS with less robust networks of providers than required of local coordinated care plans. These plans will meet CMS's access requirements as long as they pay providers with whom they do not contract at fee-for-service rates and limited enrollee cost sharing to those that would apply under the in-network levels. For example, a regional PPO may establish a network that meets the normal access requirements in 85 percent of the region. In that area, the PPO could charge higher cost sharing for beneficiaries who go out of network there. But in the remaining 15 percent of the region without a network the plan would not charge higher cost sharing for out-of-network services.

DR. REISCHAUER: Can I just ask you a question? Are we talking about where the participant lives or where the provider is?

MS. THOMAS: I don't know. Do you know, John?

DR. REISCHAUER: Imagine the situation in which the individual lives in a rural area where there is no network and chooses to go to an out-of-network doctor in an

urban area near.

DR. BERTKO: Let me see if I can rephrase and answer the question. It is really where the provider is located. So let's suppose there are two kinds of people here. One person resides in Eureka, California, which is difficult to contract in. And that person signs up for the regional PPO because it's offered California-wide. They then get exactly what Sarah said, in-network benefits. The facility presumably is paid at fee-for-service and they are okay.

MS. THOMAS: It is.

DR. BERTKO: Let's suppose my mother-in-law, who lives in the Bay area, is up in Eureka on a visit and has some need for services there. She's staying for a week's vacation in Fog City. She would then have the same benefit of being at that provider, in-network services, and she would have in-network -- the provider would be paid at fee-for-service.

So it's kind of yes to both and it's really provider dominated, depending on where it is. If again she is back in the Bay area, though, she can only get in-network cost sharing by using the facility in Daly City, California.

Too complex?

DR. REISCHAUER: For the average beneficiary, yes. For an esteemed member of MedPAC, no.

DR. BERTKO: I think actually it's even easier than that for the beneficiary. They show up in-area, they find their local facility. And out-of-area they go anywhere they want.

MS. THOMAS: There are three direct financial incentives to attract regional PPOs. In addition, carriers cannot offer local PPOs in 2006, the ones that were being offered before are grandfather in, which also may be another kind of incentive to offer a regional plan.

First of all, risk sharing for regional PPOs is structured through corridors that compare plan's costs at the end of the year to their payments. If costs are higher, CMS will give them additional funds. If costs are lower, plans must return funds to Medicare.

The Regional Stabilization Fund provides $10 billion as needed to encourage regional PPOs to enter markets and also encourages them to stay there. The funding starts in 2007 and ends in 2013 or whenever the funds run out. The payments are available in three situations.

First, a regional plan wants to be the first nationwide plan and there's no existing regional plan covering the whole country in 2006. And there's no regional plan serving every single region. So it wants to be the first national plan that comes in.

Two, a regional PPO wants to be the first to serve a region and there's no national plan already in place.

Three, a regional PPO plan otherwise will depart from a region, leaving it with fewer than two regional plans and there's no national plan.

If a national plan enters in 2006 and enters through the period, or if regional plans are in all areas, then it's unlikely that money will be paid out unless it's to keep plans in place. No other type of plans have access to these funds. That is, no local plans have access to these funds. And you may want to discuss your views of this policy.

Finally, there are essential hospital payments. Regional PPOs that are having trouble contracting with hospitals may ask CMS to make additional payments directly to those hospitals, these are called essential hospitals, to secure an adequate network. If they meet the test, CMS will

pay these hospitals, which are not otherwise critical excess hospitals, as if they were critical access hospitals. They'll pay the difference between the PPS amount and the critical access amount directly to the hospitals. The money for this provision is limited to $25 million a year and it's paid out on a first come, first served basis.

You may also want to discuss your views of this policy. It's inconsistent with the level playing field argument on a couple of counts. Medicare does pay teaching hospitals directly for the IME payments of beneficiaries in private plans but only what it otherwise would pay them under fee-for-service. This is the only instance where Medicare pays providers contracting with plans more than it ordinarily would. And second, again, these funds are not available to local plans.

Another potential issue that we've come up with relatively recently is the way that regional PPOs bid and how this bid is adjusted to reflect county payment rates. We're still working through this and I think we may bring it to you in April, depending on what we learn and how clearly we understand it at that point, how it will play out.

I'm going to switch gears a little bit now and

talk about quality. We looked at quality in two ways, first how it's changed over time for MA plans. And second, how it compares between private plans and the fee-for-service program.

HEDIS measures generally show stabilization or improvement. Patient experience measures collected through CAHPS show mixed performance over time. However, the performance, when you compare between Medicare Advantage and fee-for-service, is fairly similar.

Other the patient experience measures, I wasn't able to find measures of clinical quality to compare plans to the fee-for-service program. This is notable as you think about plans competing on two dimensions with the fee-for-service program, both cost and quality.

CMS could calculate the HEDIS measures that can be derived from administrative data and create composite measures in the fee-for-service program and then allow a better comparison of understanding what the different quality is between the two programs. You may want to recommend that the Secretary do this to help beneficiaries evaluate their choices.

As with the earlier program, the quality

requirements vary by type of plans with regional PPOs treated like local PPOs. That is those local PPOs that are not sponsored by HMOs. Most types of plans must have quality programs of some sort, although the requirements vary by type of plans and the sets of measures also will vary.

For example, MSA and private fee-for-service plans do not have to have a quality improvement program. But all plans, including these, must maintain a health information system that has to meet certain requirements.

CMS will allow some variation in measure reporting for HMOs and PPOs, at least in the early stages of the MA program. CMS expects to collect measures from HEDIS, CAHPS, and the Health Outcomes Survey for both HMOs and PPOs, but the HEDIS measures will vary. PPOs will not have to submit HEDIS measures that rely on medical record review.

CMS indicates in the preamble to the regulation that it expects to move to the same measures over time as PPOs build the capacity to report measures derived from medical records. Specialized plans may use measures derived from the MDS, the Minimum Data Set that is applied in nursing homes, instead if they do target the nursing home

populations.

There has been some debate lately about whether plans should have these differing program requirements or whether these should vary by type of plan. One view is that plans like PPOs do not set out to manage care or to be accountable entities. Thus requiring them to report on quality measures may be inconsistent with their mission and what they're really setting out to do.

Another view is that all plans, regardless of their structure, and it often is difficult to distinguish among plans on this level, should have to report on robust measures of quality. That is those that are derived from medical records.

It can be more expensive for plans to collect these measures and so there are competitive issues associated with having different requirements. Also PPOs, for example, do not provide as high quality as more organized systems of care. Beneficiaries arguably should be able to see that in the quality measures, not the lack of measures. That would be the other side of the argument. You may want to discuss this issue.

You also remember that you recommended pay for

performance for Medicare Advantage and we discussed that a little bit in the last session. CMS has recently stated that unlike some of the other demonstrations it's pursuing on the fee-for-service side, it does not plan to test this concept to Medicare Advantage. It argues the competitive nature of the program makes this unnecessary.

I'm going to shift and quickly talk about enrollment provisions. MMA implements an annual open enrollment period. In 2006, the beginning of year, beneficiaries will choose plans. And then they can switch again within the first six months but only to a similar type of plan.

Remember now beneficiaries can enroll and disenroll on a month-to-month basis. And starting in 2007 the six-month window will shrink to a three-month window for additional switches, and then that will persist on into the future.

I also wanted to point out the law did not allow all beneficiaries who developed end-stage renal disease while in fee-for-service Medicare to enroll in Medicare Advantage plans, which is something that you have recommended in the past. CMS did decide to allow these

beneficiaries to join specialized plans if these plans decide to enroll them. It's their option.

Finally, I want to talk about one benefit issue. Under the MA program, private plans do not cover hospice care. This policy works against the goal of fully integrated health care delivery through private plans. For all other Medicare covered services under Parts A and B, Medicare pays a single amount to care for the full array of Medicare services. This gives plans the incentive to coordinate all care and choose the most effective setting to improve quality and lower costs. By contrast, beneficiaries who elect hospice essentially are moved out of their plan's care system, which has the effect of discouraging plans from developing integrated approaches to end of life care.

The rationale for this provision goes way back to 1983 when both the Medicare risk contracting program and hospice benefit were started. At that time the actuaries didn't know the cost of hospice so left it out. But hospices also have argued that they have a different care system and it would be inconsistent with the managed care companies perspective.

On the other hand, if Medicare Advantage were

liable for hospice beneficiaries' full spectrum of care, they'd be more likely to coordinate care across settings, experiment with innovative end of life care programs. And indeed, there are some innovative end of life care programs being sponsored by plans for their broader populations.

It's also the current policy of treating hospice separate from all the other A and B services ends up with some administrative complexities. And now with Part D benefits available through plans, it becomes even more complicated. Plans that offer Part D must continue to do so for people who are in hospice, even though they don't typically have to provide all the other A and B services that they might use.

But the hospices are responsible for paying for drugs for palliation and that's paid through Medicare fee-for-service. It's very complicated and lots of accounting has to take place to track this benefit.

So integrating the benefit would be more straightforward and this is the final issue you may want to discuss.

Do you want to talk ahead and talk with Dan or do you want to stop at this point?

MR. HACKBARTH: We ought to and then we'll have the discussion.

DR. ZABINSKI: Throughout today we've discussed substantial changes to the Medicare Advantage program. And in regard to those changes, the MMA directs MedPAC to analyze issues related to the payment system in the Medicare Advantage program. This mandated study has several parts but today I will focus on two key issues.

One of these issues is that the MMA directs us to identify appropriate payment areas for Medicare Advantage plans. I'm sure you know that the county currently serves as the payment area for MA plans, but we have found that using counties as a payment area does create some problems.

First, many counties have large annual changes in their per capita fee-for-service spending. This is important because the Commission has recommended, as we have discussed already, paying equally between the fee-for-service and Medicare Advantage sectors. But if you can't get accurate estimates of local fee-for-service spending, there is some uncertainty as to whether you can be confident of paying equally in the two sectors.

Also, adjacent counties often have very different levels of fee-for-service spending, which is important because payment rates often depend on fee-for-service spending. If adjacent counties have very different payment rates, plans may offer less generous in the county with the lower rate or may avoid it altogether, create appearances of inequity.

The second issue the MMA directs us to address is risk adjustment for Medicare Advantage payments. Earlier I presented results from a mandated analysis that assesses the predictive accuracy of the CMS-HCC, which is currently used to risk adjust MA payments. In addition, I'll also discuss a policy where CMS is increasing payments adjusted by the CMS-HCC to offset a reduction in aggregate payments that are caused by the CMS-HCC.

First, let's discuss our analysis of the payment areas of Medicare Advantage plans. We considered three alternative payment area definitions that are larger than the current definition, the county. In one alternative we collected urban counties into metropolitan statistical areas, or MSAs, and then we collected the remaining non-urban counties in statewide non-MSA areas for each state.

In a second alternative, we collected all counties, both urban and rural, into health service areas, or HSAs, as defined by Diane Makuc and colleagues at the National Center for Health Statistics. These HSAs are collections of counties that are relatively self-contained with respect to short-term hospital stays among Medicare beneficiaries.

In the final alternative, we created a hybrid of the first two definitions, collecting urban counties into MSAs and non-urban counties into HSAs.

I apologize to Glenn, I have not updated my technology on this, but to give you a better sense of how these three payment area definitions relate to one another, the next three slides hone in on the panhandle area around the city of Amarillo, Texas.

First, let's consider the MSA/state non-MSA definition of payment areas. On this slide we show how MSAs look around Amarillo. The striped areas that are of the same color are counties that make up an MSA and act as distinct separate payment areas. The white area is counties that are not in MSAs and are part of the state non-MSA area for Texas.

I'd like you to pay particular attention to the orange striped counties in the center of the picture that make up the Amarillo MSA, because when we turn to the HSA definition of payment areas those two counties become part of this larger red area, which is the HSA for Amarillo and acts as a separate payment area under the HSA definition.

And finally, when we consider the MSA/HSA definition, the two counties making up the Amarillo MSA again become orange stripes and become a single payment area on their own. The remaining counties from the Amarillo MSA remain red and act as a distinct payment area on their own.

We used three tools to assess the desirability of these three alternatives. In one tool we asked would the payment areas have enough Medicare beneficiaries to obtain reliable estimates of per capita fee-for-service spending?

In the second tool, we asked how well do the payment areas match the market areas of Medicare Advantage plans and private sector HMOs? If payment areas do not accurately match plan market areas, plans may be in situations where payments are well above costs in some parts of a payment area and well below cost in other parts.

We actually used two measures to analyze how well

a payment area matches plan market areas. First, among payment areas where at least one county is served by one or more plans, we determine the percentage that have the entire payment area served by plans. Second, among plans that serve at least one county of a payment area, we determined the percentage that serve the entire payment area.

Then in the third tool, we asked the question are the payment areas too large? In large payment areas, the costs of serving beneficiaries can vary widely by geography and extremely large payment areas can present a problem for MA plans because the plans are required to serve the entire area. The plans may find they are profitable in some parts of a payment area and unprofitable in others, which may cause them to avoid the payment area together.

We measured the variation in costs within a payment area as the difference between the per capita spending in the highest cost county and the per capita spending in the lowest cost county.

Then, when we analyzed how well the three alternatives measure up to the three analytic tools, we found the following. First, that the MSA/state non-MSA definition provides by far the largest beneficiary

populations and the most stable estimates of local fee-for-service spending. The reason this definition performs better than the others on this measure is the large state/non-MSA areas that exist in many states such as Texas.

But we also found that the MSA/HSA definition is the best match for plan market areas for both Medicare Advantage plans and private sector HMOs. We also found that the MSA/HSA definition has the smallest variation in terms of the costs of serving beneficiaries.

So in response to those findings, we have developed this draft recommendation. Payment areas for Medicare Advantage local plans should have the following characteristics. First, among counties in metropolitan statistical areas, or MSAs, payment area should be collections of counties that are in the same state and the same MSA.

Second, among counties outside of MSAs, payment areas should be collections of counties in the same state that are accurate reflections of health care market areas such as health service areas.

An issue related to this recommendation is that plans can currently obtain waivers that allow them to serve

only specific portions of a payment area if they can show it is difficult to form provider networks throughout a payment area. And we believe plans should have this opportunity to obtain waivers irrespective of the payment area definition.

The spending implication of this recommendation would be that it should have no direct effect on program spending.

However, the effect on plan participation of the recommendation isn't unclear. On the one hand, plans may withdraw from the Medicare Advantage program if the larger payment areas sufficiently reduce opportunities for isolating payment areas where payments are favorable relative to costs. On the other hand, plans may extend their participation to counties they currently do not serve if the larger payment areas sufficiently increase payments in those currently unfavorable counties.

Now let's turn to risk adjustment of Medicare Advantage payments. The current status of risk adjustment is that, first of all, CMS began using a new system of risk adjustment in 2004, the CMS-HCC. This model uses administrative data as well as beneficiaries' conditions diagnosed in the previous year to predict beneficiaries'

costs in the current year.

In 2005, 50 percent of payments are risk adjusted with the CMS-HCC. The remaining 50 percent is adjusted with a demographic system that uses only administrative data to predict beneficiaries' costs and has been found to perform much worse than the CMS-HCC in terms of accounting for difference in beneficiaries' costs.

The CMS-HCC is being phased in with a larger share of payments being risk adjusted each year with ultimately in 2007 100 percent of payments being risk adjusted. Then, in 2006, CMS intends to adjust the CMS-HCC to include more conditions than the current model has.

Initially, our plan at this point was to discuss our analysis of how well the CMS-HCC predicts beneficiaries' costliness, but we had a change in plans and I discussed that earlier, so we can skip this slide.

Now let's turn to this policy where CMS is currently increasing risk adjusted payments to offset the effects that risk adjustment has on payments to Medicare Advantage plans. We know that CMS has estimated that in 2004 and 2005 risk adjusted payments are lower than payments adjusted by the democratic system in the aggregate. This

indicates a more precise measurement by the CMS-HCC of the favorable selections going to plans.

In response to the effect that risk adjustment has on aggregate payments, CMS is making proportional increases to all risk adjusted payments so that aggregate payments are equal to what they would be if 100 percent of payments were adjusted with the demographic system. The end effect is that plans are being held harmless from the impacts of the CMS-HCC in the aggregate but it's true that payments at the individual plan level can be affected by the risk adjustment.

A new wrinkle in this issue is that the most recent budget submitted by the President includes a phase out of this policy so that the risk adjusted payments will still be increased but by a smaller about than if this policy continues in its full force. The President's budget estimates that under the phase out aggregate payments would be $8.3 billion higher from 2006 through 2010 than they would be with no increase to risk adjusted payments.

The motivation for this policy is to promote stability in the Medicare Advantage program. But even if this policy is phased out, I want to emphasize that any

policy that increases risk adjusted payments is inconsistent with MedPAC recommendations. In particular, the Commission has recommended risk adjusting payments with a comprehensive system such as the CMS-HCC.

In addition, we have recommended that payments should be neutral between the Medicare Advantage and fee-for-service sectors. That means that, on average, payments should be equal in Medicare Advantage and traditional Medicare after accounting for differences in risk. It's the job of risk adjustment to account for those differences in risk and put the MA and fee-for-service sectors on a level playing field. But this policy that holds plans harmless from the impacts of risk adjustment has the effect of moving us away from the concept of a level playing field and payment neutrality.

In response, we have developed this draft restatement of a recommendation that we made in the March 2004 report. CMS should continue to risk adjust payments with the CMS-HCC system but should not continue to offset the impact of risk adjustment on overall payments in 2006 and subsequent years.

The spending implications of this recommendation

is that it would not increase Medicare spending relative to current law. However, the President's budget, as I mentioned earlier, projects additional spending of $8.3 billion above the risk adjusted level as the policy is phased out. Consequently, this recommendation may affect plans because they may develop strategies assuming risk adjustment payments will be increased according to the proposed phase out.

Therefore, this recommendation may cause plans to reduce the generosity of their benefits and reduce the extent of their participation in the Medicare program.

That concludes my presentation and I'll turn it over for discussion.

MR. HACKBARTH: Sarah, would you put up -- it's page 10 in our packet, on the Medicare Advantage policy issues. Summarizes possible recommendations.

We've got roughly a half-hour between now and our scheduled public comment period; is that right? So on the table for discussion are these issues.

In addition to these, the IME issue that we alluded to earlier, the proper geographic unit that Dan's been talking about, the hold harmless budget neutrality of

the risk adjustment phase-in, and then any of the neutrality issues in payment that we were discussing earlier.

Let me see a show of hands of who wants to -- why don't we start with Sheila and we'll just move down this way.

MS. BURKE: Glenn, if I can, I'd like to step away from the list of recommendations for a moment, although I want to come back to it and talk about hospice. Can we go back to the chart that showed Amarillo for just a moment? I want to be sure that I understand what ultimately you were proposing, which of the scenarios in terms of the combination of payments.

DR. ZABINSKI: The recommendation most closely reflects the third one.

MS. BURKE: That's what I want to understand. Would you go back to that for me for just a second?

DR. ZABINSKI: The idea is that the solid colored counties, those blocks are all counties. The solid colored counties all represent counties that make up a HSA but are outside of MSAs. And then the striped counties make up MSAs. Like in the lower right corner, I don't know what city that is but that's another MSA.

MS. BURKE: And so let me understand what you were proposing. The payment essentially would have two portions. One would be specific to Amarillo, to the stripes.

DR. ZABINSKI: Right.

MS. BURKE: Which would take into consideration the costs in that area.

DR. ZABINSKI: Exactly.

MS. BURKE: Separate from that would be all the red areas, the presumption being that is a market.

DR. ZABINSKI: Right.

MS. BURKE: And so those costs would be calculated on the basis of that market.

DR. ZABINSKI: That's right.

MS. BURKE: That's what I thought. I just want to be sure that I understood that and I visualized it correctly.

Tell me, having done this analysis nationwide, how clean is that analysis?

DR. ZABINSKI: In what sense?

MS. BURKE: I'm less worried about the MSA than I am about anticipating or understanding what the market is outside of the MSA.

DR. ZABINSKI: Okay.

DR. REISCHAUER: It's not a market, it's a payment area. The market is the HSA. We're cutting out the core of the HSA because service utilization in the balance of the HSA ex-Amarillo is significantly lower; right?

DR. ZABINSKI: That's generally the theory, yes. The idea was to establish something larger -- the starting point was established payment areas that are larger than the counties because the counties present some problems. Then we took the step forward and said okay, what are our alternatives? In one, we said okay, MSAs and then the rest of a state is just non-MSA. A second one we said okay, let's combine all counties, whether they're urban or rural, into these HSAs. And then this one here is a third one.

The first alternative, the MSA/state non-MSA area, we just felt that the state non-MSA areas are just too big. There's too much variation.

MS. BURKE: Help me understand. I conceptually see where you're going and don't disagree. But I want to understand. for example, the turquoise and whatever that pink.

DR. ZABINSKI: Those are other HSAs.

MS. BURKE: Those are other HSAs but they are distinct enough. The way this particular area is configured, I'm trying to understand what our presumptions are. You've got two reds and a purple down below Amarillo, a purple and then two purples below it. And I'm trying to understand what our presumptions are about how unique these areas are and how reflective they are on consistency in terms of utilization, and therefore pricing.

DR. ZABINSKI: That's the whole idea of them. All of the red ones have -- they're self-contained in terms of short-term hospital stays among Medicare beneficiaries. And all of the purple ones are, as well. Basically, the idea is that the beneficiaries in that area get their care within an area and not many beneficiaries are coming from outside to get care in that area.

MS. BURKE: Presumably, that is unique because of the location of tertiary facilities and because of delivery systems. And we are capable, through the current data we have, to know how unique -- I mean, the fact that you've got a bunch of mustards surrounding the purples that are seemingly quite distinct in distance, one would wonder conceptually, as you look at that, what is so odd about the

distribution system that would have the purples interfere in the mustards?

MR. HACKBARTH: I don't know anything about this part of Texas.

MS. BURKE: I don't know anything about Texas.

MR. HACKBARTH: It could be roads, major roads, geographic features that influence where people tend to go for their health care services.

MS. BURKE: And so we are convinced that we, in fact, can be accurate enough because of the data that tell us the billing patterns that these unique --

DR. ZABINSKI: These colored areas were developed by NCHS researchers.

MS. BURKE: The Medicare data is adequate that we feel comfortable with this?

DR. ZABINSKI: Yes.

DR. REISCHAUER: The reference you gave was a 1991 reference. I assume they've been updated since then.

DR. ZABINSKI: Actually, no, they have not.

MS. BURKE: Well then, that presents its own set of issues.

DR. REISCHAUER: That presents its own. And the

thing to note about the mustards is what they really are is the non-white and yellow striped part of the HSA that was associated with the whatever that metropolitan area is. So it's not really so --

DR. ZABINSKI: I believe that is Lubbock. I know Texas.

DR. SCANLON: Just as a clarification, could I ask -- didn't you, even though these are 1991 areas, use current data to assess them?

DR. ZABINSKI: Yes, right.

DR. SCANLON: The counties are historical, too, and the comparison was of current data by county, current data by these areas, current data by MSAs.

DR. REISCHAUER: But conceivably, if somebody plunked down a wonderful hospital somewhere else, we would rechange them.

MS. BURKE: But how quickly would we pick that up? Bill, to your point --

DR. REISCHAUER: It's probably been 15 years since this data or longer, since this data -- I mean, the thing was published in '91.

DR. SCANLON: Not the data used to evaluate them.

The data we used to evaluate them are current data; right?

DR. ZABINSKI: Right, in terms of how well they match current service areas from plans, that's current.

DR. REISCHAUER: Service area, yes. But a lot of these areas, there is no plan in them.

DR. ZABINSKI: True.

MS. BURKE: But so I understand, the data that we are using is current enough to know whether three hospitals in the purples have shut down.

DR. REISCHAUER: The data we're using is utilization; right? It has nothing to do with service patterns. It's aggregate service use.

DR. ZABINSKI: In developing these things, yes, service use was what was used to develop them.

DR. REISCHAUER: But not location.

MS. BURKE: The service use should track that pattern.

MR. HACKBARTH: They reflect where they go for the service.

DR. ZABINSKI: Exactly. It's patterns of use. The idea is to get very self-contained areas so we don't have people going in or out. Most of the care, the people

live there and they get their care within that area. And there's not many people from areas outside of there coming in to get care there.

DR. REISCHAUER: That analysis was done before 1991.

DR. ZABINSKI: Right.

DR. REISCHAUER: It's not the stuff, the calculations you did with more recent as what I'm saying.

DR. ZABINSKI: Right.

MS. BURKE: Let me try and understand this. Do we know today that the purples are being serviced by existing capacity in the purple area? Or does this reflect usage from 1991 when the service capacity might have been different?

DR. ZABINSKI: The latter.

MS. BURKE: That's not what you said before. So now I really am trying to understand how current this is.

MR. MULLER: It's '91 cohorts of service, which is the way he responded, with current utilization.

MR. HACKBARTH: What I would hope we would do, patterns of care change. Populations change, new institutions are built. So I would hope we would never

endorse a particular definition of what the markets are in North Texas and say this ought to be used in perpetuity for Medicare.

MS. BURKE: No, my concern is that we're not endorsing a model built on data that is, to start with, 20 years or 10 years or whatever it is old.

MR. HACKBARTH: So what I'm thinking, I think is consistent with that, Sheila, is what we would endorse is the analytic method of building HSAs using appropriately recent data regularly updated so that it reflects how markets have changed and patterns of travel have changed over time, as opposed to endorsing using 1991 defined --

DR. ZABINSKI: And if you read the draft recommendation, that's why I worded it the way I did, is it says some system where you have relatively self-contained health care systems such as health service areas.

MR. HACKBARTH: So this is an example of what it looked like using 1991 data as opposed to necessarily the map that would be used for Texas in 2008.

MS. BURKE: But let's take your question to the next point, which is is that data available?

DR. ZABINSKI: I suppose it is, yes.

MS. BURKE: Let me make sure I understand. We suppose that the data is currently available that is current that can tell us this. That is, if you live in Merced, California, whether you get serviced out of Modesto or Fresno? We know that? That data it is currently available, so that we can build a payment system based on current data because it is current and it is updated routinely.

DR. ZABINSKI: The people at NCHS said they would redo these things for us, if requested.

DR. REISCHAUER: You should request it. But just in addition, if you could press a button and say should we stick with the county system or with this out of date mechanism, I'd press the button and go for the out of date system over what we have now. I mean, metropolitan areas plus HSAs as defined in 1991. I don't think it's too hard to update the HSA thing. There's also the Wennberg stuff with the hospital referral district. And I think that really is more modern.

DR. ZABINSKI: But not much.

DR. REISCHAUER: Really?

DR. ZABINSKI: My understanding is they haven't updated those in awhile.

MS. BURKE: My only concern is, I'm like Bob, push the button. But what I don't want us to do is to go down a track that repeats some of the promise we face today which is data that is so old that we are building a system based on data that will never be relevant and that patterns and prices are going to be outdated before we do it.

MR. HACKBARTH: I agree with that. And then again, my assumption was that we were endorsing not a particular map but a method and approach to defining areas that I don't think we need to specify what the appropriate intervals are for updating, but necessarily it is something that requires regular updating using more recent data so that we're connected to reality. We would reflect that in the text.

MS. BURKE: Great.

Now can I just go back to your earlier list, to the list of areas of recommendations. And only to suggest the following. This is a topic that I would hope we would come back to and discuss in greater detail to fully understand the impact. And that is the issue of hospice care.

You are right, Sarah, there were a variety of

reasons we did what we did in 1983. There were questions about what we truly understood at the time and didn't understand about hospice care and about its costs. There were great fears about whether we could protect time, the requirements about people choosing between traditional care and palliative care were our own lack of understanding about how people made those decisions and the likelihood where people would bounce back where and the ultimate cost would exceed our prior costs.

Having said that, we have come a long way. And I am, in fact, very concerned that hospice remains underutilized because of the failure of the system to fully appreciate and integrate it into people's expectations. And that there is this sort of division where people have to make these decisions in a way that doesn't fully appreciate the sort of intricacy of that relationship.

So I can conceptually think very much we ought to integrate it more into the traditional view of what a range of services ought to be. But I want to be certain before we make the statement that we understand the risks of doing that, we understand what the relationships are today.

So in the course, over the next month or so, as we

look at these in more detail, a lot of the work that you guys have done in the past recently about hospice, I'd like to come back to fully understand what the relationships are and what risks there might be in putting it into a benefit package.

Because in no way do I want to, in any way, disadvantage hospice or put it at any risk. But it is not what it ought to be today because of people's failure to understand it as part of a basic benefit people ought to have.

DR. STOWERS: I agree with pushing the trigger to go on. I'm just wondering with the HSA thing being as old as it is and Medicare having really switched, also at the risk of shutting down any discussion over the definition of rural, but really where Medicare has gone now or CMS is to a metropolitan service area, micropolitan service area and then rural. That's gone through extensive research. All the definitions of rural hospitals, where all the grant programs go, are all over these new service areas which tend to break states down into three categories as opposed to the panhandle of Texas -- I won't make you go back to it, where you have eight colors, it actually breaks the panhandle of

Texas into three colors. It's supposed to be based on service areas just introduced this last year, I think. This less than 18 months old in data.

I'm just wondering why we didn't go that direction and went back to the old HSA thing?

DR. MILLER: Can I ask something here? I thought that CMS chose not to pick up the micropolitan areas in its payments. At least so far.

DR. STOWERS: Location of critical access hospitals and all of that, it's still in effect. Maybe I'm wrong.

MS. THOMAS: Not for the hospital wage index, is what I think.

DR. STOWERS: I'm just saying this is more current data on where service areas are and so forth. I was just curious why -- or was that looked at as a possibility of not having seven or eight different regions in the panhandle of Texas, which to be very honest, having been out there a lot, is very uniform in services once you get out of Amarillo.

MR. HACKBARTH: You've got a huge advantage, in terms of knowledge of Texas. My understanding of the micropolitan areas, that's sort of a byproduct of the MSA

process. The Commerce Department says there's another type of aggregation but it's not health specific. So this has to do with broader commercial patterns and commuting patterns and the like.

This on the other hand, if it's using appropriately updated data and the like, is actually specific to health care use patterns and where people go for their health care.

Conceptually, that might be an advantage that would make it more likely to track with plan market areas in some of the tests that we're applying. Let me put a question mark at the end of that. That seems logical to me.

DR. ZABINSKI: I agree with that, yes.

MS. RAPHAEL: I was just wondering if we could organize this in a way that would make it easier to deal with, because right now I'm having a hard time trying to put it all together. And also I'm not entirely clear what's a mandated study and what we're doing apart from the mandated study.

I see this as one part of this is trying to get payments to be more accurate and closer to costs, something that you raised earlier, Glenn. And I have a question about

what we know now about the accuracy of payments to costs because I don't have a good sense of that overall.

And under that, I put the bonus payments and the essential hospital provision and the IME. I don't know whether or not I put the issue of neutrality under that. And I'd like to better understand whether it fits under that umbrella.

Then I think under quality, part of that for me is better targeting payments. And that kind of harks back to something we had recommended, I believe last year, which was tying payments to Medicare Advantage to quality results. And I'm not entirely sure whether what we're doing on quality is tied to how I think about targeting.

And then we have another area of benefits, which I think only involves hospice but I'm not sure. So I just think I'd like to see some different organization of all these threads.

DR. MILLER: We can decidedly do that. Maybe what we do in this conversation is talk about some of your interest on the specific issues, and when we come back distinguish between what's in the mandated study, which is predominantly the geographic area, and the risk adjustment,

those two pieces.

Not just to complicate your typology, if you woke me up in the middle of the night I would think that risk adjustment is also a payment issue. And I think your list was about right, that the bonus payments, the essential hospital, the IME, the budget neutrality, and the broader neutrality discussion without implicating anybody's position, that all feels like payment issues to me.

To respond to your quality point, these are, in a sense, not changing anything that we're saying about pay for performance. It's more about what measure sets and how comparable they are across the different types of plans, I think is really the issue that we're focusing in on the quality. And then you're correct, the benefit piece on hospice is kind of a benefit piece that stands on its own.

But we can come back with a much clearer typology. We switched some order here this morning, which is some of the reason that we've been moving across. And I apologize for that. But it the end, we thought that there was a certain logic to housing things together. Perhaps it didn't work, but that was the idea.

DR. CROSSON: Thanks. I have two things. I have

a question on the geographic payment area and then a comment on the risk adjustment budget neutrality issue.

The payment on the geographic area is just to understand why we end up splitting dual state metropolitan statistical areas. I want to understand that.

With respect to the risk adjustment issue, again not to necessarily speak to the decision that was made by the CMS Administrator to create this policy. I know there's a good deal of difference of opinion about that. But I would like to point out one issue that, at least in our own organization and I believe in others, influences the timing of the phase out, because I think that's the new question here.

That has to do with the reality, I believe, that earlier risk assessment data appears to understate beneficiary risk where providers are not used to and don't understand the process of coding, particularly as it relates to secondary diagnoses. That certainly has been our experience.

Secondly, it has turned out to be much more difficult than you might intuit to get that to change. When you're working with physicians who, in many cases, have been

20 years working under a pre-payment system and suddenly have to learn something that was learned very early on by physicians in fee-for-service, it turns out to be very difficult to do.

So again without gainsaying the reasons why the decisions was made, the fact it was made created for our organization and others an opportunity to try to get to the even playing field by teaching our physicians over time the reality of the coding world, which in fact physicians who are paid on fee-for-service have known for a long time.

That process is not completed yet, and I guess I would say there are a number of people in my own organization and others who are currently breathing into paper bags as we have this discussion because of a concern that more time is needed. And in order to get to that even playing field that we say we want, that's an important consideration.

MR. HACKBARTH: To the extent that a group of providers like yours are less used to, experienced with coding, the potential consequence of that is that when we compare patients they look healthier than, in fact, they are because all of the comorbidities, et cetera, haven't been

completely coded.

And so if you give more time, your argument is that you may actually find what looks like a very good selection of risk. The difference between your selection and Medicare's shrinks and it has nothing to do with the changing population but simply proficiency in coding, if I've properly summarized it.

DR. CROSSON: That's correct.

MR. MULLER: [off microphone.] Help me understand the reweighting. Everything now is comorbidity and so therefore it's a more [inaudible]. How is the reweighting of that [inaudible].

DR. BERTKO: I'm not sure of the DRGs, but Dan alluded to something. There are now going to be 30 more diagnoses, roughly, added to the risk adjustment system. That makes the pencil sharper. And so yet more diagnoses will be there and those predictive ratios, if anything, should get better over time.

That is, we predict more about more diseases, the healthy baseline actually falls, and you begin sending money out to various people in more disease categories.

MR. HACKBARTH: But the way this is currently

being done, if I understand correctly, we're using those potentially flawed understated numbers to redistribute dollars within the pool, but in the aggregate holding plans harmless.

DR. BERTKO: Yes.

MR. HACKBARTH: So all health plans, that dollar pool is fixed but you might be getting more or less. For example, as a staff model group model HMO with less proficient coders, be getting less money relative to John's, who's using fee-for-service providers who are very proficient at it.

DR. BERTKO: There is actually a different element, in addition to the coding, is the data collection. Those of us who were awake at the start of this, and two of us are in the room, are doing better and have a fairly good incentive to both code and collect and submit data well.

MS. DePARLE: Actually three of us and maybe another one, including Mark. What I remember at the beginning, remember risk adjustment was supposed to have been fully phased in five or six years ago. And at the beginning, the plan said that they couldn't collect the data. So my concern about all of this is that it just seems

to be taking forever to get to what everyone says they agree to, which is a level playing field.

DR. BERTKO: May I make my other comments now, switching gears.

This goes back to the area buttons, and I'll take Bob at his metaphor, and I would ask him and collectively us, to hold your finger above the button but not push it for a couple of reasons yet.

The first it is, and this is both sides, the plan side for MMA and the CMS side. There is a huge amount of change, and thus uncertainty, flowing through the system starting 1/1/06, including regional PPOs and all kinds of stuff in the bidding.

One of the questions that I'm sure we will want to ask is what happened? And to introduce new geographic areas on top of everything else immediately would confound that. So I would say have some patience a little bit here again.

Point number two, and I know this makes it yet more complex, is I would encourage Dan at least, who I think is thinking about this quite a little bit, to consider the very large urban MSAs. And there's three of us from the Bay Area here. Jay, who lives on the peninsula, I believe.

Arnie, do you live in Mill Valley? In the city. And I live there, in Oakland. And none of us ever cross over. Alameda County is a huge county, possibly bigger than some East Coast states with a million people in it. And having a single metropolitan MSA for an area as big as this, or say New York City's five boroughs together, might be not the best thing in the world either because the delivery systems are just very difficult.

I have one more comment after that. The third is, and again this could be a reason to push or not push the button, effectively post-MMA if regional PPOs spring into existence the worry about rural payment areas may become moot because it will be boom, the state of Texas, the state of California, the state of Florida, or even bigger multi-state regions.

In which case -- and Sarah alluded to this -- there is a highly complicated interservice area region adjustment that I don't even think I quite understand yet myself. So put that on board and say patience, perhaps.

DR. ZABINSKI: On your issue of the size of some of the MSAs, I know in the Bay Area there's actually quite a few MSAs. I mean, San Francisco and Oakland are in separate

MSAs. They aren't that big. And they would serve as distinct separate payment areas. Contra Costa and Alameda make up the Oakland MSA. And San Francisco, San Mateo and Marin County make up the San Francisco MSA. By looking at it the areas that are covered by plans, they match those MSAs pretty well.

I'm not as concerned about that as you are.

DR. BERTKO: I stand corrected. I usually think of the MSAs as they are in kind of the USA Today maps.

DR. WOLTER: I was just thinking that in the quality section there might be an opportunity. I think over time one of the interesting questions will be how do incentives work at a plan level versus at a provider level. If you were to take group practices or take some of the informal but natural collections of physicians and hospitals that Arnie was talking about, is there a way to slice and dice the quality comparisons a little bit more finely rather than global fee-for-service versus global plan?

And even within plans, there are plans that are very tied to group practice and staff models and others that are very tied to more independent practice setups.

If there were any way in the text to suggest that

some analysis along those lines could have value, I think we might learn quite a bit more than just looking globally at fee-for-service versus the plans.

DR. REISCHAUER: With respect to John's hold your finger off the button, there's an awful lot of things where I think we need to prioritize and say this is the objective over the longer run. You have an awful lot of work going on and there's chaos in the sector, and all of that. And we want change to be in an orderly way.

With respect to the risk adjustment recommendation, I'm wondering whether we aren't beating a dead horse here. The budget says that starting in 2007 they will wring this excess payment out over a number of years. And Jay is saying a lot of this has to do with stability, having change occur in an orderly process. We can get all carried away with our recommendation was level playing field, we want level playing field, do it yesterday.

But maybe what we need to do is pat the president on the back and say stick with it, don't back off when Jay and John come at you and try and get you to postpone it, the way they've done for the last six or seven years, as Nancy points out.

With respect to the hospice issue, I think you make a convincing case in the best of all worlds why this is really reintegrating it into the managed-care plan is ripe. But I wonder if some of the original reluctance which was alluded to didn't have to do with a fear that managed-care plans paid in a capitated manner might encourage or market hospice more aggressively than was appropriate because there was huge savings for them to be realized by this.

Now of course, the latest data seems to show that hospice, on average, costs money. I'm not sure that would be true in this kind of setting. But anyway, I think it's an issue that we have to at least pay some attention to.

MS. BURKE: That was my point, is I want to be certain that we fully understand the implications in a managed-care environment. In '83, it wasn't even an issue of the managed-care world. So the anxieties at that time were far more related to our failure to really understand at that time what hospice meant and how one provided it and from whom it would be provided.

But I think the most recent issue is, in fact, one of is it conceptually consistent with or is it at risk in a managed-care environment where there is a great incentive to

reduce costs?

That's exactly my point, is I want to be sure we fully appreciate what the risks are. And are there any examples out there that we ought to look at where, in fact, it's been successfully integrated or part of a managed system. See you're exactly right, Bob.

MS. THOMAS: One of the interesting things is last year I did an analysis of looking at the utilization rate of hospice in managed-care. In the current fee-for-service arrangement, actually you use higher use of the hospice by managed-care companies. But there's actually quite a lot of variation by plan in that.

I also can bring back some descriptions of some of the companies out there offering plans have done some really innovative things. Aetna, in fact, has looked at creative ways of looking at a more continuum of care and providing more palliative care earlier on and not creating -- so there are models out there. Obviously, without the incentives in Medicare to create those models, that does cut out some of that innovation.

MR. SMITH: Briefly, Glenn, on two possible recommendations that we haven't talked about because of our

map fascination. And I have a map question I want to ask you when we get done.

On the payment issue, Sarah, the bonus payments that you refer to in the possibility of a recommendation, that's the stabilization fund?

MS. THOMAS: Yes.

MR. SMITH: And a slightly unfair characterization, but I'd just like to test it. This is a if it doesn't work we'll throw $10 billion at it?

MS. THOMAS: Yes.

MR. SMITH: I think we ought to see if we can't turn that into a recommendation.

The essential hospital provision, a question. Why wouldn't you refuse to contract with a plan so that you could get in the queue to get the additional pay? It seems to me it's an invitation not to make a deal.

But then there's no money to support it. So it had the feel of one of these provisions that for a place located at the following geographic coordinates, made out of brick, we will provide a tax break if...

But unless there's something I'm missing, it seems to me a $25 million pot that invites people to behave badly

seems goofy on both counts. And we ought to make a recommendation in that regard.

MR. HACKBARTH: It's one that falls less under the category of dangerous than just sort of silly.

DR. MILSTEIN: A couple of brief comments on the quality provisions.

First, due to the constraints that we faced around budget neutrality, we recommended P4P for a variety of providers that was powered by a size of incentive that in the initial years nobody believed is going to be enough to induce fundamental reengineering of anybody's practice or hospital.

One way we can begin to offset that deficit would be in the quality incentive rules that we ask of Medicare Advantage plans of all types. We have a problem that I've referred to repeatedly as sub-therapeutic dose of P4P quality incentives. Can we at least, with respect to the Medicare Advantage component of Medicare, encourage that the Medicare Advantage plans use the same quality measures as their basis of provider P4P? That's idea number one.

Idea number two relates to the fact that our current suite of quality measures for plans is pretty good,

thanks mainly to the work of NCQA. But it remains spotty. If you look at that suite of quality measures denominated against anything that a scientist would consider to be a robust measure of what's really going on in doctor's offices and in hospitals, it remains quite thin.

And so I wanted to also ask that maybe we consider adding the Health of Seniors Longitudinal Survey of Physical and Mental Status as one of the requirements for all Medicare Advantage plans. The survey is cheap, it does a beautiful job of offset gaming risk because you're measuring longitudinal change in physical and mental status of a population that's enrolled in a plan. And I think it fundamentally best captures why beneficiaries are buying health care in the first place. It's to maximize their number of disability-free life years.

MS. THOMAS: I'm under the impression that most types of plans do provide Health of Seniors data.

DR. MILSTEIN: We have an opportunity here, for example in the PPO part of Medicare, to institute it. And also, for reasons that remain murky, the equivalent number or the equivalent measure that Health of Seniors, we are no longer applying it to the fee-for-service population. I

think it's a very helpful benchmark to have when we're trying to, at some future date, the judge the effect of these various types of plans compared to the fee-for-service baseline.

DR. CROSSON: I had just asked the question earlier about the reason for not having dual state MSAs?

DR. ZABINSKI: Our basis for that idea is that the insurance laws, rules and guidelines differ between states. What I found when looking at an MSA that's partly in one state and partly in another, the plans that serve different states are often very different plans.

Philadelphia is one that really comes to mind. The plans that serve the Pennsylvania part of that MSA are very different than the ones that serve the New Jersey part of the MSA.

So our thinking was that requiring a plan to serve that entire MSA would put, I don't know, an additional burden on top of them that may make serving the MSA unattractive altogether.

MR. HACKBARTH: Under the prevailing rules, if you have a two-state MSA and it's treated as one service area, they would have to be licensed in both states. And that's

potentially a barrier. That was my thinking about it.

Now if they want to do that, that's fine. But to require it is one of those thresholds that just makes it more difficult to get people into the program

Okay, let's turn to our public comment period, with the usual ground rules, brief comments.

That's just the right length.

MR. HACKBARTH: Thank you very much. We're going to adjourn for launch until 1:45.

[Whereupon, at 12:47 p.m., the meeting was adjourned, to reconvene at 1:45 p.m. this same day.]

AFTERNOON SESSION [1:54 p.m.]

MR. HACKBARTH: This afternoon we will be returning to Medicare Part D and talking about a series of issues related to formularies and appeals grievances and issues like that. So Joan, whenever you're ready, thank you.

DR. SOKOLOVSKY: Good afternoon.

I just want to quickly draw your attention to the fact that although Rachel presented this morning and I'm presenting now, the work on Part D is a team of people working on it and their names are up there.

DR. MILLER: Joan, we're in this presentation, which has your name as the first name. And just orient them to whatever page that they are going to be on.

DR. SOKOLOVSKY: The first page.

MR. HACKBARTH: That's a radical idea today.

DR. SOKOLOVSKY: I'm going to try, although I may shuffle just to see if people are paying attention.

Last June we began work preparing the Commission for implementation of the Medicare drug benefit. We studied how formularies are currently put together and some of the issues that plans face when members transition from one plan

to another.

For our June report this year, we plan to examine additional issues related to the implementation of the benefit. Our goal is to enable MedPAC to have the tools necessary to evaluate how the drug benefit is working in 2006.

There are three ongoing projects for this chapter. This morning Rachel presented our work on geographic variation in drug spending. I will presenting some interim findings from our interviews of stakeholders on how formulary exceptions and appeals processes work in the commercial market and Medicaid.

In April, we'll be presenting the results of an expert panel gathered to discuss possible performance measures for monitoring the prescription drug benefit.

The MMA permits plans to use tools developed in the private sector, like formularies and tiered copayments, to manage drug utilization and help control costs. It also puts in place an appeals process to ensure that beneficiaries have access to needed drugs. The way in which the appeals process is implemented will help ensure that the goals, sometimes competing goals, of controlling costs,

maintaining access and ensuring the quality of the benefit are realized.

Because of the importance of this issue, we set out to find out how the processes currently work in private plans and in Medicaid. We've been interviewing physicians, pharmacists, consumer advocates and representatives from health plans and pharmacy benefit managers.

The MMA permits plans to use closed formularies where they limit the number of drugs covered in a particular therapeutic class. If a physician decides that a patient needs an excluded drug, they would ask for a formulary exception. Or, as is more commonly the case today, plans may cover more drugs but ask members to pay higher cost sharing if their prescription is for a non-preferred drug in the class. In some cases, physicians must also get prior approval before non-preferred drugs are covered. These processes are handled in the same way, both the exceptions and the prior authorization. So for convenience, I'm just going to be describing one process, which I'll refer to as prior authorization.

One of the first questions that we asked our interviewees was why a plan would place a drug on prior

authorization. This is a list of some of the most common questions that we heard. But the actual content of the interviews were really interesting and different. One plan representative described requiring prior authorization for all non-sedating antihistamines after one product in this class became available over-the-counter. In order for members to receive coverage for one of these drugs now, their physician had to document that the over-the-counter product had not controlled their allergy, a process known as step therapy.

Our interviewee said that they had to hire six new employees to handle all the calls that came in looking for exceptions for this rule but the plan calculated that it saved $10 million on this one decision alone.

Another example, and this one we heard from quite a number of people, was the case of human growth hormone. This is a product that has medically important uses but is also something that you may, in fact, read about in the newspapers that athletes sometimes use, particularly body builders. Plans wanted to be make certain that they cover the drug for the medically appropriate reasons but not cover it for body builders, for example. So this was something

that pretty nearly every plan told us was on prior authorization.

One interviewee said that prior authorization was worth doing even if almost all of the requests were approved because when a physician was notified by the pharmacy that the requested drug was not covered but that another was, the physician often agreed to use the preferred drug without ever asking for an exception. I also need to make the point that prior authorization is used very frequently in Medicaid because it is the main tool that Medicaid has to manage their drug benefit.

We then asked our interviewees to describe the process and we heard a very similar scenario in each case. Ideally, prior authorization should happen before the prescription is written but, in fact, often doesn't. Physicians frequently don't know what drugs are on their patients formularies or require prior authorization, so the patient may first become aware of the need for prior authorization when they take their prescription to the pharmacy and the pharmacist tries to process the prescription and gets a notice saying either the drug requires prior authorization or the drug is not covered but

lists other drugs that would be covered for the same condition.

The pharmacists will then usually contact the physician. At this point, when the physician is reached, they may either change the prescription to the alternate covered drug or else they will contact the plan call center and request approval. Every plan has a call center that gets requests from plans. Plan employees have written protocols that tell them what information is needed and what the answer should be in order to grant an approval.

The call center can either approve the request or, in most cases, the call center will not disapprove a request but if the request doesn't meet the criteria they will send it to a plan pharmacist or a plan physician. If the plan physician continues to think that the drug is not medically appropriate, it will either go to another pharmacist or physician within the plan or sometimes to an external reviewer.

If, after this two or three stage process, the person has still not gotten the request approved and the physician still thinks it's important, then the request would be appealed and it would go to the plan's customer

service department for a formal appeal. We heard universally that this was very uncommon.

Although our interviewees described very similar processes, they also reported very different strategies in terms of the number and types of drugs that they restricted. Most plans did say that they will usually give exceptions if they receive all of the necessary medical documentation. Plans also report that right now they have to meet many different kinds of compliance standards about their processes and time frames for handling requests. These standards would differ based upon the payer mix that they have and also what states the plans are located in. For example, some states say that only physicians can reject requests.

Plans tend to keep very detailed information on what happens to exceptions requests when they come into the call center. If they get many requests for a particular drug, they often will refer that drug to their P&T Committee to see if they should change their formulary.

On the other hand, some information never comes back to the plan. They never are able to collect it. For example, they don't know how often a beneficiary at the

pharmacy counter pays out-of-pocket for a drug when told their plan won't cover it or goes without the medicine. They also don't know how often a pharmacist contacts a physician or instead tells the plan member that their drug isn't covered. And they also don't know if a physician who has been contacted does not have the time to respond.

However as I said before, few drugs go to formal appeals.

All of the plans agreed that this whole process can create a burden for both beneficiaries and providers in terms of time and money. One physician told us that for his practice he has two call nurses that each spend about an hour a day simply handling prior authorizations.

On the other hand, plans try to minimize this burden in a number of ways. One is they try to educate both plan members and physicians about what's in their formularies. The second thing is notification. Plans told us that every time a request would not go through in the pharmacy, the member would receive a notice telling them why the prescription could not be filled and frequently giving them the names of other drugs that would be covered and telling them to ask their physicians about them.

Some plans have automated as much of the process as possible. So for example, if a plan has one ace inhibitor that is their preferred drug, they will have automated into the system if a patient has already taken that drug and it didn't work for them, they see that there has been a scrip for the preferred drug, when another prescription comes for a non-preferred drug, it would go through seamlessly without anybody having to ask for prior authorization.

Some plans choose to deal with the burden issue by simply placing fewer drugs on prior authorization and using the difference in cost sharing between preferred drugs and non-preferred drugs as their main way of steering people towards the preferred products.

CMS regulations on appeals generally support the processes that plans described to us. There were some differences however.

DR. NELSON: Joan, did you get a sense from the plans about how many drugs would be on a prior authorization list on a typical plan, whether it be 10 drugs that are commonly prescribed or whether it would be just a number of the far out drugs? It seems like how big of a burden it

would be would be related to how many drugs a physician had to remember were on prior authorization and whether a few common drugs that they prescribe all the time, where there was only one drug in that class for example, that they knew would pass.

DR. SOKOLOVSKY: It seemed to be all over the place and that is a question that we asked and we got every which kind of answer. The physicians said the main problem was they don't tend to deal with just one plan so remembering the formulary of one plan wouldn't translate to remembering the formulary of another plan.

DR. NELSON: Of course, and that's the reason why the problem would be obviously compounded by the number of plans. But if there were a relatively small number of drugs, in the first instance, it would be geometrically less.

DR. SOKOLOVSKY: I was trying to look for a pattern there and I couldn't find one.

In talking about some of the differences in the CMS regs compared to what we heard, plans must develop a transition policy for new members who are already on a particular drug that is not covered on their new plan's

formulary. This is an issue that has been mentioned as being very important to dual eligibles who would transfer from Medicaid to Medicare. CMS has not yet issued guidelines on what the transition policy should look like but we did hear from many plans that they already had informal processes in place to handle this situation.

Another difference is that more things are considered coverage determinations and may be appealed. This would include not only decisions concerning exception requests but also, under the MMA, beneficiaries can appeal the copayments. If they get a drug that is a non-preferred drug and has a higher cost sharing, they can appeal to get the preferred drug cost sharing level. And that is something that plans told us they had very little experience with.

Network pharmacies also must post notices or distribute forms telling beneficiaries how to request exceptions or repeal coverage determinations for every plan to which they are a network pharmacy.

Another difference is that the time frame for handling exceptions requests is quicker under the MMA. For an urgent request for an exception, plan must handle the

determination after they receive all of the necessary documentation within 24 hours. That was typically faster than we were told was a requirement for most plans now.

I haven't said much about grievances. It didn't come up very much. The terminology was pretty much different. But a grievance under the regulations is not a coverage determination but rather a problem with how a member is treated. Grievances are handled internally within a plan but the plan must have a process for handling them and make that process known.

There are some factors that may lead to an increased volume of appeals, and I've mentioned some of them. For example, the ability to appeal copays and to have shorter expedited time frames. This is something that could be an issue under Part D if increased volume becomes a significant expense for plans. Premiums could rise if plans put fewer restrictions, except for tiered cost sharing, on non-preferred drugs in order to minimize the number of appeals that they have to deal with. Or premiums could rise if plans have to pay the added expense of dealing with a higher volume of appeals.

Good communication is going to be very important

to prevent this and one thing that everyone agreed upon was that the development of e-prescribing and the prescription of that technology will be very important in dealing with this issue. The MMA includes a number of incentives to support e-prescribing.

One interviewee raised the question about how the structure of the standard benefit might influence the prior authorization process. Beneficiaries, you may remember, will have to pay 100 percent cost sharing for spending that's below the deductible and above the initial benefit level. Plan members might not like going through an exceptions process and then paying 100 percent of the cost of the drug if they get the exception. But if they pay out-of-pocket without going through the process, then payments wouldn't count towards the out-of-pocket limit.

Another issue that's getting a lot of attention is the difference between the Medicare regulations and the Medicaid appeals process. Under Medicaid beneficiaries are entitled to what's called a predetermination hearing before ongoing drug treatment can be ended or reduced. The program has to, in other words, continue providing the benefit until a hearing to determine the result of that request. Dual

eligibles will not have this right under Medicare. However, when we spoke to Medicaid plans and we spoke to beneficiary advocates, they reported very few drug-related appeals under Medicaid right now. But this is something that we need to watch.

Another issue that came up was the question of whether appeals and grievances should be publicly reported. This is very important to beneficiary advocates and representatives from plans and PBMs were mixed on the issue. Some of them wanted them publicly reported but others were afraid that since their strategies for prior authorizations were so different that reporting would be comparing apples and oranges.

As with other aspects of Part D, it's going to take some time to see how any of these issues are going to play out but I'll be happy to take any of your questions or suggestions now.

MR. HACKBARTH: Questions, comments?

DR. REISCHAUER: Just one little comment on your description of how a beneficiary might be irritated if they went through a prior authorization and then had to pay 100 percent of the drug because they were in the doughnut hole.

Of course, they'll be buying the drug, in a sense, at a discounted price which should be lower than the out-of-pocket price for somebody just walking in. And that will be 20 percent lower or something like that. So there still is some incentive, although not huge.

DR. BERTKO: May I add, there's a big policy incentive because 80 percent of the amount above the doughnut hole is paid for by the feds. So having the right drug at the right price is reasonably important.

MS. BURKE: Can I ask a clarification of Bob's question? Is it, in fact, assumed or is it, in fact, required that the extent to which someone is securing coverage for a drug that the plan won't cover at that point, it's an approved drug but it is one that they are within the doughnut hole, do we assume that they get the discount?

DR. SOKOLOVSKY: It's more than assumed. The law requires it.

MS. BURKE: That the discount applies at that point?

DR. BERTKO: Yes.

DR. SOKOLOVSKY: Yes.

DR. REISCHAUER: But there has to be a price at

which the plan can put into the calculation of the amount you've spent towards the catastrophic.

MR. HACKBARTH: Any others? Okay. Thank you, Joan.

Next up is Medigap and cost sharing.

DR. BERNSTEIN: Today we'd like to start a discussion about beneficiary cost sharing and private individually purchased supplemental insurance, Medigap, in light of changes introduced by the Medicare Modernization Act.

The materials we put together draw on a number of recent MedPAC reports and some new analysis of some Medigap data. Sarah Kwon will summarize what we know about the Medigap policies and I will describe some policy issues and seek your input on three possible directions for future work.

The topics, briefly, are improving information on insurance options, policy directions for cost sharing and first dollar coverage, and the potential role of Medigap models in broader Medicare payment reform.

MS. KWON: I will begin by briefly reviewing the basic characteristics of Medigap. Medigap provides

supplemental insurance coverage to approximately 10 million Medicare beneficiaries. This constitutes a little over a quarter of non-institutionalized beneficiaries.

Medigap offers 10 standardized plans, A through J. All cover Part A hospital coinsurance and Part B coinsurance.

The distribution of beneficiaries among plans has remained stable over time. Plans F and C, which cover most of Medicare's cost sharing, are the most popular plans. Plans H, I and J, which cover prescription drugs, have never been popular and will not be sold after 2006.

It is important to note two variants of these standard plans that are not shown here on this chart. The first is SELECT plans. These are Medigap plans that cover more cost sharing when beneficiaries use network providers. They generally have lower premiums than comparable Medigap plans.

According to our analysis of 2003 Medigap data from the National Association of Insurance Commissioners, approximately 1.2 million beneficiaries are enrolled in SELECT plans. They are concentrated in a small number of markets.

The second variant is high deductible plans. This option is offered through F and J plans. High deductible F and J plans offer the same benefits as regular F and J plans except beneficiaries must pay a high deductible before the plan covers benefits.

In 2003 the standard deductible was $1,650. NAIC data shows that less than 10,000 beneficiaries purchased high deductible F plans in 2003. We were unable to identify any high deductible J plans in the NAIC data although we know they exist. High deductible plans are rare but there are some areas where they are heavily marketed.

Some SELECT and high deductible plans offer innovative benefits such as case management and smoking cessation. For both the SELECT and high deductible plans, our figures for the number of covered lives are incomplete because some plans do not report to NAIC.

As this table shows, average monthly premiums exceed $100 for most plan types. For plans C and F, the average monthly premium is approximately $130, which means that beneficiaries must pay approximately $1,600 in premiums per year. This upward trend in Medigap premiums is correlated to the upward trend in Medicare spending. In the

same period depicted on this table, total Medicare expenditures per enrollee increased by almost 11 percent.

It is important to note that there is a lot of variation of premiums within and across markets. Weiss Ratings, Incorporated found that in 2004, the average national premium for a 65-year-old female enrolled in Plan C was $1,689 nationally. But across different markets, it varied from $616 to $6,271.

DR. BERNSTEIN: The new drug benefit created by the MMA involved some structural changes to Medigap. As Sarah noted, there will be no new H, I or J policies sold after January 1, 2006. The law also introduced two new policies, K and L. Both of these policies require the beneficiary pay the Part B deductible and both the policies cover all catastrophic hospital costs after a year.

Plan K covers half of the applicable coinsurance, beneficiaries have a cap of $4,000. L covers 75 percent of the applicable cost sharing up to a $2,000 out-of-pocket limit.

These limits are going to be indexed to inflation using an adjuster specified by the Secretary of HHS. I would also note that plans don't cover excess charges or

balanced billing.

The law and accompanying conference report to the MMA also asked NAIC to do two things. First, they had to revise the model regulation for Medigap to accommodate the new policies and to deal with the phasing out of the existing policies and included drug benefit. That work is completed and states and insurers can begin to operate under the new roles as soon as the states incorporate the new model regulation into their own state policies.

In addition, Congress asked NAIC to think more broadly about ways to restructure Medigap. I will read this verbatim. They were asked to "consider broader changes to the Medigap market that will effectuate reduced premiums and more rational coverage policies that create incentives for appropriate utilization of services."

The discussion in the conference report mentioned in particular concerns about first dollar coverage for Medicare covered services. NAIC is beginning to work and this broader charge. In fact, they're having a meeting that starts tomorrow where the committee working on this will begin their deliberations in earnest.

Your mailing materials review a variety of

findings and conclusions about supplemental coverage. Briefly, previous MedPAC reports, as well as recent analysis by our staff and other researchers, has consistently shown that first people with supplemental coverage spend more on health care and use more Medicare services than people who do not have supplemental coverage.

And second, that people with Medigap use more Medicare services than people with employer based supplementation. This holds true when we control for, to the extent possible, health status, income and other demographic factors. The research is not able to clearly identify how much of this additional use of services for those with Medigap is for services that are unnecessary or of questionable value versus appropriate use of care that might be obtained of beneficiaries were exposed to significant cost sharing.

There is some research that indicates that beneficiaries without supplemental coverage report more access problems and are more likely to not receive recommended services such as preventive care or other technical things.

Other research shows that seniors without drug

coverage are less likely to purchase or take prescribed drugs. However, because they use more health services, on average, than most other beneficiaries, only Medicaid duals use more, and also because they have very little coverage for services Medicare doesn't cover, people with Medigap spend more out-of-pocket counting premiums than other beneficiaries. Uncovered services include, under most Medigap policies, prescription drugs but also things like hearing, dental and vision care and some mental health services that Medicare does not cover or cover well.

Over the past decade or so, a growing proportion of beneficiaries' out-of-pocket spending has been for prescription drugs. So it's difficult to predict how out-of-pocket liability for people with Medigap will compare to other beneficiaries after 2006 when the Part D benefit comes online.

There is substantial agreement that the Omnibus Budget Reconciliation Act reforms that led to the standardization of Medigap policies and established national oversight and consumer protection requirements were successful in stabilizing the Medigap market. Medigap is quite popular with beneficiaries. It eliminated much of the

paperwork at the doctor's office and beneficiaries appear to play significant value on the predictability of paying premiums rather than having to deal with the costs of medical care as it arises.

State regulators enjoy the stability of the current market and the fact that they see very few complaints from consumers about Medigap. But there are also some basic problems with Medigap, many of which we have discussed in various contexts and reports over the last couple of years. Medigap is expensive. There's not a whole lot of competition in many local markets. Some of the standard benefits no longer make a lot of sense from an insurance perspective. NAIC will likely address these sorts of issues in depth.

There are also even larger so-called level playing field issues. Medigap is a very different form of coverage than other Medicare options it competes against. Not all beneficiaries have access to affordable Medigap plans. Although there are federal minimum standards for open enrollment and guaranteed issue for people age 65 and older, there are some significant differences in enrollment and rating or underwriting rules across the states. Some of the

more basic aspects of federal regulation are likely beyond the scope of the issues that the NAIC will be addressing but they are part of the bigger set of issues surrounding competition among the Medicare options.

The first of the Medigap issues the Commission might want to explore follows directly from work we completed late last year related to devising ways to help beneficiaries understand and make choices among coverage options. We divided this into two parts, getting information from Medicare plans, the first sub-bullet, and getting that information to beneficiaries, the second sub-bullet.

As we've noted, information on what is actually available in local Medicare markets is sometimes incomplete or insufficiently detailed. There are some technical issues here but we believe that some changes in reporting and oversight requirements would help the states and CMS, and in turn beneficiaries, get a better view of Medigap options and how they compare to MA and drug plan options. With better data, there may be way CMS can augment the information it makes available on the Medicare Personal Plan Finder or in other software that might be useful in one on one counseling

with beneficiaries.

A second topic that we are already working on is refining our understanding of how cost sharing and out-of-pocket spending affects the use of services and Medicare costs. This includes analyzing policy issues as well as the available literature on cost sharing, particularly in older populations.

We're also updating some of the analysis that we've done before using newer data available from MCBS. This analysis could support the development of general or perhaps more specific guidance that the Commission might want to offer the NAIC regarding cost sharing and first dollar coverage in Medigap.

Finally, we've identified for discussion one topic that brings us closer to broader considerations in the payment for fee-for-service Medicare. Current law and regulations grant insurers a great deal of flexibility in establishing preferred provider networks for Medicare SELECT plans, both in terms of creating networks and structuring cost sharing for particular SELECT products. There are some natural experiments in some local markets, such as the SELECT model in Minnesota that we described in last year's

report on market variation, that might help in conceptualizing ways to reap some of the benefits of care management in a fee-for-service environment.

The Commission may want to explore whether new standards or model regulations for SELECT plans or for other Medigap products could provide a mechanism for creating networks or tiers of fee-for-service Medicare providers based on accepted measures of quality and efficiency.

We look forward to hearing your comments on priorities for work on Medigap, both in terms of the NAIC's work and more broadly in terms of cost sharing and Medicare payment reforms.

DR. BERTKO: A couple of points. First, a good report. I think pretty thorough. I would just point out to my fellow commissioners, Jill zoomed past two parts which I think are fairly important. The first is on the average premium comparison, which strikes me as being accurate. But I believe in most states reflecting an attained age premium. So a 67-year-old might pay $70. A 77-year-old might pay $150. And an 82-year-old might pay considerably more.

Which leads to -- I won't say it's a recommendation. but just for us to consider. There are a

few community rated states. Medicare Advantage plans are all community rated. And in the interest, which I think is very positive here, of helping seniors compare one to the other, do we want to have any consideration of suggesting community rating as one of the alternatives? Because all of a sudden everything is on a more level playing field.

The other thing is, again zooming past it, was the enrollment features. Some, maybe most of the plan options, are only available in the six-month period after you turn 65 or after you retire from being actively at work. Which again, is completely different from what's going to be the annual open enrollment period for Medicare Advantage plans.

This is actually a two-way street. If you have somebody that chooses Medicare Advantage and was in a -- I'll pick one -- Plan J or something now with drugs. They're going to leave J forever then. But they can't go back for except for -- do you know, Jill, is it Plan C that's always available every year? Or is it a different one?

DR. BERNSTEIN: With the drug plans, they can go into a plan which is -- they have a 63 day period to go into an equivalent or less -- any plan, sort of an open

enrollment thing.

DR. BERTKO: The drug plans get better. Let me make it a little simpler, because Part D will now be --

DR. BERNSTEIN: The other ones, yes, it's only C and maybe a couple of others, A or F.

DR. BERTKO: So there's a restriction on what you can get in, although maybe that's a moot issue because most people are in C and F anyway and the other plans are almost invisible, in terms of this. But it is a one-way street in some cases. You can go out of Medigap into Medicare Advantage, but you may not able to come back from Medicare Advantage into a particular Medigap option.

MR. HACKBARTH: John, could we go back to your first point. You're suggesting that the federal government mandate community rating for all Medigap plans?

DR. BERTKO: I don't think that was our charge. I'm taking our charge here as suggesting things for the NAIC to look into. I think MedPAC's charge overall was to help seniors better understand their choices. To me, this might be one that we want to think about a little bit. I'm not even suggesting it come to the level of a recommendation, but thinking through and perhaps discussion might be

worthwhile.

DR. MILSTEIN: In some ways, I think Medicare programs should be grateful that these plans did not put the pedal to the metal in terms of doing more to reduce premium costs for Medigap. Because if you think about the band of cost that Medigap covers, if you really wanted to minimize spending in those areas, it's likely impact would be to substantially increase what Medicare would end up paying.

Think of it this way. Most of what Medigap covers is dominantly skewed toward drugs and physician office care, not inpatient care.

DR. BERTKO: I'd have to disagree with that on an actuarial basis. Medigap basically occurs after some Medicare service is provided and has, in my opinion, virtually no driving affect on the level other than the induced demand from completely filling in the cost sharing.

DR. MILSTEIN: That's the point I'm making, is if you wanted to -- I mean is there an opportunity here for us to engage Medigap plans in contributing to reduced spending growth with respect to Medicare Part A and Part B?

The idea here being most of the opportunities to better manage patient care that potentially a Medigap plan

could be potentially incentivized to encourage would be likely to reduce inpatient utilization. But in order to do it, you might have to invest a little bit more in physician utilization and in drug utilization.

If you look at this from the perspective of employers who are providing the equivalent Medicare supplemental plans, when they begin to think about should they -- they often will think should we apply the same managed-care techniques, including provider incentives, to we apply when we're primary. For example, pre-Medicare 65, they do the math and they go this makes no sense at all because if we did anything with our supplemental plans to encourage better performance, as it were, it actually would have the effect of saving the Medicare program money and costing us more money as we beef up more of the ambulatory care services.

So right now, reasoning analogously, people who operate Medigap plans have absolutely no incentive to try to better manage care and create better outcomes for the Medicare program.

So my question is, should we discuss opportunities for changing the incentives that we give Medigap plans such

that they begin to row in concert with the rest of the Medicare program and have incentives to begin to both reduce the rate of increase in the Medicare program overall and improve quality of care?

MS. BURKE: Could give me an example? I'm not sure I have a clue what you're suggesting.

DR. MILSTEIN: You operate a supplemental plan to Medicare, you're a secondary payer; right?

DR. BERTKO: Say Blue Cross of XXY.

DR. MILSTEIN: And somebody comes to you and says there's a highly effective program to manage congestive heart failure for this population. And we can reduce overall spending quite a bit. If you run the math on what a best in class congestive heart failure program would do for the Medigap insurer, it primarily would shift more burden, more spending into physician ambulatory visits and drug, of which the Medigap plans are paying a very high percentage. And its primary savings would accrue to the Medicare fee-for-service program because you're reducing hospitalizations.

MS. BURKE: I'm just trying to understand structurally what is it that you would do to the Medigap

insurance?

DR. MILSTEIN: If the objective is to change the incentives around people who operate Medigap programs such that they now feel that they're also now trying to, among other things, reduce rate of growth in Medicare per capita spending and improve quality, what you might offer is -- let's call them P4P incentives for Medigap plans.

So that at the margin, they would potentially get a payment from Medicare if they achieved quality targets, if they intervened in ways that improve quality and reduce total spending in the Medicare program. They are a potential player, I guess, in influencing total Medicare --

MS. BURKE: I'm just trying to understand, given the structure of the Medigap program, given its role, the fundamental function being filling in the gaps, I'm trying to understand structurally what is it that you would do to the Medigap industry?

MR. HACKBARTH: What levers do they have to alter patterns of care?

MS. BURKE: Since they fill in cost sharing and they fill in for blood products, I mean there are very specific things they do.

DR. MILSTEIN: For example, they could introduce disease management programs to keep Medicare patients out of trouble and out of hospitalization.

MS. BURKE: So new benefits.

MS. RAPHAEL: Basically you have to measure them against savings in the Medicare program. That has to be your main menu.

DR. MILSTEIN: Yes. They're a potential additional tool if our overall objective is to reduce the rate of increase in Medicare spending and improve quality for Medicare beneficiaries.

MR. HACKBARTH: I agree with the objective. The question is whether this product is a fitting vehicle for trying to influence. So if we want to encourage disease management, as apparently we do, we're investing in a major pilot of that, the providers involved, the beneficiaries involved are more likely to respond to an initiative not coming from the gap filler but from the primary payer, in this case Medicare. Medicare has more leverage than the supplemental insurer.

DR. MILSTEIN: To the degree that Medicare is finding ways of making this happen for the Medicare fee-for-

service program, then the need to get help from the Medigap insurers becomes much less. I agree with the point that it's better to solve the problem through the incentives we build around the Medicare fee-for-service program. But those are sometimes not that easy to accomplish and it takes a long time. So the question is should we consider this a gap filler, as it were.

MS. BURKE: I don't disagree with where you want to go, it's just I'm completely missing how you use an insurance program that is essentially structurally a gap filler to drive the fundamental structure of the primary program.

MR. HACKBARTH: Put yourself in the position of a beneficiary. Right now Medigap is most attractive to beneficiaries who say I don't want to enroll in a private plan. I want to retain control over my own health care, free choice, and that's what traditional Medicare offers me and I love that. They're not looking to the private plan to steer them to improve their care.

For those beneficiaries who are looking for private plans that might be able to steer them and improve their care, we've got Medicare advantage and an increasing

array of different types of products that they could choose from.

Again, whether we want to try to invest the resources in modifying the gap filler, I guess is the question for me.

DR. MILSTEIN: For me the question is would a more moderate change for mainstream beneficiaries potentially attract more into what I'll call this form of plan, that is a Medigap plan that was incentivized to use a variety of tools that are available to any plan sponsor to either incentivize physicians to be more successful in longitudinal cost management and quality and/or for the plan themselves to introduce disease management.

Again, I completely agree with the point that if mainstream Medicare fee-for-service is accomplishing this, then there's no need for this. But to the degree it remains infinitely postponed into the future, then this is an additional tool that we might consider.

DR. MILLER: The only thing I was going to say is I can't bridge all the way to the point that I think where you started. If it's not clear, we are trying to look at this instrument as a way to control or to help control at

least expenditures by discussing and asking for advice on whether you want us to look at designing policies that eliminate the first dollar coverage and the SELECT versions of them where you choose to buy Medigap but you choose to buy into some type of network that might give you some more push.

I can't bridge all the way to where you were going but this notion is contemplated. The quality stuff doesn't quite -- I don't know how to make that connection.

DR. MILSTEIN: The way you'd make that connection is, just like any other plan, a Medigap plan could begin to introduce provider P4P based on quality, in fact using the very same measures and incentives that are being paid by the other Medicare programs, both fee-for-service and managed care.

The point is from a physician's point of view, the more synchronization you have across all plan types with respect to what are the quality measures and that there be some income contingent on doing well in those quality measures, the more inducement you have for physicians to move more quickly to this new vision of what health care could be that IOM keeps painting for us.

MR. HACKBARTH: Other questions or comments?

DR. REISCHAUER: To repeat something I said a few years ago, one is always struck when you talk about Medigap over the fact that 90 percent of the participants in this program have supplemental insurance coverage. It, for the most part, all covers the same stuff. Which is clearly an expression that the overwhelming majority of Americans would like a benefit package that was more rich, richer than Medicare now provides.

And the simple way and efficient way of providing it is to fold all of this into Medicare, into the basic benefit or to have a high level plan. And you could do it a whole lot cheaper. But instead we have this unbelievably convoluted system that then creates a whole lot of perverse incentives that then we sit around and scratch our head and say how can we fix these incentives. And Arnie comes up with his ideas and on and on.

Jill, the question that I wanted to raise was the finding that you have that Medigap participants spent more than any other group except Medicaid on basic Medicare benefits, which struck me as an interesting bit of analysis because in general I thought employer-sponsored insurance

was, on average, richer than Medigap and would induce more Medicare spending.

I was wondering if it was done right, in the sense in the employer-sponsored group you took out the people who have A but not B.

DR. BERNSTEIN: I think the big difference is that we found over the last couple of years that the cost sharing for Medicare-covered services for people with employer-sponsored coverage has increased a lot. These guys pay when they go to the hospital, and they pay when they go to the doctor, until they reach their deductible.

DR. REISCHAUER: I was willing to go along with that until I saw it was 2001 data.

DR. BERNSTEIN: We did it for 2002 and it was the same.

DR. REISCHAUER: I'm saying if it were 2004 data, I'd be more sympathetic. I don't doubt you, but if you took out the people who were A and not B, then I have no other explanation.

DR. BERNSTEIN: It's MCBS and so they're not going to make any difference because there's so few of them. I don't know if we took them out or not. but there's very few

of them in that set, in MCBS. I mean, it's not a whole lot -- most of them have both.

MR. HACKBARTH: Bob, your point is that the Medicare spending is higher for the Medigap people, as opposed to the retirees?

DR. REISCHAUER: And those who have employer-sponsored coverage.

MR. HACKBARTH: It could be a selection difference.

DR. BERTKO: But it's MCBS, so did you adjust it for age/sex?

MR. HACKBARTH: You tell me, John. I always used to hear from the HCFA actuaries that age/sex really doesn't do it here, that people who work to retirement and qualify for retiree benefits are healthier than those who do not work to retirement and qualify.

DR. BERTKO: But there's a different component here. The Age/sex slope of the total A/B benefit is fairly steep until you hit about 82 or 85 and then it flattens almost completely, or even turns down.

So you could indirectly have an older group of one or the other which might affect the total average PMPM

comparisons, which is what I'm assuming Jill and others are reporting on.

DR. MILLER: We'll follow up to answer this question, but the three components of the question are what are the basic expenditures, what's being spent out-of-pocket, and how premiums are treated in this calculation.

And then I think we get to this calculation of how did you adjust it? We'll come back and explain the pieces to this.

DR. BERNSTEIN: We have it, but we can come back and explain it next time. It's here.

MR. HACKBARTH: Any others? Okay, thank you.

Next is the mandated study on drug handling costs.

DR. WORZALA: Good afternoon. Last month we introduced you to this mandated study that we were given in the MMA, which is to look at whether or not we need a payment adjustment for the handling costs incurred by hospitals when they deliver certain radiopharmaceuticals, drugs and biologicals in their outpatient department. This study will be part of our June report.

We're going to present a little bit of analysis today to help you to deliberate the policy questions in the

study. I'm going to start off and then turn over to Rachel. And Sarah Kwon also worked with us on this study.

So what is the policy question? The MMA changed the way hospitals will be paid for these products, radiopharmaceuticals, drugs and biologicals that were on the pass-through list in December 2002.

Beginning in 2006, the MMA requires CMS to base payments for these products on hospital acquisition costs. GAO has been asked to estimate those acquisition cost by surveying hospitals, and we've been asked to determine whether or not there should be a payment adjustment to cover the handling costs involved in storing, preparing and disposing of these same products. And if so, how should it work.

Previously payment for handling costs was included in payment for the product itself. Arguably then these costs have been incorporated into the outpatient payment pool and no new money is required. However, when Medicare moves to paying acquisition costs, the payment for the product will no longer include the handling costs. How then should the payment system treat them?

This is a slide you saw last month, which is just

a reminder of the kinds of products we're talking about. Many but not all of the drugs and biologicals are used in cancer treatment. The radiopharmaceuticals include many products that are for diagnostic nuclear imaging procedures. Some are also used in treatment. FDG is used in PET scanning.

Our study is about the handling costs that hospital pharmacies and nuclear medicine departments incur when they store, prepare and dispose of these products. This can include things like complying with safety requirements and also quality improvement activities, as well as the actual preparation of the product itself.

The components of cost we're talking about are labor, equipment, supplies and disposal fees. The study is not about acquisition costs of the products or the costs associated with actually administering a product to a patient. So for example, we're looking at the cost of preparing a chemotherapy infusion in the pharmacy but we're not looking at the costs incurred in the infusion suite to administer the IV to the patient or to monitor for complications.

So our first question is whether or not a payment

adjustment is needed. It really is difficult to answer this question due to the lack of systematic data on the costs. However, there are a number of factors that suggest one might be needed. We know that historically handling costs have been built into hospitals charges and payments for drugs. In talking with stakeholders and through a survey on charge setting practices that we conducted last year, we found that most hospitals do not currently have separate charges to cover their handling costs. Rather they tend to mark up the cost of the drug itself sufficient to cover the handling costs, as well.

Similarly, when payment rates for these products were based on AWP, payment exceeded the costs, providing a cushion to cover the handling costs. But if payments dropped to the level of acquisition costs, the payment for the product will no longer be sufficient to cover the handling costs as well.

Of course, that doesn't men that absent a payment adjustment the handling costs have disappeared from the payment pool. They would simply be distributed across payments for all services. And this point of budget neutral recalibration of payment rates is something we'll come back

to on the next slide.

Our conversations with stakeholders indicated that these costs are not negligible. Many of the products have specific storage and preparation requirements. Hospitals also have significant safety and regulatory requirements that increase their costs. For example, radioactive materials are highly regulated and require significant safety precautions with lead-lined containers and metering of staff for exposure for radiation, et cetera. Toxic drugs, including chemotherapy, require specific steps to protect both the staff and the patients.

We also looked at data from the state of Maryland, where hospitals submit detailed cost reports. We looked at three major components of direct costs, labor with benefits, supplies, and the actual acquisition cost of the drug. The data from Maryland told us that the drug acquisition costs accounted for 72 to 74 percent of the sum of those three components, while labor and supplies accounted for the other 26 to 28 percent. So again the costs aren't negligible.

Finally, if the outpatient PPS did not have a payment adjustment for handling costs there could be some distributional effects. Hospitals that provide a lot of

these products, such as those that specialize in cancer care, would be more affected than those who don't provide them as often.

So while you may decide that a payment adjustment is needed, the structure of the payment system suggests that it should be budget neutral. Our study has focused on relative payments among services. What we're asking is does the payment system need additional APCs to cover handling costs? What should the relative weights for those APCs be? We're not really thinking about the level of payments or how big the payment pool is. That's really a question we address in our update discussions.

Also, as I alluded to on the previous slide, moving to payments for drugs and radiopharmaceuticals based on acquisition costs changes the rates for those specific products but it isn't removing the handling costs from the payment pool. When CMS changes the relative weights for services, they do it in a matter that doesn't change the total payment, just the relative weight for the specific service.

There are a number of factors that suggest that these costs have, in fact, been built into the payment pool.

First, when the outpatient PPS was first set up, the payment pool was built on charges reduced to costs. And we have been told the hospital charges for the products include a markup to cover the handling costs.

Second, when CMS instituted the pass-through mechanisms, which is one of the main ways to identify the products that this study refers to, it was meant to be budget neutral. That speaks to Congressional intent.

Third, the MMA did provide for interim payments for these products that are based on AWP, and that did increase the payment pool with a certain amount of money that won't be taken out.

So that was thinking about whether a payment adjustment is needed. Now thinking about what a payment adjustment might look like, one approach could be to simply markup acquisition costs. This is advantageous because it's easy to administer. However, it probably wouldn't be accurate. That's because there is really is no reason to believe that handling costs vary with the price of a product. The price of the drugs and radiopharmaceuticals depend mostly on the manufacturer's cost of production, the extent to which there are competing products within a given

therapeutic class, and other market factors. It really doesn't have much to do with the handling costs.

The handling costs really depend on what the pharmacist or the nuclear pharmacist is doing to prepare and dispose of the product. So a newer, costly drug can have the same handling costs as an older, cheaper drug. Or it may, in fact, be less expensive. Many of the newer products are produced in a format that lowers handling products. For example, they are more likely to be produced in a liquid form rather than a powder form that requires a certain amount of time and effort to be reconstituted.

Marking up acquisition costs is likely to overpay for the handling of expensive products while underpaying for the handling of cheaper products.

Another approach would be to establish a handling fee tied to the preparation or administration of a drug or radiopharmaceutical by linking it to the work done by the pharmacy or nuclear medicine department. A handling fee would be more accurate than marking up acquisition costs. It could also vary with the level of handling costs incurred for certain types of drugs. As Rachel will go into later, different kinds of drugs do, in fact, result in very

different levels of handling costs.

This approach would have some administrative burdens. CMS would need to establish codes and payment rates and hospitals would have to bill new codes and set charges for them. While adding some burden, this approach would at least give us a source of information on these costs by collecting hospital charge data.

A third option would be to move away from paying for drugs separately and developing broader payment bundles that include the drugs and radiopharmaceuticals with related services. This option is certainly more in line with the original conception of the outpatient PPS. It would, however, require legislative action.

Now I'm going to turn things over to Rachel.

MS. SCHMIDT: With a contractor's assistance, we formed a panel of experts to help us devise a framework to define what these costs are in specific terms that would be understandable to hospital officials and interpreted consistently across facilities.

That panel consisted of seven experts in pharmacy, nuclear medicine, hospital finance and cost accounting. The framework they devised consists of four functions of

pharmacy and nuclear medicine departments that are shown as the four long boxes on this slide, as well as department-wide functions shown as the wide box along the top.

The wide box represents pharmacy and nuclear medicine management and includes typical management activities such as record-keeping, personnel and training as well as safety, quality control and regulatory compliance activities.

For example, accredited hospitals much follow U.S. Pharmacopeia guidelines for sterile compounding, as well as National Institute for Occupational Safety and Health rules for protecting workers who come in contact with anti-neoplastics.

As you can imagine, the preparation and handling of radiopharmaceuticals are subject to very specific state and federal safety standards. Storage refers to maintaining drug and drug components in appropriate conditions so that the products don't lose their therapeutic value. For example, some products need to be kept refrigerated at certain temperatures. This category also includes inventory management.

Preparation refers to mixing, compounding or

reconstituting a drug for administration to the patient. Sometimes these activities require special equipment, such as laminar flow hoods, to ensure proper ventilation. This function also includes the time pharmacy and nuclear medicine personnel spend reviewing orders and calculating and verifying proper dosages for patients.

Transport refers to delivering drug to the location where it will be administered to the patient, while disposal means getting rid of the drug, waste and supplies within the pharmacy department itself.

We designed the framework so that all types of handling costs covered by this study fit within these categories. The components of costs are labor and benefits for pharmacists, nuclear pharmacists and technicians, the hospital space they occupy, equipment and supplies and support contracts. Obviously a pharmacist may spend more of his or her time on some functions rather than others, for example on departmental management and preparation while contracting out for waste disposal.

Pharmacy and nuclear medicine handling costs vary considerably across the more than 230 products we identified as special covered outpatient drugs. For example, they

include simple oral solid pills as well as drugs that must be reconstituted slowly and prepared for IV infusion. Radiopharmaceuticals add an even greater level of complexity where nuclear medicine departments must monitor the half-life of the products and keep patients to a tight schedule in order to ensure that they get the proper dosage.

Our expert panel came up with categories of the products that are grouped by combinations of the characteristics shown on this slide.

Clearly, the expert panel suggests dividing products into nine categories, which are shown in the table that's in your mailing materials, but that number could change once we finish collecting information from case study hospitals. The strategy behind developing these categories was to group products that have similar handling costs.

The expert panel concluded that radioactive products are the most costly to prepare and store because of all of the safety and regulatory requirements involved with handling them.

Toxic products tend to have higher handling costs than non-toxic ones because of the special equipment and processes one must follow to protect pharmacy workers and to

ensure patient safety. The route of administration of a product matters because our expert panel told us that the preparation and handling of IV products generally require more resources than preparing simple injections or pills.

We're using a case study approach to validate our framework and to get a sense of how handling costs differ across the nine categories of products we just talked about. We considered surveying hospitals but soon realized that with the variety of accounting practices used in hospitals and differences in definitions of what these costs are, we couldn't ensure that survey responses would be comparable to one another.

So instead, our contractor got the assistance of pharmacy and finance directors at four facilities, two large urban and two other urban, to help us with this exercise. Three are hospitals or hospital systems and one is a outpatient cancer center at a major teaching hospital.

Those facilities are taking on two tasks. The first task is to categorize as many of the 230 or so products as they dispense into the nine categories that our expert panel devised. The second task involves undertaking a microcosting of one product, that is the same product, for

each category. Pharmacists and nuclear pharmacists on our expert panel selected a typical product from each of the nine categories to cost out. The first task was completed by all four facilities and a fifth hospital agreed to do this task but not the microcosting.

Preliminary results suggest that the categories are holding up well. With some minor modifications, hospital pharmacists placed the products into the same categories about 89 percent of the time. When there was a disagreement about where to categorize a product, it usually had to do with differences across facilities in how they purchased the product. For example, one hospital might purchase a drug in solution form while another might reconstitute it from a powder.

The second task is still underway. We will not learn about the absolute levels of handling costs, just the relative relationships among categories. This is partly to ensure confidentiality of each of the facilities' cost data but also because we know we cannot determine absolute costs from four case studies and then generalize from those results.

Note that none of our case study facilities

compounds their own radiopharmaceuticals. Most hospitals rely on commercial specialty radiopharmacies to deliver unit doses. For that reason, we think that the issue of how to pay for handling costs of radiopharmaceuticals deserves further study by CMS.

DR. WORZALA: Since this is March, we felt obliged to come up with our draft recommendations and this is our first draft recommendation. CMS should establish separate budget neutral payments to cover the costs hospitals incur for handling drugs and radiopharmaceuticals paid based on acquisition costs under the outpatient PPS.

What I read is a little bit different than what's in front of you but it has the same gestalt. Sorry about that. I didn't realize that I had something else there.

This next slide looks at a different question which is if the Commission does recommend a handling fee, how would CMS collect the data to set the payment rates? For the long run, one option would be periodic surveys, the MMA requires GAO to conduct surveys of hospitals' acquisition costs for products, followed by periodic surveys by the Secretary. So you could possibly add questions on handling costs to those surveys.

However, our experience has been that there are no standard definitions for the handling costs and considerable variability in the hospital's accounting practices that might make it very difficult to interpret the results of such a survey.

Another option might be to conduct large-scale microcosting studies similar to those being done in our case study hospitals. Given the breadth of products, it would need to be costed. And the number of hospitals that you would need to have a representative sample, this could be a prohibitively expensive option for CMS.

A final option is to set payments for the handling fee the same way CMS sets payments for all other services, which is by reducing hospitals' charges to costs. This approach is administratively easiest. It does require the additional burden of asking hospitals to develop those charges. In addition, there may be a transition period before hospital charge date are really complete enough to be used in rate setting.

These options are for the long run. CMS would also need to set payment rates in the short-term, perhaps as soon as the 2006 payment year. In the short run, a small

number of microcosting studies could possibly be done to establish payment levels and relatives across categories of products and handling fees.

Alternatively, CMS could identify the current total pool of payment for these products. And since they will be basing payments on acquisition costs, they could estimate what of that current payment pool is for acquisition and assume that the remainder covers handling costs, and then use estimates of volume and relative costs across categories to set payments in the interim.

So those are our ways of getting information and setting payment rates.

Our second draft recommendation addresses how a payment adjustment should be defined, were there to be one. It has three parts. The Secretary should define a set of handling fee APCs that group drugs, biologicals and radiopharmaceuticals based on attributes of the products that affect handling costs. The Secretary should instruct hospitals to submit charges for those APCs. And the Secretary should base payment rates for the handling fee APCs on submitted charges reduced to costs.

Up to now, and in considering those

recommendations, we've accepted the premise of this study which is that drugs and radiopharmaceuticals will be paid separately and based on their acquisition costs. However, that approach to paying for drugs is a result of significant unbundling in the outpatient PPS, which may be an issue you want to talk about a little bit.

The outpatient PPS originally bundled payment for drugs and radiopharmaceuticals into related procedures. A series of legislative and administrative actions have led to a much more granular payment system, particularly for drugs. So at the moment, there is tremendous variation in the degree of bundling across services.

If you look at the ambulatory surgeries, the bundle is really quite large, encompassing all hospital staff and supplies needed in the operating room as well as during recovery. By contrast, all drugs costing more than $50 per administration have their own APC.

As a result, there are a disproportionately large number of APCs for the separately paid drugs. If you look at the 2005 fee schedule, there are about 400 APCs for all of the clinic visits, procedures and diagnostic tests that make up 90 percent of the payments approximately. And about

300 APCs for the separately paid drugs that account for less than 10 percent of the payments.

So this very granular approach to paying for drugs takes away the incentives for efficient use of services that are built into a larger payment bundle. If a hospital uses additional drugs, it gets additional payments. Hospitals also have an incentive to use more expensive separately paid drugs over the few less expensive drugs that are currently packaged.

Having such a granular classification also makes it difficult for CMS to set payments. Given the tools available to CMS, the claims and the cost reports, it's very difficult to set payments for individual products. There is considerable likelihood that there will be variation in the payment rates from year-to-year when you get down to such a fine level.

So from a payment policy perspective, more bundling may be desirable. Identifying larger bundles could help overcome these problems that I just went through. It could perhaps also allow for more innovative payment approaches, such as looking at quality and efficiency. For example, a bundle might include a whole episode of

chemotherapy treatment rather than having a separate payment for each drug, each handling fee and each administration of a drug to a patient. And if you had a larger bundle like that, you could think about quality, you could think about efficiency, and maybe you could counteract some of the negative incentives in such a granular payment approach.

Of course, defining larger bundles would take a certain amount of research. This is something that MedPAC could possibly take up. And perhaps CMS could also be pursuing.

I'll stop here and listen to your discussion.

DR. REISCHAUER: Chantal, are there huge economies of scale in this kind of operation? Or does the average hospital fit in the range? Because there must be economies of scale.

DR. WORZALA: There are a lot of questions of scale and scope and how this differs across hospitals, since we are talking about the outpatient here. Some hospitals have one pharmacy that does inpatient and outpatient together. Other hospitals, particularly those that have a large cancer focus and have an outpatient fusion center, may have a special outpatient pharmacy.

So there are lots of issues of size and scope that would get into efficiencies. So I think it is difficult to tease out that without also thinking about the variation across hospitals and how many of these services they provide.

DR. REISCHAUER: So no matter what we do, we're going to end up with a rather approximate add-on?

DR. WORZALA: Yes. I think it would be very difficult to be precise in measuring these costs.

DR. SCHMIDT: If I could just add a little bit, I think there are some significant economies of scale, particularly when you have very specialized equipment involved. The radiopharmaceuticals come to mind where you have very specialized equipment and lots of safety regulations. So, obviously larger volume there does lead to economies of scale.

MR. HACKBARTH: Others?

DR. WOLTER: Just on my own experience, I would support trying to get to bundling larger units. I certainly hear from our staff about decisions they're facing on which drugs to choose and the financial incentives to choose one that's equivalent over another because it's a separate

payment. It would be nice if we could find our way through that.

MR. HACKBARTH: Without the benefit of Nick's firsthand experience, conceptually I've been troubled by the fact that we've been getting to smaller and smaller units. The question I would ask, though, is for help in evaluating where this fits in the grand scheme of priorities, both for MedPAC and potentially also for CMS. I'm not sure how to evaluate that.

DR. MILLER: Let me parse at least a couple of things. The handling cost issue was a mandated report. And in that sense, we want to just respond to the mandated report. It's due in June?

DR. WORZALA: It has a due date of July 1 but it will be in the June report.

DR. MILLER: So we want to deal with that and address and respond to the Congress.

The way I would think about the bundling issue is an agenda item that we've had, which has been stalled because of the MMA and some of the additional stuff that we got into, has been to look at the outpatient department prospective payment system more broadly, much like some of

the things we're going to talk about on post acute care later on this afternoon. We've had it in place for a couple of years.

Lots of things have been happening. Lots of things have been happening in particular as it relates to drugs and sort of parsing out how we pay for that. And I would see your discussion at the end of the bundling on drugs could be thought of as part of this larger effort that we're going to try and drive to as soon as we get out from under some of our other work.

Is that a fair comment, guys?

MR. MULLER: Part of my understanding that we have these add-ons and so forth is that given the whole CMS workload issue and so forth, it's just too hard to keep up updating. And therefore the argument that the new drugs and therapies weren't being introduced rapidly enough, if there were bundles -- if the APC was not appropriately updated.

So therefore, you disaggregate to have an incentive or at least have an acknowledgment of the cost of doing these things. So it does go back in some ways to that whole issue of how to update to allow for appropriate innovation.

Obviously, in the DRG system and the bigger payments, plus or minus something on drugs gets -- I wouldn't say get lost, but it's a smaller part of the overall DRG. And with all these APCs, where we have almost as many APCs as we have DRGs and climbing faster than the DRGs have, it's been harder to both update them and to capture the new product.

So I think that's an ongoing issue in the CMS environment. So I think they'll be a lot of pressure from the folks who like to bring new things in to say how do we get them updated in prompt enough time?

MR. HACKBARTH: Other thoughts on this, on either aspect? Okay, thank you.

Now we turn to a series of presentations related to post acute care.

MS. CARTER: I'll get started.

The Commission has long stated that Medicare's payment policies in the post acute setting should focus on the patient and not the setting. Providers should be paid according to the care needs and resource requirements of the patients, not where the care was provided.

To design a uniform payment system for all post

acute care, the same information about the clinical characteristics and resource needs of the patients across post acute settings is required.

Today I'm presenting our initial analysis of the patient assessment tools required by Medicare. We compared the information gathered by each of the patient assessment tools. And for the dimensions that were common, we compared the definitions of care that the time periods assessed and the scales used by the tools to see how similar these tools really are. This information will be considered in the June report chapter on post acute services. At the end of the presentation, I outline possible future research topics that we seek your guidance on.

Let's start by confirming why we need common information about patients seen in different post acute settings. As I mentioned, to design a payment system that spans post acute settings, we'll need the same information about clinical characteristics and the resource needs of the patients across all post acute settings.

Common information is also needed to monitor the amount and the timing of actual service provision as a way of evaluating how the payment system is working.

And last, we would like to use the information to evaluate the quality of care and patient outcomes achieved in each of the settings

Currently Medicare requires three of the four post acute care settings to use a specific patient assessment tool. The Minimum Data Set is required for SNFs. The OASIS is required for home health agencies. And the IRF-PAI is required for inpatient rehabilitation facilities. This instrument is based on the Functional Independence Measure that's also known as the FIM.

Long-term care hospitals are not required to use a patient assessment tool, though many do, using the APACHE or the FIM tools.

All of these tools were developed independently and for different purposes. The MDS was developed as a care planning tool. The OASIS was designed as a quality measurement tool, and to evaluate patients' ability to function in a home setting as opposed to an institutional one. The IRF-PAI is designed to evaluate and monitor patient outcomes.

Partly reflecting these different purposes, these tools vary considerably in how frequently they are

administered, the time period covered by the assessment, the time they take to complete, and the scales used to differentiate patients.

For example, in the MDS, it's administered early in the admission at day 14, and if the patient stays long enough at day 30 and every 30 days thereafter. The measures generally cover a seven-day look back period and record what a patient was able to do as well as the kind and the most amount of help the patient needed during those last seven days. The instrument takes about 90 minutes to complete. Patients are differentiated into three or four categories depending on the measure.

In contrast, the IRF-PAI is done at admission and discharge and records the patient's condition on day three and at discharge. It takes about 25 minutes to complete and differentiates patients into seven groups. The scale of the IRF-PAI is opposite the other two, with the higher number meaning total Independence, whereas in the OASIS and the MDS the higher the number the more dependent the patient is.

Looking across the three instruments, there are four common dimensions that are assessed. These include diagnoses, the comorbidities, the functional status, and the

cognitive status of the patient. But within each of these dimensions the instruments vary considerably.

Let's start with diagnosis and comorbidities. We see that ICD-9 codes are not consistently used by the tool. And when they are, the recording is not uniform. The OASIS requires only three digits, whereas the IRF-PAI requires five. The MDS doesn't use ICD-9 codes at all, but instead includes a check-off list.

The number of diagnoses and comorbidities also different. The IRF-PAI has space for 10. The OASIS has space for five.

The lack of uniform ICD-9 coding will limit whether the severity of patients can be assessed and compared. For example, although the OASIS does not gather complete ICD-9 codes, it asks that each diagnosis code be rated on a four point severity scale. While this information is used to assess the severity of patients within that setting, it cannot be used to compare those patients treated in other settings.

This lack of comparability across tools will substantially limit how their data can be integrated.

Evaluating functional status is key to assessing

post acute patients. Here are the elements that are evaluated by all of the tools. That said, the tools use different definitions of activities included in each of these elements.

For example, under walking and feeding, the tools differed in how they evaluated patients who used assistive devices such as walkers or tube feeding. Under transferring, the MDS excludes transferring to and from a toilet, whereas the OASIS includes this. In bed mobility, the IRF-PAI doesn't assess this measure at all.

In short, for many of the elements assess, what was measured differed across the various tools.

Even larger differences were seen in the cognitive status measures. The MDS evaluates 11 aspects of care compared with six by the OASIS and three by the IRF-PAI. Examples of these differences are on this slide. Long-term memory is not measured by each of the tools.

While each tool evaluates the patient's ability to make decisions, the kinds of decisions that were given as examples to correctly categorize patients varied considerably. In the MDS manual, for example, they included asking if patients know when to go to lunch and if they can

pick out their clothes, whereas the IRF-PAI distinguishes between ability to make complex decisions and problem solving such as being able to balance a checkbook and routine problems such as asking for a utensil when one is missing from a meal tray.

The tools do not systematically evaluate signs of depression.

Finally, the tools differ in the evaluation of behavior that may affect the amount of staff assistance required such as wandering or physically or verbally disruptive behavior. The IRF-PAI measures are so broad, for example one assesses the patient's ability to solve financial, social and personal affairs, that they may span large differences in patient characteristics.

In conclusion, we found that even for the dimensions of care common across the assessment tools, the activities that they encompassed and the definitions of the activities that they included varied considerably. Even for similarly defined activities, the time frames differ so they do not, in effect, capture the same information.

Finally, the scales differ so that a patient with the same care needs would be categorized differently by each

of the tools. This lack of commonality limits whether the information from the different assessment tools can be combined in a meaningful way.

Staff is looking for direction from the Commission about next steps to take. One option is to do further work on developing a common assessment tool. Staff could consider the data elements needed to measure differences in resource use across patients and settings, the reliability of the different measures and whether a site specific tool that fills in the gaps in information could be piloted.

Another option could be to consider how to restructure post acute payments. Under this option, staff could consider the design of a PPS for all post acute settings. Alternatively, staff could evaluate whether post acute payment could be bundled in with inpatient hospital payments.

Another option would be to consider case management approach that would overlay the current payment methods. Case managers would be paid to coordinate and manage beneficiary use of post acute services and be at risk for achieving savings and patient outcomes. Under this option, we might limit our focus to one aspect of post acute

care such as rehabilitation services.

What we're looking for from you here is for direction about which of these options you would like staff to work on.

I'd be happy to answer any of your questions.

DR. MILLER: I think this is clear to everybody, but I just want to remind you. We talked a while back and we all thought it was a good idea that we could begin -- in a perfect world you'd have a standard assessment instrument. Medicare would assign a payment and you wouldn't have all these siloed approaches to post acute care. We all thought that that was an interesting idea to pursue.

The subtext here is it turned out to be a lot harder than we thought it was going to be. So we're looking for some different directions to go in. And in that first bullet, we could try and pursue development of this instrument. But the thing I would want you to bear in mind is that it would probably involve either attaching something to existing instruments or developing another instrument and that has all of the burden issues that attach to it. Or we could just go off in different directions altogether.

MR. HACKBARTH: Let me pick up there. The problem

or the concern that I have is investing in developing a new common instrument or at least in the short run adding on additional burden, is a major undertaking expense to incur both for the program and for the providers. The more I learn about the underlying payment systems the more concerned I am about each of the individual payment systems for home health and SNFs and so on as you go through the post acute. So we'd be investing a lot of money in an overlay on unstable systems underneath. And that troubles me.

So it makes me interested in the concept of going back to the beginning and looking more at an integrated payment system that would do it right from the beginning. But then we're talking about a huge undertaking, not just for MedPAC but ultimately for CMS as well.

So it's a little unclear to me as to which path is the right one to go down.

DR. NELSON: I have a good deal of sympathy with the comments that you and Mark make because, as I read through this I was concerned and I'm having difficulty articulating exactly what my concerns are. But bear with me for a couple of minutes while I try and relate it.

I begin with the premise that these three kinds or four kinds of post acute care have some features in common, but they also are by and large fundamentally different services, fundamentally different products. That is the needs for a patient in a home care setting, where you have to make sure that they take their medication, that their weights are monitored and whatever is fundamentally different from a rehab unit that's supervised by physicians with intensive physical therapy. They really are different products.

And a nursing home, long-term skilled nursing facility, where they're working on toileting and so forth, that's different from either of those other two. And our interest, of course, is in having data so that we can make appropriate payment for necessary care of reasonable quality.

I see three different kinds of data that bear on this. First are the indications for entry into whichever of these settings is there. The second is to sort of define and monitor the care that is received. And the third is to make sure that there is adequate quality in that process.

The tools that are being used now by and large

address the latter two. But they really don't determine who goes into home care or long-term care.

MR. HACKBARTH: That was the gist of our recommendations around long-term care, for example. If people are going to go into this expensive setting, it ought to be people who clinically require these unique services as opposed to a broader group that may not require them.

DR. NELSON: That's the reason why for payment purposes I don't see us being able to tease out various common data elements from the existing evaluation tools because it doesn't answer that criteria for admission, which is a different bag.

I'm sure that there's been research done into what are the criteria but I've never really seen it nailed down very well. I can tell you that some of it is very fuzzy, has to do with the nature of home support, ancillary support from family and so forth. Some of it is just intuition. It's a hunch that the physician has about whether the patient is going to be able to make it or not at home or whether they'll really benefit from rehab or whether they need to go into a skilled nursing facility.

So it may be the one of the areas we would want to

focus on would be what is known about the indications for entry into these various settings before we got very far into defining a single PPS. In my view, the products are different enough that post acute care defies a single PPS at this point.

MR. HACKBARTH: Although the way I thought about it, and I may be wrong about this, is you can go down the track of saying we'll have distinct payment systems and products and define entry criteria as you describe much more clearly than they exist today.

Or alternatively, we can bundle it together and let clinicians close to the patient sort where the patient ought to go among the different settings and not try to write rules in the Federal Register that have clinicians decide within a framework that rewards quality and efficiency.

I think that's the argument for the bundling approach is to move the decision out as opposed to write it in federal rules.

MS. DePARLE: I'm still thinking about what Alan said, which was very thoughtful.

MS. RAPHAEL: Just commenting and picking up where

Alan left off, a couple of thoughts. I do believe the products have become more different than they used to be, because I think we're seeing a shorter stay in nursing homes and more of a rehab focus. So I think that's changed a product line in nursing homes. Rehab facilities clearly have a different product than in home health care.

So I think that is an important thing to think about. Because home care, in a way, is the most difficult, as we know, to define. We've been having medical students do a rotation and go on home care visits. And uniformly they have the same reaction, which is oh my god, send me back to the hospital to the bed. I didn't want to know all of this. It was so much easier in that other setting.

And it is very hard to sort of put the boundaries once you're in a home care setting, which is I think part of the reason it's harder to reach that definition.

In terms of admission, I think you have to separate out what would be clinical criteria from the process. And the process is hard to capture because first of all it's often occurring in a very short time frame. The hospital discharge planners need to get this person out. It can be in two to three hours and you have to make decisions

that are very definitive in a very short and often crisis oriented time frame.

It has to do with geographic variation and the capacity within the system at any point in time to sort of receive these people. And it has to do with patient preference because we have struggles every single week with people who want to come into home care who we don't think we can take care of safely. And they're pleading with us to come into home care.

And lastly, it has to do with cognitive impairments, which I think is a big determinant of where someone lands. So I think as we think about it, we have to separate these two parts.

I guess after I read all of this I came away with the conclusion that it was not worth investment in trying to get a universal assessment tool, that I don't think the payoff is going to be enough to try to really, in terms of what it would take. And I had thought initially that maybe through systems you could extract enough data to put it together. But when the definitions themselves are so different it really becomes very hard to do that.

I'm not in favor of bundling with hospitals

because of two reasons. One, more and more of the people we see do not come from hospitals. The trends are for more people coming from physicians, nursing homes, community referrals.

Secondly, I don't want to ever get to an incentive where you have to be hospitalized to get into the bundle and into the post acute care system, which I can see being a byproduct of that kind of approach.

So those are just some comments as I'm trying to think about where do we go from here with all of this.

MR. HACKBARTH: Carol, what about the case management idea? Don't give it to the hospital but have somebody whose role is to find the right place for patients in need of post acute care.

MS. RAPHAEL: I think these are the issues around -- I think there is value to doing that because I think having someone -- I mean anyone who tries to navigate and make decisions finds it very, very hard to do. So there is value in thinking about sort of what I call a navigator, someone who helps you find the way.

I think the problems are more from a pragmatic point of view. We are bringing more and more people home in

the evenings, Saturdays and Sundays. The pressures on the hospitals are very great. So you have to be very careful that you're not putting in layers here that really interfere with discharge of medically necessary people, which can happen and it does happen.

Because remember that states are trying very much to do this on the Medicaid side of the house. They're trying to divert people from going into nursing homes and moving them into home and community-based care by doing assessments and having sort of people at the gate care managers. And to some extent it works. To some extent it really ends up not making as much of a difference as one would think it would.

So I think it's worth taking a look at what we could do to sort of intervene. I like that idea the best of sort of the proposals that have been laid out in the last part of this.

DR. SCANLON: I agree with the principle that we really want the characteristics of the patient to be determining the appropriate setting and how we pay. I wouldn't bundle these four services together in terms of thinking about them globally and the distinctions that Alan

and Carol made are extremely valid.

Particularly the difference between institutional care and home care. We're expecting a whole different array of services from the institution. It's total care, 24 hours a day. There's patient characteristics that may determine whether that's appropriate. But even when the patient could be at home there's the issue that the institution is providing those services. And I think we need to take that into account in terms of our payment systems.

I'm not sure how high on a priority list I would put it, but I think looking at the three institutional types and asking ourselves are we doing the right thing in terms of classifying patients for these three institutional types or even within an institutional type.

I have a concern about what's happening with respect to the SNFs between those people that are served in the hospital-based versus the free-standing. I mean we, when we were looking at the differences in margins between these two sets of institutions, had a little bit of information or a little bit of data on the patients that might suggest that it was a more complex case than was the hospital, not enough to be definitive and say that we needed

to definitely do something about it, but suggest that that was the case.

So improving the assess instruments from that perspective to be able to refine payments across these three settings, I think is something that should be somewhere on a priority list. I'm not sure how high.

The bundling idea concerns me. Actually, Sheila's gone now. I first met Sheila in 1985 when we were talking about the bundling of post acute care into the hospital payment. And the same concerns about conflicts of interest, in terms of clinical judgments versus financial judgments, existed then. It's not necessarily a clinician that's going to be in charge of that payment bundle and I think that's one of the things that we need to worry about.

The case management idea, my concern would be is we don't have the institutional apparatus there today. And so it's a question of how quickly is it going to develop. If we put it out there is it going to develop in the form that we want it to develop? That would be my concern there.

MR. MULLER: These areas of care probably are more affected by payment policy than are other areas, hospital, doctors and so forth. When we see the enormous change in

home care, when the rules changed there for prospective payment. You see the entry and exit of SNFs is much more dramatic than ever happens on hospitals or doctors coming in or out of the program, which tells me that it's the payment rules more than the underlying needs of the patients that are driving what's going on in this area. So that's part one. We seem to have shaped this arena more through payment policy than we have the other areas of other providers.

Secondly, I agree with a number the previous comments that the institutional world is the one that we have to look at more fully, especially in light of all of the demographic trends that will hit us 10 or 15 years from now, as there'll be more and more need for institutional care. So getting the incentives right there is appropriate.

Third is this notion that there is an integrated system out there. I've already argued against it. There really isn't. These services that one likes to get, case management services for example, are few and far between. Oftentimes, they are located in hospitals for the simple reason that the hospitals have to get patients out and therefore invest a lot in case management because they need to free up those beds. If you try to get those services

elsewhere, you can't find them elsewhere. They don't sit out there as naturally as they do in that kind of institutional setting.

So I would also, I think, try and look for a uniform assessment in that sense. And just echoing what the rest of you said, it's probably not the right thing to focus on right now. I think making sure that the payment incentives -- for how many years now we've been arguing for some change in the SNF rules. And our findings haven't been acted upon as fully as they perhaps have in other areas.

So I think we have to keep making sure that what we're looking at, especially in the institutional setting, is consistent with what we're trying to reach. As opposed to -- for example, in the last few years there's a lot of incentive to do the rehab patient and to take on more rehab patients. I can't remember how much we predicted or people predicted that would happen with the change in rules, but it's been evident now for a couple of years, that a good share of the resources are directed to those patients and other patients are not getting the kind of access to the SNFs that they should.

So I think getting a reasonable handle on

especially institutional setting, whether the rules that -- especially the payment rules -- are achieving the kind of programmatic purposes that we want, I think is of critical importance.

I also would agree with the previous statements that these are different products. And so with our other thoughts about the advantages of specialization that we've discussed around hospitals and thinking about the advantages of specialization here is a fruitful line for us to go down.

But most importantly, the payment rules are more dispositive here than they are in other areas. So we should be even more attuned to the programmatic consequences of payment.

Whereas in the other areas there are other forces, as well, technology, et cetera, that have a big effect on delivery of care. This is much more payment driven.

DR. MILLER: Just to say one thing about that. The next two presentations actually go inside these areas and start discussing the payment elements. So in a complete contradiction, we're both looking across and down. And I think some of your issues will be dealt with there.

MR. SMITH: I agree with a lot of the cautions

particularly that Carol and Alan suggested. But I do think we ought to keep in mind, as we think about the bundle option here, that in the post acute world people are likely and do and should consume more than one of these services. Carol, whether it's your traffic cop or a case manager, someone who with a common assessment instrument, with a good definition of a product in these very different suppliers who is managing and helping navigate the way through it, when is it appropriate to be in a SNF? When is it appropriate to leave a SNF and be in home health?

We have no other way to think about the architecture of getting to a sensible set of decisions in that circumstance without a bigger bundle. I accept your concern that the hospital may not be the right place to bundle. But at the moment it is the only place where that decision gets taken. I've got to get somebody out of a bed. Where do they go? Do they go to a SNF? Do they go to home health? Do they go to a rehab facility?

If we can't re-create that informed decision with some other instance, some other way of thinking about bundling, I wouldn't take the hospital as bundler off the table at this point. I don't think we know enough about how

we get an integrated pattern of post acute care where people are -- this is not a situation where you get your knee operated on and your ankle operated on. You may well, and are quite likely to, in an episode move through more than one of these post acute settings.

MS. RAPHAEL: Can I make a comment on that? I think, first of all, you have to understand that hospitals are not the only place because a lot of people in nursing homes, they can't show improvement. And therefore, they have to leave the nursing home because they can't meet the expectations. The same for rehab facilities. So there are decisions made at that point, as well.

So I think you could also think about bundling from the nursing home on to home care. I think it can get very complicated because there are multiple points of bundling.

MR. MULLER: I just want to make a comment that the notion of this seamless acute system, it doesn't exist. So there's a notion you have all these choices. A lot of times you just have to find a nail because you only have a hammer.

So basically you may have a SNF, you may have home

care. The dimensions of home care have shifted considerably in the last few years, given the payment -- the comments I made earlier, so I won't repeat it.

So this notion that you have this array of choices, even in urban areas which are supposing more oversupplied, you generally don't have these choices. So you're looking oftentimes to put a person somewhere, which may not be the best place. And you know you're not putting them in the right place, but it's better than nothing.

So I think that reality is out there, too, before we think that if we had the right instrument we all of a sudden would be put in the right place. If you want five places and you only have two, that kind of oftentimes directs you to the wrong place.

DR. MILSTEIN: Based on Alan's reasoning, I think that we might always want to see some facets of quality assessment being institution specific. That doesn't mean all of our quality measures pertaining to this population have to be institution specific, but some would always have to be, I think, for the reasons you cited.

With respect to payment incentives, I think the pros and cons of bundled payments are well known to

everybody around the table. My best recollection of the research evidence pertinent to this is that there is evidence of substantial, both regional and within region, hospital specific variation in the mix of use of post acute care services. And that's holding constant availability of different post acute care capacity, different types of post acute care capacity.

Based on that line of reasoning, I think I lean toward Glenn and Dave's vision of if it's a close call tilting toward a more bundled system which begins to get all of your pieces focused on the question of how do we optimize over time the best both patient outcome and total Medicare spending.

MR. HACKBARTH: Anybody else? Okay, why don't we move on then to the next, which is assisting the home health PPS.

MS. CHENG: This is my first presentation on this subject for this report cycle and I also will be contributing to this chapter in the June report on post acute care.

First, I'm going to briefly review the payment system that we've come to know and love over the last three

years. And then I'm going to touch on some evidence that suggests that perhaps this PPS is not working optimally for all patients.

The second thing I'm going to do is talk to you a little bit about some research strategies that we could use to look at the PPS.

And finally, I'm going to talk to you a little bit about options that I think are briefly sketched in your paper because we only have brief notions of them at the moment. It's difficult to develop a care plan before you've diagnosed the patient. And so, we're kind of doing two things at one time here.

The current payment system that we use for home health, the basic unit of payment is a 60-day episode and beneficiaries can have multiple 60-day payment episodes during a single spell of illness, so long as they remain eligible for the benefit.

The way we pay for home health services right now is by the episode. We have a base payment that applies to each episode, and that right now is about $2,300. You take that base payment and then you multiply it by a case-mix weight. That is used to describe the relative expected

resource use needs of the patient in that case-mix. This system has 80 case-mix groups that are called HHRGs.

We also adjust a portion of the payment to reflect local prices.

The case-mix system that the home health PPS uses to put patients into these expected resource groups has three domains. They are clinical, functional and service use. The clinical is driven off things like the diagnosis, whether a patient has persistent pain, or whether they need parenteral nutrition, which is very resource intensive.

The functional domain is driven off of the functional limitations that a patient has when they are admitted to home health. So their ability to ambulate, their ability to dress themselves, or their ability to get to and from the toilet.

The third domain is service use. That’s driven by whether or not that patient came from another institutional setting. Did they come from a hospital? Did they come from a rehab facility? And also is driven by their actual use of therapy up to a threshold.

So we take their scores in those three domains and we use their scores in those domains to place them into one

of 80 case-mix groups.

DR. NELSON: On the one point, Sharon, give me some other examples of the clinical domain apart from parenteral. Just give me some examples of other clinical --

MS. CHENG: You use the ICD-9s to put them into diagnostic groups. There are orthopedic diagnoses, neurological disorders. Diabetes would be a predominant diagnosis here.

It also includes wounds, whether the patient has a surgical wound. In fact, it differentiates did they have a surgical wound, a stasis wound, or a burn to try to capture the different resource uses based on those clinical aspects.

It also has persistent pain, their vision status is included in clinical. So they're trying to use a fair number of items from the OASIS to describe clinically what that patient is. But all persons with diabetes won't necessarily be in the same HHRG. There are several case-mix groups that they might fall into.

We have some evidence that suggests with three years of data under this system that it might not be working optimally for all patients. The first piece of evidence is that this payment system is neutral to high or low quality.

We have made a recommendation that payment systems ought to be sensitive to differences in quality.

We have seen, in the three years that this payment system has been in place, consistently over adequate margins every year has produced a double-digit margin under this system.

We also see that there is a large variation in inputs within the case-mix groups. This is what we've been talking about now for the past couple of meetings. One of the things I used to describe the differences in inputs was the variation of minutes of service within these case-mix groups. And we use the coefficient of variation to describe the very wide differences in experience that patients have within the same case-mix groups.

We also looked at some other information that we get from the OASIS so that we can describe patients and we can look at their characteristics in ways that are not used to adjust payments but that we observed seem to be correlated with very high costs. We found that obesity, smoking, an inability to self-administered needed medications were related to high costs. But none of those things are used to adjust payments in this system.

So all of these things are suggestions. They are preliminary evidence that have piqued our interests and have led us to want to look closer at this payment system.

What's one of the reasons that we might see that this payment system isn't working optimally? To be fair, it was developed using 1997-1998 data. In 1997 the home health product included an average of 36 visits per episode, 1,500 minutes of care, and 9 percent of the visits were for therapy. In 2002, we're using the same data-driven payment system to pay for a product that has an average of 19 visits per episode. That's a decline of 47 percent. Minutes have declined 37 percent and therapy has increased 26 percent of the visits. That's an increase of 17 points. So as you can well imagine, unless all of these substantial changes have occurred precisely the same to each one of those 80 case-mix groups, then probably the way we're describing the relative needs of these patients is no longer correct.

Also we've seen perhaps the patients that are in these case-mix groups are not quite the same. And we've also seen the episode length decrease so that the episode that were buying might not really be describing the spell of illness and the time that patients are spending under the

care of the home health agency.

MS. BURKE: [Inaudible.]

MS. CHENG: I'll get back to you on that. Sheila asked whether the average age of the patient has changed and we can look at that, too.

So what can we do? I'd like to look at this payment system a little bit more closely. One of the things that I can do is to extend the analysis that we have discussed in the past couple of meetings of the HHRG level visits and minutes. To take it a little bit further down the road, we can differentiate these minutes. I've counted a minute as a minute. But we could see how well this payment system is doing at predicting aide minutes versus therapy minutes versus skilled nursing minutes, so we can see those differences. I can also use some other statistical techniques that I haven't tried yet and try to build some regressions and see how well this system is doing at predicting the relative minutes from group to group.

Alternatively, and this would be a little bit of a different direction, what we can use is a combination of the cost reports and the claims data and try to develop HHRG level costs. I could also use a regression of differing

statistical techniques here. The two observations I'd like to leave you with, though, is that this is very similar to research that CMS is pursuing and hopes to release soon, so our efforts might overlap there a bit.

The other thing would be a certain wariness that I think a lot of folks have over using this cost data. We could use a lot of statistical techniques and do a lot of massaging. But if the data just doesn't have much there there, then you've got to wonder what you come up with at the end of the day.

Either one of these tracks or suggestions from you could lead us to a couple of different diagnoses for this patient. What we could find is that the system as a whole isn't working so badly. Maybe all it needs is an incremental change. Maybe we just need to reweight the weights of the 80 case-mix groups and we can improve the predictive power of the system. Or we could think of other incremental changes.

Alternatively, we might find that this patient, rather than markers of frailty, has some fairly specific abnormalities that we'd like to treat. And that might lead us down the path of thinking of more substantial changes to

this payment system. So my next couple of slides are going to be possible options. As I said, it's hard to develop the care plan when you haven't diagnosed the patient yet, but these are things that staff can be thinking about and we'd like to get your reaction to these ideas.

The first one would be to look at a payment system that shares the risk. The idea here would be that the payment system would have a retrospective adjustment. This would be based on the agencies' costs and would be made to the agency revenues at the end of a cost reporting period. The idea here is that a risk sharing arrangement would reduce the variation in financial performance by removing excess revenue from agencies that produce more profits than they have costs. And it could redistribute payments or revenues to those that have more costs than they have revenue.

There have been objections to this idea from CMS and the industry. CMS has observed, from its experience under the IPS that have a system of repayments of overpayment, that overpayments are kind of tricky to get and to collect in this setting. And so they're a little bit wary of getting into that kind of system again.

The industry also objects to the treatment of excess revenue under a risk sharing system. The industry has contended that this excess revenue actually is very important to maintain their operations. In some cases, it is used to cover shortfalls from other payers. And those other payers might be other government payers and might be, for example, for other costs that are very similar to what Medicare pays for.

They also contend that this excess revenue is being used to invest in the very technologies that would enhance the quality of care.

One last observation is that a risk sharing system could conceivably penalize efficient providers. If low-cost providers were providing the same quality or higher quality care than their peers then they would be penalized for that efficiency.

Another possible option would be to imagine a payment system that had a two-part payment. One part of the payment would be a per patient payment and the other one would be per visit. The per patient would operate on a prospective basis and it could look a lot like the PPS does now.

The second part would be based on the actual visits by visit type that the patients received. That would be somewhat like the system that we used in 1997, although you could certainly conceive of doing it a little bit smarter in a couple of ways.

We could for example, rather than pay on a visit by visit type, we could use more information that we have about 15 minute increments. So we could at least narrow down the variation in visit and buy that in more reasonable increments.

Another idea that you could see under a cost-based per visit system would be to integrate new kinds of visits that we have seen in this setting, such as televisits or telemonitoring or new kinds of care provision that wouldn't necessarily have to be limited to a face-to-face visit.

This option of mixing per episode and per visit payment has a very strong incentive against stinting, although the evidence so far has been mixed on stinting despite the recent changes that we've seen in this project.

Your mailing materials looked at several different studies and those studies seemed to find little or no impact and very large decreases in the number of visits and minutes

that have followed the IPS. In our own analysis that we looked at over the past year or so, though we've seen visits continue to decline under the PPS, we have seen that our markers of outcomes have actually increased slightly.

A final possible option to consider here would be splitting the benefit. This would be something that we could consider if, after looking at the groups that are using home health, we found that there are one or two subgroups who have substantially consistently different needs and their use of the benefit is consistently different than the norm or than perhaps the larger group. If we found this pattern, you could imagine changing the bundle of services so that we could better meet the needs of these patients whose needs are substantially different from the norm. Or we could even contemplate developing a parallel benefit. It might be similar to a benefit that's being demoed by CMS right now, the Chronic Care Improvement Program that would be administered by home health agencies but would look quite substantially different from the way that we buy home health services now.

Such subgroups that you could imagine finding would be post-hospital users differing from community

referred users, those with no informal caregiver, those who are dually eligible or those who have markers of frailty. We might see that those groups differ in their use of services.

The paper sketches these resource designs, not a whole lot more meat on the bones, and to explore the various options. Staff can develop one or several of these if you wish to have more information or you want to explore them further.

MR. HACKBARTH: Questions? Comments? Solutions?

DR. WOLTER: My comments are a little bit focused on some of what I'm hearing out of the rural areas with home health. In Montana in the last three or four years, we've had about 15 agencies close. That's 28 percent of the health agencies. Three-quarters of them are hospital-based and really quite rural. And if I'm remembering right, hospital-based margins were not included in the data set that we've looked at for health margins. So that's one of the concerns they pass along to me is does that somehow or not accurately reflect some of the challenges they face.

And then to the point that you guys have been making, they're seeing a lot of COPD, congestive heart

failure, for example. The risk acuity systems don't necessarily plug in for those conditions, which they feel they uniformly lose money on when they accept those patients. So they're saying more discrimination almost against certain clinical conditions and, in some cases, mileage restrictions in terms of how far out they will go.

So I think we do have some work to do. And I know in the rural areas there's a lot of concern about trying to have the acuity systems better reflect what they're challenging or what they're facing.

The last thing I'm hearing from them is nationally there's an increase in readmissions to hospitals out of home health. And Carol, I don't know if that is what you would see or corroborate. Is that also maybe a symptom of somehow the system isn't quite recognizing what some of these patients are presenting to the home health agencies? And can we better recognize that, both in the assessment and acuity systems, but maybe in the payment system as well?

MS. RAPHAEL: Just a few comments. I do think we have to be mindful that there is a high readmission rate. I think it's high. It's in the range of about one-third of patients do get readmitted to hospitals. But I'm sure it

varies, so I think that is something to be concerned about.

Just two comments. One is I think we've worked very hard in home health care to get away from the sort of per visit mentality and what I consider a transaction-based system, which is what is it that you do? You make a visit? No, what you do is try to manage a case to get a good outcome. And we've worked very hard to change that. So for me, going back to sort of per visit payments does bring us back to yesteryear. So that's a concern that I have.

I'm sort of most interested in looking at subgroups because I think there are subgroups that use a lot of resources but don't necessarily score high in the current system that we've created. I've said this before, we find that the duals are just in a separate category. And for whatever reason, whether they crossover with the categories Nick just pointed out, but they seem to really be very, very resource intensive. So that's an approach that I would like to see us pursue.

DR. SCANLON: I have a concern. The double-digit margins are one issue. I think the thing that bothers me more, though, is the range of the margins, the fact that it's so wide and you've got people that are more than twice

the average.

When I look at the system conceptually, there's an opportunity there for abuse. In the sense that we haven't defined exactly what the service is. We don't really have a strong sense of the outcomes, especially for the outcomes for the longer-term patient. We certainly don't have any accountability at the individual agency levels for outcomes.

So the idea of getting a patient and then not providing enough services is a possibility. And when I look at this range of margins, I say to myself that's not all efficiency. Some of that is stinting. And I'm concerned about that.

From a Medicare prospective, if I want to spend this amount of money, I would rather redistribute it to make sure that I'm getting care for the people that need it. The system is not set up that way.

GAO was behind the risk sharing and I had a small part in that. I would say that some of the objections to it are overstated. CMS had problems with the IPS, in part because the IPS was such a dramatic disruption. You went from a world where we had this incredible growth over a three-year period and we suddenly capped people at the

national average of three years before, creating retroactively very big paybacks that had to be made. Whereas under the prior system, the retrospective cost reimbursement system, we had paybacks going on for 20 years. When an agency was overpaid one year, then it would come out of next year's payments.

The IPS was just such a dramatic shock that it was hard to administer.

Again, this idea that we're going to discourage efficiency. We're not necessarily going to discourage efficiencies through risk sharing. What we're going to do is we're going to discourage excessive reward for stinting, I think is what we can do. That's probably the primary thing that I'm concerned about about the system.

We saw the data, I think either last time or the time before, about growth -- and this goes counter to what Nick said -- growth in terms of the number of agencies. I worry that we will see some of the same kind of abuse of developing over time that we saw under the old system because conceptually again there's no safeguard against that within the system.

MS. RAPHAEL: Can I just make one comment? I just

think we should not only look at the number of visits, which are now 19 and were whatever before. I think the key to this system is who you admit. That's why you have the variation that you have. That's really the key point. We admit everyone. Therefore my total margin is barely 1 percent.

If I wanted to do very well, I would be very careful about who I admit. That's a much more important variable than the number of visits that I give. And I don't know how you capture that because we're very focused only on the number of visits.

MR. HACKBARTH: So what I hear you saying, Carol, is that you actually may not even have to stint in order to make a substantial profit if you properly select.

MS. RAPHAEL: Right.

DR. REISCHAUER: Then what you're saying is that the payment variation is all screwed up.

MR. MULLER: I would say, in terms of the reweighting along the lines that we've done in specialty hospitals, this area is ripe for that, too, because we didn't just go to PPS but we went to rewarding certain kinds of patients.

I agree with what Nick and Carol said. We had the same experience in our area, that the medically complex patients, you can't get other people to take them because the payment system doesn't pay medically. The rehab patients you can make a lot. So it's very parallel to our -- without extending the specialty hospital discussion too much, some of the same themes that play out there play out here. So a reweighting, as we recommended there, could be something. That's one of the things that we have in here that I think makes sense to look at.

MR. HACKBARTH: It wouldn't just be a matter of reweighting in this case. It would be subdividing and more precisely redefining the groups and then properly calibrating the weights for the different categories.

MS. CHENG: Just as a note, we do have a mandated study that we will be pursuing over the summer that looks at the relationship of case-mix and financial performance. And so we will this summer, with the help of a contractor, be looking at agencies with different margins and trying to see whether we can measure and identify different patients that are going into different agencies.

MR. HACKBARTH: Although Sharon, when we do that,

if the case-mix descriptions are too broad it confounds the results because you'll start to have people with identical case-mix as measured by the system with dramatically different profit margins because the game is subdividing within the case-mix.

MS. CHENG: And I don't think we'll get to all of that but we have asked the contractor to use some data that we have from CMS that has the entire OASIS, not just the ones that are used for payment, not just the payment items, but all of the items on that.

So in addition to looking for the patient characteristics that go into the case-mix, we'll be able to look at obese patients or smokers or dually eligible. So we might be able to get at some patient characteristics that are causing those differences but aren't in the case-mix.

MS. BURKE: I just had a question that I wanted ask Carol and follow up on a comment that Carol made which I instinctively believe is correct, which is the radical difference, in this case, between dual eligibles as they present and the resource needs for a dual eligible on average as compared to non-dual eligible patient and a more traditional patient, and whether what we can learn from that

and how you might imagine going forward one might adjust for that.

Because arguably you see it on acute care side, as well, where they present a much more complicated, much more dependent situation because of comorbidity. A lot of things, some of which you can measure and some of which you can't. Just following on that, I guess the question is Carol, how might you imagine as we look at this question, and to the extent that we're going to pick up some of that potentially this summer, whether that plays out in terms of what these margins look like.

But the question is how you would adjust for that? Because it is a particular class of patient, but almost routinely, it seems to me, present a different set of problems that end up being very resource intensive.

MS. RAPHAEL: I don't know enough about the characteristics, but I think for example there's a greater prevalence of cognitive impairment in the dually eligible population. I don't know how we're creating the case-mix now adequately accounts or what it means when you have a cognitively impaired patient who has a complex medication regime and how you have to help that person manage that

medication regime. So those are some of the things that I think we do need to take a look at.

I know the whole issue of informal caregivers is a difficult issue. And I think there is greater absence of informal caregivers in our poorer population than in some instances. I know that CMS has been reluctant to try to reward the absence of informal caregivers because they're afraid they'll encourage the absence of informal caregivers.

I think you're right, I don't know how we translate what we find out into changing the payment system. I do believe there is more CHF, more COPD, some of the more chronic conditions among that population.

MS. BURKE: It's not surprising, if you think of the presence of obesity, the use of smoking, where there are characteristics in a lower income population that may be more prevalent, dietary habits. All of that can contribute to presenting conditions that complicate things.

MR. MULLER: One place to look, and I'll ask Sharon or Carol or whoever, you may want to look. Do the Medicaid rules vary at all, the payment rules, compared to the Medicare? Because obviously a lot of these kind of social issues that go through the Medicaid population from

age one to 65, when they become duals. You just don't call them duals when they're under 65, they're only on Medicaid obviously. But a lot of these are very much -- whether one is dealing with child welfare or dealing with young adults, as well.

MS. BURKE: Is your question does Medicaid --

MR. MULLER: Do some Medicaid systems have some better adjustments of that then perhaps we have here at Medicare because they deal with those issues all the time.

MS. BURKE: They pay less.

MR. MULLER: They pay less but they may have a more sophisticated system on which they pay less.

DR. REISCHAUER: While we're peppering you, Sharon, are disproportionate numbers of duals disabled?

MS. RAPHAEL: That's a very important question. And also, you may find that the younger disabled population could be a big factor.

MS. BURKE: It could if they're SSI, if the contributing factor is whether they're SSI recipients, unlike the OASDI, which would be not necessarily duals.

DR. SCANLON: To answer Bob's question, in part they are because one of the routes to becoming a dual is the

fact that you had large medical expenses and you became medically needy and that made you Medicaid eligible.

But going back to Ralph's, most Medicaid agencies don't use home health. They rely on the home and community-based services. They may use assessment instruments. They may use them in a very qualitative way. We did a study which looked at prescriptions of services to individuals. We created prototype individuals and asked caseworkers what would these people get. And caseworkers sitting in the same office prescribed completely different packages of services for them and then they would then be paid for on an individual fee-for-service basis. But the volume is controlled by the caseworker.

It's all over the map and there's nothing like the Medicare system that I know of in any state Medicaid program.

MR. HACKBARTH: Any others? Okay, let's then move to the SNF PPS.

MS. LINEHAN: In the BIPA, the Congress directed HHS to study different systems for categorizing patients to account for resource use differences across different patient types in skilled nursing facilities. CMS awarded a

contract to researchers at the Urban Institute to fulfill this mandate and a report to Congress was due January 1, 2005 but CMS has not yet provided their report.

CMS has not indicated what, if any, action they may take this year as a result of this work. And when and if the payment system is refined, according to current law several temporary payment add-ons will expire.

The President's budget, as Rachel talked about this morning, shows savings of $1.5 billion from the expiration of these add-ons in 2006 but doesn't provide any detail about refinement.

So as we wait the release of these findings of the Urban study and contemplate the implications, I'll review problems with the current SNF payment system and past research on proposed payment system revisions in preparation for future conversations about revising the SNF PPS.

Now that I've given some context, I will review the current payment system, some of the criticisms of that system and then I'll discussed so options for revising Medicare's SNF payment policy that have previously been considered and may provide foundation for future directions.

As you know, Medicare's per day base payment rates

to the SNF are adjusted for case-mix using the RUG-III classification system. There are currently 44 categories in the RUG-III system, as depicted on the slide. Assignment to a RUG-III category is based on several items, the number of minutes for therapy used or expected to be used, the need for certain services such as respiratory therapy or specialized feeding, the presence of certain conditions such as pneumonia or dehydration, an index based on the patient's ability to independently perform four ADLs, and in some cases signs of depression.

Beneficiaries may qualify for more than one category but are assigned to the highest payment category for which they qualify. SNF patients assignment to a RUG-III is determined by assessments using the MDS. As Carol said, SNF patients are assessed using the MDS at the 5th, 14th, 30th and every 30 days thereafter in their stay.

Here are two examples of RUG-III categories and their associated indexes. The first is for a rehab RUG and the second is for an extensive services RUG. As you, each RUG-III category has associated nursing and therapy indexes to adjust the nursing and therapy base rates for relative resource use.

Here's a simplified example of determining the total case-mix adjusted rate. Each base rate is multiplied by its respective index associated with a given RUG-III and then these components are added together. All RUG-IIIs have a non-case-mix component to cover costs considered to be uniform across all patients such as room and board.

Now that I've discussed how the current payment system is adjusted for case-mix, I'll review some of its deficiencies that have been articulated by this Commission, GAO, CMS and other researchers.

The first of these is the omission of non-therapy ancillary costs such as prescription drugs and respiratory therapy from the determination of the RUG-III relative weights. Payments for non-therapy ancillary services are distributed using the same weights used to allocate payment for nursing care. To the extent that nursing staff time is not correlated with non-therapy ancillaries, payment for non-therapy ancillaries will not be distributed properly.

For example, two medications may differ substantially in cost but the staff time it takes to dispense the expensive drug and the inexpensive drug may be the same. In this case, payments to the SNF dispensing the

second expensive drug are not adjusted to reflect the higher cost of the medication. Instead, payments are distributed equally according to staff time.

This may lead to access or quality problems for certain residents, creates opportunities for favorable selection of residents, and can increase financial risks for providers.

Another criticism of the RUG-IIIs has been the classification of patients into rehab rugs according to services provided rather than patient characteristics. This can create incentives to provide therapy, especially because therapy RUGs are at the top of the payment hierarchy.

A third criticism has been the reliance of the case-mix system on the MDS. Research has questioned the validity and interrelated reliability of the MDS used to categorize patients. However, none of the options I'm about to discuss are going to have at all contemplated an alternative to the MDS.

Now I'm going to move on and review past research on refinements and some alternative payment options to the current SNF PPS, and I'm also going to review some other payment policy changes, outlier policy and per episode

payment that could be relevant to this discussion.

First, I'll review past work on efforts to refine RUG-IIIs to address paying for non-therapy ancillaries. CMS awarded a contract to Abt Associates in 1999 to review the RUG-III classification system with particular emphasis on the variation in non-therapy ancillary services within the RUG-III categories.

In their final report, the contractors recommended that CMS consider adding new groups to the RUG-IIIs for SNF patients who qualify for both rehab and extensive services categories because extensive services patients had much higher non-therapy ancillary costs. This proposal was called the RUG-III Plus model.

MS. BURKE: Can you give us an example?

MS. LINEHAN: An extensive services patient could be someone who is on IV meds receiving trach care. And because the MDS has the look back period it could be within the previous seven days or 14 days, ventilator or respirator patients, patients who require suctioning, patients who require IV feeding.

So the Abt researchers, in addition to proposing this RUG-III Plus model, also proposed applying one of two

index models to the new system. These indexes were developed from MDS items, such as suctioning, tracheostomy care and IV medication use, that were found to be significant related to per diem non-therapy ancillary costs. So residents would first be classified into one of the new RUG-III categories, and then assigned to another group within that based on the number of index variables that applied to them and the payment would be adjusted depending on --

MS. RAPHAEL: One question. If you are getting trach care or you're on a ventilator, you still are able to get rehab? Up to X hours in the nursing home?

MS. LINEHAN: Yes, I think so.

MS. RAPHAEL: I don't understand how you can fall in the both of those.

MS. BURKE: Range of motion.

MS. LINEHAN: It's physical, occupational or speech therapy so they're not necessarily getting physical therapy.

These recommendations were an attempt to maintain the RUG-IIIs structure but to better account for non-therapy ancillary costs. It did not alter the way patient were

categorized into rehab rugs according to services provided and it continued, as I said, to use MDS data.

Based on Abt's findings that this refined case-mix system had improved ability to predict variance in total and non-therapy ancillary costs, in April 2000 CMS issued a proposed rule to define the RUG-IIIs using this model. But in the July 2000 final rule, CMS announced the results of testing the models on post-PPS national level data. They found in the subsequent testing that these models did not improve the ability of the case-mix system to explain cost variance and therefore did not go through with the implementation of their proposed refinements. And as a result, the temporary payment add-ons remain in place.

In spite of the outcome of this particular refinement effort, an index similar in concept could be developed but additional research to identify variables that are better predictors of non-therapy ancillary costs would be required.

Now I'll discuss an entirely different classification system that was contemplated prior to the implementation of the PPS. Phil Cotterill at CMS tested the ability of a DRG-based case-mix index to predict Medicare

SNF patient resources at the facility level. Using DRGs derived from the SNF admission diagnosis, he found that although a significantly positive relationship existed between SNF costs and the SNF diagnosis-based index, the explanatory power in the SNF setting was weaker than the relationship between hospital costs and the hospital index.

Nevertheless, a DRG-based case-mix index may still hold some promise and appeal as an alternative payment classification system, especially if bundling with inpatient payment is being considered. Such a classification system would be based on patient characteristics rather than on services provided, a criticism of the RUG-III system. In addition, similar to what Abt researchers proposed in their RUG refinement, other variables such as measures of SNF patients' functional or cognitive status could be appended to the DRG to improve on its explanation of cost variance.

Still another model for your consideration is cost-based payment or partial cost-based payment. Some state Medicaid programs pay nursing home costs or certain kinds of costs subject to ceilings. This sidesteps the need to develop an adequate case-mix system altogether.

States may divide costs into different cost

centers, such as direct care, indirect care and administration and pay some centers prospectively and some others cost subject to certain limits. This presumably allows states to encourage spending in areas related to the product they want to buy and more tightly control spending in areas they don't necessarily want to pay more for.

But cost-based payment is inherently inflationary. For Medicare to adopt this type of payment system, the program might see a return to large increases in SNF spending like those prior to the implementation of the PPS. Given wider latitude to spend on direct patient care, it's also unclear whether facilities would target money to areas of patient care that can actually improve patient outcomes.

Finally, these last two features I'm going to discuss aren't necessary alternatives to the RUG-IIIs, but are common elements of other Medicare prospective payment systems and may be considered again in the SNF context.

The current Medicare SNF payment system does not have an outlier policy. Certain high costs in frequently provided services are currently excluded from the per diem rate but GAO concluded that CMS may not have consistently applied the criteria to exclude services from the payment

bundle and that perhaps still other services should be excluded as well.

An outlier payment may still be desirable, however, if there are cost outliers that a facility may be able to anticipate and avoid. Such a policy ideally does not undercut incentives for efficiency and encourages providers not to avoid especially costly cases. If an outlier policy were incorporated into the SNF payment system, a variety of design choices could be explored. For example, an outlier policy could be designed to compensate facilities for total cost outliers or for cases that have extreme costs in a single component of total costs on a per day or per stay basis.

And finally, the desirability of changing the unit of payment from a per day to a per stay payment may also warrant consideration. If a prospective payment system can be developed that has the ability to explain episode costs rather than daily costs for all patients or perhaps distinct subgroups of patients, then it might have the ability to promote efficiency better than a per day payment.

On the other hand, it's also important to weigh the potential consequences of a shortened length of a SNF

stay, and whether such a policy could potentially lead to adverse patient outcomes or otherwise avoidable use of inpatient hospital or other post acute care.

So this review of past research on SNF payment and the potential application of common PPS payment elements to SNF payment is intended to provide context for the potential directions that SNF payment modification might take.

We anticipate CMS's release of the BIPA mandated study on the SNF PPS alternatives and will bring these results to the Commission for consideration and continued discussion as they become available. In the meantime, we look for guidance from the Commission on any research on payment system alternatives you'd like to see moving forward into the spring and summer.

This concludes my presentation and I'll take your questions and comments.

MR. HACKBARTH: Questions?

DR. SCANLON: I'd like to expand on the discussion of cost base because I think we should consider it as an option in a slightly different context because when you talk about some states, it's actually about 45 that operate one of these kinds of systems. And in terms of its inflationary

potential, given that we hear so much about Medicaid as paying low rates, it would seem that it has some potential for controlling costs.

The big thing is that there's a major difference between the old Medicare system and what we're talking about with these state systems.

The two things that contributed most, probably, to the Medicare cost growth, was the fact that it was retrospective, and that the accounting principles allowed you to create a distinct part so that all you needed to do was to have a small number of beds that were dedicated to Medicare and you could keep books for those beds and then Medicare would pay the average cost of those beds.

When it's the average cost of the entire facility, your incentives are completely different. Your ability to incur extra cost and get them reimbursed are totally different. If you're 40 percent Medicare and you're paid on the basis of the average cost of the whole facility and you raise your cost of dollar, you have to ask yourself where's the other 60 cents going to come from because Medicare is only going to pay you 40. So it's a completely different kind of a situation that existed then.

And facilities were taking advantage of that. There were more distinct parts towards the end of the retrospective system than ever before. And you had companies with ancillary branches that were supplying ancillaries to themselves at inflated rates. This is what contributed to the bankruptcies that followed the introduction of the PPS.

So I think we're talking about a completely different world.

What is key in these is that they're still perspective systems. The issue is how often do you rebase? That influences how much inflation potential there is in one of these kinds of systems. That actually does create a need for a case-mix because you don't want a facility to be penalized because they admitted heavier care people over time and that today's costs are not in line with what they were two or three years before when they had a wider case-mix. So you really do want to think about that.

The other thing is that this is a variant of paying for performance. The research has shown a link between staffing in nursing homes and the quality of care. And states have said we would like our money to be more

directed towards staff. We want the nursing center to be more generously endowed and we want administration, more maintenance or things like that.

So you'll go into states where they will pay -- the ceilings will be up to like the 76 percent dial on nursing and down at the median for administration. So it's a way of them directing their resources towards what they think is more important, in terms of the care being provided.

DR. MILLER: If I could react to a couple or ask a couple of those things. In the Medicaid world where this goes on, isn't the key point how frequently they allow the cost -- your rebasing point? Because the unvarnished statement of they have cost-based systems and you don't see costs going up in Medicaid is very much a function, I think, of how much the states are allowing that to go up. I have a string of things I want to ask.

The other thing I would ask you to comment on is the notion of paying for inputs versus outcomes. You were saying nursing ratios. Some of our conversations about quality have tried to be oriented towards what we're looking for

And I guess the last thing is I definitely understand your point on the 40 cents on the dollar, but also what about cost allocations. Do we feel pretty confident with those kinds of issues in terms of whether Medicare could end up carrying more of the cost for other payers?

DR. SCANLON: Going back to the first of your questions. The issue of the frequency of the update is a key here. The other thing that's different between the current Medicare system and these state systems is that there is an individual rate -- I'm sorry, a rate for each individual home. So it's a function of how they allocate their costs. As opposed to the Medicare system, which is based upon an average and your behavior does not affect your revenue. That's the key in terms of creating the greatest incentive to control your costs.

When you start to link your own individual costs to your rate, obviously you weaken your incentive. But when you start to increase the amount of time between the date the rate is set and the date the costs are measured, then that incentive grows.

Some states have actually also done things like to

avoid saying that we're going to use 2006 costs to set rates for a four year period, they will use a moving average of three years costs, so that they don't have people game them in that way.

Your second question about the idea of paying for outcomes as opposed to paying for inputs is totally valid. The issue is, as we faced when we were talking about pay for performance in SNFs, is the issue of measures. Even though there may be measures within the MDS that apply to the longer stay patient, there's also a feeling that we don't necessarily capture everything about a nursing home.

Nursing homes are individuals residences. In fact, in the long-term care field people dislike the term patient because these individuals are there for sometimes several years. This is their home. A lot of our measures are much more related to their health status, not to the quality of life that they are experiencing. And so the idea of putting more money into the things that seem to matter.

The nursing centers of the cost reports are typically rather broad. It's all the staffing. So it's not just the nursing staff in terms of registered nurse or LPNs. It's the aides that are doing a lot in terms of assisting

people with their activities of daily living. That's why states think that's important.

You could also argue wait a minute, isn't the housing aspect of life important, as well? I certainly wouldn't dispute that.

Your last point was the allocation. The categories are broad enough that I think that there's some potential, but I don't think it's extreme. It's relatively clear that people are doing care functions versus people are doing -- they're janitors or they're administrators. So you don't want it to be too fine about this. You don't want to try and have 10 cost centers. Having three or four is probably much more typical of what a state will do in terms of trying to skew the funds towards what they think of as more important.

MS. RAPHAEL: I don't know if I remember this correctly, but in one of the presentations I think we heard that, in fact, nursing staffing had not increased even though dollars had gone toward on this a number of ways. It could be that it had not increased because of shortages or other reasons. I don't recall the reasons.

But I do remember that one of the things that

struck me was that nursing staffing had not increased despite an infusion of dollars directed toward that.

DR. SCANLON: That was actually Medicare dollars and the issue was that there was a readjustment of the updates and nursing homes got a very significant increase. And Senator Grassley had made a request that the money be committed to staffing. It was not something that was required.

And then when GAO studied it, and I think did you look at it as well -- GAO looked at it and it was like a one minute increase per day or something like that.

MR. HACKBARTH: Others?

DR. WOLTER: I was thinking about the previous conversation on trying to move to one classification system for post acute care. And that does seem like a big challenge when there are other fundamental issues that aren't well defined.

But I'm wondering if in this work there's any opportunity to look at, if we're going to do some new classification of patients or look at defining acuity differently, are there some subgroups of patients that really are overlapping in hospital-based SNFs and LTCHs, and

could we do a little work on that as part of this work? Or maybe there's a similar overlap of subgroups with hospital-based SNFs, LTCHs and rehab hospitals, and could that be at least a step in the direction of trying to define ways that we could be following the patient rather than having very different payment systems in the separate silos.

So it might just be a step in the right direction if we could think about how we might design this work.

DR. MILLER: So the thought there, Nick, is that for some set of patients, say rehab, or some set of patients there might be an ability to cut them out and say there's a way that you can have a payment system that would get above these three different payment systems? Is that what you're thinking?

DR. WOLTER: The one that comes to mind, maybe mostly because of my own life and experience, is ventilator care where certainly in many parts of the country chronic ventilator care is delivered in hospital-based SNFs. Or maybe they're kept in the hospital setting, quite frankly, when there are LTCHs available.

MS. RAPHAEL: One other thing that I would like to see is a little more information on length of stay of

patients or residents in nursing homes. Not just the average but what the distribution looks like these days. Because I think that would help to think about an appropriate unit of payment and payment system.

MS. LINEHAN: We were hoping to look at that. We have a data set from CMS that links the inpatient stay with the SNF stay, and we were hoping to look at some of the trajectories of care and length of stay and that sort of thing. I hope we can undertake that over the summer.

MS. DePARLE: I'm interested in your comments about an outlier policy and whether that would be something that would help, at least in the short-term. First, is it possible to, in the short-term, develop an outlier policy that would be reasonable? And secondly, is that something that could help bridge the gap between what we think the current system is doing and where we think it should be?

MS. LINEHAN: I think it's a possibility, but we haven't done any work to show what the right sort of cut points would be or how this would redistribute payment or anything like that. So I can't answer it with any evidence of how this would look.

I don't know if the CMS report is going to address

this issue but they may have -- their contractor may have looked into this issue. So that's one thing we can hope for.

MS. DePARLE: When the PPS was first implemented, there was a lot of concern about consolidated billing and the issues around certain supplies and high-cost items. Is that still a concern? It isn't really something you raised, except with respect to some of the drugs, I guess.

MS. LINEHAN: I think initially there was nothing left out of the bundle. And then subsequently Congress excluded some services. And then CMS also administratively excluded some services from the bundle.

What precisely those area, I'd have to get back to you. But initially there was no exclusion at all. And then it was seen as a problem, I think, and then later addressed piecemeal.

MS. DePARLE: So it's not seen as a problem now?

MS. LINEHAN: The only thing that I've read about that was the GAO study that sort of looked at the application of the administrative exclusions and said that perhaps those weren't consistently applied and in that there might be other services. I don't know if they specified

that could be excluded.

MS. BURKE: Just following up on Nancy-Ann's question, I have considerable concern with respect to the suggestion that an outlier policy may make sense here as it has with respect to some of the other payment systems. And Nancy-Ann and Bill may have a better sense of this than I do.

But the outlier policies as we've developed them, particularly on the inpatient side, presume that we have a fairly good and fundamental understanding of the underlying payment system, that it is relatively accurate, and that the outliers attempt to capture some aspect of what can't be easily explained or is the unusual circumstance.

My concern here is the development of an outlier policy on what we believe, at least as I understand in your materials, to be a fairly fundamentally flawed system, that there are issues about the way the RUGs are structured, the failure to account for the variations in some of the non-therapy ancillary service costs, and the fact that it's basically based on a service rather than a patient characteristic.

So to presume that an outlier policy can be

developed assumes all of those things are fundamentally solid. And then it's just a question of adjusting as needed in unique circumstances.

So I worry about going very far in that direction and furthering essentially our failure to deal with the underlying question, which is does the underlying payment system make sense?

MS. LINEHAN: I think that's a good point and I think I mentioned that in my mailing materials, that if we think that there's a systematic problem with the non-therapy ancillary payments, it's probably more appropriately addressed by fixing the payment system rather than putting an overlay of an outlier policy to address it.

MS. BURKE: That's what I guess I was reflecting on is having read the document, I think Nancy-Ann having raised it, I do think we ought to underscore that as being less likely than some of the other possibilities in terms of future work. And I just wanted to support that basic statement, that it really does assume a fairly solid system. And I think we're pretty well agreed that it is a pretty flawed underlying structure.

DR. SCANLON: I would agree. We should have a

solid system. That should be the goal, number one.

Having done that, though. in terms of the non-therapy ancillaries, there's a question of whether all of them can be accommodated into a case-mix kind of adjustment or whether these exclusions are the appropriate kind of thing. Actually, when we looked at them in GAO, we had three criteria for thinking about exclusions. One is that they were rare and that would make it hard to create a class for them.

MS. BURKE: And it might appropriately go.

DR. SCANLON: Two, they were expensive. And three, they weren't gameable. And so if you met those three criteria, that was something that you may want to exclude. And you could call it an exclusion but in some respects it's an outlier, as well.

The other aspect of this system which maybe obviates the need for an outlier policy is the fact that it's a per day system. And so we deal with the fact that some people take longer to recover with the per day payment.

If we didn't change that, that again maybe says we're adequate. But we probably need to address the fundamental issues with the system first and then see where

we are in terms of outlier kinds of policies.

MS. BURKE: I guess part of my problem, Bill, is that you're absolutely right. One could define reasons for doing adjustments, the rarity of the event, the extraordinary size or degree of the difference.

I guess I think, in sort of the old way of why we did an outlier policy. It was the extreme. It was outside of what we thought were the ranges that were reasonable. And I thought of it less as an excluded activity than it was one where it was just an unusual and rare occurrence where it was too much or more of some thing that was already assumed in the base, rather than an adjustment that's an exclusion.

MR. HACKBARTH: Any others? Thank you.

And that was our last item before the public comment period.

And I've been sitting here thinking about the meeting today and I don't know about for you. This was hard for me. A lot of loose ends. I think part of the reason for that is that in my time on MedPAC now I've discovered distinct cycles that we go through. And when we first broach new issues I often have this feeling that we're not

getting anywhere, we're just throwing comments out on the table, I'm not sure where we go from here.

But we get through that phase and then it gets a lot easier as we start to crystallize the issues and can debate those more clearly and we have analysis to bring to bear.

We were that way back in January when we were doing specialty hospitals and the update factors and some of the other issues. We will get there again, I'm sure. But we need to persevere through this phase again.

Okay, we will have a brief public comment period and you know all of the ground rules very well from past experience, so please keep your comments brief. Thank you very much.

MS. SMITH: My name is Elise Smith and I'm with the American Health Care Association.

I just wanted to correct one fact here. Commissioner Scanlon, you referred to a GAO study on the forecasting, the correction of the market basket because of poor forecasting. This is known as the forecasting correction.

That has happened within the last two years.

There is no report out yet from the GAO or the OIG, but it is on the agenda, I believe, of the OIG. I think what you were referring to was the 16 percent addition to the nursing component and that the GAO did a study on that.

We responded to that study. We had problems with the time period, the length of time after the receipt of the 16 percent increase in that component, it was a temporary increase, and some other issues we raised. And we are very appreciative of the fact that MedPAC did acknowledge some of the points that we had made.

I think the increase in staffing was not as de minimus as you had thought or had provided, but I cannot remember any numbers.

I have only one other point. The issue raised on consolidated billing, there is one remaining issue in consolidated billing -- well, there are more than one remaining issues. But a very important one, and I think especially to rural communities, and that is the site of service issue. In order for services like MRIs or radiation therapy to be excluded, the SNF must take the patient to a hospital, even if there is any kind of freestanding clinic closer to the home, the exclusion will not apply.

This is an increasing problem that we believe can be corrected administratively, but I believe it is CMS's position that we would have to pursue legislation. We have found out that this is a problem that is increasing in rural areas.

Thank you.

MS. WOODY: Hi, my name is Yara Woody and I'm with the American Association of Homes and Services for the Aging.

I would like to call on the last presentation and bring first the idea of cost-related payments as an option for revising SNF PPS. We, at AAHSA, want to make sure that the Commission understands that a cost-related system does not necessarily mean that we're going back to the old days of retrospective cost reimbursement system.

Currently most state Medicaid programs use a prospective modified cost-related payment system that better targets direct care spending and hence improves quality. These modified cost-related systems have been empirically verified to work as they were intended to work and states using these payment systems have higher nursing staffing and better quality care than states that use the flat rate like

with the Medicare system right now.

This is not to say that the amount of Medicaid payment is appropriate or adequate, but instead we just wanted to emphasize that much can be learned from these payment systems.

There are numerous studies that support this idea and as the Commission considers SNF PPS and pay for performance, we urge that you look further into this modified cost-related payment structure has an option for improving the SNF PPS.

Thank you.

MR. HACKBARTH: Okay, we're adjourned until 9:00 o'clock tomorrow.

[Whereupon, at 4:54 p.m., the meeting was adjourned, to reconvene at 9:00 a.m., Friday, March 11, 2005.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

Ronald Reagan Building
International Trade Center
Horizon Ballroom
1300 13th Street, N.W.
Washington, D.C.

Friday, March 11, 2005
9:02 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair
ROBERT D. REISCHAUER, Ph.D., Vice Chair
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P R O C E E D I N G S

MR. HACKBARTH: I'd like to welcome our guests, Peter Neumann and David Eddy. I've long enjoyed reading your many writings on this subject. It's one that I've been interested in for a long time, since I served in HCFA back in the mid-1980s and we tried to do some things on this front. Unsuccessfully, but we tried.

Nancy, I think you're going to do the formal introduction.

MS. RAY: Good morning. Recall last month we began to discuss issues surrounding Medicare's use of information about clinical and cost-effectiveness when making coverage decisions and also in the rate-setting process. This month we've brought two experts and if they are going to give their perspective and talk a little bit about their research on these topics.

Our first speaker is Dr. David Eddy. Dr. Eddy is a physician and a mathematicians and an independent consultant living in beautiful Aspen, Colorado. Dr. Eddy is also senior adviser for health policy and management at Kaiser, and chief scientist at the Blue Cross-Blue Shield Kaiser technical evaluation and coverage program.

Dr. Eddy wrote the first national guideline explicitly based on evidence, wrote the seminal paper on the role of guidelines in medical decision-making, wrote the first model applied to clinical problems, and wrote the original criteria for coverage decisions, and was the first to use and publish the term evidence based. Dr. Eddy is author of five books and more than 100 first authored articles, and he also has a series of essays for the Journal of the American Medical Association.

Our second speaker is Dr. Peter Neumann. Dr. Neumann is associate professor of policy and decision sciences in the Department of Health, Policy and Management at the Harvard School of Public Health in snowy Boston. His research focuses on the role of cost-effectiveness analysis in health care decision-making. He has conducted numerous economic evaluations of medical technologies, including an evaluation of treatment for Alzheimer's disease. He also directs a project that is developing a comprehensive registry of cost-effectiveness analyses in health care.

Dr. Neumann has contributed to the literature on the use of willingness to pay on quality-adjusted life years, QALYs, in valuing health benefits. Dr. Neumann is

the author of a recent publication, a book, Using Cost-effectiveness Analysis to Improve Health Care, and he is contributing editor of Health Affairs and president-elect of the International Society for Pharmacoeconomics and Outcomes Research.

Dr. Eddy will start and then Dr. Neumann will conclude and then they'll be able to take your questions and answers.

DR. EDDY: Thank you very much, Nancy, Glenn, and commissioners. I'm very pleased to -- I thank Nancy, Glenn, and the commissioners for inviting me to come and discuss this really very interesting and obviously extremely important topic. I'm delighted that you're taking this on. It's a problem that needs your attention and I'm really looking forward to your efforts to try to bring some rationality and effectiveness to this kind of approach to the kinds of decisions that have to be made in the Medicare and Medicaid programs.

I'm going to move through my slides pretty quickly. Most of them speak for themselves, and also you know the answers to most of the questions that I'm posing here. But Nancy suggested several questions to me when we

talked on the phone so I've tried to go through this list. The first was, should CMS consider costs in its decisions and my answer is a simple, yes, I think it should.

Down at the bottom there the bullet you see a duh. I should have put that in parentheses to be a little bit more gentle, but the thought is that we obviously have a cost problem and you can't control costs without considering costs. To me that's the end of the story. If we're trying to design an efficient system that maximizes the quality that we are delivering for a given budget, you have to consider the budget side of that equation. So I don't see any way to escape it and I feel that until we do address it and do it in a reasonable way we are never going to solve our cost-quality problems in health care in the United States. That was fairly blunt.

Now the question is how CMS might use cost-effective information and there are obviously lots of different ways. I've just listed a few on this slide. The most obvious perhaps is to decide coverage decisions and perhaps withhold coverage for things that are "not cost-effective." But there are a lot of other ways to do it as well and there's no reason why all of these have to be done.

So you, I think, can pick and choose from this list.

Another way is to decide the amount that you're going to pay for a new technology, to set priorities for disease management strategies, to design performance measures, guidelines, pay for performance programs, and things of that nature. As you can appreciate, some of these are much more visible than others. Some will be more acceptable than others and so forth. But I think it's important to keep the entire list in mind.

The next question was whether or not the use of cost-effectiveness analysis could harm beneficiaries, and that depends on whether you're talking about the health effects or the cost effects. We have to admit that health-wise, yes, it could hurt beneficiaries a little bit because by its very nature it makes trade-offs. It looks at whether or not the magnitude of benefit to be gained from the technology is "worth its cost" and makes some hard decisions and it will conclude in some cases that the magnitude of the benefit simply isn't big enough to justify the cost. So the people who would have gotten that procedure will lose.

On the other hand, we just need to accept that because, as I say, that's a very nature of making difficult

decisions, and it also fits well within lots of other decisions that we already made where we trade off health benefits versus costs.

The next slide was whether or not the use of cost-effectiveness analysis would help beneficiaries, and in terms of the cost of care it should help it a lot, because if we did take costs into account in making some of these decisions, then by definition we're going to have a more efficient, more effective program and that's in the interest of everyone, I think.

Now the question is going to be whether the trade off of benefits versus costs is worth it, in some sense, and cost-effectiveness analysis, if done correctly, by definition means that it will be worth it. If the trade-off is not worth it then you don't make the trade-off. You only make the trade-off if the trade-off is deemed to be worth it. So by definition all people in general, the population, if you will, will come out ahead if cost-effectiveness analysis is used properly.

Will it hurt innovation? I think yes and no. It will hurt the innovation of technologies that are not cost-effective. On the other hand, it will stimulate the

development and help the development of technologies that are cost-effective. That is, it will put a new signal into the marketplace in the same way that things that like emission controls have put a signal into the marketplace and it will cause people who develop medical technologies to do them in a way that are in fact cost-effective.

What are the problems with using cost-effectiveness analysis? There are several. One is the law and I'm not going to say much about this because there are lots of people in this room who know a lot more about how the law applies to cost-effectiveness analysis and what you are and are not able to do. But we have to admit that there are very important legal issues that need to be taken into account and I will leave that to others to comment on.

Another very important problem is the politics. We know that cost-effectiveness analysis is very unpopular with some very vocal groups. This is an appropriate way that society makes its decisions, but we can expect as much resistance to the application of cost-effectiveness analysis today as it has received in the past. People or organizations, corporations that promote technologies that may or may not, or possibly will not make the grade in a

cost-effectiveness analysis will, I put up here, scream. I should have softened that a little bit. They'll argue. Beneficiary groups might scream. The benefits in terms of lower taxes and lower costs accrue to different people than the current beneficiaries. And the benefits tend to be much more spread out, and the people who receive them are much less visible than the organizations or individuals who might claim that they are being harmed.

So all of this creates a very difficult political issue. I have no magic answer to that except to say we would try to apply cost-effectiveness analysis in a way that helped everyone to understand that in fact it will improve the public in the long run if it is done correctly.

Now there is another class of problems that I think it's important you understand. This really gets closer to my personal area of experience and so forth. I say this with a little bit of hesitancy because I don't want to discourage you from using cost-effectiveness analysis. On the other hand, I believe that you should be fully informed, at least of the world as I see it, in terms of the methods of cost-effectiveness analysis.

There are several methodological problems that I

believe need attention. One is that the state-of-the-art of modeling, I don't believe, right now can uniformly be assumed to give correct and accurate answers. I'll give more information about that in a moment. In fact the last three bullets on this slide address that. In fact very few models in use for cost-effectiveness analysis have been validated and there is good evidence, strong evidence, and I'll show you some in a moment, that different models give different answers to the same question. So just depending on which model you happen to be using, which group happens to be doing it, possibly what the objective of the analysis is, you could easily get different answers to the same question. And when you get an answer, unless we're very careful and design a system that will help us understand which answer is correct, it can be very difficult to determine whether or not the cost-effectiveness that has been calculated is in fact an accurate reflection of what will happen in reality.

Now I'm going to give you some examples. This is an exercise in which seven modeling groups modeling diabetes got together. They've been getting together for several years now. They agree on a standardized problem. They keep

it as simple as possible, and then they all do a calculation of the effectiveness, the cost, and the cost-effectiveness. So it's an excellent opportunity to, if you will, compare how similar or dissimilar different modelers can be in terms of the results that they produce.

I'm giving you one example. This is an example that has been used for two years in a row because the first year the answers were quite discouraging so they decided to sharpen the assumptions and try again the second year. So I'm showing you the after picture, if you will, not the before picture.

This is a particular case, a 65-year-old white, European male who's had diabetes for five years. You can see the other results on this slide. The point is that define a very specific person and they ask each model to calculate the chance that this person will have important outcomes like heart attacks and so forth. You can see on the bottom sub-bullet there, there are at least 28 different assumptions or details that were specified about this patient to try to make certain that all the models were going to analyze the same question.

I should also point out that each of these models

had a common root. They all come out of a single model, and they all use the same sub-model for calculate heart attacks. It's a mark off model and for that particular transition probably they're all using the exact same sub-model. So these are highly inbred.

Here are the seven models' answers of the chance that this particular patient on the previous slide will have a non-fatal heart attack. You can see that the answers are all across the board. Depending on which model you use you could get answers that vary by a factor of almost five. So you have to wonder what is the -- it's absolutely certain that not all of these models are correct because they're all giving different answers, and it just begs the question of which one, if any of them, is correct and how you would determine what the correct answer is.

Now that's the chance of all heart attack. In cost-effectiveness analysis we're interested in the effect of a treatment in reducing the chance of a heart attack, or an important outcome. In this particular case they specified that each modeling group should use the exact same treatment, which would lower the hemoglobin A1c, a measure of glucose control, from 10 to 8.5 percent. So they're

looking at the exact same treatment, and these are the answers they got. In some cases the effect of the treatment was to reduce the chance of a heart attack by almost 5 percent. One model actually showed that it might increase the chance of a heart attack. So here you see differences on the order of two or three, something like that.

I don't have to point out to you that a little tiny shift in the estimated probability of an outcome or the effect of a treatment on the chance of an outcome can have a huge effect on the cost-effectiveness that you calculate, especially when you project this out over a 70-year period or something like that, which is what you need to do if you're going all the way out to life expectancy.

They also addressed costs. They made the same assumption about the cost of the treatment, $300 a year, and these are the estimates they got of the cost of the treatment. So this is the cost part of the cost-effectiveness equation. Again you see answers that range enormously. It looks like a factor of about seven there when you compare model two versus model three.

Then finally in terms of cost-effectiveness analysis, after agreeing that they would all use the exact

same assumptions for the quality weights that should be assigned to various outcomes, they produced this. Some showing that it would save money, two showing that it would cost money, and there's a wide difference there.

Now you might be impressed that they're all fairly low. I'll just tell you that if you change the problem, change the patient, change the treatment or anything else, that Y axis, if you will, the vertical axis could change enormously and these numbers could be going from minus $20,000 to plus $100,000 and so forth. The point is that these models are giving extremely different answers to the essentially the same question.

Now in an attempt to alert people to the uncertainty that can occur in a cost-effectiveness analysis, modelers have a variety of techniques. I think one of the most useful is to take all of the assumptions of the modeler, or at least all the important ones, put probability distributions on each one of the assumptions and then do a Monte Carlo analysis to get a feeling of the range of uncertainty about the answer across individuals. But I fear that that doesn't work.

Here's an example of that. This is a slightly

different problem but it will still illustrate the same point. So it's not patient three, which I showed you before, it's an analysis of -- actually it's not diabetes prevention. It is cholesterol treatment in people with diabetes. In any event, on this bar you can see the error bars, at least you can see the upper part of the error bar poking out the top, and if you look closely you'll see the bottom part of the error bar sitting in the bar part of the bar. So the thought is that while the model might be uncertain, it might make a best guess that the cost for quality for this particular program is on the order of $24,000. It's admitting that there's some uncertainty saying it could be as low as about $22,000 and could be as high as about $28,000.

The problem is that that range doesn't capture any of the results of any of the other models that worked on the exact same problem. If I take model one, which is the one I showed you on the previous slide -- this slide, it's a little bit difficult to compare because I've changed the limits on the Y axis, but in the bold lines there going horizontally I've shown you the upper and lower bounds where modeling group number one thinks, I might not be exactly

right but I'm pretty darn sure it lies within those bold lines. You can see that none of the other four groups have answers that actually lie within the bold lines. So I don't think that the current methods we have for trying to assess the degree of uncertainty about a model's results so far have solved the problem.

But I do think the problem can be fixed, and the way to fix it I believe is to anchor models to reality. That is, ask that models do calculations that simulate real experiences that have happened in real populations and compare the model's results to the real results. I can show you an example. This is just an example. I'm expecting that other models either can now or will be able to do this so I'm not trying to push this particular model.

For example, you might as the model to analyze a problem that has in fact been studied in a real randomized, controlled trial, and ideally the model will not have seen the trial before when it does the calculation. So this is an Archimedes calculation of the effect of simvastatin in high risk people. On the left we have the outcome, the probability of a heart attack in the control group, and on the right we have the probability of a heart attack in the

treated group, and the error bars are shown there for the calculation.

What we can do is compare that to what actually happened is the real 4S trial in this particular case, because that's the trial we're trying to simulate. So I think if models do this kind of thing, then you get a feeling that the model in fact can and has reproduced reality and you get a better sense of confidence that when you hand it a new problem it will be accurate. Especially if you do this over and over and over again. The two sets of bars on the left are the Helsinki heart study, the two middle bars are the systolic hypertension something or other program -- I've forgotten. 4S you've already seen, that's on the right. The heart protection study, deaths, major coronary arteries, the Hope study, Care, so forth and so on. You keep doing this over and over again and you get a sense that the model in fact is anchored to reality.

For this particular model we've done this over 100 times now with only two cases in which the model's answer falls outside of the confidence intervals for the real trial. As you know, there's a lot of uncertainty about the real trial as well.

So I would propose that we push models in this direction and ask them to show this kind of evidence that in fact they match reality before we begin to place a high degree of confidence on them for a new problem. There's more here, lipid and so forth. If anyone is interested, this has all been published and I can get the references to you.

I'm closing now with a list of things that I think CMS would need in order to pull off the inclusion or incorporation of cost-effectiveness analysis in its decisions. One is, it addresses the problem that I posed in the previous four or five slides, and that is, I do think that it would be important to have explicit criteria or a checklist of things that document the validity of a model. I just think that's extremely important. I think it's long overdue.

I think that there will have to be a standardized list of costs, otherwise different modeling groups can just use different costs. I'm not saying they'll do it intentionally but they'll end up using different costs and come out with different answers simply because they have different assumptions on costs. And the same message

applies to the measures of effectiveness or quality, such as the quality weights that you put on various outcomes.

Then finally we have to have criteria for determining what cost-effectiveness is or it isn't. I know you're all aware of the NIC in England which sets a particular threshold and asks comparisons to be made to that. If there is to be a threshold like that then I think, obviously, enormous care has to be paid to exactly what the threshold ought to be, and that might be something --I'm expecting Peter might well talk about this and it might be something that will come up and I'll add more comments later.

Then I'll close by going back to one of the earlier slides which is where CMS might start to apply cost-effectiveness analysis. You remember this list. I'll just say that they are not all equally easy to do in a political sense. I think that coverage decisions are far and away the most visible and that would be a difficult place to start for political and perhaps result legal reasons. But there are other ways that you can get cost-effectiveness analysis into decision-making in an important way, such as deciding the amount of payment, setting priorities, designing disease

management programs, setting performance measures, designing pay for performance, and things like that.

So for example, many of these point the finger at certain activities that are very important to do. You can make sure that those are cost-effective activities. If they're activities that are not cost effective, you just don't point your finger at them with a pay-for-performance program or a performance measure or a guideline or something like that. I think this would prove to be a more acceptable way to get cost-effectiveness analysis in.

Then finally I'll say that I hope you do it, because we really, really need some way of incorporating cost in our decisions. Our health care system is out of control in ways that you know much better than I do, and I think an integral part of solving that problem would be to add cost into the equation for how we decide what was we're going to do and how we're going to do it.

Thank you very much.

DR. NEUMANN: Thank you very much, Mr. Chairman, members of the Commission, for your invitation to speak today on the important subject of the use of cost-effectiveness information by the Medicare program. I'm also

delighted that you're taking this on, and also want to say I'm delighted and honored to appear here with Dr. Eddy who has contributed so much to the field.

We'd all like the Medicare program to obtain good value for its expenditures in paying for drugs, devices and procedures. In my remarks today I'd like to discuss how the use of cost-effectiveness analysis can help us in this goal. I'll touch upon four issues.

First, a little bit about the cost-effectiveness paradigm and the advantage of using formal cost-effectiveness analysis to help us achieve better value.

Second, some illustrations about what interventions are and are not cost-effective for Medicare.

Third, my own thoughts about limitations of cost-effectiveness analysis and why the Medicare program hasn't used this technique, despite some previous attempts to do so and despite the fact that it is used by health reimbursement authorities in many countries worldwide.

Finally, I'll conclude with some discussion of ways in which we might move the system towards one that uses cost-effectiveness analysis, and hence, reflects value-based purchasing.

The field of cost-effectiveness analysis and economic evaluation of health and medicine more generally has been an active area of research for many years, as researchers refine methods to quantify the clinical and economic consequences of using health care. This slide shows we can conceptualize the impact of any intervention in terms of its impact on costs and on health. Cost-effectiveness analysis shows the relationship between the total resources used, costs, and the health benefits achieved, effects, for an intervention compared to an alternative. In the words, where are we on this cost-effectiveness plane?

Often a standard metric such as life years, or quality-adjusted life years gained, QALYs, is used as the measure of health benefits. Consensus panels, including the U.S. Panel on Cost-Effectiveness in Health and Medicine have recommended using the standard metric cost per QALYs for purposes of comparing diverse conditions and treatments.

On this slide an intervention in quadrant one would decrease health and increase costs. An intervention in quadrant four, on the other hand, would increase health and decrease costs. An intervention in quadrant three would

decrease costs and health. Typically, with new technology we're in quadrant two. The new technology increases net cost but also increases health.

We might have a technology, example, that results in a net cost per QALY of $20,000, which most people seem to view as relative good value for money. Alternatively, we might have a new technology that results in net costs of over $100,000 for every QALY gained. That is, it's much more expensive to produce health.

What interventions might be cost-effective for Medicare? Here are some illustrations. This study suggests the flu vaccines, for example, save net costs and improve health. Some interventions increase net costs but still represent good value for money. Some examples include beta blockers after MI, under $10,000 per QALY; cholesterol management with statins for secondary prevention, $10,000 to $50,000 per QALY.

Other interventions with cost per QALY ratios in the $50,000 to $100,000 for QALY range. For example, dialysis for end-stage renal disease. There are also examples of interventions with cost per QALY ratios above $100,000 including technologies recently covered by

Medicare; lung volume reduction surgery, left ventricular assist devices, PET for Alzheimer's disease.

Data like these underscore several important points about the cost-effectiveness of medical technology. First, a great deal of information like this has become available to policymakers. Unlike many unsupported assertions made about the cost-effectiveness of drugs and other medical technologies, these studies quantify costs and health effects using data and a standard, well-accepted methodological technique.

Second, according to many peer-reviewed articles, many interventions, including many technologies are indeed cost-effective. These interventions provide good in the sense that they provide health benefits for relatively little cost or actually save money for the health care system sometimes despite high price tags.

Third, cost-effectiveness does not mean cost savings. Over the years people have sometimes confused these terms. But restricting the term cost-effectiveness to cost-saving interventions would exclude many widely accepted interventions which do not save money but are cost-effective in the sense that their additional benefits are worth the

additional costs.

Fourth, a discussion of medical technology's cost-effectiveness needs to include a specific description about how the technology is used and on whom. A technology or in any intervention is not intrinsically cost-effective or cost-ineffective. It is only meaningful to say that a technology is cost-effective compared to something else. A drug prescribed to lower an individual's blood pressure may in fact be cost-effective compared to the option of no treatment but not necessarily cost-effective compared to an alternative intervention such as an intensive program of diet, exercise, or other medication.

In addition, claims of cost-effectiveness often depend on the population under investigation. For example, statin drugs used to lower individual's cholesterol have been found to be relatively cost-effective as secondary prevention in persons with existing heart disease, but considerably less cost-effective as primary prevention.

Finally, in the third column of this slide I have provided some rough estimates on the degree to which the Medicare population is actually using these technologies. For example, roughly 40 to 70 percent of beneficiaries

receive flu vaccine, 85 percent receive beta blockers post-MI, 30 percent receive statins for secondary prevention, 90 percent receive dialysis. This slide also shows projections of use of certain technologies with high cost-effectiveness ratios, including lung volume reduction surgery, left ventricular assist devices, and PET for Alzheimer's disease. While these estimates are rough, the point is that using cost-effectiveness analysis we can identify possible areas for reallocation from less efficient uses of resources to more efficient ones, in the process, obtaining more overall health for our Medicare dollars.

Why doesn't Medicare use cost-effectiveness analysis? Logically one might expect them to do so. How do we explain this paradox, cost-effectiveness information provides a useful analytic tool yet payers like Medicare are not using it? There are several theories about this, some of which Dr. Eddy touched upon and I'll discuss as well.

One is that we mistrust the methods. Dr. Eddy spoke about this and researchers have long observed that many published cost-effective analyses do not adhere to recommend protocols for conducting and reporting analyses, and that different models may come to very different

conclusions. A related problem pertains to a perceived lack of relevance. Observers point to a disconnect between abstract societal perspective taken by many published studies and the short-term horizons of many actual decision-makers.

Another explanation questions not the methods of CEA but the motives of investigators and/or their sponsors. On the one hand, CEA is seen as a smoke screen for cost-cutting efforts, and sometimes, conversely, as an advocacy tool by those with a financial gain at stake to increase health expenditures.

Another explanation mentioned by Dr. Eddy points to legal and regulatory barriers. That is, decision-makers are afraid they'd be sued if they withheld an effective technology because of its high costs, or that Medicare rules prohibits its use. But each of these explanations, I'd argue, falls short.

Mistrust of methods and motives undoubtedly plays a role. Still why haven't policymakers in the U.S. funded or conducted their own analyses or tailored them to their own needs as they have in other countries?

Legal and regulatory factors also fail as a full

explanation. Nothing in federal statute explicitly bars Medicare from using cost-effectiveness analysis. While health plans and doctors may fear lawsuits if they use cost-effectiveness analysis openly, there are also plausible reasons to believe that health plans could withstand these challenges as they have withstood challenges to other cost-containment initiatives.

The best explanation seems to be that at its roots the resistance to cost-effectiveness analysis is grounded not in methodological or legal barriers but in Americans deep-seated distaste for explicit rationing. Other countries' acceptance of cost-effectiveness analysis confirms that our failure is driven more by our own cultural, political, institutional conditions rather than the techniques' inherent methodological shortcomings.

A final thought. Why would analysts continue publishing studies in the literature if the information is being ignored? It is possible that we are using cost-effectiveness analysis, but quietly, under the radar. Cost-effectiveness analysis may actually enjoy some influence in the U.S., not as an explicit instrument for prioritizing health services but as a more subtle lever on policy

discourses. Cost-effectiveness information may influence clinical guidelines, formulary policy, even Medicare coverage to some extent, Medicare coverage payment coding decisions and so forth, but not in a direct or open way.

Finally, I would end by offering five observations as we look ahead.

First, cost-effectiveness analysis should be used flexibly. Leaders in the field have always warned against using it mechanically and experience teaches us that rigid use of cost-effectiveness analysis will likely be resisted. Cost-effectiveness analysis should inform decisions, not dictate them, and there may be selected opportunities to use them. For example, in covering preventive services, or as Dr. Eddy mentioned, in informing payment policy. We might even apply different cost-effectiveness thresholds in different contexts or account for other important factors such as access and equity.

Secondly, cost-effectiveness analysis may or may not save money. Cost-effectiveness analysis is not really a cost-containment tool, but rather a technique to improve value. Indeed, wider use of cost-effectiveness analysis would likely uncover examples under-utilized services that

increase costs but represent good value for money, as well as cost-ineffective and over-utilized services. Whether cost-effectiveness analysis save money will depend on how generously or strictly policymakers apply the cost-effectiveness threshold.

Third, process matters. The process for using cost-effectiveness analysis will be important. Transparent procedures with appeals to the best scientific evidence and models, and opportunity for public comment and stakeholder participation will be very important. CMS has developed a more open and rigorous process for scrutinizing clinical evidence in recent years for its national coverage decisions, for example, which could serve as a model for future deliberations about cost-effectiveness analysis.

Fourth, the incentive in the system matter a great deal. Debates about the use of cost-effectiveness cannot be separated from debates about the underlying health care system and the incentives it embodies. How to reconfigure these incentives facing providers and patients is a related critical challenge.

Finally, will get harm innovation? Some have, perhaps understandably, expressed concern that adoption of

cost-effectiveness analysis will impede innovation of medical technology by creating another hurdle to reimbursement. However, I would argue by itself cost-effectiveness analysis doesn't necessarily impede innovation. Innovation depends on many factors, including systemwide incentives, society's overall willingness to spend money for health, and how firmly a cost-effectiveness threshold is applied. The use of cost-effectiveness analysis, as Dr. Eddy argued, could even stimulate manufacturers to bring more cost-effective products to the market in the first place.

Moreover, the absence of cost-effectiveness analysis does not necessarily translate into an innovation-friendly environment. It simply means that payers find other less obvious, and sometimes less honest ways, to ration care, by cutting payments, for example, and restricting access in other ways.

Application of cost-effectiveness analysis for Medicare Vatican will likely require an ongoing campaign to educate policymakers and the public, require outreach to an array of stakeholders. In theory, CMS could simply grant itself the authority to use cost-effectiveness analysis with

a broad interpretation of its statutory language to cover reasonable and necessary services.

Alternatively, CMS could pursue such an action in formal rulemaking, though to date both of these channels have proven impossible. Another avenue would involve congressional action. Congress could legislate, for example, the criteria, including cost-effectiveness analysis, that Medicare should use in covering new technologies. When adding new health benefits to the Medicare program, Congress could mandate that CMS determine the most cost-effective ways for doing so, for example.

In closing, let me emphasize that whether a medical technology or any strategy offers good value is a question that can best be informed by a careful analysis. I would encourage the judicious use of cost-effectiveness analysis by Medicare in the years ahead.

Thank you very much. I look forward to your questions.

MR. HACKBARTH: Thanks to both of you. One of the Commission's interests is pay for performance, and we're eager to move the Medicare program and the health care system in general towards paying more for better

performance. Each of you alluded to the potential use of cost-effectiveness analysis in guideline development. Could I ask you both to say a little bit more about that? To what extent is it currently used? Are there differences in practices? And if we chose to go that route of urging the use of cost-effectiveness analysis in guideline development, how might we go about doing that?

DR. EDDY: I'm sorry, your question started off talking about pay for performance, but you'd like me to answer it in terms of the use of cost-effectiveness analysis for guidelines?

MR. HACKBARTH: Let me be explicit about the link that I see. One type of pay for performance is paying explicitly for certain things being done based on clinical guidelines. That raises the question in my mind of whether the guideline itself has been developed using cost-effectiveness analysis, which I think is one of the issues that you used. That's a door that you could enter this process through.

DR. EDDY: Yes, I can give you some examples. I can't tell you how pervasive this is. That is, the extent to which it's use, because I can only see the guideline

world through my eyes. But I can go back to 1980 when the American Cancer Society wrote hugely important national guidelines for cancer screening -- front page of the New York Times -- and there was cost-effectiveness analysis all through it. I don't think people realized it but it was all through it.

It recommended, for example, three-year Pap smears instead of annual Pap smears, and the logic was that you get 98-plus percent of the benefit with a three-year Pap smear compared to an annual Pap smear and the extra money was much better put into making sure that everyone gets at least a three-year Pap smear. Probably most of us in this room are candidates for colonoscopies, and something like that, that's recommended every five to 10 years. Don't tell me that an annual colonoscopy wouldn't provide a little bit more benefit. It's just not cost-effectiveness, in a sense.

So there a fair number of examples like that where cost-effectiveness analysis certainly, I think, contributed to a recommendation that makes a trade-off between the amount of quality you're getting and the amount of cost you're paying.

Can I make a comment quickly about pay for

performance?

MR. HACKBARTH: Before you do that, the inference I was drawing, and maybe incorrectly, from what you said earlier in your presentation was cost-effectiveness analysis is used sometimes, but not always, or perhaps inconsistently, in guideline development. Did I understand you correctly?

DR. EDDY: That is absolutely correct.

MR. HACKBARTH: So you cited an example of where it was at least implicitly applied. Is that the usual thing?

DR. EDDY: No.

MR. HACKBARTH: And how do people -- that's what I'm trying understand better.

DR. EDDY: I don't think so. Again, I don't know of a survey but I would strongly suspect that cost-effectiveness analysis would -- I'm talking about real guidelines that are actually issued by organizations and really changes things as opposed to papers that we might write that may or may not change things.

I'm sorry, I've just drawn a blank. Ask me the question again. Just give me the key word.

MR. HACKBARTH: So how common is it that cost-effectiveness analysis --

DR. EDDY: Not very common. You very frequently see national guidelines that, for example, push the target for cholesterol treatment down to lower and lower levels and there's no explicit cost-effectiveness analysis behind that. Try as hard as we can to put cost-effectiveness analysis into performance measures, it's just been very difficult to do that. There are some examples where it's been done, but there are a lot of examples where it hasn't been done and there's no explicit cost-effectiveness analysis behind it. My guess would be -- this is a guess -- 10, 20 percent of guidelines would have some element of an explicit cost-effectiveness analysis behind it.

MR. HACKBARTH: Then the other piece related to that was, again, we're eager to see Medicare pushed down the path of saying there should be more guidelines, and payment link in some cases to those guidelines. What are the levers, if we want to see guidelines that incorporate cost-effectiveness analysis, what are the levers that you try to pull to change the guideline development process? Any thoughts about that?

DR. EDDY: That would be fairly straightforward. You can add a requirement, if you will, that there be a cost-effectiveness analysis behind it as well.

DR. NEUMANN: I guess I would add a few things. I would start by agreeing with Dr. Eddy, it does seem like clinical guidelines, published guidelines, typically do not use or even cite cost-effectiveness analyses. There was a paper a couple years ago that looked at hundreds of guidelines simply to look at whether anywhere in the clinical guideline there was a mention or a citation to a cost-effectiveness analysis, and the vast majority did not even have such a citation.

There are a few exceptions. The cholesterol guidelines, at least in the old days, would cite some of the published cost-effectiveness studies, although as Dr. Eddy mentioned, some of the more recent cholesterol guidelines seem to be pushing beyond what most people would consider cost-effectiveness. The U.S. Preventive Services Task Force has discussed this very actively over the years. In its latest edition, at least at the outset said it would in fact use cost-effectiveness analysis or appeal to such analyses in helping to inform its decisions, although as the

guidelines have come and been published over the last few years, it doesn't seem as though they're actually using cost-effectiveness analysis.

I'd agree with Dr. Eddy, you could simply try to require that guidelines appeal to cost-effectiveness information. You could also, and this perhaps gets more to the pay for performance question, you could try to encourage or perhaps require that decision-makers use cost-effectiveness analysis.

Formulary committees is one example, and maybe this is something you just put information out there and let the private decision-makers make those decisions for the Medicare beneficiaries. But it could be that a cost-effectiveness analysis informs the formulary decision. It could be a high-priced drug actually is better as first-line treatment because it's cost-effective in a larger sense. And conversely, it could be that a low-priced drug is not cost-effective because it's not going to give good value.

MS. BURKE: I wonder if I could ask a fairly simplistic question? That is -- really twofold. One, on average, what would it cost to do a cost-effectiveness study? And what period of time is normally required for one

to occur?

Secondly, currently, to what extent is information available on the breadth of things that Medicare currently covers?

For example, if we were to say that all coverage decisions ought to in fact take into consideration cost-effectiveness going forward, but also retrospectively, the things that we currently do, if we wanted to validate as we move towards pay for performance and look at the validity of the things that we currently do, to what extent could we in fact do that with current studies? That is, to what extent are all the range of things that Medicare currently does, is there information available that would allow us to do those studies today?

DR. NEUMANN: Starting with how much it would cost and how much time it would take. Certainly, evidence costs money and cost-effectiveness analyses require resources and time, and in some sense I suppose you get what you pay for. I think the experience in the U.K. with NIC perhaps is a good example. It probably varies by technology and complexity, but my sense is they are contracting out those studies and I would give a rough ballpark, on average it

takes a few months and $50,000. Sometimes you can probably do some quick, dirty, back of the envelope calculations. Sometimes you probably, given uncertainty and what's at stake, want to collect primary data and take longer and costs a lot more than that.

As far as your second question, how much information is currently available. I guess I would say there's a fair amount of cost-effectiveness analysis out there. My colleagues and I have been collecting this and putting it into a database and hundreds, thousands of studies. Not all of them of high quality, but a fair amount to inform decisions.

Having said there, they're clearly are information gaps. I think part of this whole discussion probably needs to talk about those information gaps, and who puts information out there for decision-makers. Any attempt to use cost-effectiveness analysis will require some prioritization, and you might well want to start with big ticket items, expensive technologies, and probably requires some additional analyses.

MS. BURKE: I was quite struck at the closure of your remarks, Dr. Eddy, the sense that there may be other

ways to start, or other places to start rather than just right at the coverage point, but that we may be informed. One of the things that occurs to me, Glenn, as we look at this issue and look at how one might begin to incorporate this information, is the extent to which we move towards pay the performance, is the extent to which we move towards other decision points.

The reason I asked the question is, how realistic is it? Given all of the other things that occur -- Nancy-Ann has probably got the best sense of how much of that could currently be taken into consideration. But it would seem to me from the Commission's standpoint that some attempt at understanding and suggesting some order of priority and some areas of intervention, whether it's in pay for performance or others, might well be something we ought to consider and think about, taking into consideration the amount of information currently available, whether you start with the highest priority items, the big-ticket items, the ones that are the most frequency, or the ones around which there is the greatest question as to its current relevancy in terms of current practice. Might make some sense to give some thought to that in further conversation.

DR. EDDY: I agree with Peter generally about the cost and the time; it varies a lot. $50,000, in my experience, would be at the lower end. It can go to $100,000, $150,000 or something like that.

In terms of your second question about how much work has already been done that we can simply draw on, a lot of work has been done but I'm nervous about drawing on it. The main reason is that whenever you do a cost-effectiveness analysis there is a very specific population, a very specific intervention, very specific outcomes that are in mind, and we might think that we --

For example, have done a cost-effectiveness analysis -- just to pick a recent example in the Annals of Internal Medicine of "diabetes prevention." Whether you're talking about people who don't yet have diabetes, or they've got impaired fasting glucose and impaired glucose tolerance, or just impaired glucose tolerance, or impaired glucose tolerance plus their BMI is over 25, and whether we're talking about a group-delivered method for getting them to lose weight, or a personal physician-based, you can throw that cost-effectiveness all over the place. So although a good analysis has been done -- let's assume it's a good

analysis -- it's of a very specific population with a very specific intervention, and you'll get a totally different answer simply by redefining the problem.

So now let me go to your third point, which is whether something like pay for performance might be a place to start. I, indeed, think it would be, because pay for performance is a guideline with real teeth, I mean real teeth in it, and there's a finite number of these measures that are being considered for pay for performance. I think it's on the order of a couple score maybe to 100 or something like that. It is feasible to, I think, do analyses of those. And because it's pay for performance you'll have very specific definitions of the populations, the numerator, the denominator, and you can really do an analysis. And it will be done right, and it will be from the start, if you will, an agreed-on set of methods that I think you can really trust do in fact address the problem that you're asking.

So I think it would be very difficult to go back and get things. You might well want to do that for selected cases where you have something that you really suspect is eating you alive financially and you want to do a cost-

effectiveness analysis. That would make sense. But to try to do something across the board I think would be difficult. But I would strongly propose that you do it going forward and like Quicken, when you buy Quicken you've got to decide whether you're going to hand enter all your transactions from the past 15 years or you're just going to enter them from that year forward. At least let's make sure that we're doing it from this point on, and in a couple of years we'll be in pretty good shape.

MS. DePARLE: I wanted to go back to Dr. Eddy's slide about what will CMS need to pull this off. I don't know if you can put it back up there easily, Dr. Eddy, but you listed four things, I guess starting off with criteria for deciding whether a model is sufficiently valid and accurate to be used to estimate health outcomes. I think I would add several other things. So in addition to criteria, I think there are a host of other things CMS would need, in my experience. A lot of courage, and congressional support, among other things, would be important. I think, Peter, you alluded to that as well.

But it looking at this list here -- and by the way, Peter, you talked some about whether or not CMS could

just do this through its reasonable and necessary authority. Legally, you're probably right. They probably could. But I think it's a big enough change and an important enough change that it should be something that -- again, maybe I have an overly idealistic view of government, but it should be something that we discuss explicitly, and people agree on and understand.

By the way, I think, notwithstanding, what you said, Dr. Eddy, about at least doing it going forward, I agree with that, although I do think sometimes we hold new technologies and new things to a higher standard than the old stuff. When you look at how many millions of dollars Medicare is spending every second that we sit here, much of it on stuff that doesn't work, then I have a bit of a problem with just saying, let's do it going forward.

But if we were ever to get to a point where we could institutionalize something almost like an environmental impact statement that you would always do about whatever procedure or intervention you have, it seems to me we need these things that you've listed here, and I don't think CMS can come up with those on its own.

So what would ask the two of you is, given what

you said, Dr. Eddy, about the state of the art of cost-effectiveness analysis, is there a group of people who are experts in this, along with beneficiary representatives and stakeholders from the medical device industry and clinicians, who could sit in a room for a year in a negotiated rulemaking and come up with something that we could use as a standard so that we could do this routinely? If that were the case, then spending $50,000 on a study, frankly, is nothing compared to what we're spending every day, so I think people could support it.

But without that, I don't see how Congress is going to get behind something like this, and therefore, I don't see how the agency can really move forward. We could do it in payment, and I think both of you said we're doing it right sub rosa, just by local coverage decisions and LMRPs and those sorts of things, and payment policy. But I would prefer, if this is the right way to go, and I'm convinced it probably is, we do explicitly. Let's all agree this is what we're going to do.

There's a lot imbedded in that, but could people get together and come up with something that everyone could agree is legitimate and a good way to assess new

technologies?

DR. EDDY: Sure, I do believe that. For one thing, Peter is the upcoming president of ISPOR, International Society for Pharmacy Outcomes Research and they've already got a paper on methodology for the cost-effectiveness analysis, and if it's expanded a little bit I think that could do it.

If you want something that might be considered by some to be more impartial because it's not just pharmacoeconomic research and so forth, an organizations like NCQA could do it. I can image the Quality Forum doing it. So, yes, there are lots of groups that could take the leadership. I personally would favor NCQA, but that's just a preference that I've got, because they've played that role in several other things. But in many fields we see successful attempts to standardize approaches to extraordinarily complex problems, such as information systems, for example, and the standardization of information transfer. So that certainly can be done.

I also agree with you, and I might not have emphasized it quite as much, that if we do -- my answer to Sheila Burke's question was I don't think we can do an

across-the-board analysis of all the old technologies from existing cost-effectiveness analyses. But by all means, if there is some particular technologies out there, I think I used the term are eating you alive. Perhaps it's too informal. But in any event, that are very expensive and so forth, I think it would make very good sense to go and look at those.

I think I'll stop there. I have some other thoughts about how to do that in a process way but I don't think it would be important to go into that now.

DR. NEUMANN: I'd just add a few things. I agree with you, legally Medicare probably could do it or do it through rulemaking. I think practically, it's proven impossible and it needs, if not congressional action, which maybe is what it needs, it needs certainly a lot more buy-in from a lot more stakeholders.

As far as whether we could do it, I would agree, not only can we, but there is experience, again, in the U.K. and elsewhere in Europe, in Canada, Australia, decision-makers have done it. They've gotten people together. It hasn't always been easy. There have been challenges. There's been resistance. And undoubtedly there would be all

of those things for the U.S., but it has been done. People have agreed upon rules and they have gone forward using this technique.

DR. REISCHAUER: I'd like to thank you for two really excellent presentations. They were both clear and very informative. Of course, when one thinks you know something about it and then the real experts come, you realize how inadequate your understanding is. I have a million questions but I will just raise a few.

One has to do with Dr. Eddy's feeling that we should test the models against the real world. I always thought my profession, economics, had a tough time with models but we have a lot of data from the real world. And one thinks about this area, and when we're talking about something old that's been around for a long time I can see it. But a lot of what is being done has to do with new procedures, new devices, new pharmaceuticals where the costs over time should change radically, decline often.

In the simplistic example, this would be a pharmaceutical coming off patent. While lowering cholesterol might be cost ineffective at the price of Lipitor now, Lipitor in a generic form might change the

equation radically. And then you think about effectiveness, and presumably there's some learning by doing, and effectiveness could improve over time. And how you go about modeling that. If you say, provisionally we go ahead with this stuff at one threshold of cost-effectiveness, assuming costs are going to fall and effectiveness is going to rise, by the time you have the information to do the hard-nosed analysis from the real world data you have an interest group with offices on K Street, you have the whole profession providing this service and not wanting to do it, so it becomes a takeaway, which makes it a lot more complicated from a political standpoint.

The other observation I'd make is that it strikes me just from the news that's come out over the last few years that true cost-effectiveness depends very much also on the secondary effects, which you don't pick up until many years later when you have huge masses of data from large populations and you find that this procedure that you did on the knee or whatever turns out to cause strokes in people who also are taking vitamin E or something like that, and suddenly -- or eating pork chops, something that is a normal, standard behavior of most people, and suddenly it

becomes terribly ineffective, and what do you do about that?

DR. EDDY: Those are all very good points and they are, by and large, very real limitations to cost-effectiveness analysis that we can try to understand, but almost by definition we can't really get rid of. Let's start with the evidence. First of all, for any new technology very often there is no randomized, controlled trial or something like that sitting right on top of it. Or if there is a randomized, controlled trial you're going to use the randomized, controlled trial and it will drive the analysis, so a lot of the modeling questions begin to disappear.

My proposal for anchoring a model to existing trials would be applied to new technologies in the following way. I would ask that if the model is going to be asked a question that has not yet been studied in a clinical trial I want to see that the model has accurately predicted what I'll call adjacent clinical trials, trials in similar populations involving the same kind of organ system and outcomes, involving similar treatments and so forth. So I would propose that that's a way of gaining confidence that a model can handle a problem that has not yet been addressed

in a trial.

Now let's talk about the problem that everything is changing out from under you. The costs are changing, the effectiveness can change. That is also absolutely true. But that's where sensitivity analysis, I think is really helpful. If you're sure that your basic model is correct then you can begin to play with assumptions about whether the cost of a drug, for example, drops to a generic cost or something like that.

For the effectiveness, a good model can handle the human behavior parts of what happens in reality. That is, it can capture that. And if one really wanted to go to an extreme, although it's not very expensive -- it costs tens of thousands of dollars -- you could do a little pilot study that gave you a sense of how, for example, the implementation of a treatment in a real setting might differ from the implementation of a treatment in a clinical trial or something like that where you're getting your baseline assumptions.

So if you believe the basic model, then good will have the ability to address those and give you a sense of how important they are.

Then in terms of the secondary effects, by definition a model or an expert or anyone else can't see it. By definition it's invisible until you get an enormous data set, and we only can guess how many are out there which remain invisible because it takes too many people and too big a data set to ever find them. What a model can do is take that information into account once it's discovered. But I'm not going to pretend that a model could have predicted the effect of Phen-Fen on mitral valves. It would have, by the way, found the effect of Vioxx on coronary artery disease because there was information out there that a good modeling group would know about and would incorporate in their model. So it can handle some of that but it's not going to find the totally unexpected things.

Finally I'll say, all the things you've mentioned are very real and they're limitations for models, but they're also limitations to any other method you use that doesn't address cost-effectiveness analysis. For example, it's not as though expert judgment, or I don't know what, common practice patterns or something like that are going to solve any of these problems. They're all very real problems that just have to be considered.

DR. NEUMANN: I guess I would just emphasize that last point. You identify many important problems, changes over time and so forth. My experience has been, discussions of cost-effectiveness often focus on its limitations, its methodological problems and so forth, and there's almost a temptation to throw up our hands. But the real question is, and the right question is whether it's better than the alternative, as Dr. Eddy said. And cost-effectiveness analysis, in addition to identifying the costs, at least probable costs, and benefits can also often help us identify uncertainty and characterize uncertainty, and help us think about the costs and benefits of collecting additional information.

I guess the final thing is, groups like NIC in the U.K. often revisit decisions over time. They just, last week, revisited their decision on Alzheimer's disease from 2001, for example, in light of new information that's become available. That undoubtedly would be something to consider in the future.

DR. MILSTEIN: Given that we wouldn't be trailblazers if we went down this path, that we the U.K. and Australia ahead of us in this activity, I wanted to ask if

you both would be willing to run a spontaneous model in your minds and respond to the following request for a guesstimate. If tomorrow the Medicare program were to put the available stockpile of credible cost-effectiveness studies, maybe drawing on NIC and others that would pass your minimum test for methodological robustness, if the Medicare program tomorrow were to put that evidence to work in one or other of the following two ways, order of magnitude, what difference would it make do you think in terms of percentage point reduction in per capita Medicare spending trend? Let me tell you the two. I realize according to Malcolm Gladwell it's fair for me to ask you this because you're the experts.

First, what if essentially Medicare were to apply the same thresholds that are being applied in the U.K., how much would that meaningfully impact Medicare? How many percentage points, if any, would that meaningfully impact Medicare spending trend?

Then let me ask you to model a less extreme application, and that would be, if Medicare simply made as a condition of coverage something analogous to step therapy where if there were two treatments that had -- both likely

to have a favorable outcome for a patient with a given condition, what if the Medicare coverage required that the more cost-effective treatment option be tried first before the less cost-effective options were applied? Order of magnitude, would that be a tenth of a percentage point, 10 percentage points? I'm trying to get a sense of how potentially beneficial this therapy might be with respect to meaningfully impacting Medicare cost trend.

DR. NEUMANN: A couple of things. Of course it will depend on how one applies the cost-effectiveness analysis and what threshold is used.

DR. MILSTEIN: That's why I suggested for the first question we use whatever the U.K. --

DR. NEUMANN: The U.K. has been using a threshold of roughly 30,000 pounds, now it looks like 20,000 pounds, which by U.S. standards seems to be low. Even in the U.K. it seems that overall spending is not necessarily decreasing over time despite application of that threshold, and the reason is there's many other things going on in their system, and they're changing incentives, putting more money into the system, and so forth. So part of my answer would be it also depends on those things in our country. In fact

it probably depends largely on those things.

My guess is total impact on health spending would be rather minimal, for a couple of reasons. We're getting new technologies that are worthwhile and probably offer good value, we're aging, and all the rest. There would be a lot of pressure to use those technologies, and even to use cost-effectiveness analysis to argue for more spending for many technologies.

So I hate to put a number on it, but I think it would be 1 percent lower maybe. And a lot will depend on political will on how you would use it. You certainly could use it to do much more much more of a strong tool to contain costs. That hasn't been the experience of payers who have use it.

DR. REISCHAUER: Your 1 percent was a level adjustment or a change in the rate of growth?

DR. NEUMANN: I guess I was thinking change in rate of growth.

DR. REISCHAUER: Whoa.

DR. NEUMANN: You think that's big. I did say less than 1 percent.

DR. REISCHAUER: You got our attention.

DR. MILSTEIN: Do you want to take on the step therapy question?

DR. NEUMANN: What was the precise question?

DR. MILSTEIN: Instead of using simply using it as a cut-off, a less severe approach would be to simply say, when there are multiple therapeutic options that would be reasonable for a patient for the same condition, that the Medicare coverage rules require that the more cost-effective option be tried before going to the less cost-effective option. I take it it would be something south of one percentage point.

DR. NEUMANN: Right. Again, probably minimal impact of spending. The other part of this whole thing is how much you require and how much the government puts out information and does analyses for the private plans, Part D plans, for example, to use the cost-effective information to enact their own policies. So for example, AHRQ, someone might do the analyses, put it out there, and let the plans use it to inform formulary policies, step therapy, tiered copays, prior authorization, preferred privilege, whatever.

DR. EDDY: Having had a little bit more time to collect my thoughts, first I'll just repeat but perhaps

stress even more the importance of the threshold. Obviously, that's absolutely critical, and I had to say I'm very nervous about a threshold in the range of $50,000, for example. If you take to account the fact that the gross total family income in the United States is on the order of $45,000, perhaps $50,000 and that's covering three and-a-half people. We don't have that much money per person.

Now I understand that we're talking about average versus marginal cost-effectiveness and so forth, but I just think that someone really needs to think very carefully about that number. If any of you know the history of how we come to various thresholds you'll appreciate that it's not the result of a really rigorous analysis with true agreement by "society" about what the threshold ought to be. So I think costs might well go up if we had a threshold of, for example, $50,000 or 40,000 pounds.

MR. HACKBARTH: Could I just ask for a clarification on that? I thought Peter said the NIC threshold was 20,000 pounds, which isn't too far from what you're talking about, $50,000.

DR. EDDY: That's right. That's why I picked that number. Actually what Peter said, it's 20,000 to 30,000.

It's at 30,000 now going down to 20,000. So with the exchange rate at 1.93278 --

MR. HACKBARTH: So you're saying that that sounds like I a high number to you relative to incomes.

DR. EDDY: It sounds high; absolutely. I just know that, for example, if we all had a disease that caused us to die on January 1st and there was a pill that we could take to keep us this alive until December 31st, we could not begin to afford it if we spent the entire gross domestic product on that pill.

Now understand, a good economist here knows exactly the trick that I just played on you. But the fact is I think we need to think much more carefully about what the threshold ought to be than we have so far. That's not to disparage the thinking that's gone into it, it is just there are lots of different constituencies, if you will, that are pulling and pushing this threshold because that is of huge importance. I think that is one of the things. I think I've got it on my list, don't I? Yes, it's the last bullet there. You really have to pay a lot of attention to that. I don't think that that the problem is solved.

Now having said that, to try to answer your

question, Arnie, I'm trying to guess -- this is a guess and everyone understands that, and there's no one that's going to write this in some pink sheet sitting behind me, right? I'm just trying to guess what proportion -- I'm trying to think of how many -- the extent of under-use of cost -- let me go back to a point Peter raised. Cost-effectiveness does not mean cost-saving. You can spend money --

All right, so the question is, to what extent are we under-utilizing cost-effective things, so we'd use more of it, as opposed to we're over-using cost-ineffective things, which means if we could apply this technology or the methodology we should be saving money? I tend to think that the forces that are at work from patients, from physicians, from pharmaceutical companies, from newspapers, from the courts tend to push more towards the over-use of things that will turn out to be cost-ineffective than the under-use of things that are cost-effective. So I think you would probably see a decrease.

But there are lots of caveats wrapped around that, and the biggest one is going to be that there's an under -- some of the things that are under-used now that we strongly suspect will be cost-effective, can affect a huge proportion

of the population. They are some of the preventive activities for things like coronary artery disease where almost every adult can end up taking -- and if you, for example, aren't very careful in terms of which drug is recommended and how much you pay for that drug and so forth, that can have an enormous effect on the answer to that question.

DR. NELSON: I want to take something that Arnie started with you, a bit further and ask how you would apply better cost-effective analysis to the development of formularies under Part D. The cost estimates are enormously variable and probably understated, and the folks who will be developing the formulary, understanding that a good bit of the therapeutic category bands have already gelled and they're fairly narrow and may not provide as much opportunity for cost-effective theory to be applied as would otherwise be the case. Nonetheless, it seems to me that the enormous marketing clout of the industry is going to be a challenge for the formulary committees and that solid cost-effectiveness information around a half dozen different categories of drugs, statins, anti-hypertensive, oral agents for metabolic syndrome, outpatient antibiotics, for example,

would be enormously helpful in guiding rational decisions as those formularies are constructed.

So my question is where you see the opportunities for assisting in those rational decisions and how MedPAC might assist that process to go forward.

DR. EDDY: I do think it's possible to identify some particularly important formulary decisions. By particularly important I mean they affect large proportions of the population and there are a variety of ways that, for example, the treatments can be given that could swing costs a lot. I do think it would be possible -- so there is a finite number of these things. We might identify a dozen that are particularly important, which means that I think it's quite feasible to do.

If I might go back to a point that Ms. DeParle raised, $100,000, $200,000 is a lot of money to someone doing an analysis but it's peanuts compared to the amount of money that goes into this. You're talking billions of dollars, and a cost-effectiveness analysis could really have enormous leverage in terms of helping make sense out of those costs. So I think there's a good opportunity there.

DR. NEUMANN: I'd agree, and conceptually it makes

sense. It, in theory, will move us off and move formulary committees off simply looking at prices and rebates and so forth into a better discussion about overall value and health and so forth. In practice, there will be challenges as we discussed, but I would agree with Dr. Eddy that we can prioritize, probably find some areas where it can be very important, some big-ticket items.

The other area I'd just go back to is an information problem. There is this provision in the Medicare Modernization Act, Section 1013, that talks about comparative effectiveness, not cost-effectiveness. But the idea is we may need more information to put out to the formulary committees and have them try to construct value-based formularies, given some of the constraints you mentioned around therapeutic class and so forth. But there does seem to be a need for more and better information and that is a role that I think could be discussed and a role that the government could play.

DR. NELSON: Providing the information is certainly an important first step, but there may be some leverage beyond that that can properly be applied to assure that some of these factors are considered as they make their

decisions. We're talking about pay for performance across a whole range of services within Medicare. I'd like to think of ways that incentives can be provided for committees to assist their decision-making, apart from just having the information available, which is going to be arrayed, again as I said, against the tens of billions of dollars that the industry has used in marketing, including direct to consumer advertising.

DR. NEUMANN: I'd agree, information itself won't solve the problem and will only go so far. Even with information put out to formulary committees, Medicare still has its Part B drugs and technologies, its national coverage decisions. I talked in my remarks about the fact that when Congress adds new benefits, as it did with MMA, various screening benefits, for example, it might either use cost-effectiveness analysis to determine which benefits should be added or provide some language that CMS should use cost-effectiveness analysis in terms of deciding which particular strategy under the general heading of a new screening procedure should be used.

But I agree with you also that incentives are a big part of this and anything we do in cost-effectiveness

should be accompanied by serious consideration of changing incentives.

DR. CROSSON: I actually have a question for Peter although, David, you may want to comment too. It has to do with the point you made about the fact that in other industrialized countries cost-effectiveness analysis seems to be more common at the moment than it is in the United States. The question really is about the underlying -- it guess it was one of the unspoken issues here -- is the underlying cultural issues or underlying cultural values, because I think -- I understand there are payer differences and at least when people tend to talk about this we hear things like this works in England or it works in Europe but it won't work in the United States because we have a different set of cultural values. I'm not sure whether that's the case or not but people believe that.

For example, David, in the paper we read, your conversation, your conversation with your father, you talked about the fact that cost-effectiveness analysis is predicated on the idea that resources are limited, and without that predicate it makes no sense. So I guess there are questions about whether we actually, in this country,

believe resources are limited or whether some people believe resources are limited for some but not everybody.

There's the question of whether there's a common good and whether that common good should have any influence at all over choices that are available to individuals. I think, at least to me these are some of the underlying issues that then are reflected in some of the political obstacles that we've talked about.

So my question is this, from an international perspective, do you believe from your observations that there is such a difference? Then the second part of the question is, is this a static thing or is it dynamic? From the perspective of other industrialized countries, do you see in fact cultural values changing as more information is made available, there's a public discourse about issues like this? Is in fact this a static difference or is it something that can and could be influenced over time in this country with a dialogue about values and things of that kind?

DR. NEUMANN: I think you put your finger on the heart a lot of what underlies this discussion. I do believe there is a difference, cultural, political, values, and in

fact it is striking when you talk to people and read about what's done in England and elsewhere and Europe, even in Canada, Australia. They will not cover a new drug or technology because it is too expensive given the health gains, even though there's agreement that there's some positive health benefit, in ways that have never been acceptable here. And why not acceptable here? You mentioned perceptions, beliefs that resources really aren't limited, a sense of entitlement about these funds, and you can't explicitly ration, and so forth. So I think that seems to be the case for reasons that we probably could spend a lot of time on, historical and so forth.

Whether this is dynamic or static, my best sense is this is very much dynamic. There is a view that all of these countries went through their own long-term social changes and got to a place where they can use it, even though they started, perhaps, in different place. We're probably on a different trajectory. Undoubtedly we are. But my sense is that over time we'll get ourselves there. And maybe it takes awhile, and it maybe falls short of what they're doing now, but certain things, as simply fiscal trends continue, will probably become acceptable because

alternatives may be worse. My sense is the conversation will change slowly and we'll see, but my sense is it will.

DR. EDDY: Your point about everything that we're talking about here is contingent on an assumption, if you will, that resources are limited is a very good one, and it's possible that we will decide that we actually don't have a cost cause problem, in which your report would say basically, stop complaining, to everyone. We're tired of seeing newspaper articles and fights between unions and employer groups, and complaints about rising insurance costs and the uninsured and so forth. But all the signals I get are that it's a huge problem.

To just, very briefly, cultural differences and so forth. I actually am very pessimistic about the prospects that our country will be able to take on explicit rationing in my lifetime, for example. It's not as though this is a new idea and we're just approaching it. It's been tried by great people for decades now and with really very little headway, I think. So I'm actually pessimistic, which is why I tend to look more for things that are much more implicit, much softer, emphasize important things, don't put sharp refusals on cost-ineffective things and so forth. Try to

find ways to do it that's more acceptable. But a straightforward approach to try to make rationing explicit I just think will bloody everybody.

MR. MULLER: I too enjoyed your presentations. A lot of what you discussed today also is available in the NCQA guidelines, NQF and so forth, has to do around drugs and medications and so forth. But a lot of the drivers of health care costs are from new surgical techniques, new diagnostic procedures, the spread of imaging, and we've taken some of those issues on, specifically imaging, at MedPAC in the past. But a lot of the work coming out of the Dartmouth group focuses on the variation that comes from that.

How deep is the knowledge of clinical effectiveness in those areas? Again most examples commonly -- I shouldn't say most but a lot of examples usually are around medications, but how about in those other areas, where is the body of knowledge going? Is there a lot of work being done in those areas?

Obviously, one could see a lot of thrust from the supplier sector there in terms of all these new interventions, imaging, et cetera, diagnostic techniques

driving this health care economy. So could you just comment a little bit about what's happening in those spheres?

DR. NEUMANN: In our database of cost-effectiveness analyses, for example, 40 percent of studies are on pharmaceuticals, which seems like a very high number given total spending on pharmaceuticals compared to total health care is maybe 10 to 12 percent. The other 60 percent are representing a wide variety of interventions, imaging, surgical procedures, education, behavioral interventions even. But in general, a disproportionate share of the attention has focused on drugs and would, in my view, probably need more attention not only on imaging and procedures but on broader disease management strategies, public health strategies, other kinds of care delivery strategies.

DR. MILSTEIN: Just to follow up on Ralph's point, the Dartmouth research showing a substantial variation across geographies and within geographies for delivery systems with respect to so-called supply-sensitive services suggests that there's some geographies that are creating equal levels of measurable health and patient satisfaction while spending 30 percent less per Medicare beneficiary on a

maximally risk-adjusted basis.

But if drill deeper, what the Dartmouth people are telling us is that the differences primarily relate to areas in which effectiveness research and cost-effectiveness research have not yet touched. Questions like, for patients that are borderline with respect to whether they need to be in the hospital, do you put them in? Patients that are borderline with respect to whether or not they need ICU care, do you move them into the ICU? With what frequency do you bring back chronically ill patients to monitor them for more frequent office visits? What's your threshold for referring somebody from a primary care physician to a specialist? It's in those categories of medical decision-making that most of the variation in supply-sensitive services, and this 30 percent guesstimate on opportunity for Medicare to save through reproducing the practice patterns of the lowest spending deciles occur.

Why don't we have more effectiveness and/or cost-effectiveness research with respect to these basic questions around which so much variation in spending seems?

DR. NEUMANN: My theory is a lot of it's reimbursement driven. A lot of studies in our database, for

example, the 40 percent on drugs fall into the categories of is drug X cost effective for condition Y, often sponsored by, but not always, but often sponsored by the companies involved, because they want formulary placement, they want reimbursement. I agree, the studies that need to be done are the kinds that you described, much more richly descriptive about the strategies and where patients are going. The problem in the past is that there hasn't been a great incentive for anybody to get reimbursed for that procedure and probably requires the payers and perhaps the government to do those studies. Conceptually, you could do that study with all the descriptive richness that you described.

DR. EDDY: I'm not sure that we really disagree and probably wouldn't if we could talk more. I'll just say, even if it might be feasible, those are inherently harder cost-effectiveness analyses to do because they involve the software, if you will, of medical practice. When you talk about thresholds, borderlines, frequencies and so forth, they're not hard technologies like giving a drug or putting in a stent. It takes a much more powerful model to do it and get it right.

Also, the answer you will get will vary from setting to setting because these have to do with what the specialists are, and how much they charge, and things like that. So you can get an answer in New York and have vary -- get an answer at Memorial Sloan-Kettering and have it vary quite a bit from an answer in the Joslin Clinic, for example, or something like that. So they are more difficult to do, and I think we ought to recognize it as an area that would be harder for cost-effectiveness analysis to make inroads in than some of the other technologies.

MR. SMITH: This was both provocative and very helpful. David, I share the pessimism, skepticism that you expressed a minute ago about a bright edge opportunity in the near future here. Peter, I was struck both in your paper and your remarks about the observation that we're beginning to do this sub rosa anyway. But when Nancy-Ann asked whether or not we ought to proceed with some attempt to forge a national consensus on this both of you seemed to think that that was both appropriate and, to some extent, Peter, I think you more sharply suggested it was necessary. That we couldn't take full advantage of the potential here unless we're able to do this above-board and explicitly.

I wanted both of you to reflect on that a little bit, but I'd also like to ask the clinicians here Alan, Ray, Mary, to what extent you think Peter's observation about the availability of the information finding its way into clinical decision-making anyway, to what extent you share that observation? And is the political cost, political risk associated with a much more explicit effort worth it, given your judgment about the extent to which this kind of information and analysis is finding its way into the kind of decision-making that you and your peers are making today?

DR. NEUMANN: First, I suppose I don't want to convey the impression that I'm very optimistic that we'll start using this soon. I probably agree more than not with Dr. Eddy. This is going to take a long time. It's not going to be easy. I don't think we're anywhere close to having a bright line where we're going to say this new technology is effective marginally, enormously costly, therefore we won't cover it. Certainly not for certain kinds of conditions where you have a patient whose already ill.

I do think take there are opportunities to use it in prevention, to inform frequency of screening, for

example, maybe -- we talked about formularies -- to inform where somebody is on a formulary, which drug they get first, which drug they get second, and so forth. Maybe to inform other kinds of conditions on coverage, even coverage in settings or coverage with certain other criteria. But I do think there's movement, and the fact that we're discussing this today is one reflection of that movement. I think were inching our way forward and there will be a lot of resistance.

DR. EDDY: Just make a quick comment. For quite a while I've thought that we really should address this head on and, in a sense, put the country into therapy and really help it come to terms with this, and I've bloodied my head a fair amount beating it against various walls and I guess I decided to stop. Ideally it should be done that way.

On the other hand, I think that if we're really going to make progress in the near term, meaning over the next five to 10 years, I just think we need to take a soft approach. But I'm very conflicted about that because the intellectual in me wants to do it the right way. The practical person in me says, it just hasn't worked over all these years and we probably have to choose a more indirect

way to approach it.

MR. HACKBARTH: It almost seems like there's a catch-22. On the one hand, these are very difficult issues to have the sort of national debate that Nancy-Ann referred to, envision Congress deciding explicitly that we're going to do this and the quality threshold is whatever it might be.

On the other hand, I often hear from people in the private sector running health plans that it's very difficult for them to do without government leadership because it's not perceived as legitimate if it's done by a private plan; it's potentially tainted by economic incentives and the like. Please react to that.

DR. EDDY: So here's an idea, setting aside the methodology of cost-effectiveness analysis, can you just make a statement that costs are important and rationing-type decisions simply have to be made? In a sense, just legitimize the concept.

MS. RAPHAEL: I think in line with what you were saying, you have to also legitimize the process, and I don't think we yet have a legitimate process. In fact I would say we're going in the opposite direction, because given the

recent furor over Vioxx and Bextra I think people have even less confidence in the process. So I think it's also important, if we're going to have a public process that buttresses even private decision-making that we think through what would be a process that would be legitimate, that would incorporate the stakeholders, that could revise decisions, because I think it's important that you have a process to review and come back to decisions. So I think that has to be part of any discussion we would have.

DR. MILLER: If I could comment for just a second, because this now hits where I was keeping notes, trying to follow along what -- something that the Commission could do. This is three thoughts. I had a lot of other thoughts and questions but at least three things that occurred to me.

One was trying to comment on what a good process would be. So rather than saying, you need to ration, you might begin to try to break down some of the mistrust and the concerns that often get in the way by saying, there may be a way to do this that is a better way to do this, and start talking about what a process like that would look like. That's not completely different than some of things we're talking about even in our pay for performance where we

referred to it, didn't spend as much time drilling into that but we certainly talked about the need to carry it on.

A second point that occurred to me as I was listening to all this is maybe pointing in directions where you might put your first focus. A different word I think I needed there, but you might look first at these types of things, or these areas might get the most fruitful. Again, not calling it but saying, these are the places to devote the first efforts to.

Then finally, and this is a question, it struck me that one piece that is crucial to benchmarking the models, getting the information out there underlying a lot of this is the clinical trial and how the clinical trial is structured, and whether there's something that the Commission could say about how trials should be run and brought to the federal government for approval through the FDA, through payment processes at CMS, the kinds of information that would be included in that, because that struck me as a linchpin to a lot of the models as well as the information. But I don't know if other people saw that, the head-to-head type --

DR. NEUMANN: Just a couple of quick comments.

One, I agree with both of you about process being key here, and experience with process in other countries and also with Medicare with the national coverage decisions I think has shown the importance of it, but also some of the elements that would comprise good process: transparency, participatory process with ability to comment for stakeholders, appeals once a decision is made, pre-specifying criteria and gaining that legitimacy. All of that I think is right.

Secondly, about the clinical trials, you remind me, one, that Medicare has now been moving to coverage under protocol and coverage with much more strict conditions about data collection. While not cost-effectiveness per se, in many ways it's trying to get at a cost-effective solution, and in many ways I think the notion that we can or cannot use cost-effectiveness, or Medicare can or cannot is in some sense a false choice. That there will be ways in which to make decisions, coverage decisions, payment decisions, probably and certainly decisions that could be informed by cost-effectiveness analysis. So we'll cover, but only for those people who meet the clinical trial conditions, or we'll cover but we'll put all the people into a new clinical

trial or registry or data collection effort and learn more and make another decision in a year or two, that kind of policy.

DR. STOWERS: Just to answer David's question. I really believe that at least from our perspective as a provider we're very sensitive to the cost-effectiveness of care, and I do think there's, as was mentioned before, kind of a confidence issue out there about it. I think, obviously, the doctors don't have the data or the model to go off of so there is some confidence added when major payers like Medicare, CMS, take on a payment policy. That's why the rate of pneumovax went up considerably when it was decided to be covered. It wasn't just the $5 or $6 that it cost for the shot or that kind of thing. There was a message sent by CMS at that point that they had confidence that it was a cost-effective thing to do.

I hate to raise an ugly head here that hasn't been brought up that does happen a lot in clinical. As much as we talk cost-effectiveness, when it comes to physicians making their decisions, in the tort system that we're in, cost-effectiveness is not taken into account. So 20 years ago if I had a swollen ankle come into the emergency room I

didn't x-ray it if I really didn't have the clinical signs of being fractured. I would wrap it, cold therapy, do that kind of thing. If it's bothering you in a day or two we'll get some x-rays of it. Today you x-ray it. Now is it cost-effective to x-ray every swollen ankle?

I only use that as one example. But until our legal system and that kind of thing also begin to accept cost-effectiveness as a legitimate part of the decision-making process that the physician goes through, or the provider, the hospital, home health or anyone else, I think that's a another major hurdle that we have to cross out there that just hasn't been mentioned today but I think it needs to be as we go down the pike on this particular issue, if we're looking for confidence from those who are making those decisions towards cost-effective care.

I didn't know if you had any comment on that.

DR. EDDY: A little bit, yes. First of all, your point is exactly right, the tort system is just not aligned with cost-effective medical care. It is not possible to bring it up explicitly as a defense, but I think it is possible to incorporate cost-effective thinking into ways that would protect physicians through guidelines, because a

physician is protected if they're following a nationally-accepted guideline or a commonly-accepted practice. So if you get good cost-effectiveness thinking into the guideline, then I think, in my experience -- I've testified in some of these trials -- it works.

DR. STOWERS: I agree.

MS. BURKE: Just one thing in follow-up to Mark's summary of how we might begin to think about this, but also Carol's concern and follow up on the process issue, that legitimacy to the process will help move us along in a variety of ways.

We have a tendency, and I've heard it again this morning, but we have a tendency to try to talk about these issues in very separate boxes. We have a quality conversation and we spend a day talking about quality, and this morning we have a conversation about cost-effectiveness. It is rare that we consciously combine those two things.

I think one of the issues as we go forward and as we think about the issues that Mark has raised about how we would, as a commission, begin to focus on these issues and move it forward is I think we have to consciously begin to

link those two things. Because the issue around cost-effectiveness must also reflect decisions about quality. That there is a direct relationship to choosing the right kinds of things because they're effective, both with respect to cost but also with respect to the quality of the care that's being delivered. And whether we begin to think about it in the context of pay for performance and link it directly to quality decisions, performance that's based on both cost, the integration of cost sensitivity, but perhaps more importantly, the quality issue, people have to begin to think of these things together.

I think we consciously have to begin to combine them in our conversations, and I think we tend to think in those boxes. I don't think we believe it, but I think that's the way we frame it and I think we need to, as we approach it, as Mark suggests, in looking at ways we can begin to apply it to our work. I think we have to consciously begin to connect those two things in our conversation.

MR. HACKBARTH: To me that's part of the intriguing aspect of pay for performance and the use of guidelines. It's one of those places where you can readily

imagine the two conversations coming together. And if we're using pay for performance as a way to reshape the system and move it in a particular direction, it would sure be nice if we could move it in a direction that incorporated cost-effectiveness thinking.

DR. EDDY: Just to give you a one-liner on that, the questions around pay for performance are, how much do you pay for how much performance for which technologies? That is an ideal place -- not only is it an ideal place to insert cost-effectiveness, but if you don't do it you could easily, because this is a guideline with teeth, send everyone going off in the wrong direction.

MR. MULLER: Just in follow-up to Mark and Sheila's comment, I would like to urge us in terms of our comparative advantage to not get too focused on the pharmaceuticals and the drugs, and especially with Part D coming and so forth. There will be a lot of scrutiny there just because it's there. I think some of the comparative advantage, given the work we've been doing the last couple years, is in fact in the other areas. As David said, tougher areas to try to measure, but I think given the work we've been doing we may be the only one around -- that's too

much. We may have a comparative advantage in looking at those other areas that were referenced in Arnie's remarks and my remarks earlier.

So I think there's a tendency because FDA is out there in that process on the front page of the New York Times all the time to want to weigh in on that, but these other processes, imaging, and diagnostics and surgical technique, none of which have anywhere near the scrutiny that a Vioxx decision has, and they get out there very fast. I'm not trying to defend how they did the Vioxx thing but there's a lot of other things that get into practice with much less scrutiny, far more conflict of interest, and just because they don't have a public process to legitimize it is there's not a process to criticize.

I think we have to look at those things that really drive costs that in many ways are under the scrutiny that the FDA gets. So we shouldn't just be looking for the keys under the lamppost but we looking where in fact the real drivers are.

DR. EDDY: I'd like to close with a big picture comment. There's obviously a lot of uncertainty and a lot of difficulty here, and I would just point out that any

action you take, whether it's a broad frontal attack or you just have a single beachhead with something like pay for performance, and even if you don't know the exact effect, for example, on the budget, without question, if it's done at all right, you will increase the ratio of quality you're getting for your costs. That we can be sure of. That we can be sure of. That is the nature of cost-effectiveness analysis, so it will achieve that.

MR. HACKBARTH: Any final comment, Peter?

DR. NEUMANN: I would agree, and I commend you for discussing it today and look forward to more in the future.

MR. HACKBARTH: Thank you very much. It was outstanding presentations and great, thoughtful comments. Thank you very much for coming.

Next up on the agenda is the mandated report on critical access hospitals. We're going to need to press ahead since we took some extra time on the first session. Jeff, would you like to borrow my tie?

DR. STENSLAND: I'll tell you the story on the tie later.

MR. HACKBARTH: I have a guess. Just so this isn't a private joke. Jeff has a new daughter that's what?

DR. STENSLAND: Three weeks old.

MR. HACKBARTH: You can figure out the rest of what happened to Jeff's tie.

DR. STENSLAND: Good morning. Today I'm going to talk about critical access hospitals and our mandated study.

The Congress has mandated that MedPAC produce a report on the rural provisions of the MMA by December 2006. As an interim step we are also required to produce a report specifically on the critical access hospital provisions of the MMA by June 2005. In today's meeting I will review the current status of the CAH program, discuss how Medicare payments have increased to converting hospitals, present data on the improved financial performance of converting hospitals, and discuss some policy issues regarding the CAH program.

There are several restrictions on which hospitals can become CAHs but most are not binding. CAHs must have an average length of stay of four days or less. However, most CAHs have swing beds. The CAH can discharge Medicare patients to post-acute status. The same patient can stay in the same bed and generate the same Medicare reimbursement. CAHs must also be 35 miles by highway or 15 miles by

secondary road or be declared a necessary provider by the state. Essentially, all small, rural hospitals have been designated as necessary providers. Therefore, the distance criteria is almost never binding.

CAHs must be in rural areas. However, a state can declare any town rural for CAH purposes, even if it is in an MSA. Hence, about 10 percent of CAHs are in MSAs. Many of these are in fairly rural census tracts of the MSA.

The binding constraint is that CAHs are limited to 25 beds. Because this is usually the only binding constraint, over two-thirds of the nation's general and surgical hospitals with under 1,900 admissions per year have converted to CAH status.

Back in 2000 we had 139 CAHs, but the program has grown rapidly from 2000 to 2001 and to 2002, 2003, the beginning of 2004, and the end of 2004. At the start of 2005 we had approximately 1,070 CAHs. As you can see, some of these CAHs are in isolated rural areas of the country and some are fairly close to other CAHs. In addition, some CAHs are close to PPS hospital. The point being there's a great diversity amongst the different types of hospitals and their location in the CAH pool.

This figure illustrates how close CAHs are to other hospitals. Most CAHs are between 15 and 25 miles from another hospital. However, we did identify 151 CAHs that are 15 or fewer road miles from the nearest hospital. Again, they become CAHs through that necessary provider provision I discussed earlier.

Why do hospitals convert to CAH status? Hospitals primarily convert to CAH status to increase their Medicare payment. Conversion tends to result in large increases in payments for outpatient services. Payments for outpatient services include payments for laboratory, therapy, and for physician being on call. For the on-call payments to be reimbursable, the providers must be within a 30-minute drive of the CAH, unless the CAH is in a frontier area, then the provider can be a 60-minute drive away.

Payments for post-acute care to patients in swing beds also increased substantially. But payments for inpatient services often do not increase substantially following conversion because acute care costs under CAH cost accounting are often close to prospective payment rates.

We compared changes in outpatient payments for 498 hospitals that converted to CAH status between 1998 and 2002

with 551 similar hospitals that did not convert. The comparison hospitals were all located outside of core urban areas and had received 1,000 or 900 fewer discharges, which is the largest number of discharges for a CAH in 2003.

From 1998 to 2003 we see that outpatient payments for certain services rose 69 percentage points faster at hospitals that converted to CAH status and received cost-based reimbursement. There are several potential reasons.

First, CAH Medicare payments were about $100,000 less than reported costs in 1998.

Second, CAHs received reimbursements for on-call payments located outside of the hospital. PPS hospitals don't.

Third, CAHs have lower incentives for cost control due to cost-based reimbursement.

And fourth, CAHs may be increasing service offerings due to increased prices they receive for those services. We will report further on how volume has changed at CAHs in our April meeting.

I should note that the above figures may under-estimate the true growth in outpatient revenues because they exclude payments for laboratory and therapy services which

were paid on a fee schedule in 1998.

MR. HACKBARTH: Jeff, could I just ask you a question about that? So these changes are a function of both unit cost growth and volume changes?

DR. STENSLAND: Right. So this is the overall effect and we're going to try to protect that down in April, in between volume effect and price effect.

MR. HACKBARTH: Bill has corrected me that these are the payments as opposed to any measure of cost.

DR. SCANLON: The reason I brought it up is because knowing the margin changes, it says a lot about what costs are doing.

DR. STENSLAND: Swing bed payments to CAHs -- for those of you who don't know, swing beds are beds in small, rural hospitals that can be used for acute care or post-acute care. These swing bed payments at CAHs rose to slightly over $1,000 a day. A 40 percent increase in swing bed days plus a roughly $700 increase in payments per day fueled the $463,000 increase in swing bed payments. Because CAH cost accounting allocates a large amount of cost to swing beds, the remaining costs allocated to acute beds are often not much more than PPS payments. Therefore, acute

inpatient payments did not rise significantly following conversion.

Looking at this slide you may ask, what are CAHs' incentives to increase swing bed use? When a hospital has a swing bed patient stay one additional they will receive roughly $1,000 in additional revenue for that day. However, a swing bed day or any type of patient day results in spreading the hospital's fixed costs over more inpatient days. Hence, the expenses allocated to Medicare acute days will be reduced when Medicare swing days are increased. Accounting for this reduction in payments for existing Medicare acute patients, the net increase in Medicare payments for an additional post-acute swing bed day may only be $400 or $500 per swing bed day. This is approximately $100 to $200 more than SNFs receive for providing similar care.

This issue of reducing payments per Medicare day when patient days increase is most troubling when applied to charity care. The financial incentives to provide charity care at CAHs differ significantly from the financial incentives at traditional hospitals. When a charity care patient is treated by a traditional hospital, the hospital

must absorb the marginal cost of treating that patient, primarily supplies and nursing time. When a charity care patient is admitted to a CAH, the hospital must first absorb the marginal cost of serving that patient, and second, absorb a reduction in Medicare reimbursement. The more charity care the CAH provides, the less Medicare pays. This is a troubling incentive inherent in cost-based reimbursement.

The slide presents an over-simplified example of how increased care for the uninsured reduces Medicare payment rates. First, assume a CAH has 1,995 inpatient days, that's acute and post-acute, of which 1,200 are Medicare days. If the hospital had $1 million in fixed, routine costs, the hospital would receive $601,534 from Medicare to recover routine costs. However, if the hospital admitted one more charity care patient who stayed for five days, the share of the $1 million allocated to Medicare patients would decline and Medicare payments to the CAH for routine costs would fall by $1,534. In this example, Medicare payments falls by roughly $300 for every day a charity care patient stays in the hospital.

We do not know whether this incentive results in

rural hospitals having slightly more restrictive charity care policies for non-emergency care. However, we can see how this creates a strong incentive for CAHs to discharge charity care patients quickly and reduce the total number of uncompensated care days in the hospital.

CAHs have a tendency to expand services where they receive increased payments under cost-based reimbursements and drop services that are less profitable under cost-based reimbursement. For example, a University of Minnesota study found that CAHs are expanding imaging, laboratory, and rehabilitation services, all of which are cost based. We found that these same hospitals slightly reduced their offerings of obstetric, SNF, and home health services. Offering these last three services would result in a hospital's overhead being allocated partially to these services and would cause a slight reduction in Medicare inpatient and outpatient payments to the hospital. The changes in service offerings at CAHs are consistent with their financial incentives.

In total, payments for inpatient, outpatient, and swing bed services rose 47 percentage points faster at CAHs than comparison hospitals. As we see on the following

slide, the rapid growth in Medicare payments was accompanied by an increase in total profit margins.

This is the real success of the CAH program on the slide. When we look at CAH financial performance we focus on all-payer margins for two reasons. First, we wanted to see if converters appeared to have better overall financial performance and a lower chance of closure.

Second, changes in Medicare margins are difficult to interpret because conversions to CAH status results in a change in cost accounting rules. If we looked at Medicare margins it would not be clear the extent to which a change in Medicare margins is due to a change in cost accounting or to a change in actual financial performance.

Prior to conversion, many critical access hospitals were facing low volumes, high costs, and low margins. Following conversion, Medicare payments and profit margins increased substantially. With improved profit margins, closures have almost ceased. We are only aware of one closure in 2004 and a for-profit entity is considering reopening that CAH.

We can conclude that the CAH program has been largely successful in achieving its mission of keeping rural

hospitals open. However, some of the hospitals the program is keeping open may not be critical for patients' access to care.

The 2003, CAHs received approximately $2 billion of cost-based payments; 17 percent of those payments went to hospitals located 15 or fewer miles from another provider. Fifteen percent of payments went to hospitals more than 35 miles from another provider. In 2005, we expect cost-based payments to CAHs to be approximately $4 billion. Cost-based payments to CAHs are expected to roughly double, primarily due to an increase in CAHs, but also due to an anticipation of increased costs per CAH. Payments per CAH have historically risen by more than 10 percent per year.

Spending additional Medicare dollars to keep small hospitals open when they are more than 35 miles from the nearest alternative source of care is relatively uncontroversial. Keeping hospitals open that are 15 or fewer miles from another hospital is a more difficult decision. If quality improves with volume, then merging small hospitals that are close to one another may be beneficial. The key question is whether the benefits of increased volume and cost savings outweigh the burden of

additional travel time for beneficiaries. In our April meeting we will discuss the quality of care and patient volumes at CAHs.

Starting in 2006, the MMA requires that states will no longer be able to declare to new CAHs necessary providers. However, the 151 hospitals that are less than 15 miles from another hospital will be grandfathered in as CAHs. The Commission may want to consider whether having low volume providers close to one another is the best way to care for Medicare beneficiaries, and whether CAHs should be 15 miles from all other providers.

The Commission may also want to discuss changes in the payment for post-acute patients is swing beds. A typical CAH will receive a net payment of $100 to $300 more per swing bed day for post-acute patients than local SNFs receive for post-acute care. Twenty-eight percent of CAHs themselves have a distinct part SNF. Hence, payments for two patients receiving identical care in the same building may differ. Medicare may be $300 for one more SNF patient day and pay $450 for one more swing bed patient day. An alternative to cost-based payments for post-acute care patients is to pay CAHs the same rate that is paid to local

SNFs. However, this would result in a reduction to CAHs payments from Medicare.

A third issue to discuss is the profit margin provided to CAHs. Currently, CAHs receive 100 percent of allowable Medicare costs. As costs go up, their Medicare profits go up. This can create an incentive to have a highly leveraged facility, as was the case with SNFs when they received cost-based reimbursement. An alternative to paying hospitals a 1 percent return on their costs would be to pay hospital's return on the equity in their physical assets; physical assets minus liabilities. Under this system, when members of the community make donations to their CAH and the hospital therefore reduces its debt it would not have a reduction in Medicare payment rates. The rate of return on equity could be set so that average payments to CAHs do not changed but incentives would improve.

One way to avoid the problems with cost-based reimbursements is to provide CAHs with a single, lump sum payment. Hospitals with under 25 beds that are more than 15 miles from another provider could to be given a fixed payment. For example, $500,000 per year, plus the

prospective statements given other hospitals. The fixed payments would help defray the cost of providing standby emergency room service in a low population density market. If our objective is to retain access to emergency room services, we could pay directly for standby emergency department capacity.

There are several advantages to this approach. First, CAHs would have stronger incentives to control costs. Second, providing charity care would no longer cause Medicare payments to decline. Third, Medicare revenue would be less volatile because it's tied less to patient volume. Fourth, it would provide rural communities with more flexibility in how they want to structure their local health care system and the relationships with nearby facilities. They would no longer need to retain high volumes in services, such as imaging or swing beds, to cross-subsidize the emergency department.

So to summarize, I think we have at least four discussion topics which I'd like to hear your thoughts on. The first is requiring all CAHs to be 15 miles from other hospitals. The second is setting post-acute care rates for CAHs equal to those of local SNFs. The third is paying a

return on equity rather than a return on cost. And the fourth is a change to a fixed subsidy rather than cost-based reimbursement.

Thank you.

MR. HACKBARTH: Jeff, let me ask a question related, I think, to the first one. To the extent that we have more CAHs and that they serve more patients, is there not an impact on the non-CAH hospitals that are close to them, many of which are small themselves? So assume for a second that there's a finite pool of patients, and if we're shoring up the CAHs, that means there are fewer patients that might go to the rural hospital in a little bit larger town, thus reducing its volume, its ability to add programs, or its financial well-being. Is there any way to get at that impact on the adjacent hospitals?

DR. STENSLAND: I'll have to think about a way to get at that, but that certainly is an issue. For example, when HUD considers making loans to CAHs, one thing they do is they go talk to the other hospitals around that CAH and ask out that CAH affects their business, and whether there's duplicative capacity. And in some cases they decide there is duplicative capacity so we're not going to make a loan to

that facility because we think it would harm the nearby facility. Then there's also the volume issue and quality.

DR. WAKEFIELD: With regard to the subsidy discussion, I just have to say that I mentioned to Ralph right before we got into this, just before we started this formal discussion, that if we're talking subsidies perhaps that GME subsidy that he's always so fond of could be -- we could be looking at orders of magnitude for this subsidy for CAHs. He then responded that he's really quite pleased that I'm leaving the Commission this year. I'm trying hard not to take that personally.

[Laughter.].

DR. WAKEFIELD: Just a few comments and I'll get you the rest of my comments because there's not enough time and everyone will become nervous that I'll wax on and they'll miss their flights, so I won't do that. But I do want to make a couple of comments about tone, first, of the chapter, because I think that predisposes at least me to a certain view about the information that's presented. And secondly, a few comments on some of the data from the research you've conducted and maybe some ideas about things to think about as you continue with the next presentation or

the presentation that we'll have in April and the work that will have to underlie that.

I also want to say on the front end that you ought not construe my remarks as being supportive of this program exactly the way it currently exists, and that it in fact supports every single CAH out there as being a well-documented essential provider. I think like anything else there's obviously room for aligning the intent of the program with the way the payment policies are structured, and certainly there's room for improvement with this as there is with everything else. So I don't want you to think that this is just -- I'm hunkering down here and suggesting it ought to stay just the way it is. That's not what I'm saying.

On the other hand, the flip side of that for me is, let's make sure that when there are changes that are made that the brush is not so broad that we do collateral damage to what was the intent of this particular program, which was to assure access, essential access to what could otherwise be construed as a pretty vulnerable population, that is Medicare beneficiaries. We already know that they are not the ones who tend to travel down the interstate to

go get care 80 miles away, if they can avoid it. The 22-year-olds in rural areas do, but the 75-year-olds don't necessarily. So that's the balance that I think we need to be thinking about achieving, aligning it but being careful not to do damage to access, which is the original intent of the program.

With that let me just make a couple of comments about tone, as I said, and then reference some of the content in the document that we received, and then also some comments about the findings.

In terms of issues that were presented, first of all, in the chapter we talk about the MMA sunsetting governor's authority to designate small, rural providers as necessary providers. On page 4 we state that state officials can increase the flow of Medicare dollars into their states by declaring more hospitals necessary rural providers, so they have declared essentially all of them in order to maximize that Medicare flow.

I think the outcome is probably just the same, the response is the same, but I don't know that that stimulus is actually accurate. Obviously, that happened with the Medicaid program in some states, but I have never heard of

that as the rationale, that is boatloads of federal Medicare dollars coming into states, as the rationale for designation. I do think that there probably is political pressure teed up and governors probably had to deal with that, so I'd say that might be fair in some cases. But your rationale here doesn't mean a whole lot perhaps, but it's just nothing that I've ever been privy to.

Also, I'd say that the simple fact is that with BBA '97 states were allowed to establish the rural hospital flexibility program and within that critical access hospital status. The states had to apply to then-HCFA in order to achieve that designation. So there were application criteria that HCFA imposed. It wasn't just governors designating it and it was done. In fact there was a process that had to be followed for designation; the designation of necessary providers, and that those necessary providers had to be part of a broader rural health plan. So that was a document and an application process that was in place.

CMS allowed fairly loose, some would say, necessary provider criteria, and once you open that wide then other hospitals followed suit. So I'm just suggesting that here the tone is, bad things are going on out in the

states, and I would suggest that perhaps some of what created more CAHs to be designated than what might actually make sense in terms of the intent of the program could well have been the fact that we didn't have terribly tight criteria on the front end against which plans would be reviewed.

Also, states don't redesignate urban hospitals as rural hospitals. As application process has to be made to CMS. They can't just say, you're rural, and suddenly for Medicare purposes it's rural. So we can talk about the states' role, but I think we also ought to be talking about CMS, because in fact maybe some of the solutions to some of these issues may rest there too, may rest with CMS. Not just with what we're doing out on the frontlines with the states.

MR. HACKBARTH: Mary, could I ask about that so I'm sure I understand it? The way the law was written, was CMS granted the discretion to say, we don't like the state's plan so we won't accept the designations? Or was CMS's review strictly procedural, so long as the appropriate steps were followed the discretion was the governors?

DR. STENSLAND: When I talked to the people at

CMS, that was their impression, they didn't have a lot of discretion to say no. I think this is actually something we can actually quantify if we need to because when you look at the whole issue, we start out with there's maybe 1,500 small hospitals in the country with 1,900 or fewer discharges, and about 100 of those are in real core urban areas. Many of those are physician-owned specialty hospitals like spine hospitals and that kind of thing. So if we throw those out we have about 1,400 left. Out of that 1,400 we have about 1,100 have converted already, so we know those were eligible to convert. Then there's only about 300 left. So we could even, if we wanted to, we could go through those and see if there is five or 10 that weren't eligible. But it's going to be the vast majority of that 300 that's left over.

DR. WAKEFIELD: To your question, I don't know the exact answer. I think worth pitching. Clearly in the field, I can tell you, that the sense was that there was an approval process that was put in place and that it wasn't an automatic; you submit the data and it gets checked off and rolls through CMS. But I can't say that with certainty so it would be worth going back and finding out.

The other part of that and why I make the point is

to say, as we look for solutions we might also be looking there in terms of future review processes. If there's a reason to tighten things up that might be a place to try to leverage appropriate criteria, if you will.

MR. HACKBARTH: Let's just try to nail that down, who was vested with the discretion here, whether it was CMS or the governors.

DR. REISCHAUER: We can also look at the number that were sent to CMS and the number that got designated. There's different dimensions to this. One of the criterion might have been interest in winning the state in the next election.

DR. WAKEFIELD: Not that that would ever happen.

But the point is, at least from my perspective, perception was criteria were really quite broad. Yes, there were criteria. Criteria had to be met. Criteria were quite broad. How that really played out you'd probably have to go back and find out.

Just another comment on the mileage issue, the zero to 15, 15 to 25, 25 and higher, et cetera, and your good parsing of the hospitals that fit within those categories. It might be more than what we'd want to do but

since you've got two bites at this apple -- I hate to say it, but 15 miles or 20 miles isn't always 20 miles, isn't always 20 miles.

I do a lot of work with designations on mileage and minutes to health care facilities because it's so critical. Where I sit right here I might be able to get to two different hospitals within 10 minutes as I sit right here. But as I sit in a mountainous area of the state of Virginia, that 20 miles might translate to something quite different in terms of time. So I'll just tell you that out in a different arena there's a lot of work being done about what access really means. Mileage is a proxy but as we're carving these into categories I think that there's some finer tuning that probably could be done there. At least you might want to try to look at anyway, instead of just these firm designations, because I don't think they mean what on the face you might think they always mean. Which isn't to say that in that zero to five miles and you've got two hospitals, that those are legitimate in terms of the intent of this program. I want to make that point. But I don't know that it's as black and white as it's listed here.

A couple of other issues. On footnote two we say

that hospitals can always discharge their patients to swing bed status and receive the cost-based payment holding the same patient in the same bed. First of all, that statement implies, I think, that the hospital is making the decision when in fact it's probably the physician who's making the decision, and in fact there are swing bed criteria, clinical criteria about moving a patient out of a hospital bed and into a swing bed, and a physician makes that decision. Hospitals can get nasty letters about quality, and physicians can get nasty letters too if those criteria aren't followed. Now you might argue the criteria, but it is just to say that that footnote suggests something a little bit more than what I think is actually the case.

Next on page six you talk about before hospitals deciding whether to convert to CAH status they almost always have a consultant or an accounting firm to estimate whether their Medicare payments will increase. True enough. In fact the flex program actually funds some of that activity. I think that's just good business. I think that Ralph's shop probably has a good CFO that can run the numbers and maybe for people who work with him or her. That's not the case in a lot of these little critical access hospitals.

The CEO might be the same person who's out there shoveling snow in the front of the building, it might also be the one with pencil and eraser trying to figure out impact. So in fact the feds deliberately tried to wrap around some support through the broader flex program to support sound business decisions being made.

I'd say that if you've got a sentence like that and the tone that it implies; i.e., gamesmanship, you might as well be tossing it into just about everything that we write because any time there's a switch in payment people ought to be doing exactly this. Now where they take it to might be a different story. But that's what I mean about tone.

On page 13, some personal communication from Charles Davis at HUD. Again we're saying that they declined, and you made the comment a little bit earlier, several potential applicants to the HUD 242 loan program. But I can't tell from that if that was seven applications or 17 applications or 70 applications. But where that language leads me is to think, we've got a significant problem here; potentially it could lead me there. So that's what I'm talking about when I'm referencing tone.

Likewise, the comment about radiology services and the expansion. Again, true enough. Certainly there is and has been an investment in technology. I think perhaps a worst case scenario would be an MRI, and there are CAHs, as you point out, that have made that particular purchase. So if we're trying to illustrate the extreme, you've done that. If we're trying to illustrate what is this investment in, and you can have different opinions about that, the investment is more likely to be in CT scans, for example, with MRIs really being truly the extreme.

Also profit margins at the hospitals having increased substantially. I think maybe a little bit more word about how to interpret that -- and I know you'll be building that into the report -- would be helpful. It's profit margins moving from what to what? If we're moving from a negative 16 percent margin to a plus 2 percent margin, that's a pretty substantial increase. That may not be all bad, pulling them up out of negative and into a low positive, for example. So some of that kind of explicit information might be useful too.

Last point that I'll make about tone. There's a discussion of the proposal to provide fixed payments to

reduce CAHs' current disincentive that you talked about to indigent and Medicaid patients. While there might be some CAHs out there that are closing their doors to those categories of patients, I can tell you I have never heard that. I've never heard CAH CEOs talking about the problem with that, and I've never heard them even alluding to the fact that that's really a budget buster for us and we're not going to go there. So I would say if you put that in as rationale for a new payment methodology we might try to figure out where that's happening, to what extent that's happening, and so on, because we're writing that in as part of the rationale and that just doesn't gibe with what I've seen.

You might also think a little bit about DSH payments then for CAHs as a way to address -- if you redo the formula as MedPAC has suggested and then think about DSH for CAHs as a more direct way of dealing with some of those issues.

That's probably enough on tone. I'll just make a couple of comments on methodology and then I'll let other people talk.

One, I'm wondering, I guess, what we might learn

if our two groups, the converters and the non-converters, were compared on Medicare allowable costs; costs to costs rather than payment to costs, and what might that tell us about the nature of those two groups and what's going on with them. Right now it's a little bit apples to oranges. I understand why you're trying to do that, I think. But there's also an apples to apples comparison that might be informative to look at too.

Secondly, there is a fairly significant difference in the converters and non-converters, I think, on the inpatient revenue side, almost twice as much, about $2.4 million, I think, versus $1.2 million on inpatient, I think. That might also suggest that there are some important differences to look at between those two comparison groups too. I don't know, but if you drill down there a little bit more, if I'm not wrong about that, that might be worth looking at.

On page eight, table two you've got a column there that talks -- this is the table that talks about CAHs benefitting from large increases in outpatient and swing bed revenues. You've got a column there that talks about total Medicare inpatient, outpatient, and swing bed payments after

the CAH conversion. That's where I think you're drawing the $850,000 more that CAHs have received in payments than their comparison hospitals. I'm wondering though if you could also tee up a little bit of rhetoric around the next column which speaks to change, and that difference is $505,000 between the two categories, not $850,000. So what does that tell us, and is it worth explicating that smaller difference as well? Something to think about.

On page 17 there's a discussion of profits and the fact that CAHs receive 101 percent of Medicare allowable costs, a 1 percent profit margin. You might want to put in there maybe, or in some way that's cleaner and more precise than this, what that 1 percent amounts to. We estimate here that there are about 1,055 CAHs and that computes to just under about $3.8 million per CAH, I think, and 1 percent of that then would be about $38,000 each. The $38,000 associated with that 1 percent is probably going to buy you, if you're lucky, a nurse in terms of benefits and wages. So we're not talking big dollars there. That's sort of a real rough cut, but it's to try to help the reader get some sense of magnitude, order of magnitude here in terms of what's actually occurring there I think.

The last comment I'll make -- I've got more pages but I'll -- you're happy now that I'm suggesting I'll just send them to them by e-mail. Just a couple of other -- one more comment or two.

The ER on-call doctor issue gets some play in the text. But I'd say, keep in mind that CAH costs for an on-call doctor are significantly less than if they're paying that physician to be there for 24 hours a day on site, and the cost center is the emergency room, which is typically not a big -- it's not used heavily typically in most CAHs by Medicare beneficiaries. Maybe about 20 to 30 percent. You can verify that. But in some cases, I will tell you, significantly less than that. That's not just where those patients typically tend to come through. So that Medicare utilization is probably pretty low.

What does that mean in terms of real dollars to the Medicare program? Say a CAH pays $250 per night for one of its physicians to take calls 365 days a year? The allowable cost might be just over about $91,000 for that on-call doctor. Thirty percent reimbursement of that is about $27,000. So again we're focusing attention on something, but in terms of total dollars there aren't big dollars. You

raise the issue, but I think we need to give order of magnitude to it as well.

I guess I'll stop there and maybe reserve the right to come back in if it's okay.

MR. HACKBARTH: You've got a lot of important information there, and I know Ray has got a lot of things to say on this as well.

What I'd ask each of you to help us with is ways that the program can be improved and better targeted. I accept the premise which is, as I understand it, that there are certain institutions that are necessary to provide access to people in remote areas. A fear that I have when I look at those maps and the series of red dots spreading across the country and many areas of the country is that the basic purpose is being lost sight of, and ultimately that threatens the program, it doesn't strengthen it. At some point it just loses credibility because it's so detached from its original mission. So if you can help us say, here are ways that we can achieve that mission, which is a critical mission, and refine the rules, better target them, that would be extremely helpful.

DR. WAKEFIELD: If I could just add on that point,

I'd strongly suggest, and actually I mentioned this to Jeff, a few people I think he could also talk with, now that you've got the data to run this by, who might have some ideas besides us. MedPAC staff have accessed panels of individuals before -- not to come and talk to us, but where they've accessed panels of individuals before to get some input and reaction to data. I think that's critically important. I've given you names.

I'd also deal in that mix, Office of Rural Health Policy. They certainly have a couple of people over there who are really expert in this program, and you'd have a different fed agency perspective about potential changes to the program too.

DR. STOWERS: First I'd like to repeat everything that Mary said.

DR. REISCHAUER: But slower.

[Laughter.]

DR. STOWERS: I really will try to cut to the quick here but I've got a few points I think are -- one on the political pressure thing. On this political pressure, I think we've got to be real careful where we go on this, that a town of 2,000 people is going to swing a governor when

they're down the road from 50,000 or 100,000 votes for a particular thing. I think the general consensus here is everybody does not want these hospitals to close, and generally there's very little opposition from neighboring hospitals, and if there is, they don't tend to go down that path. So I think we've got to be real careful because politics is votes, and there's not a lot of votes in a lot of these small communities, so we've got to be real careful on that one.

I have to really add just a tiny bit to this thing on the government push on this thing. We tend to look at them like they're going out and playing the system and doing that kind of thing. But the flex grant is, just so you're aware, literally mandated the state offices of rural health to go out and do consults and offer this program to every single eligible program out there. The consults were paid for by federal dollars. The consults also were mandated that the decision to go PPS or stay PPS or go to cost-based had to also be based on bringing that hospital up to current efficiencies. If there were behind in accounts receivable or other managerial problems, that had to be taken into account before they would get the green light to go on to do

that kind of thing. All of this was mandated, and money from Congress to push the conversion and that kind of thing. So I think that atmosphere, I agree with Mary, needs to come across in this chapter, the concerted effort that came out of HRSA and the Office of Rural Health and all that kind of thing, to do that.

I won't belabor this either, and this was really, I think, a significant thing that we need to change in the chapter, at least look at, and that's this idea of net increase. We've admitted in the chapter that there's not much increase in the inpatient and payments and that kind of thing. But even when we talk the outpatient we tend to talk total dollars that have changed in outpatient here, but I like Glenn's idea because I think it's very true, there's kind of a fixed amount of patients out there and a fixed amount of outpatient work that basically needs to be done. It may be more of a shift of location, where it's being done. As one of your slides showed, there's an increase in laboratory, increase in x-ray that's now accessible to these rural communities. It would be natural that their volume would go up because now people are not having to drive 15, 20, 30 miles to get their x-ray done, or even their CT done.

I'm not personally aware, although there may be one or two in the country that have an MRI like she said, but several have managed to get up to the level of being able to have a CT. So I would expect the outpatient to go up.

It's also attracted a lot of physicians into these critical access hospitals who are more specializes, because now they can afford an outpatient suite to do outpatient, so there's a lot more GI doctors that are traveling out to do these services one day a week or that kind of thing in the rural hospitals.

So I'm not so much worried about how much more money is shifting out into these rural communities. I saw that as a goal of the program as much, as what the total increase in outpatient services has been to the program, because that's what we ought to be looking at here is increased cost to Medicare for doing this.

I agree with the order of magnitude thing here. We've had 1,100 hospitals convert and we talk total dollars, but the cost per hospital here -- this volume is huge, but in the other case we need to look at that.

Another thing that came out in your slides, I think it was page 13, on there where we -- I'll wrap this

up, Glenn -- and I do have some thoughts on what you were talking about. When we talk about the total amount of payments for hospitals, the programs came on because we had literally hundreds of hospitals in the country being threatened to close. I'm not so much worried about the percentage in increase in these hospitals, but now where we stand in comparison to their comparison hospitals. We get down to where there's very little difference now, even though there's been a big percent increase. That was the purpose of the program.

But again, the net cost to the program as we go on in the future is the difference between in the $1.06 million and the $1.038 million, and it's the ongoing cost to have this access available that I think we ought to be looking at, not the increase that's occurred over the implementation of the program. There's like 1,400 in the nation that totally quality and we've already got 1,100 of them, so there's only 300 potentially out there. The vast majority of them have had this consult done by the feds and have been told they're better off to say -- so there needs to be some magnitude in here of how many still potentially would do better with cost reimbursement. I would estimate that that

is a very small number because almost everyone has been through this consult process by this time, and have been told with efficiencies they're better to stay in the PPS.

I can't go without saying that I think this charity reach is really a reach. They're the only hospital in the community. I think the cost reimbursement has allowed them to do more charity care. But to say that because there's the potential out there that they might have a cut -- I think we need a lot more solid data before we would ever -- that they really have stinted on charity care in their communities.

The HUD program, by the way, we have one of the only two hospitals that have been approved and recently constructed under the HUD program, and it's within very close, probably a little too close proximity to a neighboring hospital. The neighboring hospital was in full support and became their sponsor hospital. So we've got to be careful on this HUD statement. There's only been two in the nation that have opened under the HUD program, so I agree with the magnitude thing there, that we need to be careful with that kind of thing.

Glenn, I totally agree with you and with Mary that

we need to look at the system and be careful, and I think probably the one main issue is this distance, that has gone through the governmental process. I would contend that the 35 miles is way too far. I know it was an arbitrary number in the beginning. I practiced with one 17 miles north of me, and the other hospital that we went to every day was almost 40. When you have somebody having a heart attack or an acute anaphylactic reaction or that kind of thing, by the time you load them, transport them and that kind of thing 20 miles can be a very long distance.

My daughter had an acute allergic reaction with near anaphylaxis in Tulsa. Would have been in a small town five years ago. Ended up being transported to a major medical center. Waited 45 minutes in the emergency room. Had to go through extensive recovery from that. I'm only getting around to the thing you're coming to next month and that's going to be talking quality. I can guarantee you in the small hospital, the adrenaline and that kind of thing would have been given immediately, and that the care would have probably been more expedited and better.

The only caution I'm putting there is that the data out there on quality in these hospitals, for what they

do, is somewhat preliminary, but it's showing for what they do it may even be better, and it's probably not a lot volume related in that. And that the centers of excellence type volume is better type principles will not probably apply here. So I'm just giving some thoughts and word of caution on that.

Glenn, I think, again, that probably tightening up the process somewhat on distance and being sure there's consensus from the hospitals around and that kind of thing are going to be a good thing. I've got a lot of other things too but I think we've just got to be real careful with the tone of this chapter.

DR. WOLTER: Just a little background -- maybe it's disclosure. My organization actually manages seven critical access hospitals, six of them are in southern Montana and one in northern Wyoming, and in a couple of all those communities we also employ physicians. In Montana, which as the chapter said, pioneered the program, of I think about 53 hospitals in the state, 41 are now a critical access hospital. I think only three of them would be affected by tightening up the 15-mile rule, although they would strongly argue their case, I would think.

A couple comments. I would agree, I did think the tone was a bit overly negative, and the charity care, I can just tell you, is certainly not in play in anything I've ever observed. In fact these are not-for-profit community-governed organizations. There's a huge commitment to that in a state that has 21 percent of the population uninsured. That one is really a stretch in terms of what it might be implying.

In terms of the consulting dollars, my organization would consult hundreds of thousands of dollars more annually than the critical access hospitals are able to. They really struggle. They don't have the infrastructure in terms of resources to do facility planning, human resources, billing, and accounting, consulting. I think that's really one of the issues that they face.

As far as the big increase in outpatient payment, our analysis of that would be, that was where the problem was. Because under PPS, critical access hospitals more or less made it on the inpatient side, at least those that I have experience with. But where they really struggled was in the outpatient arena. So the cost plus 1 percent has

filled a gap that was really the problem that I think existed. So I would take that information and make sure it's in an appropriate context.

As far as the new service development and services dropped, of our seven hospitals, four of them often OB and two have dropped it. They dropped it having nothing to do with critical access versus PPH, but they would do 30, 35 deliveries a year, very low volume, and anesthesia costs be $200,000, $250,000 a year to try to cover that low volume, and it just wasn't sustainable to stay in that business line, especially with some of the advances. So those were very difficult decisions, I might add, and created a lot of community consternation, but those decisions were made.

As far as moving into other services, I think there are some similar impulses in these communities that we see in large urban communities. For example, imaging. Traditionally, the DRGs coming through a small rural facility are those DRGs where there is either very minimal profit or there's a negative. As we have seen in the DRG system, there's the universe where there's a margin and there's the universe where there isn't, and they live in the universe where there's not cardiac surgery, orthopedics, and

neurosurgery. So it would be natural for them to look at services that might make sense in their community where there would be profit. Certainly, imaging is one of those, and we have had a couple of our communities and move into CT scanning.

There's a clinical reason for that too. With the advent of pacts, when there's trauma, having a CT reviewed seconds later by a radiologist in a larger community 50 miles away can make a huge difference to patient outcome. So I think there's some common sense to some of the trends we're seeing. It isn't all about finances, although certainly some of it would be.

On swing beds, it would be fair, I think, for us to acknowledge that one of the underlying issues on that thinking is SNF payment. Hospital-based SNF payment, especially in low volume critical access SNFs, it's a losing proposition. Although we are quick to throw out hospital accounting practices as the reason, I can tell you that's not it. It is that you lose money on the SNF side, so the swing bed is at least a place to try to get yourself back to something that's a little bit more reasonable. So we should acknowledge, I think, all sides to this conversation.

As far as return on equity as a possibility, I don't know how that would work. In our experience, we have mostly low debt facilities now, but they are not very high equity facilities because they are 40 and 50-years-old. They haven't had the dollars to invest in new infrastructure. They in many cases are grandfathered around many code violations. They don't have the dollars to put new technology and information systems in place. And certainly even the cost plus 1 percent isn't correcting that. Many of the facilities haven't even been able to fund depreciation in recent years.

With the experience Montana has had, and of course we were early on in this, we've gone from -- this would be all the critical access hospitals across the state -- from the group averaging net negative margins to 2003 there was a positive 0.19 percent margin. I think that's a total margin or an all-payer margin, rather, not just a Medicare margin.

Then on cost control, I see a lot of incentives in our facilities to manage their costs aggressively because they're still so at the margin in terms of their overall bottom line. It's not like they are seeing opportunities to really pad anything. So at least I see a lot of cost

control activities.

Glenn, I would certainly agree with your thesis, we need to be very careful that what transpires doesn't endanger the original mission of this, but I do want to be careful that we have the right tone and information about where this program really, I think, is succeeding. So those would be my comments.

MR. HACKBARTH: We are well over time. Any urgent final comments from anyone?

DR. SCANLON: Normally, I think I would want to look at this in terms of these hospitals compared to some group and see how they're faring, and I think the problem is that we don't really have a very good comparison. Given that distance is going to be, I think, a critical part of our thinking, it would be helpful if we could do some of these tabulations by the distance to the other hospital, to know what group we might be affecting by looking at a recommendation with respect to distance.

MS. BURKE: Just one cautionary note, and it's one that Mary raised. I will take some blame here having been involved in some of this originally. Certainly, in the swing bed creation and in some of the issues of treatment

for rural hospitals.

A mile is not a mile, and I would only raise the cautionary note that we be careful about using absolutes. It is certainly something that ought to be considered. It certainly does raise some appropriate questions. I'm just like Glenn, I worry about the behavior of some putting at risk what was a fundamental commitment that I think still makes sense. But I think that we ought to be very careful, and the Office of Rural Health is a place where we can go to understand in fact what the reality is here. In mountain states and states with horrific weather patterns, there are real issues that need to be considered that differ depending on the time of the year and the location.

I would agree with you that is an easy way to start that analysis but I would just caution that we need to look very carefully at what that mile actually means in all cases.

DR. STOWERS: A final word. I would just like my final word to be a question, and that I think the chapter needs to make very clear. That is, if I have two critical access hospitals that are 14 miles apart and I close one of them and now all of the people travel to other communities

30, 40 miles away, how have I saved Medicare or CMS any money by closing that hospital?

So we're worried about numbers here and even distances, but if two hospitals are getting along and they're 12 miles apart, and we're talking saving costs to CMS here, how have I reduced cost to CMS by having those people from that community lose their hospital and economic base and all of that and go to town B? Where's the savings? I think that's where I'm a little confused, where our objectives are here. I'm just throwing that out. And what would the net savings be of closing that hospital to CMS?

DR. REISCHAUER: I can give you an answer to that, although I'm very sympathetic to the points that have been made. The answer is, some of those people would go to a PPS hospital. But it's a fraction of 100 percent.

MR. HACKBARTH: Thank you, Jeff.

Our last presentation is on improving outpatient dialysis payment policy.

Can I see a show of hands among commissioners of people who urgently need to leave right at the end of the meeting, or whether we can maybe stay an additional 10 minutes or so? The scheduled end of the meeting is what I'm

referring to. The scheduled end of the meeting is 12:15. If I could get people to stay until 12:30, that would be helpful. What I would do is shoot to have us out of here no later than 12:30.

MS. RAY: I will try to be brief. This session on outpatient dialysis payment policy is a follow up on issues that we raised about the MMA and the new regulations in the December and January meeting.

You've seen this table before. This shows how outpatient dialysis services are being paid in 2005. We're going to focus on the bottom row, how Medicare is separately paying for injectable drugs, and then we will focus in on how Medicare is paying for the composite rate services, including the add-on adjustment.

First, let's talk about issues with the changes to drug payment policies. The MMA mandated that providers be paid acquisition cost. As implemented, there are now multiple ways to pay for separately billable drugs. Average acquisition payment is used to pay for most separately billable dialysis drugs. AAP is derived from average acquisition cost data gathered by the IG last year. And average acquisition payment is used to pay for the top 10

drugs in freestanding facilities -- that includes EPO -- and for EPO in hospital-based facilities.

However, average acquisition payment is not the only way Medicare pays for drugs. For drugs other than the top 10 in freestanding facilities, Medicare pays ASP plus 6 percent. And for drugs other than erythropoietin in hospital-based facilities Medicare pays reasonable cost. So this means that payment for drugs, other than erythropoietin, differs between freestanding and hospital-based facilities.

There may also be concern about the long term sustainability of the average acquisition payment data. Like I said, the IG collected this data. This data represents 2003 acquisition cost for the top 10 dialysis drugs. The IG is not mandated to go back and update this data over time. So what that means is that over time the average acquisition payment may not accurately reflect acquisition costs if negotiating strategies between providers and manufacturers change.

By contrast, ASP might be a better source of data in contrast to average acquisition payment data. It is updated by the agency quarterly. It contains information on

all drugs, and it would better reflect providers' acquisition cost in the future if negotiating practices change between manufacturers and providers. It's also consistent with how Medicare pays other Part B providers. And it would certainly reduce the complexity in paying for dialysis drugs because it would be just one way to pay for the drugs; one payment rate.

This leads to the issue then, at what level should ASP be set? In CMS's proposed Part B reg they initially proposed paying for dialysis drugs and ASP minus 3 percent. They arrived at ASP minus 3 percent based on the data from the IG report that found that the four national dialysis chains, which represented roughly 70 percent of all freestanding facilities, paid ASP minus 6, and the all other facilities, which represent 30 percent of facilities, pay 4 percent over ASP.

In our comment letter to the agency we raised the concern that not all providers might be able to purchase drugs at ASP minus 3 percent and suggested that CMS consider setting the payment rate at or above ASP to maintain beneficiaries' access to care. In the final rule, as the first table showed, the agency retreated and used the IG

acquisition cost data to set payment for the top 10 dialysis drugs in freestanding and EPO in hospital-based. And they took the 2003 data and they updated it to 2005 payments rates using the producer price index.

This leads us to our first draft recommendation, that CMS should eliminate differences in paying for separately billable dialysis drugs between hospital-based and freestanding facilities, and use average sales price data to base payment for all separately billable dialysis drugs.

This recommendation is consistent with MedPAC policy that providers' decisions about site of care should be on based on clinical, not functional, status.

As you can see from the recommendation, we didn't specify a particular level of ASP however. We conducted an impact analysis to better understand how aggregate payments might change if you use different levels of ASP. In our impact analysis we tried our best to replicate CMS's approach, and I'd be happy to answer any questions you might have about the methods we used.

One point I do want to raise here, however, is that our impact analysis includes all drugs provided by

freestanding facilities and EPO by hospitals. Our impact analysis that I'm presenting today does not include non-EPO drugs provided by hospitals. To replicate CMS's impact analysis it's necessary to use the payment rate per drug per unit data, and that data is available for the top 10 drugs. For non-EPO hospital-based we had to turn to the claims data to try to derive payment per unit, and we're still doing this, and we will report back to you in April. But right now we are looking at the accuracy of that data to derive payment per unit.

So here you see the payment per unit for the top three drugs. We focused on ASP plus two and ASP plus three for this month because we thought these were both best approximations of the average acquisition payment data, the payment rate already in place, and that would stick to the spirit of the law in paying average acquisition cost.

So you see here the impact and the change of payment per unit for dialysis drugs. We're comparing this to pre-MMA payments. So overall, you'll see that under the current policy of paying average acquisition payment, payment for drugs went down 13 percent. Again, this is all drugs provided by freestanding and EPO by hospital-based.

You'll see for ASP plus two and ASP plus 3 percent, that difference is pretty close to the 13 percent.

Here is the aggregate change in payments. Again, this data is preliminary and we'll come back to you next month with more data analysis. I think what I want to point out here is, you'll see on the bottom row that the payment for drugs will vary depending on how you pay for them. But the story doesn't end here. Remember, I told you we have this add-on adjustment, so the difference in the pre versus post-MMA payments is shifted to the add-on adjustment that's associated with the composite rate. So we haven't lost any dollars here. These are all designed to be budget neutral and I will show you that in a couple slides from now.

Let's move on to the composite rate. The MMA did not --

DR. MILLER: Just to be clear, so in other words, even though you see negative signs on these drugs, these differences get built into the composite right side, and we're about to move into that discussion. Is that fair?

MS. RAY: That's correct. Thank you.

Quickly moving on to the composite rate then. The MMA did not change the difference in the base payment rate

between hospital-based and freestanding facilities. The base rate differs. There is a four-dollar difference that was mandated when the composite rate was initially put in place in 1981.

We also have concerns about the design of the add-on adjustment. It's complex. If the intent is for the add-on to address the cross-subsidy between the profits for separately billable drugs and the composite rate, then the two payment rates should be combined. In reality, both the composite rate and the add-on are added together before payment will be case mix adjusted beginning on April 1st of this year.

So this leads to our second draft recommendation, that the Congress should direct the Secretary to eliminate differences in paying for composite rate services between hospital-based and freestanding facilities, and that the composite rate and the add-on adjustment be combined.

This recommendation, again, is consistent with the MedPAC principle of payment not varying across different sites of care.

I just want to point out here that although this recommendation combines the payment, we don't want to lose

sight that we ultimately want to figure out what services should be in the bundle, particularly the broader bundle, and that's addressed by our third recommendation that's coming up.

So if you were just to look at the composite rate by eliminating the four-dollar difference and spreading that four-dollar difference, the dollars associated with those treatments across all treatments, just the composite rate by itself would change by 0.4 percent for freestanding and decline by 2.7 percent for hospital-based.

I want to raise some concerns here about eliminating the four-dollar difference that have been raised by some stakeholders. They contend that hospitals are fallback facilities, and that hospitals treat patients who were more complex and might be more disruptive than freestanding facilities. Some stakeholders also contend that hospitals provide higher staffing of RN's, social workers, and dietitians, than freestanding facilities.

Just to briefly address those points, and I think commissioners could discuss them if they'd like. First is concerning that hospitals are fallback facilities. Payment, beginning in 2005 in April is now adjusted for case mix, and

I think that this case-mix adjustment will only get better over time, particularly as we expand the bundle and case mix adjust for a broader bundle.

Concerning whether or not hospitals provide more care, I think here, again, Medicare needs to think carefully about what services need to be included in the bundle, and that those services are available for patients in both freestanding and hospital-based facilities.

So then if you were to take the recommendation to the next step and you would combine the composite rate and the add-on adjustment and you would eliminate the four-dollar difference you see the three different payment level. Again, the payment levels differ depending upon how you pay for a drug because of that add-on adjustment. The add-on adjustment, one more time, is the excess dollars that were associated with the drug margin. So the more you pay for drugs, the smaller the add-on adjustment. That's why under this scenario, the ASP plus 3 percent is slightly lower than the ASP plus 2 percent payment rate.

So here we are back putting the change in the drug payment policy, combining the add-on adjustment and the composite rate, and eliminating the four-dollar difference.

Again, you will see that payment slightly differ depending upon how you pay for the drugs, but that in total this is done budget neutral so total payments don't differ.

Now I'd like to just take you briefly towards modernizing the payment system. The MMA does not bundle the composite rate, injectable drugs, and other services commonly provided to patients. The separate payment, as we pointed out many times, does not give the right incentive for the efficient use of services. The MMA, however, does mandate a three-year demonstration on a broader payment bundle, and that this demo is slated to begin next year.

So our draft recommendation reiterates our recommendation that we made in 2001, that Medicare should broaden the payment bundle. And I think some thought needs to be given here as to whether it should reflect dialysis care or the care of the dialysis patient. That payment should account for factors that affect efficient providers' cost, including case mix, dialysis method, and dialysis dose. It is very important for Medicare to monitor and report on the quality of care. And for holding providers accountable for the quality of care, payment should be linked to quality.

Next month I'm hoping to bring you back some additional information about purchasing strategies of dialysis facilities, looking at the impact of using more current wage indices, and different ways to case mix adjust a broader payment bundle.

MR. HACKBARTH: Nancy, could you talk a bit more about the relative impact of the series of changes on freestanding versus hospital-based? There's some pluses and minuses in terms of eliminating the four-dollar differential on the other hand, but then on the other hand spreading the add-on for the drug overpayments across both as opposed to just the freestanding from whence it came. How does all of this net out in terms of the relative impact on the two types of facilities? Did that come out clearly? Do you know what I'm asking?

MS. RAY: Right. I don't have those numbers here in a table for you. I can get those for you in April. It does change it slightly. But again, because we picked the drug payment levels that closely approximated average acquisition payment, what I can say is the impact of going from pre-MMA to the current law, that that impact is pretty similar if you go from pre-MMA to either ASP plus two or ASP

plus 3.

DR. MILLER: But if you took that in isolation, I think part of the reason -- to try to talk about this comprehensively, the thing not to miss in this is -- and Nancy, make sure I don't miss anything here -- we're fundamentally rejecting the MMA's approach to this add-on, where you keep this piece that continues to look at drugs, estimate the profit, and pour it into the composite rate. So we're fundamentally saying, for a lot of reasons that we went through in previous meetings, very complicated, probably not a great policy, et cetera, so step one.

Step two, at the same time we're messing around with how to pay the drugs. Wrong word. We're saying rationalizing -- a better word -- rationalizing how we pay for drugs across the three categories, which also, depending on the distribution of drugs in the different -- will have an effect, and also affects what we end up putting in the composite rate for our one-time fix, if you will.

The third thing that's gone on that also changes the distribution is we're taking the four dollars from the hospital-based and taking that out and saying that should be equal, which will send money in the other direction, as it

were.

Then finally, a little piece that we don't have, if I understand all of this, is the non-EPO drugs in the hospital. We are definitely trolling through the data trying to figure out how to get unit estimates to estimate that. So giving you a net-net by the types of facilities is still little bit escaping. But I think your last point is pretty dominant here. To the extent that the ASP plus two, plus three is close to acquisition cost, in isolation, that effect remains the same, and then the offsetting effects of the four dollars moves the money in the other direction from hospital-based to freestanding.

MR. HACKBARTH: Just to be clear, I think moving towards a single payment system, regardless of the two types, I think is a very important goal, but I think we need to understand the impact as best we can on the different types.

MS. BURKE: Nancy, in anticipating a more detailed discussion of this in April, following on Glenn's point, there are a couple of things that I'm not sure I fully understand and would appreciate understanding as we go forward. One is the fundamental move from the acquisition

price to the sales price and why. What is it inherently about the acquisition price that makes us -- given that they are so close, what is it that would have us go from one to the other? And does that create any strange incentives on the sales price where this will suddenly encourage certain kind of behaviors on the pharmaceutical side? I just want to make sure I fully understand what the impact is of moving from one to the other.

The second question that I would appreciate understanding as we go into this is the issue around the removal of the difference in payment between the hospital-based and the freestanding. We, as I recall -- and I don't recall the details of it -- have looked at the differences in quality indicators as we've gone forward in terms of dialysis patients, and your point that there's an argument made that on average there has been a higher rate of nurses, other staffing on the hospital side, I just want to have us come back to and again relook at what is it that that information told us? What do we know about whether there are any differences in quality indicators between hospital-based and freestanding?

To what extent any of that, if there is a

difference, and that's what I can't frankly recall from our earlier discussion -- if there is a difference, to what extent can we in fact attribute that to a higher ratio of staffing, things that at least historically was suggest that there is a direct impact? If you have more nursing hours there to be a higher quality result. What do we know particularly about this issue, and how would we apply that knowledge going forward if we're about to get rid of that difference?

MS. RAY: Let me just clarify. Some stakeholders contend that hospital-based provide more RN's. I have not validated that.

MS. BURKE: I understand. That's my question is what do we know from the data, whether that's true or not.

MS. RAY: I think to answer your second question, CMS's clinical performance measures, to the best of my knowledge, don't differentiate between freestanding at hospital-based facilities, and that is the information that we have presented in the past about monitoring the quality of dialysis care.

MS. BURKE: So we have generic, not specific?

MS. RAY: That's correct, because that is based on

a sample of patients. I will see what is out there that looks at hospital-based and freestanding and will report back to you in April.

MS. BURKE: That would be great. Thanks. And I would also appreciate understanding more fully what the difference is moving from acquisition price to sales price.

MS. RAY: Sure. I think the issue with the average acquisition payment data is that the IG collected it in 2003, so it represents the negotiating patterns as of 2003, so I would presume it's pretty accurate even now in 2005. The concern here is as you go out over time -- the IG doesn't have to go out and collect it again for these top 10 drugs, so what probably will happen is, if the Secretary continues to use it, I would guess that the Secretary would probably just keep increasing it by the producer price index or some other update proxy. So if negotiating patterns do change then that 2004 data won't reflect --

MS. BURKE: Let me tell you my fairly simplistic concern, and there may be no basis for this concern, is when I hear sales price I hear the opportunity for sales, the price that is essentially charged, to increase, if there's every incentive to do so. So I'm trying to understand -- I

understand your point about some data is going to be updated and some data is not. What I'm trying to anticipate is to what extent is there going to be an impact in either direction for a price increase because we will pay it? And whether this leads towards a behavior on the part of the negotiation where there is suddenly no inhibition on -- the price was 10, now it's going to be 20, because in fact what Medicare is saying is they're going to pay for the sales price.

I just want to understand whether there's an incentive in either direction, depending non the term that we use or the data that we use, that will suddenly provide an opportunity for price hikes solely as a result of the way we calculate what those numbers are going to be, if there's no inhibition. That's what I want to make sure I understand. I understand your desire for absolutely more current data. That goes without a doubt. I just want to understand what the difference is in this impact.

DR. MILLER: Joan, you may need to help us out here. Your fundamental concern, most attached very much to the average wholesale price in which that was a sticker place, nobody paid it. What the average sales is supposed

to represent -- and there is where I want Joan here -- is the transaction price net of discounts.

DR. SOKOLOVSKY: Let me start by saying your concern about Medicare paying the price, whatever the price might be, is well taken, but well taken on both sides. Average sale price is not the price. It is the data that manufacturers must report to CMS every quarter on their returns for each drug that they sell, net of discounts.

DR. MILLER: So it's supposed to be a transaction price, and it's supposed to be kind of like an acquisition cost, but the source of the data and the frequency of the data is what drives us more in --

MS. BURKE: What is the difference? Where we get it or who gives it to us?

DR. MILLER: That is certainly --

MR. HACKBARTH: So the sales price comes from the manufacturer. The acquisition cost comes for the provider of the services; is that right?

MS. RAY: That's correct.

MR. HACKBARTH: So what I hear being said, and correct me if I'm wrong, is that there's an existing mechanism for collecting the data from the manufacturer.

Right now there's just an every once in awhile survey to be collected from the provider. So if we were to use -- they seem logically to produce similar results, and in one case we have got an easy mechanism and the other case it's a harder mechanism.

MS. BURKE: So the assumption is -- I mean, we collect information from hospitals on a variety of things all the time, so if we wanted to we could say, we want your acquisition price. But our presumption is because there's so little difference between them that we can assume going forward that having done one you'll get the other; that there is no difference?

DR. SOKOLOVSKY: There are limitations in both sets of data. They should return very similar numbers. The limitations are different for each set of data, but I think the most important thing is that there is a mechanism in place to regularly, each quarter, collect data.

DR. REISCHAUER: But the real issue is that under both there is an incentive of the sort that Sheila is referring to, and the question is what we do about that. It would be one thing if this were a drug that was widely used by other people, but they're pretty specialized and not sold

in other settings.

MS. DePARLE: You mean an incentive to not be truthful about the transaction.

DR. REISCHAUER: No, but why should the center care? You double the price, I get 3 percent on top of whatever double the price is, so I'm indifferent.

MS. DePARLE: That's why we've recommended bundling.

DR. SOKOLOVSKY: I think part of the incentive driving ASP -- to go to ASP was the very fact that these are not drugs with huge markets, and that if the price went way beyond what Medicare will pay, the providers would have reason to balk. We're paying based on the previous quarter's ASP, so if they buy it that quarter --

MR. HACKBARTH: You're saying the lag effect holds down --

DR. REISCHAUER: As long as it doesn't rise by 3 percent, or whatever the margin is, over the course of the period.

DR. SOKOLOVSKY: Nancy can tell you about dialysis facilities, but I can certainly tell you that in the oncology market the providers are very worried and concerned

about when a drug goes -- when they can't get a drug for below that ASP plus six -- and it happens upon occasion -- that is a problem for them. They don't say, we'll make it up next quarter.

MS. BURKE: I can appreciate that and I think that's exactly right, but I'm not sure it's exactly an analogous situation because in this case we're paying a composite rate, plus we're paying for the drug plus 3 percent. The oncology guys are in a slightly different scenario, where I suspect they are a little more price sensitive. This is a more captured environment where you're essentially paying for everything that surrounds it, and the composite presumably pays for whatever the costs are that are incurred in providing the service. The oncology guys I think are in a slightly different scenario, but I certainly understand your point.

But it is what it is. We're going to pay the price plus 3 percent.

MR. HACKBARTH: Let me ask this. So we're paying a price based on ASP, which is an average. If an individual provider of dialysis services actually acquires it for less than that, they benefit directly; is that right?

MS. RAY: Even now under the average acquisition payment that is the case, yes.

MR. HACKBARTH: So there is a PPS-like incentive to negotiate hard, try to acquire for less, which then would flow into the calculation of the average. So it's not a straight cost reimbursement system. There is a reason to bargain.

MS. BURKE: Good to know. I guess what would be helpful to understand is what does that -- in reality, do we know what those boundaries look like? If it is an average -- I didn't understand that essentially what you're getting is you're getting an average. You're getting a reported amount from a pharmaceutical company, correct, on what their average price?

DR. SOKOLOVSKY: Weighted average.

MS. BURKE: Do we know what those -- this is a fairly select group of drugs from a fairly select group of manufacturers. How big are those margins when they're talking to a fairly limited number of dialysis? Are there huge variations in how much they negotiate depending on volume?

MS. RAY: We're going to try to report back to you

in April about the purchasing strategies by different types of facilities.

MS. BURKE: Because it's not like they've got a lot of other choices.

MS. RAY: But I want to say what the IG found. Again, I'll repeat this, is that the average acquisition cost of the four national chains was ASP minus 6 percent. For a sample representing all other freestanding facilities they, on average, paid ASP plus 4 percent. So the payment rates that are in effect in 2005 is the weighted average acquisition payment, weighting it basically 70/30.

MR. HACKBARTH: We have time for maybe one more quick --

MS. DePARLE: You may have answered this in the exchange you had with Glenn and Mark at the beginning, but on the add-on payments does our recommendation contemplate going back to the policy that CMS articulated last summer and reconfiguring it so that -- remember that the hospitals which get paid on a cost basis for those drugs also got the add-on spread to them? So would we contemplate fixing that are not? I wasn't clear.

DR. MILLER: Not dollar for dollar. We're trying

to look across a set of payments here, the $4, how we're paying on drugs, how we're making those changes. We'll come back to you with a net effect. But we're not trying to -- and if this is an objective we need to talk about it. We're not trying to take all of those dollars and put them back into the freestanding environment.

MS. DePARLE: Others may not agree but when you presented last year the proposed regulations about the MMA, that was something I thought -- and we discussed it in here. I don't know how people feel, but I didn't think that was appropriate that they spread it across both the hospital facilities and the freestanding.

MR. HACKBARTH: There is a trade-off, isn't there? If you value a single rate without regard to type of provider I think you, by definition, have to spread it. If you say that we're going to keep all these dollars on the freestanding side you've basically said we're never going to a single rate. I think that's the trade-off.

MS. DePARLE: We can talk about this later. I don't see why you couldn't go from where they were last summer, where CMS was, only give it to the facilities from whom it came, the add-on, and then take the next step

towards a level playing field without going back there.

MR. HACKBARTH: I guess the other logical option is to level up and say, we're going to allow the freestanding to keep these additional dollars and to the extent that the hospital-based would end up with a lower rate we will add an increment on to theirs so we get to a level playing field. But if you have a budget neutrality constraint, the only way to get to a level playing field is to spread the add-on dollars across both types.

As Mark points out, in other cases there are pluses and minuses. That's why I asked earlier it would be good to know what the net impact is.

MS. DePARLE: I think we'll see that. I need to think about this some more but I at least felt that that policy last summer wasn't fair, and I hear you about where we're trying to get to.

On broadening the payment bundle, are we saying -- I know this was the recommendation in 2001, but are we saying that we think CMS should broaden the bundle in the demo, or that -- are we just reiterating what we said before?

MS. RAY: We are reiterating what we said before.

And I think this would take congressional action, not just -- I don't think CMS would have the authority to do this by themselves, but just reiterating that, for it to be done.

MS. DePARLE: Although one thing you would assume we might learn from the demo is whether this works or not and what the bundle should be and should not be. At least on those lines one thing that you talked about last year at some point that I thought was very compelling was about some of the things that aren't covered now, or maybe not as much as we think they should be, such as the nutritional products. I don't know what you're thinking of as far as how it should be broadened, but I thought some of those things you said were compelling and that we should, if we're going to do this other report in June that we should reiterate some of them.

Also the vascular access point. I don't know the extent to which that is encouraged in the way that we pay right now, but it should be, I think we all agreed, so I would like to see that in there as well.

DR. MILLER: It isn't encouraged, and I think the contemplation here when we say this again is that we are saying all those things again. I think probably the one

pause -- it's not that we're against the demonstration at all. I think there's some sense of a need to move faster on this; is that --

MS. RAY: Yes, I think that's it. If it gets into place and going in 2006 it goes for three years, but then it has to be evaluated and so forth. I think like other payment systems, this one I think might be ready to just have the payment bundle broadened. I think that there needs to be a lot of careful thought about what services go into a broader bundle. Again, I think, is it just dialysis services or is it services to treat a dialysis patient? That would get into the nutritional care which is related to dialysis, as well as vascular access, as well as perhaps some care related to diabetes. Cardiac reasons is the biggest cause of death among dialysis patients, and can we think about the broader bundle and perhaps ways to include other services that a dialysis patient needs into it? That would potentially have the long range implication of improving quality.

DR. NELSON: I was just going to say, next month if you could dilate a little more on the case-mix adjustment that would help us understand better the rationale for a

broader bundle and also for standardizing payments across sites.

MR. HACKBARTH: Thanks.

We will have a brief public comment period. You all heard my commitment to the commissioners so please make your comments very brief. Thanks.

MS. SMITH: I will make them brief. I just wanted to make one comment. I'm Kathleen Smith from Fresenius Medical Care and I can talk as fast as Dr. Wakefield so I'll be quick and brief.

I just wanted to address the question of impact that you asked, Glenn. I'm not clear exactly whether you're talking about the going forward impact or not, but the starting point impact I think would be the impact that the final rule had on payment for both provider settings. In the final rule, the impact on freestanding providers was a negative 0.4 percent, and the impact on hospital-based providers was positive 6.6 percent, so we're starting from that.

Also, when you talk about eliminating the four-dollar differential in the hospital-based, hospital-based outpatient dialysis treatments are apparently 15 percent of

the total treatments done each year, so you're taking $4 from 15 percent and talking about spreading that out over the other 85 percent, so that certainly dilutes the impact in that shift.

The other comment is, what's a little bit confusing here is, because the legislation went part way to a broader bundle, not quite but this intermediate stage, which has called a great deal of confusion, such that we have the composite rate and add-on payment for the previous AWP margin protection that was intended for the freestanding, but we also have a separate stream of revenue from the separately billables going forward still. So we're talking about both the payment for the drugs going forward as well as what's in that add-back piece. I just wanted to say that it seemed we were talking sometimes about one and sometimes about the other here this afternoon.

Thank you very much. Safe trip home, everyone.

MR. MAY: Thanks. Don May from the American Hospital Association. Just two quick comments. First on the ESRD issue.

We do believe there are differences between hospital-based ESRD services and the freestanding services,

not only in the patients they're seeing but also in where they're located. I was just on the phone the other day with a hospital in Camden, New Jersey who talked about the case mix in his facility, the comorbid conditions of the patients the come in there, and that there aren't any freestanding facilities nearby to take them.

As you weight the options of combining a composite rate and getting rid of the differential, we've historically been in favor of larger bundles. I think though the case-mix tool needs to be -- we need to be thoughtful of the case-mix tool. The case-mix tool that was put in place for RUGs is woefully inadequate, and look how many years -- that was put in place in 1998. Look how many years we've gone without refinement of that. So I think before we start to tinker with the differential -- we know there are cost differences in those patients -- we need to think about how quickly that can be fixed if that case-mix tool isn't where it needs to be.

The second issue around CAH hospitals. Just want to reiterate the comments we heard today from Mary and Nick and Ray. I think they really made some good points. I think the key thing I learned listening to the presentation

was how important the CAH program is to these rural facilities, and really had the PPS systems, both for inpatient and outpatient and actually also for SNF, have really failed small rural facilities and isn't working. It really shows the need for a program that protects access in rural America. I think that this program is succeeding in what it was meant to do and it's very important, and just encourage you to remember that as you develop the report and finalize that.

Thank you.

MR. HACKBARTH: Thank you all. See you next month.

[Whereupon, at 12:32 p.m., the meeting was adjourned.]