MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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COMMISSIONERS PRESENT:

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1	P R O C E E D I N G S
2	MR. HACKBARTH: We have a guest Dr. Kramer,
3	welcome again for our first session today, which is on
4	quality in skilled nursing facilities.
5	Carol, do you want to do the lead in?
6	MS. CARTER: Sure.
7	Most of you know Dr. Kramer. He is the head of
8	the Division of Health Care Policy and Research at the
9	University of Colorado at Denver and Health Sciences Center.
10	He is also the Peter Shaughnessy Endowed Chair in the Health
11	Care Policy and Research in the Department of Medicine.
12	Dr. Kramer has authored more than 90 articles and
13	major policy reports and his researched focuses on the
14	quality of care and outcomes for critically ill older
15	persons.
16	We are delighted that he has worked with us on
17	this topic.
18	DR. KRAMER: Thanks. Well, I'm very pleased to be
19	here again.
20	As you recall, it was just September that I was
21	here before. And in that September presentation, I reported
22	an increase in rehospitalization rates in skilled nursing

facilities and a decline in 30-day community discharge rates among skilled nursing facilities. And although we answered a number of questions, like any good researcher I made sure there were many unanswered questions so that there would be continued work. And so since that time, I've been the recipient of continued funding to explore these issues much further.

8 I think there's still very much more to learn from 9 where we are.

10 So the basic purpose of the study then is to 11 understand these temporal changes in community discharge and 12 rehospitalization, and in doing this really to understand 13 the factors that are associated with these changes and also 14 just these rates of community discharge and

15 rehospitalization.

So the background, very quickly, I used this slide before. There's 15,000 skilled nursing facilities, 2.5 million admissions per year. The way quality is reported on these post-acute skilled nursing facility patients is three QMs, one called delirium, one pain, one pressure ulcers. We'll talk about them today.

22 They depend on the 14-day Minimum Data Set

information. One of my ongoing objections to it is by the time you get to 14 days in SNFs, half the people are gone. And the half that are gone is not just a random disappearance. It's actually highly selected by what happens to those people that leave your facility.

6 MedPAC has raised concerns in the past on 7 validity, coding, risk adjustment, and some of those 8 concerns, we'll talk about some today.

So we really looked at two alternative measures 9 10 based on claims data and MDS. In is rehospitalizations for 11 potentially avoidable causes. A key issue, given that skilled nursing facilities have very important work after 12 13 hospital discharge to try to keep people stable. And the other one is discharge to community. Also critical because 14 15 78 percent of skilled nursing facility admissions in the RUG system get rehab. So if we're not looking at rehab 16 17 outcomes, and you can see none of those MDS quality measures 18 have anything to do with rehab, we're not looking at the major thing that is going on in skilled nursing facilities. 19

The previous findings were that risk-adjusted measures for community discharge and rehospitalization are reliable in facilities with 25 admissions. That only

1 excludes 10 percent of facilities and less than 1 percent of 2 the MDS stays.

So in contrast to how many stays get excluded -where 50 percent get excluded on the MDS quality measures that are being publicly reported as we speak -- in this case you lose 1 percent of stays. You don't lose very much with these measures because they don't rely on 14-day MDS data.

8 We also found that between 2000 and 2004 length of 9 stay increased for patients discharged to community; i.e. 10 there was a lower rate of 30-day community discharge. There 11 actually wasn't much of a change in 100-day community 12 discharge. So it really means that the length of stay 13 increased.

14 We also found a pretty big increase in risk-15 adjusted rehospitalization.

16 So we want to determine the resident, facility, 17 and community factors associated with these rates and then 18 also the extent to which those factors explain the changes 19 that occur over time.

The sample: we have all non-HMO Medicare SNF stays between 2000 and 2004. That's about 13,000 facilities per year that have 25 or more stays. 1 We used OSCAR-reported staffing levels that were edited to look at staffing. Now those of you who have seen 2 3 any of my work know that I'm not a big fan of OSCAR data. 4 In fact, in every study we're working on now, we're pushing 5 payroll data as the source for staffing data, with a good 6 deal of success, in fact. Payroll data are accessible and 7 potentially usable for reporting staffing levels. In other 8 work we've done, we've used Medicaid cost report staffing 9 data.

10 So frankly, when we were looking at staffing 11 levels, I was thinking there was going to be so much noise 12 in the channel here that the question is are we really going 13 to be able to see the signal? But there are editing rules 14 for it and you'll see we actually could see a signal that 15 came in pretty loud and clear, even using OSCAR data. So it 16 must be a pretty robust effect.

We also used the Area Resource File for community characteristics. We got into number of hospital beds per capita, managed care penetration, regional issues. So we have a great deal of information there.

21 And we used the Post-Acute Quality Measures. 22 Just to measure definition so we're all on the

1 same page, a community discharge, as we defined it, is a 2 discharge directly to home, assisted living, or some other 3 setting that is not a nursing home, not a hospital occurring 4 in 30 days. We focused on the 30-day one because that's 5 where the changes occurred over time.

Rehospitalization are people who are transferred
directly to the hospital within 100 days. We have these
five conditions here that account for about two-thirds of
the rehospitalizations.

10 Recognize that according to a number of chart 11 review studies, people have claimed that about 50 percent of hospitalizations from nursing homes are, in fact, 12 potentially avoidable. And they are often the ones that are 13 for these causes: infections, particularly respiratory and 14 15 urinary tract infection; sepsis; electrolyte imbalance, which really reflects things like dehydration; congestive 16 17 heart failure, the classic frequent-flier, people that keep 18 coming back to the hospital. So these are the conditions that you can have some impact on. They're like the 19 20 ambulatory care sensitive conditions for ambulatory care. And they are big. They account for a lot of the 21 22 hospitalizations.

1 That's not to say that every one of them is 2 avoidable. It's to say that these are areas where you can 3 have an impact.

4 And then deaths are excluded.

5 In this case, we started off with observed rates 6 and then showed how we adjusted things from there. The last 7 work we really emphasized the risk-adjusted measure. So 8 when you take just observed rates and you don't risk adjust them at all, the 30-day drop in community discharge goes 9 10 from 23 to 21.9, a drop of almost 2 percent. The 11 rehospitalization increase is about 3 percent, 14.7 to 17.5 12 percent. And this is the unadjusted one. Risk adjustment 13 alters those things. But that's where we started.

I present this next slide for several reasons. First of all, this is the days until the rehospitalizations occur. It's obvious from this slide that people are rehospitalized at higher rates in the early days when they are least stable. Then, as time goes on, they get rehospitalized less frequently with lower risk and that makes a lot of sense.

21 But it's also important because one of the big 22 debates is always well, is it the hospital's fault or is it 1 the skilled nursing facility's fault? And who do we

2 attribute these hospitalizations to?

And in that debate one of the points that always comes up is well how soon did these occur? And people, even in the pay-for-performance demonstration for skilled nursing facilities, the current plan is to not count hospitalizations that occur in the first three days because it's not clear that that's the skilled editing facility responsibility. That's 15 percent if you look at those

10 first three bars. So there's still 85 percent that aren't
11 in the first three days.

12 But what's magic about the first three days? 13 Other people have said well, you ought to look at seven days. Other people have cut it off at five days. This is 14 15 an area we really have to study because I don't think we understand the dynamic of why these rehospitalizations 16 17 occur. Some people say it's lack of information that 18 doesn't get transferred to the skilled nursing facility so they don't know they're receiving. Other times it's argued 19 20 that it's Friday night and the patient just gets dumped to the skilled nursing facility. But do we really understand 21 22 that?

Other claims are that skilled nursing facilities really aren't looking, aren't assessing the patients clearly before. And they can't because they are competing for patients and the hospital is in a situation, and they don't want to say no to a hospital because the next time the hospital may not come to them.

So there's a lot of dynamic here. And I think we
better understand that dynamic far better than we currently
do before we can really attribute rehospitalizations one way
or the other.

11 So let's look at now the factors associated with 12 outcomes. These factors come from a fairly simple modeling 13 approach where we adjusted for case-mix and we adjusted for 14 time, the 2000 to 2004. And then we plugged in a series of 15 other factors stepwise, one by one. The reason I'm going to 16 highlight these results and not so much the full model is 17 there's a lot of collinearity between these factors.

For example, hospital-based facilities are staffed far higher than freestanding facilities and there's a correlation between those two of about 0.89. If you put them both in it's hard to tell what -- is it the hospitalbased nature? Is it the staffing nature?

And if staffing is associated with outcome because it's a hospital-based provider or because it's a for-profit where they are staffed lower, or because they are in a certain region, that's a somewhat secondary question than the question of does staffing itself, regardless of the reason, influence some of these things.

We also did models where we forced models where we put everything in. These same things were significant but the coefficients changed.

10 What I'm reporting here is regression coefficients 11 which actually show the change in the outcome relative to 12 that change in that factor. So the first one is the time variable, 2000 versus 2004. That's just a simple dichotomy. 13 14 You get the exact same change attributed to that regression 15 coefficient that you do when you do the two group 16 comparison. You get a negative 1.8 coefficient, implying 17 that there -- which is consistent with a change of 1.8 18 percent over time. Similarly, you get 2.8 percent. So 19 that's what this modeling does.

After we adjust for time and after we adjust for case-mix, we put in whether the facilities were 2000 only. Whether they were only present in the 2000 sample. Because

one of the big questions is well, the change between 2000 and 2004, is it attributable to facilities going out of business that were here in 2002 and new facilities coming into business in 2004?

5 Incidentally, there were 1,040 facilities that 6 actually -- which is 8.5 percent of the total -- that were 7 there in 2000 that disappeared by 2004. There were 2,162 8 facilities, which is 16 percent of the total in 2004, that 9 were new in 2004. This was a really interesting issue and 10 it's one that MedPAC actually really pushed us to look at 11 and made some very good suggestions along these lines.

12 I'm going to talk to you a little later about what 13 was special about the 2000 and 2004 facilities. But I'd like to go through some of the other factors because you're 14 15 going to see those are some of the factors that explain this. But the 2000 only facilities were all a whole lot 16 They 17 better than the ones that were there the whole time. 18 had a 17.5 percent higher community discharge rate in 30 days. The community discharge rate was 20-something 19 20 percent. They had a huge benefit on community discharge. This is after case-mix adjustment and after adjustment for 21 22 time.

1 They had 4 percentage point lower

2 rehospitalization rate.

Those 2000 only facilities, those 8.5 percent, there was something pretty special about them. We can talk about what that might be in a minute.

6 The 2004 facilities, actually I didn't highlight 7 them up there, but they actually had a lower community 8 discharge rate than the ones that were there both times. 9 They had a minus 7 percent. They were actually about the 10 same on rehospitalization as the ones that were there during 11 the whole period. So they weren't terribly different on 12 rehospitalization. But the 2004 only were different. We'll 13 talk about those facilities in a minute.

Let's talk about length of stay. Length of stay was not really associated with -- hospital length of stay was not. Now there wasn't a lot of variability in acute hospital length of stay after case-mix adjustment. But nevertheless, acute hospital length of stay is not the reason why you get high rates or low rates.

20 Region. Well the West, relative to all the other 21 regions -- and these are the coefficients for Northeast, 22 Midwest, and South relevant to a reference of West -- you

get lower community discharge rates in the other regions relative to the West. And you get higher rehospitalization rates. So the West seems to be doing a nicer job in this. And this actually persists after we adjust for things like managed care penetration and number of hospital beds and some of those other things. These regional differences are true regional differences.

8 Let's look at staffing. Here I sort of was 9 critical of the OSCAR staffing data and said I couldn't 10 imagine we were going to see an effect. Look at this 11 effect. For every hour of RN time per patient day increase you get 8 percent increase in community discharge. For 12 every hour increase in the licensed staff, that's RN or LPN, 13 you get a 5 percent increase in community discharge. CNAs, 14 15 less striking. So it's not just total staff. It's got to 16 do with what kind of skilled staff you actually have in the 17 facilities.

18 Rehospitalization you see the reverse. For every 19 hour of RN time you get a decline of almost 2 percent in 20 rehospitalization. For licensed you get a decline of almost 21 1 percent. Again, CNA has some effect. CNA hours are much 22 bigger so there's many more of them, so an hour isn't as big

1 a portion of the total.

But nevertheless, these staffing issues, even with OSCAR data which are pretty -- not terribly strong, they come barreling through.

Hospital-based, even after risk adjustment using
models that were actually pretty good, 50 percent to 60
percent R-squared, you get a 19 percent increase in
community discharge if you're hospital-based and a 6 percent
decrease in rehospitalization.

For-profits, you get a lower community discharge rate and a higher rehospitalization rate. Now again, there's collinearity between hospital-based and staffing, there's collinearity between for-profit and staffing.

So let me talk for a minute about who were these 2000 only facilities and what was unique about them. First of all, you need to know that these facilities, 50 percent of them were hospital-based in contrast to about 9 percent of the facilities that were there in both times and about 5 percent of the new ones in 2000 only. So they were disproportionately hospital-based, not surprising.

21 Now again, hospital-based may also be unexplained 22 case-mix and it's something we ought to talk about later. Hospital-based, we try to explain case-mix but there's something about hospital-based case-mix we probably can't with these measures. Some is case-mix. But nevertheless, there's also reasons why hospital-based may.

5 And one of those reasons is staffing. These 6 facilities were disproportionately high staffing. They had 7 four times the RN staffing levels of the facilities that 8 came into being in 2004, four times the RN staffing levels, two times the licensed staffing levels. Not very different 9 10 in CNA staffing. But they were really very different. The 11 2004 facilities that had somewhat worse outcomes were actually lower than the ones that were there over that 12 period of time. 13

14 They tended to be more from the West, they tended 15 to be more non-profit. So those are some of characteristics 16 of these ones that went out of business but they support 17 these other analyses on what are associated.

So what happens when you control for all these factors, what happens to the change over time? Unadjusted, you can see it's 1.8 and 2.8, like we said. Case-mix adjusted, the case-mix adjustment takes away some of the community discharge difference and some of the

rehospitalization. Much of that R-squared at the bottom is, in fact, from the case-mix adjustment. That is the big driver. I mean, 0.61 R-squared comes from case-mix and time. And the other 0.08 part of the R-squared comes from these other factors. A similar thing for the rehospitalization.

But after you adjust for case-mix, facility, and community factors, there's still something left on the community discharge side, although not a lot. But there's a portion of it that's still unexplained.

For rehospitalization, there's a huge portion of it that's unexplained. So on rehospitalization there's something going on beyond all of these community factors, staffing, ownership factors that is contributing to this change over time. That's why I'm going to get into these next issues a little bit.

First of all, let's look at the relationship between the community discharge and rehospitalization measures. These things ought to be related at least somewhat. Yes, they shouldn't cover each other -- they shouldn't be perfectly collinear. But there ought to be some relationship.

1 It turns out they are. They agree. High community discharge rates or good quality were associated 2 3 with low rehospitalization rates, which is good quality. So 4 you get a negative correlation and the negative correlation 5 is 0.5. High community discharge rates, good quality in 6 community discharge, with low rehospitalization, which is 7 good quality. Good quality is associated with good quality. 8 You would expect that.

9 Let's look at the CMS quality measures in both 10 community discharge and rehospitalization. Now these are 11 the measures were there's huge attrition issues. They disagree. High QM scores are poor quality. That means 12 13 you've got a lot of delirium, a lot of pain, and a lot of pressure sores. Those are associated, poor quality, is 14 15 associated with high community discharge rates, which is 16 good quality. And negatively associated with 17 hospitalization, low rehospitalization rates, which is good 18 quality.

So in other words, if I do a great job on my QMs because -- and you can sort of hypothesis what might be going on, because I hospitalize anybody who's getting real sick and I don't discharge people who are real healthy, but

I get great QMs. If I do really well on my QMs, look what's
 going to happen. I'm going to be having poor community
 discharge rates and I'm going to be having high
 rehospitalization rates.

5 There is a selection bias in that 50 percent 6 that's left in the facility. That is a problem. That is a 7 problem. What's publicly reported is these MDS QMs and they 8 are not associated with some of these other measures that 9 include all of the residents.

10 So here's the summary: outcomes are strongly 11 related to geographic location, licensed staffing levels, 12 hospital-based after case-mix adjustment. The hospital-13 based issue is a very interesting issue. Is some of it this 14 unaccounted for case-mix? What's going on? But 15 nevertheless there is that striking difference after you 16 adjust for case-mix.

Hospital-based facilities are going out of business. The changes over time is only partially explained by the loss of facilities present in only 2000 hospitalbased and higher staff and by resident and community factors. So there's other things.

22 And there is an inverse relationship between

quality, as measured by the publicly reported quality measures, and both rehospitalization and community discharge. An inverse relationship in quality, if you will, regardless of signs. But quality measured by the QMs and quality measured by these other measures, for which there's not an inverse relationship between these two measures.

7 So what's the conclusion? Well, community 8 discharge and rehospitalization should be used as publicly 9 reported quality measures for SNFs. There's really no 10 question we ought to be using these. They include more 11 residents. They are valid. You can look at things over 12 time. They make sense. They're associated with staffing. 13 They make a lot of sense.

And the existing QMs require MDS measurements at admission and discharge, not just 14 days, or you're going to have this huge attrition problem for everybody who leaves the facility.

18 There's also a few other concerns that I'm going 19 to allude to, and then I want to open this up for 20 discussion. And MedPAC has raised these concerns in the 21 past. But let me just take one example. Let's take the 22 example of delirium.

1 So the DSM criteria, the criteria for delirium, are a symptom complex disturbance. There's disturbance of 2 3 consciousness and change in cognition over a short period of 4 time that's somewhat fluctuating. That's how they define 5 delirium. And primary data suggest that it's got an incident of about 20 percent in admissions to skilled 6 7 nursing facilities. 8 Let's look at the QM. First of all, it's 9 triggered by one symptom, any symptom. In other words, 10 fidgeting is delirium using the MDS QMs. 11 [Laughter.] 12 DR. REISCHAUER: Guilty. 13 DR. KRAMER: But even being triggered by any one symptom, it's only got an incidence of 2 percent. What is 14 15 going on? Well, all the delirium are going to the hospital 16 or getting discharged? What's going on? That's a valid 17 measure of delirium? I mean who are we kidding? That's 18 what we're using to publicly report quality of skilled nursing facility care. 19 20 It's clearly insensitive and it's clearly nonspecific. So what's good about it? 21 22 I could tell you some of the same problems with

the pressure ulcer one. And there's problems with the pain one. You can ask me if you want to hear more about those things but I'd like to open it up to you. But they have really -- they are classic situations where there was not true clinical input and basis for those measures. They were MDS measures that somebody created and said hey, let's call this delirium. Those are problems.

8

Take it away.

9 DR. MILSTEIN: As someone who's been active in 10 participating in vetting of quality measures across all 11 categories of care, this problem is not unique. Absent very good electronic health records that continuously allow you 12 13 to quantify changes in functional status, almost any measure -- not just in this category -- you speak of them as to how 14 15 valid they are, not whether they are perfectly valid because 16 none of them qualify.

My question is if you look at the QMs, they are what we would call intermediate outcome measures. But they're important, if you're a patient, to avoid them. Could you talk a little bit about whether there are facilities that excelled across all five components of quality? 1 That is, as presented, it sounds like there's an 2 inverse relationship, that one of the ways you can do well 3 on discharge to community and avoiding hospitalization is to 4 dump your patients that have -- but were there not some 5 facilities in your sample that excelled across all five 6 measures of quality?

7 And if so, could you comment on -- I mean, is the 8 answer to ditch the three quality measures that can be gamed 9 and have some identifiable validity problems? Or is it to 10 add to the quality measure mix the two that you have used so 11 that gaming is discouraged? In that case, it would be 12 offset. And we're essentially creating incentives for 13 facilities to do well across all five dimensions of quality. DR. KRAMER: First of all, very good point and 14

15 it's going to help me when I come in and say I need to do 16 more analysis. Because that is the analysis that we haven't 17 done and we really need to understand it better. So that's 18 the answer to whether we've analyzed that.

As to where I would recommend -- first of all, I would definitely recommend adding the two. Do I recommend abolishing the three? I actually recommend revisions on the three. First of all, you can use a symptom complex for

delirium rather than just a single symptom. You should also 1 use a longer time frame for delirium. A 14-day marker of 2 3 delirium -- you've got to think about what happens to 4 nursing home residents. There is a lot of odd symptoms that 5 occur when people first get discharged to a nursing 6 facility, particularly since they've just come out of a 7 hospital, which has been a very traumatic event. These are 8 older people that end up going to the SNFs. So 50 percent of baseline cognition -- so we ought to look at it over a 9 10 longer period of time. That might get our prevalence marker 11 up and we might be able to do a less specific -- a more 12 specific one.

Similarly, we ought to be collecting it at discharge for the people who are discharged and we don't lose half of them. So I'm not necessary recommending throwing those out. I think delirium is important. I think pressure ulcer is important.

I actually have, in my work on revising the survey process for the Centers for Medicare and Medicaid Services, we've developed some other measures of post-acute outcomes that use the MDS. Now most of our measures don't use the MDS. They use chart review and resident interview and

resident observation and things that I think are closer to
 what quality is about. But we still do use MDS measures.
 And we have some other ones on functional changes and things
 like that. Those kinds of things ought to be considered.

5 So I agree with you. There's imperfection in 6 these things, but my argument as we can make them a lot 7 better, not just throw them away.

8 DR. SCANLON: This is really excellent. I had a 9 bunch of questions which you've answered all during the 10 course of your talk.

11 But to follow up on Arnie's point, I think that I haven't been surprised about finding these inconsistencies 12 13 at the individual facility level. And this is a problem for someone that wants to try to make this information usable to 14 15 the consumer and to see that we've got five measures or 10 16 measures or whatever and they're going in all different 17 directions. When you start to introduce survey and 18 certification deficiencies, you get more inconsistencies.

What's very, I think, surprising and also disturbing about what you found was you've got in terms of a correlation across all facilities this inconsistency, which really raises a much more serious question. Because the

former, when you've got the variability at the individual facility level, we had a challenge of let's find a way to create a composite measure with appropriate weighting so that we can get an overall score.

5 You're raising more fundamental questions about 6 the actual measures we use and you've got some strategies 7 for dealing with them but this is something we really have 8 to pursue in terms of refining the measures so that when we 9 look at them in the aggregate picture that we get some 10 consistent results.

MS. BEHROOZI: Thank you, Dr. Kramer. I'm not one of the economist in the room and you've really even helped me understand it. So thank you.

So as we're refining the measures, obviously you brought up a lot of information about how adding community discharge and rehospitalization would give a better picture. It really seems like we should add staffing to the picture.

Because turning back to page nine, of all the factors associated with outcomes that you list they are all status factors, right? Where you are, whether you're hospital-based or not. All of those things that once you open your doors that's the kind of provider you are. 1 The only thing that a provider has a choice about, that a provider has control over, is their standing levels. 2 3 It seems like that's exactly the kind of thing that a 4 patient would want to know about an institution. You live 5 in the Northwest or the Midwest or the South, you're stuck 6 with the providers in the Midwest or the South or whatever. 7 But you can choose between the providers that make the 8 choices about staffing.

9 And anticipating Mark's response that he made last 10 time about you don't just want to throw bodies at the 11 problem, I would suggest that there must be -- while there's too little staffing, right? And as you add more it gets 12 better? There's probably a tipping point. There's a 13 saturation point where the bodies start bumping into each 14 15 other and you don't achieve better outcomes or the returns 16 diminish.

17 So in the interest of keeping you around a little 18 longer, maybe we can ask you to study what the right 19 recommended range or whatever would be. But when I need to 20 go into a nursing home, I want to know about their staffing. 21 DR. KRAMER: I would concur with the points you 22 made across the board. I've been pushing for better

staffing measures and reporting them, not just staffing 1 levels by type of staff but staff turnover, staff tenure. 2 3 There's a number of others that we can get, and we can get 4 those from payroll data. You can get them systematically 5 from payroll data. And you can get them defined the exact 6 same way for every facility from payroll data. We've done 7 some very interesting work with payroll data. So I concur 8 with that.

9 In some of our preliminary work we actually have 10 found the thresholds that you mentioned. Yes, they do exist 11 when you look at hospitalization rates. The curve is just 12 what you'd expect. You start reaching this point of 13 diminishing returns and it levels off. There is a point at 14 which staffing levels don't buy you more.

But one of the problems is we're at the low point of the curve, by and large. So we need to do more with that preliminary work we did in that area and really start doing it.

19 The other think I should mention is that Nursing 20 Home Compare does, they do report staffing levels. Big 21 problems with the way they report them. First of all, it is 22 OSCAR data. Second of all, although we found some potential

uses, it's not risk-adjusted. It means nothing. You look at that staffing level and this facility has 1.3 hours of RN per patient day and this one has 0.8, and their case-mix is completely different. The 1.3 may be understaffed and the 0.8 may be overstaffed.

6 Case-mix varies immensely across nursing 7 facilities. They should not all be staffed the same. And 8 so why aren't they case-mix adjusted? Yes, it's hard. But 9 really, it's irresponsible to report them without case-mix 10 adjusting them.

DR. REISCHAUER: This is really excellent work that you've been doing. I really enjoyed your presentation and the papers that you've contributed.

But just on Mitra's point, it's certainly important to have this kind of staffing information, appropriately adjusted, available to the consumer. But if we're thinking of rewarding performance through differential payment, what you really care about is the outcome, not how somebody got to that outcome. And you can create a set of incentives that lock in place certain mechanisms of

21 production in too rigid a form.

And maybe we're at the stage where we never can

have outcome measures that are appropriate, but I think in some of this stuff where you're doing you're saying yes, there are outcome measures. And so if we incent people to have good outcomes, the logical way for them to go at this point would be to increase staffing.

6 MS. HANSEN: Andy, thanks a lot for this and the 7 concurrence. The points actually have been made but I do 8 want to underscore them because whether it's the staffing level -- but I think we've talked about this before 9 10 separately at another venue relative to the whole issue of 11 turnover is absolutely crucial in the continuity factor. So from a consumer perspective I do think that's valuable, the 12 13 ability to look at a policy level, as Bob was saying. I do think it is on the outcome side of it. 14

15 With that point, the whole aspect of the discharge 16 levels and the rehospitalization, I think these are 17 extremely valuable. But two points related to that.

One is the sense of that timing of those reports. Your first three days, your first five days, the whole issue of hand offs is one of the areas that I think is coming much more to light. So the ability to get some more sensitive measures of that whole aspect. And you may have already done the work but I think that has to be elevated so that
this bumping back and forth, whether it's the hospital's
fault or whether it's the nursing home's fault, really has
to be, I think, highlighted much better as to what happens.

5 And then the final thing about them, the thing 6 that I'm just taking one more factor, I think this is a theme that I tend to bring up, is looking at what happens to 7 8 the person over time. So one, these are the metrics to 9 report, say the community discharges. But I also know that 10 sometimes what happens is when you start shining a light on 11 that people start unloading people to make sure that their 12 discharges are relatively good because then their 13 responsibility is over with.

But my question on the patient level, the beneficiary level, what happens say a week to two weeks after that? That, to me, is also an indication truly of a policy of quality of an episode for a period.

So I don't know whether there's an ability to look at that or whether this is something that is considered of value from a policy standpoint, but if we're looking at quality over time, that the beneficiary doesn't get rehospitalized, doesn't decompensate because of early ironic

1 discharge from a nursing home, not from a hospital now but 2 from a nursing home, whether or not that could be looked at.

3 DR. KRAMER: I think looking at those things are 4 very important. Two parts to that. One is looking at the 5 people who get discharged, making sure they're not bouncing 6 back somewhere, making sure it was an appropriate discharge, 7 I think that is a key transition.

8 Similarly, the people who don't go to hospital. 9 There's a limit. Evercare drops rehospitalizations 50 10 percent. They have an ability to bring acute resources to 11 bear. They capitate. They can do lots of things. They can 12 drop them 50 percent. They can still only drop them 50 13 percent.

And we need to make sure we don't create an 14 15 incentive that says the lower the better. You want to give 16 people credit for getting down to a level that is an 17 appropriate level. So what's an appropriate level? Well, 18 you study what seems to be the margin and you don't give 19 them any credit when they go below that margin. You set a 20 threshold on it. You set that threshold based on a riskadjusted level. 21

22 It's tricky business. You don't want to drive an

incentive to rehospitalize everybody. You're never going to reach Evercare levels without a program like Evercare where you can bring in physicians and double the staffing in the places. So we need to do that.

5 And similarly, on community discharge, we don't 6 want to drive them to push people out the door just to get 7 good community discharge rates. So those are key points. 8 MR. MULLER: My thanks as well to you for this

8 MR. MULLER: My thanks as well to you for this 9 good work.

10 In looking at what's page nine, at least in our 11 handout, I remember that in looking at the pool of the 2000 versus the 2004 facilities, the way I read this is that in 12 13 2004 there are fewer hospital-based and fewer not for profits. In some sense, we've seen in our previous work a 14 15 few months ago that the hospital-based had like minus 85 16 percent margins. As we discussed at that time, if you've 17 got minus 85, at some point you may not do business anymore. 18 So I think that's probably one of the consequences, understanding that it's not all just staffing differences 19 20 but it may be becoming that.

21 My second point, just briefly, is in some of the 22 quality work that we've been doing -- not so much on around

nursing homes but around hospitals and physicians -- we've 1 been looking at process measures. So for example, if one is 2 3 looking at discharge to community, whether one should look 4 at the amount of therapy services provided in the nursing 5 home, whether in terms of rehospitalizations whether one 6 wants to look at whether medication reconciliation -- I'm 7 just using one example. Obviously, there's 10 or more 8 examples one could use.

9 Are we ripe for that here? Or are there so many 10 bigger issues to get to first, in terms of the measuring of 11 quality, that looking at kind of process measures there as 12 an intermediate step towards the outcomes that Arnie 13 mentioned, perhaps this may be not the best place to put our 14 time right now?

DR. KRAMER: Good question. Let me comment briefly on the first one.

We do really need to look into this hospital-based issue, for sure. They are going out of business. They do seem to be the predominant ones that are going out of business, if you look at them. They are staffed higher. Interestingly, the other thing is if you look at

21 Interestingly, the other thing is it you look at 22 the 2001s that went out of business, they went out in places
1 that have a very high rate of skilled nursing facility and 2 nursing facility beds per capita. So they went out in 3 places that were competitive.

We need to dig into this. We need to understand what's going on.

6 Obviously, hospital-based facilities don't need to 7 rehospitalize as readily. They've got the resources, the 8 lab, the x-ray, the physician right down the hall. That's 9 huge. You know how hard it is to get an x-ray at night in a 10 nursing facility, get lab data. That's a huge issue. So 11 yes, we need to get into that.

As for process measures, we've done quite a bit of 12 13 on process measures. I think they're very interesting. The 14 question is where you go on the public reporting side versus 15 where you go on the sort of provider quality assurance side. 16 If you've got a low community discharge rate, you ought to 17 look at what you're doing in rehab. If you have a high 18 hospitalization rate, you ought to look at why you have a high hospitalization rate. 19

20 One of the areas we've found that's been huge on 21 hospitalizations actually has to do with people who go to 22 the hospital and die in places that have very poor advanced

directive programs and very low rates of do not resuscitate and do not hospitalize orders and things like that. They have very high hospitalization rates and those people -- and if you look at how many die within 24 hours, it's can be pretty large at a very high cost.

6 So those are the kind of things we do need to get 7 into as a next step.

B DR. KANE: Just a couple questions. One is in your case-mix adjustment, is there something about socioeconomic characteristics of the patient -- for instance the dual eligibles -- in explaining the community discharge rate? I know they often are a large portion of the people in the long-term care, likely to stay longer. I didn't see anything in here that might adjust for that.

Actually, before you do that because I know once you answer I'm going to have to move on. They're very efficient here.

18 The second question is a little bit of can we 19 unsilo our analysis a little bit and link this up with a 20 hospital readmission study and see if there is a propensity 21 -- in the hospitals that have high readmission rates, is 22 there also a high remission back from the -- because in 1 trying to figure out who's responsible, perhaps there would 2 be a good variable there.

One of the studies we'll be talking about later on today is around hospital readmission rates. I'm just thinking, can't we put those two together a little bit and see if there is a combined -- if some hospitals tend to have a higher nursing home readmission as well as a community readmission rate?

9 DR. KRAMER: Let me hit question two first really 10 quick, and that is that yes, we should combine those things. 11 It's part of that whole thing where I was arguing we need to understand what's going on in that interface better. 12 13 Somebody in my group, Eric Coleman, does work on care transitions. And care transitions have to do with the 14 15 sending end and the receiving end. We need to couple those 16 things.

One of the problems we're doing in pay for performance is that we're doing that in silos, too. This is great. We're attributing at all to one provider. It isn't that simple.

21 We have used socioeconomic markers, as well, and 22 they are related. I'll have to dig into these a little bit

1 more and get back to you on how strongly they are affected 2 here. And we also use community factors that are 3 associated.

DR. MILLER: I want to make one quick point. You're making a data point, can we put the data together? We'll certainly look into it.

But I also want all the commissioners to understand we're looking at readmissions in the hospital. To the extent you bring these measures in on SNF and you're looking at readmission, we're also discussing this in other post-acute settings. Even though it's siloed, we've got everybody look, you need to be looking at your readmissions.

So we're also trying to get at it from a policy
perspective by putting this pressure on each silo, as it
were. But your point still stands. That's not to disagree.
DR. WOLTER: This really is nice work and I really
like you recommending that we look at these other measures

18 which some people would call looking at the big dots, as
19 opposed to something that's not truly an outcome.

And then I want to make sure I'm drawing the right conclusion, a little bit related to the point Ralph made. It seems to me that the hospital-based SNFs have other than 1 cost allocation reasons for their higher costs, and some of 2 that is staffing?

3 DR. KRAMER: Yes.

4 DR. WOLTER: Some of it might be the availability 5 of these other resources. I think that is an issue we've 6 discussed here over all my years on the Commission. I think 7 we might want to rethink where we stand with these negative 8 80 percent margins on hospital-based SNFs when you look at the wholesale departure of some parts of this industry. 9 10 DR. KRAMER: Yes, I would concur with that. 11 MR. HACKBARTH: I agree with that, Nick. But nobody ever said that the whole 89 percent was cost 12 13 allocation. The point was always that it was confounded, potentially confounded, by cost allocation issues. 14 15 So thank you, Andy. Good to see you again. 16 Excellent work, as always. 17 DR. KRAMER: Thank you very much. 18 MR. HACKBARTH: Our next panel is on comparative effectiveness and we have two quests well known to us. 19 20 Welcome, Gail and Marilyn. Good to see you again. Nancy, will you do the honors? 21

22 MS. RAY: Yes. Good morning.

1 Recall that at the March meeting we discussed the importance of comparative effectiveness research and issues 2 3 surrounding producing such information. Two of the leading 4 nationally known experts on health policy are sitting next 5 to me, Marilyn Moon and Gail Wilensky, who will provide you 6 with their thoughts on this topic. We are grateful that 7 they are here. Each is widely published and has served many 8 senior positions within and outside the government. Their 9 credentials are so impressive that it would take too long 10 for me to go through them so I'll just touch on a few 11 highlights.

Gail Wilensky is Senior Fellow at Project Hope. From 1997 to 2001, she chaired MedPAC. From 1990 to 1992, she was Administrator of HCFA. Currently she is affiliated with the number of health care commissions, including the President's Commission on Care for America's Returning Wounded Warriors and the Department of Defense Task Force on the Future of Military Health Care.

Marilyn Moon is Vice President and Director of the Health Program at the American Institutes for Research. She previously served as a public trustee for the Social Security and Medicare trust funds. She was also the

founding director of the Public Policy Institute of the
 American Association of Retired Persons.

After each panelist provides their thoughts about comparative effectiveness, you will have the opportunity for guestions and discussion.

6 We are going to start with Gail and conclude with7 Marilyn.

B DR. WILENSKY: Thank you. It's nice to be here,9 different to be on this side of the table.

I'm going to share with you some thoughts about how I think about the use of comparative clinical effectiveness, the institutional structures, a little bit about the funding. I don't have a slide. I just thought this morning that that was a missing piece but I'll share with you what I'm thinking about, and procedurally how it might proceed.

A problem, I think, is one that you have identified in the work that you have done. We have found ourselves in a triply bad world. That is spending growth is continuing an unsustainable rates, and at the same time that happens we know we have lots of problems with patient safety and a lot of problems with quality in terms of making sure people have the kind of health care that is appropriate
 given their medical conditions.

3 For many on MedPAC the unsustainable nature of 4 spending growth rates has long been recognized. I'm 5 actually a relatively recent convert to that notion, maybe 6 the last couple of years. Looking at if what has happened 7 in the past 40 years were to continue in the next 40 years 8 truly does make both the impact of Medicare on the federal budget and the impact of health care spending on the rest of 9 10 our allocation of resources totally untenable.

11 It's not just a U.S. issue. It is true that we spend more on a per capita basis, a lot more. But growth 12 13 rates are actually not as different as our absolute rates of spending. Although if you look at over the long-term, some 14 15 places like Canada, Germany, the U.K. have done better in 16 terms of not having quite as rapid a spending growth. But 17 in general our spending growth rates, which is really what 18 now is gripping me, as opposed to the absolute level. I regard that as providing opportunities for savings in the 19 20 short term while we figure out to get to a better long-term 21 position.

22 If that's going to happen we need to do three

1 things. And I'm going to really focus mostly on the first 2 one. We need better information. We need the systems to 3 support it. As an economist it's hard for me to talk about 4 spending better without mentioning that.

5 We also need to have better incentives or else we 6 have to have really, really, really serious controls in 7 place. I do believe that could limit spending although not 8 get spending right if we were willing to do that. My 9 observation is the United States is not willing to do that, 10 in which case we really better make sure that the incentives 11 are right.

In the U.S. we have this tremendous disconnect between the sophistication of the training of our health care professionals, of the devices and therapeutics that we have, and everything that supports that. It is a really odd disconnect in that we have extremes on one side in terms of cottage industry with regard to information in the systems, and these very sophisticated medical devices and

19 technologies.

And as you know, and Bob Reischauer and I got to struggle with for a long time, the financial rewards do not reward the institutions well or the clinicians who provide high-quality efficiently produced care. So it is a
 complicated problem.

I, in somewhat of an apology, frequently explain why exactly a public finance economist has gotten so taken with this issue of comparative clinical effectiveness. It's not obvious to me and I assume it's not obvious to anybody else why that would be.

It's because it has occurred to me that this is 8 9 the basic building block in order to figure out how to get 10 spending smarter. And as important as realigning financial 11 incentives are to get to a better world, this one is first. 12 If we can't get information about what works, when, for whom provided by maybe only certain kinds of facilities or, in 13 some cases, duly licensed community hospitals, it will be 14 15 very hard to figure out how to spending smarter.

It also requires a recognition that our usual binary yes/no is not a good way to look at information on comparative effectiveness because technologies, broadly defined to include medical procedures, are rarely into the always effective/never effective. It is trying to figure out when, for whom, under what circumstances and just how much clinical gain are we talking about? 1 Other countries have been working on this longer than we have. NICHE in Canada, this common drug group --2 excuse me, NICHE in the U.K., CDM in Canada, PBAC in 3 4 Australia, although each of them are parts of larger 5 organizations. But the focus tends to be on drugs and 6 devices much more than other medical procedures. It tends 7 to be on new therapeutics rather than on existing 8 therapeutics.

9 I believe very strongly that while I understand 10 why the focus started there, it misses the point. The point 11 for me is trying to figure out how to spend smarter. That 12 means if you don't get medical procedures broadly defined as 13 well as drugs and devices you're wasting a lot of effort and a lot of political capital. If you don't look at existing 14 15 as well as new technologies, you're going to miss a whole 16 lot of where the money is.

So I appreciate why they started there but I think it is critically important to understand this is not just about drugs and devices and it's not just about new if we're going to figure out how to be spending smarter.

21 Generally, when you look around at what's been 22 done in the past, they're mostly centralized processes.

1 They usually include economic assessments. They tend to be 2 a lot of existing reviews of existing studies, literature 3 reviews, sometimes new clinical reviews. Not surprising 4 there, because these are using in counties that have 5 nationalized government health care systems, so it's not 6 surprising they are there.

But there is a lot of difference in terms of both the transparency of what is done and the mandatory nature of the recommendations.

10 I believe if we're going to have a chance to have 11 this happen we need something different. It is appropriate 12 to focus on the condition rather than on the intervention and therapeutic. As I've mentioned, I feel very strongly 13 14 it's important to include procedures and not just drugs and 15 devices, because that's where the money is, and to recognize 16 that a lot of this is investing in what is not yet known and 17 that's a dynamic process. It's not like you can put money 18 forward for a randomized clinical trial and think you're done for all time. All of this is going to require frequent 19 20 updating depending on the quality of the information and the validity of the studies. 21

22 I'm open to lots of different sources of

information. It ought to be clear what that information is reflecting, the "gold standard", Sean Tunis' concept of real world randomized clinical trials, epidemiological studies, medical record analyses, administrative data. We ought to use what's there. The ignorance is mind-boggling. We just need to be clear about how good the data is that's underlying the findings.

8 Needs to be objective, credible, timely, 9 transparent, and understandable. If it doesn't meet all of 10 those and maybe one or two more it is never going to make in 11 the United States. There won't be enough regulatory 12 authority that could have it be acceptable if it doesn't 13 meet these kinds of standards.

I think there's different places that you can 14 15 place this. My attitude is quite agnostic. Generally, the 16 bottom line is close to government but not too close. 17 There's a lot of concern that I've heard, both on the right and the left, if it was actually inside government as to 18 19 whether it could maintain its credibility and objectivity. 20 These freestanding ideas like quasi-government, IOM, or the FFRDC -- and I know you have provided some 21

information about some of them that exists. Lawrence

22

Livermore is actually one that is several billion dollars and a fair amount of time. So there are some structures around that are in the ballpark of the kind of money that I think that we're talking about and that have existed.

5 It is, to me, a pretty good model of what close 6 but not too close might look like. But again, the specifics 7 are something I'm agnostic about.

8 I didn't include a funding one. But if I had my 9 druthers it would be by appropriation. This is as much a 10 public good as I could think of. The realistic side of me 11 says well, maybe we need to augment that and have, in 12 addition, a tap on the Trust Fund. Medicare would be huge 13 beneficiary. And also a tap on all of those who are privately insured because the private plans would, in 14 15 addition. It's got to be able to include the ERISA-exempt, 16 or there's no point in doing it. So I would not mind that 17 as a secondary way. It ought to be done by direct 18 appropriation like the NIH.

I'm not thinking about this as a way to make coverage decisions. I think about this primarily as a reimbursement strategy so that what is paid makes sense to what the gain is. I think that distinction, although

1 sometimes it gets difficult in practice, is a very important
2 one.

I don't see decisions being made at the center. The public payers and the private payers ought to be able to draw the information and it ought to be clear what that information is.

And I don't see it as a cost-effectiveness center although I absolutely believe and support the notion that cost-effectiveness is a perfectly legitimate part of decision-making. I just think for its political health and well-being it ought to be funded and done separately.

12 This ought to be as pristine objective credible 13 information as we can have it for the center's sake and for 14 the rest of ours.

I don't need to spend much time here. It's not the only problem. The question then is how could you make use of this? I like the notion of the value-based insurance that Mike Cherno [ph] and others have talked about where the copayment or tiering is tied to the clinical effectiveness for a particular intervention for a patient rather than whatever the PBM gets the best buy on.

22 But the notion is out there that you tier and try

1 to steer accordingly. Let people buy up if they want to do 2 this.

3 One of the issues that I've heard from industry in 4 talking about these ideas is whether or not this necessarily 5 delays entry because I think there's a lot of legitimate 6 concern given the delays already experienced by the FDA 7 approval process. And one of the ideas that I've been 8 discussing that, at least in principle has resonated, is the notion of going at risk for a preliminary period of two or 9 10 three years while information on comparative clinical 11 effectiveness is being collected.

12 At the end of that time there's a true up. And if 13 it is delivered as promised, any additional incremental reimbursement can be kept. If there was additional 14 15 reimbursement over the standard of care and there is not the 16 delivery as promised, that some preset amount of the 17 incremental payment, 50 percent or 75 percent or 25 percent 18 whatever the agreement or whatever the regulations say, 19 would be provided back to the government.

Those firms that didn't want to do this on risk could accept existing payment standards until such time as they have the evidence available.

1 So it does raise the bar. That is, you only 2 should expect to get more if you do more. It needn't delay 3 the 18 or 24 months that NICHE is charged with putting onto 4 the process.

5 The biggest difference, because this is applying 6 to medical procedures and not drugs and devices, is reaching 7 out to the medical community and trying to bring them 8 aboard. In the discussions I've been having with this issue 9 I find it not as strange a concept for many in industry 10 because it's not different from what many of them have to 11 face now in Western Europe or in Australia or in New 12 Zealand. This will be a very different kind of concept for 13 the medical community. And so one of the things I think is important is to start bringing them and their thoughts into 14 15 this process, which embarrassingly did not occur to me until 16 a couple of months ago.

17 Thanks.

DR. MOON: Thank you. It's a pleasure to be here today. And it's very nice to follow Gail because she said a lot of the things that I don't have to say because I'm in basic agreement on a lot of issues with her. I think she's done a very fine job of laying out some of the challenges 1 and the issues.

2	I talk about a center for evidence-based medicine
3	and I'd only say that I think the terminology is something
4	that ought be talked about and worried about a lot. Because
5	I think one of the things that people are really going to
6	need to do is spend a great deal of time, if there's such a
7	center, in talking about what makes sense to people to think
8	about this as a plus and not as some layer of oversight or
9	regulation that will hurt people in some way.
10	And so I think that the use of language, the term
11	comparative effectiveness versus cost-effectiveness and so
12	forth, is a very challenging one. I'm not wedded to this
13	but that's my term. So I'll just refer to it as a center
14	and Gail and I can be in sync in terms of that sense.
15	I thought about this, first of all, in terms of
16	what is the need for a center. I think there's a real need
17	for filling in a gap. That affects a little bit what I
18	think the structure ultimately would need to be. But I

19 think there is a need for advancing the science or at least 20 paying homage to the idea of advancing the science. When I 21 had some of my colleagues at AIR, who do some of this work, 22 write some things for me what was clear to me is there's

still a lot of controversy of whether quality of adjusted life years is the right measure, whether patient reported outcomes is the right measure, whether something else is the right measure when you begin to talking about the value of things that go beyond just basic effectiveness or at efficacy kinds of issues.

7 I think there needs to be then a sense that an 8 organization like this would spend a great deal of time 9 worrying about and advancing the science which, among other 10 things, means getting people on board right away to talk 11 about this and for this to be seen as a good place for 12 consensus to be developed.

I think there also needs to be a lot of effort that would be placed on validating why you would do this. This is, if nothing else, a PR kind of activity. Again, I think that there are folks who are still skeptical about its need and it would need to be done very carefully from that standpoint.

Visibility and credibility then follows along and that builds on what Gail was saying in terms of bringing on board the communities that are going to be effective,

22 stakeholders. And the stakeholders have to include patients

as well as providers of care. I agreed that we should think about this not just in terms of drugs and devices, although that's really some of the low hanging fruit that you can start on and work on fairly effectively. But I think it has to be clear that the intent is that all types of health care service and devices should be part of this whole process.

7 And then I think of a center as really helping 8 fill the gap in terms of readiness for policy change. I agree with Gail that this should not be seen as the place 9 10 where reimbursement decisions get made. But it's more in 11 the nature of here's the analysis, here's our best analysis that indicates what works, what doesn't work. And then 12 other bodies that are going to be critically interested in 13 this are going to make those decisions. And they may differ 14 15 across different parts of our health care system, which is 16 pretty fragmented as we all know.

That doesn't mean that over time there couldn't be some intent of having actually some challenges to providing services at all. I think that should be out there but I don't think that should be a first goal, a first activity. There are a lot of important cautions that need to

22 be thought about in terms of this. Certainly the first of

1 which is don't reinvent the wheel. Already out there there's a lot of good information that's being developed, a 2 3 lot of good analyses that are being done. And ironically, 4 some of the things that I read about in the news and in the 5 journals have been funded not by the United States but have 6 been funded by other countries. The atypical antipsychotic 7 work that was just done recently, for example, I know was 8 funded by the British government. So we should really be free riders wherever possible and not reinventing the wheel. 9 10 That also means bringing into this process all the 11 people who already feel they're doing good work in this 12 area, have a stake in it. I think, for example, AHRQ plays a very important role on two dimensions. First of all AHRQ 13 is funding the evidence-based research centers. 14 That's 15 something I think should continue and makes good sense to 16 not have to be necessarily part of a center. A center might 17 do some funding of filling in gaps here and there or looking 18 at very specific kinds of issues that are not being done elsewhere. But in large part I think it can draw on a great 19 20 deal of information that's already out there.

It's going to be a long time before we have perfection and in the same way we talk about continuous

1 improvement in health care we ought to think about it in this sense, as well. You don't have to wait until you have 2 3 the perfect measures before you start to move forward and 4 help people understand what it's all about to have an 5 evidence-based sense of health care in the United States. 6 As I already mentioned, credibility with 7 stakeholders is really key. We need to have this be seen as really a critical step in the process of health care 8 delivery in the United States with strong agreement. 9 10 I included this little chart just to make two 11 points. First of all, AHRQ, in a good example of not reinventing the wheel, already has a clearinghouse for 12 13 practice quidelines, a clearinghouse for quality measures. I think that might be a place to build on to expand that. 14 15 And then a center would draw from that clearinghouse, for 16 example, to say okay where is there a good body of evidence 17 that already exists that we could do a final review on,

18 a meta-analysis, some kind of additional review, and really 19 try to come to some kind of consensus.

That means then that it's not just the development of a review or a consensus though, that you also need to do other things. I see a center of this sort as also being

1 involved in the dissemination and education of not only individuals but the provider community as well. Training 2 3 and technical assistance might either be housed here or be 4 certified here, for example, where once you develop good 5 methodologies and standards for what the state of the art is 6 then providing that training or participating in training 7 and technical assistance to expand the role. The extent of 8 good information I think is very important.

9 Practice adoption is, I think, the voluntary side 10 of all of this effort. If you've got good stakeholder 11 interest then I think then you can expect that practice 12 adoption will occur.

And the role of a center then would be not to 13 14 oversee the practice adoption but to analyze its impact and 15 to see, once it's more widely disseminated, for example in 16 the case of prescription drugs or other things, that it's 17 really doing what it's supposed to be doing. So that then 18 creates a feedback loop, again to think about this as a continuous activity. Because some things that we think make 19 20 good sense and the early data suggest they do, later on we find other impacts, effects, and so forth that should be 21 22 thought of as this.

1 That also means that stakeholders ought to be able 2 to come back and say the evidence has changed either for the 3 good or the bad and that that should be an important part of 4 all of this.

5 In terms of the structure, I think of this as 6 quasi-independent. I like Gail's close to government but 7 not too close. I think there's a danger of putting it 8 inside an organization such as AHRQ for two reasons. One, 9 it's easy to have then a political change affect what goes 10 I use, in a paper I've written, a national -- I've on. 11 totally blanked on what the acronym stands for, NREP, which 12 is done by SAMSHA for substance abuse policies and practices 13 was working really well. There was a change in not so much 14 even the politics but a change in the people involved in 15 oversight and changed the focus and the whole thing pretty 16 much fell apart.

I think it's very much important to have it be a very visible piece wherever it is and not just part of the activities of an agency that has other things on its mind and other activities going on.

21 We also know that AHRQ get into a lot of political 22 trouble with the stakeholders when it did some practice

1 guidelines. I think you have to have a sense that this
2 group is pretty independent.

I think it can be a relatively small size, particularly if it's not doing its own analyses. It's farming out a little bit of analysis but depending upon others. And even depending on AHRQ, for example, as a clearinghouse for some of the information.

8 It's critical that there be highly qualified 9 staff, that it be viewed as a desirable place to go. It 10 might even be a very good model to think about bringing in 11 people for a couple of years who serve and work in that kind 12 of environment and then go back to their own institutions in 13 the sense of almost a sabbatical type of activity for some of the staff, again to keep it to be part of the mainstream 14 15 and really part of the whole process of health care in the 16 United States.

There ought to be strong links to other organizations. Those organizations might even have a say in terms of appointments to who serves on an advisory panel, for example.

I suggest, in some work I've done, that you think about two different kinds of panels, one that's really very

scientifically oriented and pretty much heads in the cloud kind of group, and another that is much more grounded in terms of what will fly, what won't fly, whose ox is being gored. They would obviously interact in various ways but I think it's very important to do both of those kinds of activities.

As I've already mentioned, I think technical assistance and training and dissemination ought to be a part of this because the best possible outcome would be if the health care community embraces this idea and moves forward on its own and so that the incentives fall in line eventually rather than to try to force people to change their behavior over time.

With that I will stop. I think the important 14 15 thing is that this is something that could be done at relatively low cost. Like Gail, I think it should be 16 17 largely paid for by government because government is 18 actually a major beneficiary. But more important, this is something that no individual entity can do successfully on 19 20 its own, such as an insurance company. There's just too large of a free rider problem that would arise. 21

It might well be that it would be desirable to be

structured such that some of the key foundations that fund a 1 lot of health care work fund either work that would feed 2 3 into this or fund part of the center itself. I think that 4 would be a reasonable thing to do as well, although there 5 needs to be a lot of care again that it not be captured or 6 be viewed as captured by an industry. It needs to be viewed 7 as pretty much the gold standard that's out there and above 8 it all.

9 If it's through an appropriations process rather 10 than tied to something like the Medicare Trust Fund then I 11 think it would need to be funded over multiple years for a 12 considerable period of time to really give it the time to be 13 a little controversial, get established, develop credibility 14 and get beyond the first initial angst that will undoubtedly 15 follow of any organization that's set up of this type.

16 Thank you.

MS. DePARLE: It sounds like there's a fair amount of agreement between the two of you and among all of us on the urgency of this and what it should do. On this question of who should do it, I just want to probe that a little bit. So you both agree that it should be some sort of

22 public/private or quasi-governmental group. But I know you

1 both to be pragmatic. So if I were to tell you, if you were to assume that it would take -- to do something like what 2 3 you describe, Gail, an FFRDC with some combination of 4 appropriated funds and perhaps funds contributed by private 5 insurers, private plans -- that that would take 10 years or 6 maybe our most wildly optimistic five years to get that 7 done, would you still say you want to keep waiting for that 8 to happen? Or would you say we should go ahead and do it in 9 some second-best way with a tap on the Trust Fund and get it 10 into AHRQ, for example?

11 I'd be interested on your views on that.

DR. WILENSKY: I don't think it would take five pears. I think you could get something like this up and running in two to three years. And I certainly don't buy into the 10-year, because we know what they look like. That's the advantage of having things like the Lawrence Livermore Lab. And RAND has had these things for a long time.

The real question, to my mind, is what's the critical mass that you need in order to be able to demonstrate to the skeptics and those who, for whatever reasons, think this is not such a great idea, that the

1 information produced could really be valuable so that you
2 get a buy-in from the people that you need?

Not based on much of anything and desperately wanting to hear from others what they think, I think maybe the order of magnitude of a couple of hundred million dollars as opposed to the relatively small amounts. It's not like this kind of work isn't getting done. It's being done not just funded by AHRQ but the program out in Oregon and various other groups that are doing things like this.

10 But it tends to be too narrowly focused and 11 specific. Although I'm always a big one for low hanging fruit, I think it is urgent that we show by doing a couple 12 13 of high-cost, high-volume examples, as well as a couple low hanging fruit drug or device examples. And we keep seeing 14 15 how important that is, the angioplasty study that was 16 reported just as the latest in a series in terms of 17 cardiovascular.

So I think that being able to demonstrate what it is we mean is what has to happen, I think you could get an FFRDC up and running within a two or three year period.

21 MS. DePARLE: I agree with that part. I guess I'm 22 talking more to the political consensus.

Frankly, I think this would take a Congressional enactment. That's why I'm skeptical, and you've written on it recently, and Marilyn has, too. Maybe you're having lots of Hill staff who a re eager to work on this. But I don't see it moving as quickly as we think it needs to.

6 DR. WILENSKY: There is a lot of action, actually. 7 Now you know as well as anyone around this table, 8 but there are a lot of people around this table who know well, talk and writing of specs -- which is going around a 9 10 lot in this area. I mean, I go back and forth as to whether 11 all of this is a good thing or a bad thing. In some ways, I wish there were one or two people totally deeply committed 12 13 and that's all, and either they could make it happen or not.

I'm not sure what it means to have quite so many people expressing an interest in something that sounds vaguely like comparative clinical effectiveness. You may well have a lot of different versions and I don't know how you get them reconciled.

19 This is one of those few things that actually 20 could happen because it crosses the spectrum of interest for 21 people who don't have a lot of other areas of interest. 22 The real issue is could you -- I'm nervous about

having it start in AHRQ because that's where it's going to stay. I would be much more comfortable in trying to have it start in something that reports to AHRQ but that isn't there. I don't know that that is what will happen. I think most of the legislation probably will expand to function in AHRQ.

7 That's a model that will blow up AHRQ in the sense 8 that it won't be able to do any health services research, 9 and that's the only place that that goes on. And I think 10 for the reasons Marilyn suggested and I agree with, it's 11 politically vulnerable. And it doesn't meet the close but 12 not too close definition that I have.

13 So this structure of what can we do so that you get the buy-in, this kind of information that really could 14 15 help Medicare make a decision. Instead of beating our 16 brains out about one drug eluting stent versus another, 17 trying to get some serious work focused on the spectrum of 18 treatment of cardiovascular disease between conservative 19 medical treatment through the whole range to bypass surgery, 20 of indicating, of picking a couple of examples and really trying to focus that go beyond drug A verses drug B, stent A 21 22 versus stent B.

1 DR. MOON: I would only say that I think that 2 rather house it in a government agency temporally, where it 3 tends to then end up staying, if there was a feeling that it 4 couldn't happen right away perhaps one could get RWJ and two 5 or three other places to say we're going to get this 6 started. We're going to create the model. We're going to 7 put \$200 million into this for two years and really launch 8 it that way, where it starts out as independents in that 9 sense.

If you could get key opinion leaders, key thought leaders that are really respected in the health care community to join in with a consortium of foundations, that would be my druthers, rather than starting out with a small amount and a government agency that would then tend to be just tapping, as Gail said, what else was available in the way of resources for that agency.

DR. WILENSKY: I would have no problem with that.I'm not sure it would happen any faster.

DR. CROSSON: I actually have two things. One is a question for Gail and the other is a comment on Marilyn's presentation and I'll start with that.

22 First of all, thank you very much for both of

1 these. These are extremely good.

2	On the issue of dissemination, I just want to
3	emphasize the importance of that. About 10 years ago in
4	Kaiser Permanente we put together something we called the
5	Care Management Institute which was really centered at
6	trying to develop or at least assemble the evidence tables
7	for both existing procedures and other things that are new.
8	And then, throughout our organization, once we had concluded
9	what we thought was the most sensible approach, to try to
10	get that implemented.

As we moved through the first year or two we realized that the dissemination piece was a good deal larger and more complex than figuring out what the right thing to do was, and ended up actually with an allocation of twothirds of our resources in the dissemination area.

At the time we also had the example of AHCPR which had developed some very good things which ended up as pamphlets gathering dust on the shelves of physicians' offices. So I would just emphasize that I think in the end, and it may not speak to necessarily the role of this entity, but in terms of the effectiveness of the approach the dissemination issue is going to be important.

In thinking through what dissemination actually means, to whom, by what process, and as you mentioned how that's linked to payment incentives is going to be very, very important.

5 The question I had for Gail was I agree 6 absolutely, again, that including procedures and not just 7 drugs and devices, and certainly existing procedures, drugs, 8 and devices as well as new ones is very important. It 9 brings up the whole issue of prioritization. We have some 10 example from NICHE as to how to do that.

But you also mentioned very quickly that you thought that focusing on conditions was important. I wasn't quite sure what -- I think I agree with it but I wasn't quite sure what it meant. So I was wondering if you expand a bit on that.

DR. WILENSKY: It's an attempt to not focus on the therapeutic in a device per se because you get yourself in too many silos in terms of your thinking. So if you're thinking about -- although as part of focusing on the condition you may very well at various points look at different therapeutics as part of the treatment of a particular condition.

1 What I am concerned about is, and I'll use the examples frequently that have come up in terms of 2 3 therapeutics that are going to treat some chronic disease, 4 either diabetes or congestive heart failure -- in areas that 5 focus primarily on therapeutics, not really looking in a 6 disease management concept of the impact that having 7 therapeutic of a particular type or combination with 8 advanced nurse practitioners or whatever can have on the 9 clinical effectiveness that goes beyond looking at 10 therapeutic A verses B. And so it's focusing on the 11 condition you're treating, like cardiovascular disease or 12 chronic diabetes or whatever, that allows you to focus on the right -- allows you basically to ask the right question. 13 So that's really -- it's having your focus be the 14 15 condition rather than the specific narrowly defined 16 intervention.

And the where, again I don't think Marilyn and I have a lot of disagreement in terms of the governance concepts of this overlaying between stakeholders and the need for having a broad scientific advisory group and then having specific -- like I think of links down below for issues that are cardiovascular, having a cardiovascular

1 specifically designed panel of advisers but an overall

2 advisory, and then an overall stakeholder that goes probably 3 above.

How you choose high-cost/high volume and where you have options so that it would make a difference. That's sort of the basic strategy about how you choose where to intervene. It's got to make a difference and it's got to have an option.

9 DR. CASTELLANOS: Gail and Marilyn, thank you. 10 That was an excellent presentation.

As a physician, I can speak a little bit from the medical community. I think of this is done appropriately you'd not only get encouragement but enthusiastic support from the medical community.

And Gail, I congratulate you for reaching out early in the stage to the medical community. We want to get involved. Right now we don't have good evidence-based medicine to plan our treatments and what we're doing.

I truly agree with you. We don't want to look just at devices. We don't want to look just at drugs. We want to look at procedures and care patterns.

22 As you said, I think this is how we spend the
1 money, we need to spend it smarter.

2	One of the things I really believe is that this is
3	good educational process in the medical education field.
4	When this gets started this would be an enthusiastic thing
5	to put in the training early on. This is what we have
6	discussed on some other projects with MedPAC and I would
7	certainly wholeheartedly support early intervention and
8	support by the medical community.
9	DR. WILENSKY: You may hear more from me.
10	DR. MOON: I'd just like to add that I think that
11	that's an example of thinking a little more outside the box
12	in terms of dissemination, of getting involved very early on
13	and getting groups involved in it so they feel they have a
14	stake in the whole process. You have to think beyond
15	pamphlets. You have to really think about changing behavior
16	and affecting people where they have a chance and an
17	interest in listening.
18	MR. MULLER: My thanks to you, as well. I
19	personally favor something very much along the lines that
20	you suggest. In fact, I like the NIH model where you have
21	intramural as well as extramural expertise because you want
22	to take advantage, as you both said, of all the work that's

being done, whether it's through universities or the RANDs or the think tanks or the health plans around the country. You want to take advantage of that through grants and so forth, as well as have some intramural base.

5 I want to follow up on the line of questioning 6 that Jay and Ron raised and whether what goes under the 7 label of dissemination or implementation. As Gail's 8 presentation pointed out, also echoed by Marilyn, we have a system that we've all been thinking about for 15 or 20 years 9 10 where the incentives are to kind of just do more. You have 11 doctors, you have hospitals, you have pharma, you have device. You have everybody now who knows how to read the 12 13 signals in that system.

I think one of the critical challenges is how do 14 15 you implement anything? Obviously, once you get into implementation its fraught with much more political 16 17 consequence and, in some sense, danger for this. As opposed 18 to if one of you said you want some people who just have 19 their heads in the clouds and do science. But I think to 20 really get any changes in the system one has to look at the kind of interplay of how the system works with its 21 22 incentives as well as good science in terms of evidence-

1 based medicine, as Marilyn coined it.

2	How much would you have this agency, this group,
3	whatever, get into the world of dissemination and
4	implementation? Because I think one of the real critical
5	challenge is not just knowing the right thing to do but how
6	do you get people to do the right thing? Is that a field
7	you would broadly get into?
8	So it's not just a matter of whether you use bare
9	metal stents or drug eluting stents, but how you have to get
10	people to change their conduct? I think we heard from one
11	of our panelists a few months ago that when the first
12	evidence came out the drug eluting stance versus bare, in a
13	system like the U.K. where you have the central funding the
14	behavior changed quite directly overnight. The behavior is
15	changing modestly inside the U.S. in terms of whether
16	they're using the drug eluting stents. And obviously in
17	systems where they have more central control one can force
18	behavior in addition to encourage behavior.
19	How much would you get into the world of
20	implementation as something that you want to look at
21	evidence on? Or is that something that is a little
22	dangerous to get into?

1 DR. WILENSKY: I'm a little uneasy that -- it's sort of like this -- I want to really protect this center. 2 3 I don't challenge or question the importance of the 4 dissemination. My gut instinct is this is a significant 5 sizable activity, up at a full running stage. I've talked 6 in the past \$4 billion to \$6 billion, could be. It could 7 justify more than that. But this is not a small activity. 8 It's very much the intramural/extramural model of the NIH. 9 I'm a little easy, especially any time early in 10 its history, of having the dissemination function be it. 11 Now it may well be that that's a terrific function for an AHRQ to undertake. 12 13 DR. REISCHAUER: Can I ask a clarification between 14 dissemination and implementation? I thought you're really 15 talking about implementation, not spreading the information. 16 That is for other groups to DR. WILENSKY: No. 17 make use of. 18 What we are lacking now, for institutions and clinicians who want to do the right thing, and for payers, 19 20 public and private, who want to incent more sensibly, they

22 because the kind of information they would need is just not

21

can think they're doing that. But, it's pretty darn hard

available. I think some people are more acutely aware of
 that than others.

This is to say we've got to get this information available that other people can use in trying to change behavior, depending on how they design the reimbursement systems.

Again, I look at this primarily as a reimbursement sissue not a coverage issue. I think that should go on. But for sure I do not want that anywhere near this center. I think that's immediate death.

MR. MULLER: Let me clarify. What I was looking at was not just information on stents or devices and so forth, but information on such and such a health plan has really done this well. This public agency in Oakland versus Denver has really figured out how to do diabetes management and so forth. Is that something you look at?

DR. WILENSKY: I don't see the report card writing again being a function of -- Bob Reischauer has mentioned, not in a direct dialogue on this, the need to include information on delivery systems on the comparative clinical effectiveness. Now having it be broadly enough defined so that the delivery system impact on clinical care and

1 clinical outcomes, since there can be an awful lot about how 2 well the physicians and hospitals are integrated and what 3 kind of -- you could imagine a lot of reasons why that could 4 impact the clinical effectiveness.

5 Again, I'm all for reporting and scorecards and 6 all the rest. Not here, somewhere else.

7 DR. MOON: I would just say though that I think 8 there are a couple of areas in which you could have this involved. I think one thing is if you felt that if the 9 10 center was, for example, came out with a finding and some 11 entity was going to implement it and then you were going to 12 do an analysis with it, I think there's nothing wrong with that and having that be part of the center. I think it 13 might be very good then to give it a stamp of approval. 14

15 It would be nice to find some positive ways to 16 reinforce behavior as opposed to just the negative ways of 17 saying we're going to stick it to people in terms of 18 reimbursement or coverage.

19 The other thing that I think, again in terms of 20 thinking creatively about dissemination, is we're on the 21 verge of all of these changes in technology in terms of 22 electronic medical records and so forth. The integration of

that information with information on good practice where it 1 gets integrated, I know the forward thinking places like the 2 3 Kaisers and so forth, where a prompt comes up in real-time 4 as someone is talking to someone that says do you know the 5 new finding says that this is the better approach to use. 6 That gives the physician something, a tool right at that 7 moment rather than expecting him to read one of the I don't 8 however many thousands of medical articles there are that come out every year these days. 9

I think making it easy for people to get good information should be part of this because you don't want this to be so pie in the sky that everybody says this is great and ignores it.

DR. WOLTER: A couple of things surprised me that 14 15 I heard, maybe just because of the way I was thinking about 16 things. The first one is I had in my mind kind of two 17 buckets of work. One is things like drug eluting stents or 18 lung reduction surgery or the efficacy of off-pump cardiac surgery, kind of medical things I guess you might say. 19 And 20 then the other, Maryland, are the things that you're talking about. I guess you might call it health care delivery 21 22 organization and how that can affect outcomes. Do rapid

1 response teams decrease CPR, et cetera? Do ventilator

2 bundles reduce ventilator associated pneumonia, and some of 3 the work that's going on in terms of clinical improvement.

In that latter category I think we're vastly underfunding research right now and I'm glad to see that being highlighted by you.

7 I guess what surprised me is I was thinking about 8 those as maybe being done in different places, as they're 9 somewhat different skill sets or types of research, although 10 hearing you I can see how they can both be done in the 11 center. But some of these things are now being done in 12 AHRQ, the health delivery research for example. I wish we 13 could be doing more of it.

The second thing that surprised me just a little bit, Gail, was the comment -- I think I heard this -- that maybe we wouldn't want to include cost effectiveness in this work.

DR. WILENSKY: You definitely heard that. Again,let me try to be clear.

20 DR. CASTELLANOS: Can I just say that what I was 21 thinking about that, it seems to me we're at a point where 22 we should get the culture of medicine in our country to see that as worthy as clinical effectiveness. And is there some way that we might do both in advancing that cause? I think there's pros and cons to the discussion, I guess you might say.

DR. WILENSKY: Again, I believe they should be done separately by separate entities. One is a purely political strategy. I think it is the kiss of death to have them come together. And because I think it's so important, I don't want it to happen.

But I also regard the cost effectiveness as --10 11 this is hard, and to some extent, ephemeral in terms of trying to establish comparative clinical effectiveness 12 13 across various medical procedures and that's why it's an iterative process. It's always going to be a work in 14 15 progress and some of it will be better than others. And it 16 will go on elsewhere. Just as the NIH is not the only place 17 that biomedical research goes on, it goes on in many other 18 places, some of it funded by NIH but a lot of it just funded and done outside of NIH. I assume that that will be the 19 20 case here.

21 But also, it is even the concepts again, while 22 appropriate to be considered and used in terms of ultimate

decision-making, the concepts in terms of cost effectiveness and cost benefit analysis are even more ephemeral than in comparative clinical analysis because the ability to measure costs and what it is that you can measure and count as cost is more difficult. The costs change over the life cycle of many technologies based on both the volume and the experience level.

8 And while I don't want this to be regarded as not wanting to make investments in cost effectiveness and having 9 10 that be an element in terms of decision-making, because I 11 believe in both of those, I think this is a sufficiently 12 significant difficult activity on its own ultimately of a 13 very significant volume, closer to NIH than AHRQ in terms of what's going on, that I think it will be better to have it 14 15 be regarded as a place where what is known on comparative 16 clinical effectiveness but including the impact of different 17 delivery systems on clinical outcomes is available and 18 updated and that it is the basis that various public and private payers can use along with cost-effectiveness 19 20 analysis and others to make more rational decisions.

21 And I don't view it as a take away. I view it as 22 the best shot we have of making sure that the stuff that

really is likely to provide good clinical benefit to people who will benefit is being made available, as opposed to trying to find arbitrary ways to exclude because we don't have enough information to understand the subgroups in the population that are really going to benefit.

Because I actually believe almost any these new
strategies coming out, and a lot of existing ones, make a
big difference to some group. But we have very little
information about which group that is.

10 So I don't regard it as take away. I regarded it 11 as the best shot as getting people as fast as we can to what 12 will work for them even if it's really expensive.

DR. MOON: I guess I agree that you've got to be really careful because you don't want to set up a center like this for failure.

On the other hand, I don't think you can go very far for very long in this area without coming up against that issue because some of the comparative effectiveness analysis is going to suggest two things are pretty equivalent. And if one costs 100 times the other, how can you avoid talking about that? So it seems to me this shouldn't be the primary goal. But since I also see this as a place to vet and really try to improve the methodologies that get used and develop some consensus on that, it seems to me that costeffectiveness would be then a natural evolution over time.

5 I think the worst thing to do would be to say 6 there shall be no cost-effectiveness. You will never look 7 at that. Because that kind of precludes what could be done. 8 I'm not saying that you promote it or that you do that 9 initially because I think you have a ways to go to foster 10 the credibility.

11 But I do think that it's something that should be out on the horizon and thought about because otherwise 12 13 realistically we're not going to be talking about this as a lot of people think of it as this is the next magic bullet 14 15 for saving the health care system. I think that that goes 16 too far and I wouldn't ever make that claim. But I do think 17 that the opponents of this approach are going to be 18 opponents whether cost-effectiveness is on the table or not. 19 And the proponents are also going to be in the same boat, to 20 some extent. It's only a few people in the middle who can't quite decide and one sounds more threatening than the other. 21 22 So I'm a little agnostic about it. I wouldn't

1 think that this is something you would promote initially.

But I don't think it's something you want to totally rule out and say it's beyond the pale. And the way to start that would be on something that's incredibly obvious or where you just can't escape it effectively, it seems to me.

DR. REISCHAUER: I have very reluctantly been
convinced by Gail's arguments on this. I think there are a
lot of big political hazards here.

9 I think Marilyn is right on the money saying you 10 don't want to preclude it forever but step very gingerly 11 into this.

12 But if we think about what is, in effect, 13 comparative cost-effectiveness analysis, the benefits are likely to depend critically on characteristics of the 14 15 individual to whom the treatment or whatever is being given. 16 And the costs are likely to depend critically on the nature 17 of the delivery system. Kaiser is going to do this at a 18 very different average cost than some other entity is. For 19 that reason, coming out with averages really riles a lot of 20 people up and doesn't provide any useful information to insurers, to plans, to consumers. 21

22 So I think we'd do well to listen to the advice of

1 our expert panel.

DR. MOON: Gail certainly knows more about the 2 3 politics than I do, but I would say that I'm on an advisory 4 panel for a program in California that looks at the cost of 5 mandates, for example, and what would be the cost of adding 6 new things to mandates. And I found it very interesting, 7 and they do this struggle and I think they do it in a way 8 that's a very useful kind of discussion that has kind of 9 brought to the fore what are the challenges. And they talk 10 about those kinds of issues, public issues, private issues. 11 It's been a great educational experience and I think that it shouldn't be promoted as policy initially, but 12 13 I just think that it's important not to take something off 14 the table. 15 DR. WILENSKY: Again, never say never, number one. And the second is this economist isn't going to say that 16 17 cost doesn't count for decision-making. I just think it is 18 possible and appropriate to have a center that is establishing a huge amount of information that is not 19 20 currently known on a wide variety of clinical areas and to have those who -- and to not have payers look like they are 21 22 having anything to do with that because of the credibility

and objectivity issue, and to have payers appropriately thinking and worrying about cost issues although it's not only do I agree with you that it depends where it's being delivered, it frequently depends on who is doing the purchasing as to what the cost is.

6 So for all of those reasons, it's important, it 7 ought to be done, it could be possible for a university or 8 foundation work to do some estimating that would say if the cost does not exceed a certain amount or the price does not 9 10 exceed a certain amount it would provide effectiveness using 11 traditional measures as developed by NICHE or whatever in terms of not exceeding 20,000 per life year saved or using 12 13 any of those.

But again, I would not have this be part of the activities of the center. I believe the politics are a really serious issue.

MR. HACKBARTH: Nancy, did you have your hand up? DR. KANE: I think I've gotten a little bit clearer what I wanted to ask because I've listened. I guess it goes back to what Jay started with, which is around the dissemination and what do you mean by that.

I started off looking at your training and

technical assistance and saying who would you be training to do what? And then I thought maybe you're training people how to do this kind of analysis better. But then I thought you were trying to train delivery systems and payment units and the medical schools how to use the information better. I guess I'm still back on I'm not sure what that means.

7 So I guess I'd like to get your thoughts more on 8 what information development and dissemination means to you 9 and whether or not you think that's perhaps just an area 10 that we need to do a lot more research to understand what's 11 the best way to get the findings of this kind of scientific 12 analysis out there into practice.

DR. MOON: By putting these two things on the table I was really trying to emphasize the fact that I don't think that this should be viewed as an academic exercise that doesn't have applications. And particularly if you are keeping it aside from -- which I think is appropriate -- the actual decision-making of this should be covered, this shouldn't be covered, et cetera.

20 So from that standpoint I think then it's very 21 important to spend some time. The training and technical 22 assistance I had in mind was really more in terms of if this was viewed as a body that said okay, we've reviewed these 12 randomized clinical trials and we find that these three really work the best and here's why. Then I think technical assistance and training of researchers in terms of best practices of sharing information and good ideas and bringing people together that way, that's really what I meant in terms of training and technical assistance.

8 On the dissemination side, I had something broader 9 in mind. And that was the notion of making everybody who 10 has a stake in the system, providers, payers and consumers -11 - which is a big task -- aware of it. And some of it may well be just making it available and then assuming other 12 13 people will jump in. We have lots of examples in the government where we develop things and develop the materials 14 15 and then there are whole industries that develop around 16 training people and disseminating information.

But I think it also involves thinking creatively about if you've got the buy-in of the provider community, of also getting them to talk about okay, how do we get this information out to your people? What are the best ways? Can we write algorithms that could go into electronic medical records to provide information on a real-time basis 1 as opposed to the news flash in the paper that says here's
2 this latest study?

Are there things that there's a website that has key findings at five different levels? Like NICHE does, here's the one-page summary, here's the three-page summary, here's the 35-page summary, where people could delve into it at different lengths.

8 That ought to be viewed as a key opportunity 9 that's a responsibility of the center as well as developing 10 the consensus around information.

11 DR. WILENSKY: There's a training that I haven't 12 given a lot of thought to but Jack Rowe does. And since 13 we've been speaking together a lot he's gotten me thinking about this. And that is whether or not there are enough 14 15 people out there with the appropriate training to be doing 16 all of this comparative clinical effectiveness? Probably 17 the economist in me has always assumed put the money out 18 there and they will come. But I'm willing to concede that at least early on it might be necessary or worthwhile to 19 20 have some money set aside for training grants. I don't know how much work needs to be done on the methodological part in 21 22 terms of trying to make that more robust.

1 So it is possible that even if you could take the attitude put the money out and they will come, it would 2 overwhelm any other activity. So the notion of trying to 3 4 help, at least in the short term, to make the equilibrium happen faster is worthwhile. I don't know that I know a lot 5 6 more than that. But it's an issue that it might be worth 7 thinking about if this really gets ginned up to be a very 8 serious investment.

9 MR. BERTKO: A quick comment and then a question. 10 The first is, like others, I think this has been a very 11 thoughtful presentation. And Gail I like your close but not too close, with say the idea of getting the buy-in and 12 13 support from the private sector, both the insurance industry who would use this public good, and the large employers who 14 15 are somewhat separated because most of them are self-16 insured.

And then along those lines, I think you mentioned using administrative data. I think of this as follow-up studies. Would you view whatever this agency looks like, the center, as being a place that might my collect some of this administrative data from the private sector? DR. WILENSKY: I hadn't thought about that, but

there's no reason why not. I had put that down to indicate, 1 I don't think it's appropriate, nor would I want is to be 2 3 exclusively looking at randomized clinical trial data and 4 nothing else should enter. It's important that people 5 looking clinically or as patients or as payers understand 6 the robustness of the studies that are underlying what is 7 known, including the quality of the data. But I certainly 8 would use administrative data. But I'll give some thought 9 to that.

10 I don't have any objection.

DR. MOON: I think another advantage might well be if this was viewed as a place where you could get repositories of data that are not normally available, again that would attract staff just for the purpose of being able to do interesting studies that couldn't be done elsewhere, as well.

DR. REISCHAUER: I think also you want a place that can clean and standardize and protect identities of data in a common kind of way so researchers can access and use this stuff more efficiently.

21 MS. HANSEN: Thank you again, and I can see both 22 the protection of it, and then I'd like to kind of hook onto

1 some of the conversation about the application side. I
2 think I sit on this panel as kind of your beta test of
3 drilling it all of the way down to the practice side of
4 this.

5 The technical assistance, Marilyn, I understand 6 the idea of that. I think what I like to assure is that 7 some way that the hook on, whether it's with the center or I 8 think as Gail was saying you want to keep the purpose, the 9 mission fairly clear and tight. But the ability to see that 10 the usefulness of the information really happens on the 11 ground level. Because there are good information and it comes from different sectors, whether it's the treatment of 12 13 heart attacks that come from the cardiology side or the diabetes protocols. But it's not really fully integrated. 14 15 Some of it, I think, was brought up that it's a culture 16 issue. If you don't have something like a Kaiser or some 17 places that really look at that. Then it's the 18 implementation piece, I think, that I just don't want to get lost because oftentimes it's a 1 percent of inspiration but 19 it's the 99 percent perspiration that really will make the 20 change of all of the stakeholders. 21

And I don't know whether having the physicians

22

involved early will make that difference to make sure these practices are done. And that somehow the ability to have these really evidence-based practices that may get changed over time but nevertheless are really out in the field expected, the incentives built into it, the public reporting goes along with it as well. So that it's all the way through.

8 Because it's wonderful to have this set up and 9 that is the building block. But without the execution, the 10 excellent important execution that is both technical and 11 cultural, I don't know that it wouldn't be again another 12 great and really highly regarded place.

But I'm kind of representing the masses and the ability to see that it really happens, the people's care is better. And indirectly then the costs are done. Because I don't want to pay \$100 for a medication when I know that the efficacy is better at the \$20 level.

DR. WILENSKY: Or comparable. The answer is yes,I support what you said completely.

DR. MOON: I think another role for an organization like this is trying to provide, especially if it has credibility, a place where people can go for

1 information that they know is going to be accurate. It's 2 not that we lack information right now. It's just how do 3 you sort through it? If you Google anything these days 4 you'll get a million hits. The question is which of those 5 million should you listen to?

6 Unfortunately I see, to some extent, in students 7 and other people this change in which sort of as long as 8 it's out there the information must be good, as if journals 9 that do peer review are just the same as websites where 10 people can plunk up there whatever they want. I think there 11 needs to be some attention to that. You're not going to get rid of the bad stuff but hopefully you can at least have 12 13 ways in which people can feel assured that they know where 14 to go.

15 Unfortunately, not everybody knows which are the 16 good websites.

MS. HANSEN: As they say, it's not just the go to information. It's really having a turnkey process that it drills all the way down so that it makes a difference in quality of care, in cost, based on the evidence that's there.

22 So I just would like that not to get lost in this

1 process that perhaps comparable funding or some kind of
2 emphasis in our support of this kind of policy change that
3 has practical implications get drilled all the way through.

4 DR. WILENSKY: I think the idea of having 5 physicians participating early is important at all levels in 6 terms of having this both happen and having it impact 7 practice patterns. Realistically there are a whole lot of 8 other changes that are going to need to occur in addition to 9 the significant investment in a comparative clinical 10 effectiveness center in order to have all the things that 11 you just mentioned happened.

So I would not want to suggest that if the kind of investment I'm suggesting is made all this other will necessarily happen, which I agree it needs to occur. It's just there are a whole other series of steps that will need to happen. But the early involvement of physicians, certainly won't hurt and it is, I think, an important necessary element to have this have any chance.

DR. MILSTEIN: At our last Commission meeting, if one were to run calculations based on responses from Peter Newman on what this might do, not only for the health of the beneficiaries but also for the sustainability financially of

the Medicare program, the returns on investment associated with such a center were very robust. They were off the charts if you even take the low end of Peter Newman's estimate of recoverable waste in current treatments that are not well matched to patients.

I'm very supportive of a center but I wanted to
follow up on Nancy-Ann's concern regarding political
feasibility, which is a domain in which I consider myself
not very knowledgeable.

10 Congress, in its most recent legislation, has 11 signaled support for the concept of pay for reporting preceding actual pay for performance, essentially pay for 12 13 performance simply as a form of a variable payment based on comparative clinical benefit, which is the goal of this 14 15 center. Do you think it would be any more politically 16 feasible to use something along the lines of two-tiered 17 payments and/or copayments to incentivize suppliers and 18 providers to fund credible third parties such as AHRQ-19 designated evidence-based practice centers to conduct and 20 report robust comparative effectiveness studies? It's simply a different way of getting to the same destination. 21 22 Is it any more politically feasible? Or perhaps it's less

politically feasible. I guess I'm asking for a political
 feasibility rating.

3 DR. WILENSKY: It seems a little convoluted. 4 DR. MILSTEIN: Essentially it's building the cost 5 of the study into the cost of the producers who are 6 benefitting economically from the treatment rather than --7 DR. WILENSKY: It just seems to me there are 8 better ways to get them to contribute like to be included in 9 a tap on funding than to do it that way because you have 10 much less control over what gets done and how it gets done. 11 I actually like using tiered copayments as a steering mechanism a lot. But I think about it more as 12 13 having the lowest copayment for the most clinically 14 appropriate, to do the steering that way. And also the 15 notion of reimbursing more if you get more. But rather than 16 saying no, the reimbursement is geared toward what we know 17 clinically.

This just seems a little too convoluted for me. I'd be glad to think more about it. If you've written it or if you write it so I can think about it, that's just sort of an initial reaction.

22 And obviously issues of political feasibility are

1 judgment, at best, in trying to learn from sensitivities to past successes and failures. You don't want to get too hung 2 3 up on not trying things. But it does seem that this is an 4 area in which there are a lot of strange bedfellows that are 5 getting grouped together because they see this as a helpful 6 building block for what needs to happen, although I suspect 7 if you look into what needs to happen down the road there 8 will be some huge disagreements. But since they all need 9 this it's not a bad place to start.

10 DR. MOON: I also think it sounds a little 11 convoluted and I'm only a little -- I think that some of the trends to do too much tiering of copayment and so forth and 12 13 expect consumers to be really good consumers without providing the information gets to be backwards. When people 14 15 talk about consumer empowerment I always start to put my 16 hand on my wallet and run for the door because it just makes 17 a little nervous that way.

I don't have a problem once the information is there and people can make good choices. I think to expect it to happen just through economic incentives is an issue. DR. WILENSKY: It has been an interesting some of the early reports on pay for reporting, just the public reporting is producing some organizational change. And that is positive. I initially was quite against pay for reporting. It was like, no, no, if you don't provide the information you don't get Medicare payment. But I have mellowed and decided that we've managed as long as we have. And if this pushes us into getting good reporting, that's a first step.

8 And while I'm a little skeptical that just the 9 reporting will continue to produce desirable behavior 10 changes over time, I'm happy to get what we can get early on 11 since we're not really ready to go much further.

12 So I regard -- I mean, there are just a lot of 13 things that need to be done to try to move where you're more likely to get good clinical outcomes and efficiently be 14 15 provided health care system. And a lot of, I think, the 16 things that get talked about might help us move to a 17 different delivery system, including information about the 18 difference it may make for clinical effectiveness, when you 19 have physicians and hospitals actually working together, for 20 example.

21 MR. HACKBARTH: Okay, thank you both very much. 22 Excellent presentations, and we really appreciate your time

1 and your insight.

We're going to have a public comment period which 2 3 will happen behind you. I suspect that some of the comments 4 may be related to this topic, and you're welcome to stay for 5 that. 6 So we will begin the public comment period with 7 the usual ground rules. Please keep your comments brief and 8 begin by identifying yourself and your organization. 9 MS. LYNCH: My name is Ann-Marie Lynch and I'm 10 speaking on behalf of the Advanced Medical Technology 11 Association or AdvaMed. Thank you for the opportunity to 12 comment this morning. 13 AdvaMed is strongly committed to evidence-based research and we support comparative effectiveness research 14 15 to improve clinical outcomes in quality of care. 16 AdvaMed believes that there are certain key 17 principles that should be applied to any entity or 18 initiative involving government funded comparative 19 effectiveness research. 20 First, comparative effectiveness research should provide better evidence for physicians and patients to use 21 22 in making individual clinical decisions.

1 Second, patient access to optimal care for his or 2 her condition is paramount and must be protected. So we 3 agree with Gail that a government funded entity performing 4 comparative effectiveness research should neither make 5 coverage decisions nor make recommendations about coverage. 6 And AdvaMed has serious concerns about using comparative 7 effectiveness research to deny Medicare coverage.

8 Such research typically analyzes which medical 9 intervention, on average, is usually more effective across a 10 population. However, the intervention that is generally 11 best may not be best for an individual patient. So we 12 therefore urge the Commission to exercise great caution in 13 this area in order to protect patient access to care.

14 Third, the medical device technologies pose unique 15 challenges for comparative effectiveness research. Device 16 innovation is iterative and evolutionary. And the 17 effectiveness of a particular product often depends on the 18 health care professional training, experience and skill. So comparative effectiveness research must consider those 19 20 effects of both training and experience on outcomes and should only be conducted once a technology really has an 21 22 experience base and is widely available.

1 The fourth principle is that comparative 2 effectiveness research should include studies of health 3 systems changes that affect the management and delivery of 4 health care such as the use of preventive care, screening 5 services, and the interventions to reduce medical errors, 6 and information technology that were often discussed this 7 morning.

8 Fifth, we agree that the process used to conduct 9 this government funded comparative effectiveness research is 10 crucial and should be open and transparent. The process 11 should allow stakeholder input in setting research priorities, the methodology and proposed findings, and the 12 stakeholders should include patients, physicians, hospitals, 13 and experts from the whole medical innovation sector among 14 15 others.

16 Sixth, in thinking about comparative 17 effectiveness, it should be evaluated over an appropriate 18 time period to ensure that all the relative benefits are 19 considered. The episodes of care should be specific to the 20 condition of the disease, not artificially set at 30 days or 21 60 days or even a year. The appropriate time period may be 22 a hospital stay or an episode that includes acute and postacute care, or the appropriate time period may be several
 years for some technologies.

Finally, any government funded comparative effectiveness research initiative should only perform clinical effectiveness research, and it should be used to inform medical decision-making. By focusing on welldesigned clinical effectiveness research, the quality of care should improve and ultimately should be a favorable impact on the overall efficiency of the health care system. Thank you very much for your time. MR. HACKBARTH: Okay. We will adjourn for lunch and reconvene at 1:30. [Whereupon, at 12:29 p.m. the meeting was recessed, to reconvene at 1:30 p.m. this same day.]

1 AFTERNOON SESSION [1:33 p.m.] MR. HACKBARTH: I think we've got most of the 2 3 commissioners here. 4 Nancy's going to lead us into a continued 5 discussion of comparative effectiveness. 6 MS. RAY: Good afternoon. 7 Gail and Marilyn discussed why the U.S. needs more 8 information about the comparative effectiveness of health care services and the need for an entity whose mission it is 9 10 to sponsor and disseminate such information to the public. 11 The goal of this session is to get your feedback about a chapter on this topic for the June report. We'd 12 13 like you to raise any points that you didn't make at the previous session. 14 15 You may want to consider a draft recommendation about the importance of a federal role in producing 16 17 comparative effectiveness information. 18 Spending on health care is substantial and 19 increasing rapidly. Public and private payers are looking 20 for ways to get more value. Comparative effectiveness is another tool that has the potential to promote care that is 21 22 more efficient and of higher quality for both public and

1 private payers.

Comparative effectiveness will help fill in the 2 3 gap between what providers know and do not know. Increased 4 health care spending does not seem to be producing uniformly 5 better outcomes. Providers and patients have little 6 information that shows what treatment works best. Several 7 recent examples demonstrate this. For example, an older 8 drug class works as well as a newer class of drugs for the 9 treatment of hypertension.

10 There is no one public entity whose sole mission 11 is to produce comparative effectiveness information. For 12 example, AHRQ looks at comparative clinical effectiveness. 13 The Agency has set up the infrastructure and has already 14 completed reports and disseminated information to the 15 public. However, AHRQ's mission is broader than just 16 comparative effectiveness.

17 Comparative effectiveness is underproduced by this 18 private sector. Last month we discussed that some 19 researchers contend that it is a public good. So private 20 groups have less of an incentive to sponsor the work. And 21 when they do sponsor this type of research, researchers have 22 raised concerns that some studies are less transparent and 1 are biased.

Here are the key reasons to generate comparative 2 3 effectiveness information. Providers and patients could 4 become better informed and value conscious. Private and 5 public payers could use the information to make better 6 payment decisions. Over time it might reduce geographic 7 variation and improve quality and safety. 8 It may not necessarily reduce health care spending if it increases the demand for services that are recommended 9 10 but are underprovided. But it may improve the value of 11 health care spending. 12 The second half of your mailing materials begins 13 to flesh out some of the key functions and activities of an entity whose mission would be to produce objective and 14 15 credible comparative effectiveness information that is 16 useful to patients, providers, and payers. Such an entity 17 would be independent, would identify research priorities by 18 seeking input from patients, providers, and payers to better 19 ensure that its agenda items were relevant. 20 It would sponsor intramural and extramural research. The entity does not have to reinvent the wheel. 21

22 It will not be necessary for the entity to conduct all of

the research in-house, rather the entity can make use of existing resources. It would operate under a transparent process and methods. It would re-examine the effectiveness of services over time -- Marilyn and Gail referred to it being dynamic -- particularly when new information about a service's effectiveness and safety becomes available.

7 It would disseminate information to providers,8 patients, and federal and private health plans.

9 The entity would not have a role in making either 10 coverage or payment decisions for public or private payers. 11 Rather payers could voluntarily use the information to, for 12 example, design payment policies or pay for performance 13 policies.

The draft chapter also begins to discuss some pros and cons about different ways to structure an entity and finance an entity. The chapter does not reach a conclusion. The Commission could study these issues in greater depth in the future. An entity could be either public,

19 public/private or private.

I'm just going to briefly talk about two of the public/private options. The one that some researchers have talked about is called a Federally Funded Research and
1 Development Center

FFRDCs are private not-for-profit research 2 3 oriented organizations operated by universities and 4 corporations but directly linked to an Executive Branch 5 agency. Another public/private option is a Congressionally 6 chartered entity. It is more distanced from the federal 7 government than FFRDCs. Some Congressionally chartered 8 entities are research focused. Both of these public/private 9 entities can accept some private funding.

10 Within each of these options existing federal 11 agency, new federal agency, public/private entity, or private entity, an external board of experts might oversee 12 13 the development of its research agenda and ensure that the 14 research is objective and methodologically rigorous. Unless 15 potential users regard the entity as producing objective 16 data, they may neither accept nor use the information it 17 produces.

18 Its funding could come from some public and some 19 private sources or from all public sources. Funding could 20 be voluntary or mandatory. The entity's governance and 21 financing will affect its stability and its ability to 22 conduct independent and objective research. For example, an 1 entity that relies on appropriations might be more

2 susceptible to political pressures than an entity with 3 mandatory public funding. Private groups who voluntarily 4 fund the entity might attempt to influence the entity's 5 research agenda.

6 On the other hand, mandatory funding could mean 7 that the entity is less accountable to those who fund it.

8 I'd like to conclude my presentation with this 9 draft recommendation for you to discuss. It reads that the 10 Congress should charge an independent entity to synthesize, 11 produce, and report on comparative effectiveness of 12 alternate health care services and disseminate this 13 information to patients, providers, and public and private 14 payers.

The implications of this draft recommendation are on the slide. Because there is no provision in current law, increasing the capacity to assess comparative effectiveness could, depending on how it is funded, increase federal administrative spending relative to current law. Such information could improve decision-making by patients and providers and payers.

22 MR. HACKBARTH: Questions or comments?

1 DR. WOLTER: This isn't well formed in my mind but I'm still interested in this issue of alternate services, 2 3 lung reduction surgery or certain technologies, et cetera, 4 versus other things in health care delivery that can create clinical effectiveness, whether that be -- as I mentioned 5 6 earlier -- rapid response teams. We saw an example of an 7 interesting thing this morning, RN hours, some things like 8 that.

9 And do we need to create some clarity about what 10 we would expect this agency to do? And would we expect them 11 to do both of those types of effectiveness work?

And maybe we don't need to create that. That's why I say I'm a little unclear on this myself but it keeps coming back to my thinking.

And then the phrase in the recommendation "comparative effectiveness" probably doesn't create clarity around the conversation we had this morning on the cost aspect of effectiveness. I don't know, maybe we want to stay away from that. But it certainly could be interpreted to include it, I guess you might say.

21 MR. HACKBARTH: Actually, I think it might be a 22 good idea for us to spend a minute on this cost

1 effectiveness issue. I'd like to get a sense of where the 2 commissioners are.

In my own thinking, and Mark and I had a brief conversation about it. It sounds like his might be a little bit different than I had been thinking if it.

6 I had been thinking, like Gail, that this entity 7 would focus on producing information on comparative 8 effectiveness. Decisions about its use would be made by 9 providers and patients and the various payers. Translating 10 the comparative effectiveness into cost effectiveness, I 11 thought, might be something that the payers would do since 12 the cost element that would be affected by the payers' policies and that part of the analysis. 13

And so I had been thinking of separating the two 14 15 in that way. Mark, you had a different thought about it. 16 I think mine were more along the DR. MILLER: 17 lines, I think Marilyn probably captured it best in the end, 18 that you don't take it off the table, that you can have a situation where you say these things might be equally 19 20 effective but vastly different in cost. And so you might want to leave open the notion -- and she sort of said this, 21 22 as well. You can find yourself staring this question in the

1 face time and time again, even with the clinical comparison. If it were entirely up to me I would be absolutely 2 3 clear, and I think there's general agreement on this, this 4 entity doesn't have line authority. It doesn't make 5 coverage decisions. It doesn't make payment decisions. 6 But if it were entirely up to me I would leave 7 open the notion that it can pursue cost effectiveness as 8 part of its agenda and put that information out for then 9 insurers to take and say well, I buy this number precisely, 10 or in my population I think it would work this way. 11 That's kind of the way I was thinking of it. 12 MR. HACKBARTH: Nick, what were your thoughts on 13 the cost effectiveness piece? DR. WOLTER: I hadn't thought about it until 14 15 today, so I probably need to think a little more. I 16 certainly agree that the credibility of the new center and 17 the focus on clinical effectiveness is very important and 18 that done poorly the cost element could create some issues. 19 I certainly agree with that line of thinking. 20 On the other hand, I was thinking of this recent study on the drug eluting stents. And as you get into 21

22 looking at something like that how inevitably the

1 alternative of medical therapy, et cetera, et cetera, you
2 almost immediately start thinking about cost. Somehow it's
3 hard to avoid that.

MR. MULLER: I agree. I don't see how you can go more than an inch deep on any of these questions without getting into cost. One may, for political reasons, not want to put it out there. But the point is these things are always interlaced with cost in any practical discussion. It comes up no matter what.

10 After some of the political travails around this 11 you don't want to lead this as a charge. But clinical and 12 cost data are just interlaced.

13 MR. HACKBARTH: I don't want to belabor the point. 14 I agree with that, when you get to the decision point. But 15 the premise of this is this is not a decision entity but 16 rather an information entity.

And so when you get to deciding, unquestionablycost is part of it.

MR. MULLER: Also, we obviously do not have a single-payer system. So the people who are going to implement this are the health plans and the state Medicaid agencies and Medicare, et cetera and so forth, and the ERISA 1 plans and so forth.

With the multiplicity of payers inside this 2 3 country -- and that's not going away anytime in our lifetime 4 -- I think that those decisions will continue to be made by 5 all of those actors. 6 MR. BERTKO: Can I add a comment on the cost part 7 of it? I think the cost part is yet another level of 8 complexity. And taking one of the simpler ones, drugs, what the cost actually is after rebates is invisible, 9 10 proprietary, and having the comparative effectiveness 11 available, and then using that to inform the tier placement 12 would be a pretty useful but couldn't be done by the agency. 13 DR. SCANLON: This is also going to relate to what 14 I was going to say later. I think this agency or this 15 entity is going to have a different row to hoe. We talked 16 this morning about involving stakeholders and getting by and 17 et cetera. We're talking about threatening what I'll call 18 the balance of power here. There's going to be strong reactions to it. The agency or the entity has to survive 19 20 long enough to really become established. That's going to be important. For that reason, I wouldn't add cost to its 21 22 charge because it's one more bit of baggage that it's going

1 to have to deal with early on.

2	For me I think the issue is that if you can get
3	good comparative effectiveness information out there you've
4	gone a long way to allowing others to do the cost-
5	effectiveness work. And that would be a real
6	accomplishment. Over time you can address the cost issue
7	more centrally, as opposed to trying to say that that's my
8	charge from day one.
9	MS. BEHROOZI: I don't know exactly how you
10	incorporate this. I don't think it comes into the
11	recommendation, maybe in the chapter. But I think there's
12	two different kinds of cost comparisons. There's the
13	marginal cost comparisons that a payer is going to do, like
14	about drug rebates and things like that. But there is the
15	decision that the entity has to make about which areas it's
16	going to focus on. Where's the biggest opportunity I
17	Gail referred to it, either Gail or Marilyn did.
18	So cost is going to be incorporated, I think, into
19	the decisions made by the organization, not about coverage
20	but about what it's going to study. Right? I mean, where
21	there are two vastly different types of treatments with
22	vastly different costs to everybody, to the whole medical

1 health care system. You can't ignore it from day one 2 really.

MS. KANE: Related to that, should we say anything about a preference for understanding that Medicare burdens, first? At least from readings I understood, it sounded like there was less done about the Medicare population than might be done about the under-65.

8 Do we want to say perhaps that the determination 9 of what to study should be somewhat influenced by the 10 highest class?

DR. REISCHAUER: Wouldn't that depend on who's paying for this? I mean, we're looking at is a public good, a public/private funding for that thing. And you don't want to say well, it's our folks.

DR. KANE: Except isn't part of the reason we're talking about it not NQF because there is no NQF for Medicare?

18 MR. HACKBARTH: NQF doesn't do this work for 19 anybody.

20 DR. KANE: They do a clearinghouse on clinical 21 effectiveness.

22 MR. HACKBARTH: Not of the sort or scale that

1 we're talking about here, I don't think.

2	I don't think we ought to have, as evidenced by
3	the draft, a detailed recommendation on how priorities are
4	set, what criteria are used, and the like. To me, the basic
5	point of our discussion to this point is that we need an
6	agency that's perceived as independent and credible. And
7	part of that, to my way of thinking, involves an open
8	process for the establishment of priorities and a critiquing
9	of analysis. And that's what we want to emphasize here, is
10	not that it ought to be the most costly things first or the
11	Medicare people first.
12	Let's establish a credible institution and then
13	good things, hopefully, will flow from that.
14	So I'd prefer that we stay at a higher level on
15	those sorts of issues. We can discuss them in the text but
16	I would want to keep them out of the recommendation, per se.
17	DR. CROSSON: I would agree with what you just
1 0	

18 said. I can sort of sense a split here on the Commission, 19 which we sometimes get, between the zealots who are out in 20 the field and then the wounded warriors who have actually 21 tried to implement things and have a more practical bent. 22 And I understand that.

I think also that it's going to be difficult in the end to have this actually perform the task that it is intended to if it shies completely away from issues of cost. How many times do we have to put up on the slide there the problem that the Medicare program faces?

6 But I still think we also have sort of lexicon 7 problems here. Cost effectiveness means one thing to one 8 person and it means something else to somebody else. There may be a value in this, in addition to saying what it's 9 10 going to do, to say what it's not going to do and what it's 11 not intended to do. Because I don't think anybody has ever suggested here that we would be using this entity to do what 12 13 is done in England, which is to do cost effective analysis that ends up in a yes/no determination or an absolute 14 15 coverage determination. That's not what we're talking 16 about.

But I agree with those who think that if we somehow say early on that cost is not going to be a factor in prioritization and that there aren't going to be issues of cost in the comparisons that are created that that's not likely to be actually what happens. And it's going to be very, very difficult to do.

And I wouldn't say, though, that in any way the 1 entity should be creating something that's determinative. I 2 3 do agree with you that in the end the payers and others 4 would be the ones who are making determinations of 5 differential copayments or whatever has to occur. 6 Now I've got Bob totally confused so he doesn't know whether to raise his hand or not. 7 8 DR. REISCHAUER: No, I was just saying that the 9 information that this entity develops will be used by some 10 payers for yes/no decisions. But this entity will have no 11 sort of authority or responsibility in payment decisions or coverage decisions because that's not its bailiwick at all. 12 13 DR. MILSTEIN: Going back to the question of whether or not we do or do not recommend, we do or do not 14 15 take cost effectiveness off the table as within the purview 16 of this entity, my perspective I think is a bit more aligned with Mark's. I think this is a variant of the question of 17 18 how much of the cargo do you throw out of the plane in order 19 to clear the mountain?

20 My notion would be to leave it on the table and 21 then, if in order to clear the mountain later on in the 22 process, Congress decides that this cargo has to get thrown

out of the plane, then let them do it. But I personally would prefer not to be the entity to recommend that we explicitly exclude cost effectiveness analysis, particularly from the Medicare program's perspective, from the purview of this proposed agency.

6 DR. WOLTER: I'm sort of taken by all of the 7 arguments here, actually. They all make sense to me.

8 [Laughter.]

9 DR. WOLTER: But I think my point is if you read 10 the chapter and if you look at the recommendation you could 11 really interpret it to include cost effectiveness. That's 12 how I would read this.

And what I'm hearing is a lot of concern about that. And so if there were some sentiment that the primary goal is clinical effectiveness and we wouldn't take anything off the table necessarily, would we want to be a little clearer in the recommendation? I think that's kind of where I was coming from.

MR. HACKBARTH: It sounds, Nick, like you're sort of where I am. I wouldn't write this cost effectiveness is absolutely prohibited and that's the headline. But as I see it you've got to build your way up. In the raw material to 1 do the cost effectiveness is a good comparative

2	effectiveness which is in desperately short supply. We
3	don't even get the engines turned on on the plane unless we
4	get something going here. And why have cargo that's going
5	to blow the plane up before the engine is even turned on?
6	So yes, maybe at one point it will delve more into
7	cost effectiveness but let's get comparative effectiveness
8	up and running and allow payers to make decisions based on
9	their cost structures, as John described, to make final
10	coverage decisions or payment policy decisions.
11	So no blaring headlines on this one way or the
12	other but the priority need is comparative effectiveness.
13	That's building block number one. Let's focus on getting
14	that first.
15	DR. CASTELLANOS: I'm just talking from a clinical
16	viewpoint. I think the physician community really wants
17	evidence-based medicine. They want to know what's effective

18 clinically.

Now the cost will always be there, there's not a question. But the real data that's not there is what's effective based on evidence-based medicine.

22 So I would stress that we just kind of clean this

1 up by saying this is an entity that's going to produce comparative clinical effectiveness. Once that data is 2 3 available, the costs will speak for itself. [Inaudible.] 4 MR. HACKBARTH: 5 DR. MILLER: By role reversal, do you mean I'm in 6 charge? Okay, that will be my last statement. 7 [Laughter.] 8 DR. MILLER: So the way I'm trying to interpret 9 what's going on here is that so far the recommendation has 10 not been changed. What we're talking about is the text 11 underneath the recommendation. Strong emphasis on clinical 12 comparative effectiveness, no statement of taking cost 13 effectiveness off the table. MR. HACKBARTH: Maybe it would be good just to 14 15 quickly review, since we focused on a place where we're not 16 maybe in 100 percent agreement. There are some things that 17 I've heard both in our public discussions and my individual 18 discussions with you really substantial agreement, if not 19 unanimous agreement, that this information is being 20 underproduced currently. It's a public good. And therefore increased public and private investment would be 21 22 appropriate.

1 We don't want to displace all of the existing centers and work in universities and the like. What we want 2 3 to do is continue to build that up. And so we're talking 4 about an entity that doesn't do everything in a big building 5 here in Washington member and bring all of the research 6 inside. It may be a little intramural but much more 7 extramural, as Ralph has described. It needs to be an 8 entity that focuses on establishing credibility for this 9 work through standardization of methods, a public forum for 10 setting priorities and critiquing results, decentralized 11 decisions about how to use the information. This is not a 12 decision-making entity but an information body, a research analysis organization. 13 14

14 I think those are all major principles on which I 15 think there is complete agreement.

We start to have different emphasis -- I don't think disagreement maybe -- different emphasis when we get to cost effectiveness. But let's do the things that we agree on in boldface and then we can talk about the comparative versus cost in the text and I think adequately represent the views of the commissioners.

22 So we're on to some other subject than cost

1 effectiveness.

I guess the other verb I might want to 2 DR. KANE: 3 put in here, besides synthesize and produce, which I think 4 Marilyn's presentation did a nice job of, is talk about 5 standardizing the way this is done. So we say produce but what I think we're even more interested in is influencing 6 7 the way it's produced by others then it is to produce. 8 So synthesize and produce and report, but could we say -- or use the word synthesize, standardize, promote and 9 10 report? Or report on credible, comparable -- somewhere in 11 there the fact that it should become a standard setter for 12 others doing the research as opposed to emphasizing produce? 13 DR. REISCHAUER: Can't we put in the text 14 something about methodological development, which is what 15 we're talking about standardizing methodologies or approaches to answering these kinds of questions. 16 17 DR. KANE: Yes, but in the recommendation you use the word produce but you don't use word standardize. And I 18 19 guess I'm just saying where do you want to emphasize the 20 action of this agency as opposed to that work of others? Or just put the word report on credible -- put the word 21 22 credible comparable --

1 You know, I think Marilyn made a great point that a lot of work is -- that's why I asked what's training for. 2 3 It's to standardize what others do, not necessarily to 4 produce. So I don't think it's captured in the 5 recommendation. 6 MR. HACKBARTH: What I hear Bob saying is rather 7 than trying to add more verbs to a sentence that's already 8 got a lot of them --9 DR. KANE: Take out the word produce and put the 10 standardize in. 11 MR. HACKBARTH: -- would be to put that in the text right after the recommendations. 12 13 DR. REISCHAUER: Now that we're into this and 14 wordsmithing, produce makes it sound like this entity is 15 going to do it intramurally. 16 DR. KANE: That's what I was getting at. 17 DR. REISCHAUER: And what you want is produce and commission, something like that. 18 19 DR. KANE: Commission and standardize. 20 MS. RAY: Sponsor? 21 DR. REISCHAUER: Sponsor, generate. 22 DR. KANE: But I think it should be in the

1 recommendation that the role is to also raise the standard 2 on how people standardize and upgrade the quality of what 3 producers are doing out there. So synthesize, sponsor, 4 report on.

5 DR. REISCHAUER: If it's sponsoring then it's 6 telling you how it's going to be done.

7 MS. HANSEN: This is just to pick up from this 8 morning, and I think this is not in the recommendation, but 9 being really clear in the text that this is the entity, of 10 course, that is helping to generate this for use. But I 11 just want to make sure that in the text that we really cover 12 the full dissemination, whether it's the kind of protocols 13 that may come out of it, the ability to drill down for this knowledge to be used. 14

It is the building block. But once it generates knowledge, I just want to make sure that that diffusion occurs and really has a true -- I think the impact on payers and providers is it could have an impact on quality. I think it should have an impact on quality. That it really gets used for that purpose.

21 So we're generating knowledge for use. So that's 22 my emphasis.

1	MR. DURENBERGER: Thank you, Mr. Chairman.
2	I think the way in which the draft recommendation
3	is currently proposed, with maybe one exception that I'd
4	like to talk about in just a minute, the best I can say
5	about the discussion is I'm glad we're not trying to pass a
6	piece of legislation and fund it at \$6 billion or something
7	like that and we're simply trying to I think we're trying
8	to capture a trend that's been developing as long as I've
9	been on this Commission, which is how do we, as a nation,
10	build evidence of value into the decision-making process in
11	health care?
12	I'm not speaking for Sheila Burke, but Sheila and
13	I have been at this for 30-plus years in one way or the
14	other.
15	MS. BURKE: Thanks a lot, big guy.
16	[Laughter.]
17	MR. DURENBERGER: She was a high school intern in
18	my office.
19	[Laughter.]
20	MS. BURKE: Let's don't go there, either.
21	[Laughter.]
22	MR. DURENBERGER: Excuse me, resident.

1 Now where were we?

20

2	MS. BURKE: Somewhere else.
3	MR. DURENBERGER: Since the last meeting, when I
4	looked at a paper that frankly look like, I thought, it read
5	like a puff piece for let's build one of these big buildings
6	and I said it. But I then went back and did a little more
7	work on some of the things that we and others have been
8	involved in over time.
9	And to the credit of the government, which we want
10	to sort of like be independent of in a conversation like
11	this, somebody in this government since way back in 1965 has
12	been concerned about the growth in technology, and
13	particularly on the health care side. There's just a
14	variety of institutions that have been created both by the
15	Congress, in the Congress, the OTA is an example, in the
16	Public Health Service. And all of this goes back from the
17	creation of Medicare and Medicaid onward.
18	The first part of that history is largely we can
19	see technology coming. We know when it lands in a place

21 effect, and every person demanding the latest and the 22 greatest. We're going to have some problems and we need to

like America, with every doctor being its own king, in

approach this in a logical, more logical process. The way to do that is to develop information so that we can all understand something we don't live with every day; i.e. technology and medical technology in particular.

5 At or about the time, in particular I think around 6 the time of the passage of PPS, but even leading up to 1983, 7 the role that cost played in making decisions about 8 technology, about procedures, whatever it is, began to play an increasing role. And it was clearly, as somebody who 9 10 lived through it, it was clearly at that point in time in 11 which it became much more difficult for our government to make the kinds of investments that its leaders as late as 12 13 1981, I think when we reauthorized the -- the National Center for Health Care Technology -- some of its leaders 14 15 felt we needed to do. There was this counter pressure to let markets work and do a lot of things like that which 16 17 ended up, in the case of the Health Care Technology Center, 18 ended up in the Reagan Administration just defunding the thing. So off that one goes. 19

But OTA survived. It survived, I think, because it was advisory to the Congress and it gave Congress really good advice. At least that survived until the Contract with 1 America time and so forth.

But I lay that groundwork because it's not made in 2 3 the paper, and I don't know that has to be made in the 4 paper. But if you start with my premise, which is this 5 Commission, in trying to advise the biggest payer in the 6 country, the most influential payer in the country, 7 Medicare, needs to reflect the various ways in which we 8 believe it's important to build evidence of value into the decision-making process. And that covers all kinds of 9 10 decisions. 11 Now, to have come out of that is the issue of comparative effectiveness, that's a component part of it. 12 13 It's not the only thing. But to wrestle with the issue of cost effectiveness, yes or no, or should we include 14 15 procedures as well as devices, diagnostics, et cetera, I'm 16 not sure we ought to try to make that case at this particular time because we make it in various of our other 17 18 recommendations along this path towards building evidence of

19 value in some way.

20 And so it's helpful to me to think of this 21 recommendation as a component part of that search for value. 22 Meanwhile, everybody else out there is trying to

look at clinical guidelines for practitioners in one way or another and so forth, and there are lots of other efforts in which the government and others and payers are engaged as well.

5 And so if this can be seen as a part of that 6 larger effort, I hope that it is helpful to the practice of 7 medicine, to organized medicine. I hope it's helpful to the 8 drug and device industry. I hope it's helpful to a lot of 9 other people to understand that they, like all the rest of 10 us, have a stake in where this goes.

11 The last thing I'd like to say is with regard to 12 the issue of that -- there's much more than I want to say 13 but I won't -- around the issue of the independent entity. 14 If you kind of look at the -- I don't know what is the 15 political science of this or the public policy side of this 16 -- the two big issues that are involved here are one, 17 legitimacy; and the other is accountability.

We want whatever comes out of this organization to have not just the aura of legitimacy but the reality of legitimacy because it's really hard to shoot that down just because your particular ox happened to have been gored if, in fact, all the way along this process, whether it's the openness of the process or the advisory committees, which history will show you we've tried to build into all of these processes. But that's always the most critical part of it.

So when I said last time where I said to you privately about wooly heads and blah, blah, blah, blah, blah, blah, blah, blah, we can't afford that sort of thing. It really has to come from us, in a sense, particularly if we're going to be in the public funding business as well.

9 But the second part of it is the accountability 10 issue. And that's the one where we tend to think that it 11 won't work at AHRQ, it won't work anywhere in the government 12 because somehow or other the government can be gotten to by 13 all of the special interests and all of that sort of thing.

But the flip side of that is if we're going to 14 15 invest, as we should, large amounts of public money in 16 producing a public good someone has to be accountable that 17 the legitimacy of this effort is sustained, that the 18 appropriateness of the charge is followed through on. And as somebody who, way back in 1986, actually proposed that 19 20 Medicare should be financing this kind of comparative effectiveness work I, for one, don't think that having it 21 22 way out there away from the government but spending billions

1 of dollars a year of public funds is a good idea.

Having said that, I don't have an easy answer for 2 3 you because I think this is a quandary that as soon as we 4 hand this sort of thing off or anybody hands it off to the 5 Congress, they're going to have to face, too. But I think 6 we should face up to the quandary. We should acknowledge 7 it. We should do whatever we can to build both the 8 legitimacy of the recommendations and the entity and also to recognize that issue of accountability if there's a way to 9 10 do it.

11 MR. HACKBARTH: I'd like to spend a minute on this because I think there really is a quandary here. Gail, in 12 13 her writings, has talked about very, very large amounts of money. It is very difficult to imagine Congress sending 14 15 such big checks somewhere without any ability to influence 16 and control what it does. In most institutions there's some 17 connection between who pays the bill and accountability to that person or organization for results. You can't just say 18 19 that ought to be severed and have a credible system.

But it seems to me that there are matters of degree. If an entity needs to go back annually in the appropriations process, and you and Sheila know much more

about this than I do, I think that there is one level of accountability and that there's annual scrutiny and a process that lends itself, I think, to political intervention.

5 If there were a direct, automatic tap on the Trust 6 Funds Congress can change that. It's in law and the law can 7 be rewritten. But it doesn't require somebody to go back 8 annually through the appropriations process. It creates 9 fewer opportunities for political intervention. So the 10 accountability is not severed but maybe, I think, the 11 potential for political intervention is reduced.

Am I thinking about that correctly? MR. DURENBERGER: If I may, I don't think there's any question about that and I have no idea what motivated me back in 1986 but probably by then I was experienced enough

16 or well enough advised to realize that that was a critical

17 factor. And all the history before that had been

18 underfunding and inadequacy of funding, so you couldn't even 19 do a good job.

20 MR. HACKBARTH: So if I'm characterizing that 21 correctly, I don't think that we want to, in this document, 22 recommend a specific funding source. I think Bob, at the last meeting, had said the message should be there needs to be a secure and sufficient source of funding. We may say this is a critical issue. How do you get it far enough without ultimately cutting the accountability for the use of public money? And an option that you can look at is a direct tap on the Trust Fund and move on.

7 MR. DURENBERGER: I'll just quit here but the main 8 point I was making is around the word independent and the 9 implication that somehow or another we would be funding 10 something that is independent of an accountable, a currently 11 accountable entity.

12 The other thing that relates to that, and the last 13 thing I want to say, is that from '87 and '89 when we passed it on we tried to build a replacement for all of our other 14 15 efforts, now called the Agency for Healthcare Research and 16 Quality. No one has ever adequately funded that. From time 17 to time somebody will give them a specific charge but for 18 some reason or another they won't get adequate funding to do it or something like that. 19

And so I hope that as we press on the issue of comparing and effectiveness and things like that we will recognize that we have tried to build the capacity into the

1 government. We have not funded it, Congress has not funded 2 it the way they should, and that we need to look at all of 3 this of a piece.

4 DR. REISCHAUER: We've talked about this being a 5 public good and, as such, if public funding is involved in 6 whole or in part supporting it not through the appropriation 7 process, which we all think has its limitations, but rather 8 through a more automatic mechanism, I would assume that the 9 entity would be accountable to the public in the form that 10 the Federal Reserve System is where twice a year the 11 Chairman of the Federal Reserve Board is required to come and report to the Congress. And some mechanism like which 12 13 would be the forum at which a discussion of the entity's 14 role and achievements during the year would be appropriate 15 without the ability of the Congress to exercise detailed 16 control over the day-to-day actions of the entity.

DR. SCANLON: This follows up on both Dave and Bob because I've really been very focused on the whole idea of what independent means and not just an entity that is not part of a cabinet department but something that is truly independent and can remain truly independent.

22 And in thinking about that, actually, the Federal

1 Reserve has come up for me as a good example because it's an 2 agency that is recognized as being critically important, yet 3 loved and hated at the same time, and survives some of the 4 intense periods of hate because we recognize that over the 5 long run it serves great value.

6 So looking to it and looking to its model, we 7 don't have 90 years to say that this entity has existed and 8 therefore it's built its track record. But looking to the 9 bottom of the Federal Reserve, I think, is useful. They do 10 have independent funding. We can't put this entity into the 11 same position in terms of generating revenue. But the idea 12 of tapping into the Trust Fund is a potential means of 13 eliminating the appropriations process.

I don't think it should be perceived as we're saying Medicare alone is paying for it. The money going into the Trust Fund is coming from all Americans. We're closing in on 45 percent coming from general revenues and another probably 40 percent coming from a very wide-based payroll tax.

One of the things that could be done is to say that we're going to tap into the Trust Fund but we're not going to have it affect the Part B premium so that the elderly do not pay a disproportionate share of this public good, because this is really a public good and so it should be financed broadly.

In discussing it that way, perhaps you get away from this idea of how do we go around and figure out how to get the private sector to pony up? Because they're already ponying up through the money going into the Trust Fund.

8 Other features of the Federal Reserve, I think, 9 that are important to think about is the leadership there is 10 appointed, in some respects, with some independence from the 11 political process because the terms don't coincide with presidential terms. We've got significant overlap across 12 13 presidential terms. And I think that helps contribute to They operate under different personnel rules 14 independence. 15 and different ethics rules than the federal government.

16 These things all contribute to the independence. 17 I think they would be important for this kind of an 18 organization.

And I was exactly where Bob was in terms of accountability. They've got to do things in public so that they can be criticized even outside of the times they go to the hearing. But they should be going to the Congress on a periodic basis, reporting on what they do, and justifying
 what they do because that's part of the accountability.

3 Is it perfect? No. But I think we need to think4 about how do we make this independent.

5 Some of the other examples of independent 6 organizations, they've had an easy time. They're not 7 controversial. That's what threatens independence is when 8 you step into some area that becomes controversial and 9 somebody is out to try and eliminate you.

10 MR. HACKBARTH: If Doug were here I think he would 11 pick up on the discussion about the public financing. When 12 I talked to him about it last week he said what he wants to 13 be clear is that he thinks on the private side sponsors of new products should continue to help fund trials and 14 15 research. And he doesn't want the message to be no, all of 16 that ought to be supplanted with public funding. And I think we could address that in the text and meet his 17 18 concern.

DR. SCANLON: We've had today a very wide ranging discussion exactly what research would be funded by this entity or what this entity would do. And the idea that really taking on all of the clinical trial work is something, I think, that is an extreme version of anything
that we discussed. It's not, I believe, in anybody's mind
here that that's the option that we're talking about.

4 MS. BURKE: I want to just agree with Bill in a 5 number of respects and add a couple of other thoughts.

6 The Federal Reserve is a very interesting model to 7 look at for a variety of reasons. But I think one of the 8 most important things that would argue not only for 9 independence, which I think we would all agree however we 10 would define it.

11 But the credibility issue here I think, which is going to be one of the challenges, is going to be the method 12 13 by which one determines priorities. That is how one goes about deciding what it is that we're going to be looking at. 14 15 Buy-in to the outcomes, that is that people essentially agree about the credibility of the content and its 16 17 usefulness and its application ultimately in their own 18 decision-making. Whether that translates into the decision on coverage, whether it translates into choices about how 19 20 you pay for things or cost effectiveness.

The question really has to be how we make certain that, in fact, whatever this entity is is, in fact, seen as

an entity that is broader than Medicare. Because in fact
over the long term what has to occur is a buy-in in to a
process that looks across broadly patient groups and service
needs and puts in play a process by which we can look at
questions of effectiveness across a broad population.

6 So anything that looks solely at the Trust Fund, 7 even if it is a dedicated pot and isn't in the normal 8 appropriations process, increasingly looks just like Medicare, which I think we don't want to do. I think 9 10 somehow getting buy-in from the private sector either in the 11 construction of the board, whether you do it in a Federal Reserve sort of manner that has terms and they essentially 12 13 don't coincide with political terms, but has a board that is made up of people that bring buy-in to the process and 14 15 legitimacy of the product, I think, is what ultimately will 16 have this thing survive or not.

OTA survived for the period that it did for a variety of reasons, not the least of which was Ted Stevens and his strong support of it. But this has to move beyond Medicare. It has to move beyond the federal purchasing and the federal payer to an acknowledgment across a wide range of players that we have to get into this business and we

have to develop a process like the Federal Reserve that everybody, irrespective of how big a bank you are or where you play in the monetary system, you acknowledge is the place the decisions are at least vetted and there's a credibility to the people in the decision-making.

I think that requires us, whether it's one of these FD whatever it is that we contract and do these semiprivate -- it has to allow for private money. It has to allow for something other than Medicare. It has to allow for credibility both in the use of the product and the production of the priority and the process that gets buy-in from the private sector.

So if it's a Federal Reserve model or something else, it can't be dependent upon trust money entirely. It can't be dependent upon essentially Medicare as the driving priorities for the services that get looked at. It has to get buy-in. So it has to be created in a structure.

All the work that was done in the '80s was largely around the federal payers. That's where I think we make a mistake, if we think this is only about federal payers. Whether it's Arnie's crowd or Jay's or anybody else's, they have to be at the table or this ultimately will fail. It will just be about Medicare. And that's where we have
failed before. It's the story that Arnie has been telling
for years, which is you can't have a player that is the only
player and expect the other people to participate and have
to be a credible process. So I think that has to happen in
whatever the structure is.

7 MR. HACKBARTH: Let me make a proposal on how to 8 word the recommendation. The general idea here is to 9 simplify the wording of the recommendation but then use the 10 ensuing text to elaborate on some key words.

11 So the language I'm proposing for the 12 recommendation itself is the Congress should charge an 13 independent entity to sponsor credible research on 14 comparative effectiveness of alternative health care 15 services and disseminate this information to patients, 16 providers, and public and private payers.

And then in the ensuing text I'd pick up on some key words. Independent means -- and these won't be the exact words -- things like secure and sufficient funding from public and private sources, board representative of the parties at interest.

22 Sponsor, the verb sponsor means some intramural
research but more extramural research, taking advantage of
 existing research capabilities.

3 Credible means things like standardization of 4 methods, open process for setting priorities and examining 5 results.

6 Comparative effectiveness is an essential building 7 block but this does not preclude decisions about cost 8 effectiveness being made by other payers using this critical 9 information.

Patients, public and private payers emphasize decentralized decision-making. This is not a decisionmaking body but an information organization.

13 So use that framework, simple recommendation, not 14 too many tests. And then play off key words in the ensuing 15 text. Does that make sense to people? Any objection to 16 that?

MS. BURKE: Can I ask one question? It's a semantic and I may just be brain dead. Alternate always makes me think of alternative, sort of like alternative investments if you're doing hedge funds. But it's like you're looking at something homeopathic.

22 DR. REISCHAUER: Herbal therapy.

MS. BURKE: Is alternate the right word? It sounds like we're going to look for something other than traditional medicine. I think we ought to find a different word.

5 MR. MULLER: While we normally don't do this, I 6 think the way you summarized the two months of discussion 7 we've had on this, both morning and afternoon, those four or 8 five points, we normally we don't kind of a long recommendation. But I think rather than putting it just 9 10 buried inside the 30 or 40 pages of text, the ones you just 11 summarized again, I might suggest you do that in a box right 12 away or some subpoints and so forth, as a way of crystallizing the things on which we do agree upon. 13

I think obviously our recommendations tend to be a sentence or two long. But since we had so much conversation on this in two months you may, in fact, want to put those four or five points in. It's not a payment, it's the extramural nature of the information gathering, et cetera and so forth.

DR. SCANLON: The point about the board representing a variety of interests, I think that's important but I would say we need to be clear. I would be of a mind that it's a Federal Reserve type of board, as supposed to a MedPAC. It's not a group of people that come together eight times a year for a couple of days. This is a dedicated board of people whose sole job is this function.
DR. REISCHAUER: It would be the perspectives of

6 as opposed to represented.

7 MR. HACKBARTH: I caught that myself. We don't 8 want people to be representing interests. We want them to 9 bring perspectives, much as we do here.

10 Good suggestions. Others.

11 So with Sheila's amendment, we would delete 12 alternate and so it would be comparative effectiveness of 13 health care services. Comparative itself includes the 14 notion of head to head comparison, which I think is an 15 important element.

16 People feel comfortable with that wording? Are we
17 ready to vote?

DR. CASTELLANOS: Can you repeat the whole thing?Just the recommendation.

20 MR. HACKBARTH: The Congress should charge an 21 independent entity to sponsor credible research on 22 comparative effectiveness of health care services and 1 disseminate this information to patients, providers and 2 public and private payers.

All opposed? All in favor? Abstentions?
Okay, thank you, Nancy. Good work.
Next is the mandated report on wage index reform.
MR. GLASS: Good afternoon. This month we'll
answer some of your questions and present some draft
recommendations arising out of your discussion from last
month.

Again, this is the Congressional mandate. Our report is due by the end of June. We're planning on making it part of the June report. If you choose to make recommendations, CMS has to take them into consideration as it prepares the FY '09 proposal rule the IPPS, which will come out sometime in April 2008.

16 CMS is also to consider the issues you see on the 17 slide, use of BLS or other data, which we discuss. Also the 18 definition of labor markets. Minimizing variation between 19 markets, the occupational mix question, minimizing 20 volatility year-to-year, and modification or elimination of 21 reclass and other adjustments. We'll talk about that in 22 today's presentation. We'll also talk about the impacts. Jeff will talk about applying this to other
 settings.

Just to review, last month we discussed some of the exceptions to the current system and we looked at how in Connecticut 27 out of 32 hospitals are exceptions to the rule right now. When hospitals are an exception, the other providers in the area are left behind. That is if a reclassifying hospital gets a new wage index the SNF that's door to it or even in it does not.

Even with all these exceptions, there's still cliffs remaining in the current system. Jeff explained how the difference between North and South Dakota and how crossing that border it's not obvious they' re separate labor markets.

15 The current system is volatile from year to year. 16 The wage index for the same place can change fairly 17 radically. And there is a circularity in the system. That 18 is if a hospital controls its wages it will get a lower wage 19 index and then it has to control its wages even more which 20 will give it an even lower wage index. And it's a vicious 21 spiral that many providers complain about.

22 It's particularly a problem if there are only a

1 few hospitals in the market. And in over half the markets 2 there three or fewer hospitals.

3 The occupational mix is very difficult to correct 4 for if you start with an average wage, as the current system 5 does. So if one hospital decides to invest in IT and hire a 6 lot of computer people and another hospital decides to hire twice as many billing clerks, they'll get very different 7 8 average wages. But that will say nothing about the 9 underlying wage levels in an area. And that is actually 10 what we're trying to adjust for with the wage index system. 11 The new approach we've discussed in the past, but

just briefly the new approach has two key features. First, the new wage index is designed to reflect input prices in the market, not necessarily each individual hospital's costs.

Second, the new methodology limits the errors that can be caused by imperfect data. We know that both the current CMS cost report data and BLS data are not perfect, so it's important to have a system that kind of takes that into account.

The new approach, again we start with the BLS data in market areas, which are MSAs and statewide rural. It's

important to note it's data from all employers in an area, so it's a much better approximation of the underlying wages. It uses a fixed occupational weight technique so you don't have to have the occupational mix adjustment.

5 And then it's used as cost report data to adjust 6 for benefits because we discovered that they do vary by 7 geography.

8 We then use census county level data to adjust 9 within market areas so that the central area in an MSA tends 10 to get a slightly higher value, the outlying counties a 11 slightly lower value, and the reverse in the statewide rural 12 areas. And this tends to erode the cliffs.

And finally, we smooth between adjacent counties to reach a target difference. And we use a difference of 10 percent.

16 So you asked about impacts and let us look at 17 that. We'll first talk about volatility just for a bit. 18 This is some new data on volatility. We looked at the 19 change in wage index from 2006 to 2007, and we can see that 20 the CMS wage index has higher volatility. In fact, in over 21 10 percent of the hospitals their wage index changes by more 22 than the update. In the MedPAC index the volatility is 1 less.

To further look at this, we had our contractor go back about six years and they found very similar results. And they also looked at ad if you average just the CMS data over three years what does that do to volatility? That also decreases volatility, as one might expect, and it makes it look somewhat similar to the MedPAC index which again starts with BLS data. That's a three-year rolling average.

9 The commissioners asked for an impact analysis by 10 hospital group and also dollar weighting. We looked at the 11 usual groups and they are in your paper. They have urban 12 and rural, we look at teaching status, ownership. The only 13 groups with the big differences are those who currently have 14 an exception to the basic wage index. Those are the groups 15 we show up here.

This is a good thing because it's a geographic adjustment system so we wouldn't expect it to have any systemic advantages for major teaching or anything like that. So the fact that the only groups that show major differences are the ones that with exceptions to the current system should make us feel good about the new system.

22 So in total by definition, because the new system

is budget neutral to the current, the dollar weighted payment change is zero, and that's the top number in the middle column there. But in wage index terms there is a slight gain from using the new system.

5 If we look at no exceptions, that's two-thirds of 6 hospitals, we see a slight increase dollar weighted and a 7 slightly larger increase in the wage index for those 8 hospitals. That also makes sense because they're 9 essentially paying for the exceptions that the hospitals 10 with exceptions get so we expect them to increase a bit 11 under the new system.

Other exceptions, which is kind of a grab bag of things, in outcommuting they both gain a small amount in payments, a slightly larger amount in wage index under the new system.

And reclassifying hospitals lose some in payments and loose a bit more in wage index under the new system. Again, that makes sense. Some of the reclassifying hospitals can gain quite a large amount from reclassifying. And when they do, their neighbors who don't get to reclassify are put at a bit of a disadvantage. So we would expect, because some of those can gain like 20 percent, that

1 they would decrease a bit under the new system.

And finally, those special exception hospitals -there are only 18 of them -- sees some major drops. Those are hospitals that don't meet any of the many criteria that they currently have for exceptions so we would expect them to drop under the new system as well.

7 Mitra asked us for a step by step change, how this 8 impact worked step-by-step. That is first using BLS data 9 then adding benefits and then doing the county level wage 10 index and smoothing. That change is shown on this slide. 11 The final column here is the same as the final column we saw 12 on the previous line. So this is hospital weighted change 13 in the wage index.

14 Again no exceptions. They gain some using the 15 basic BLS data and then drop little bit. So they make a 16 small gain under the new system. Again the other exceptions 17 in outcommuting dropped a little bit and then make it up. 18 The outcommuting makes it up, particularly when we move to a 19 county level system with smoothing. That make sense because 20 the outcommuting exception goes to counties that border higher wage index counties and that's very much like what we 21 22 are accomplishing under the new system.

Finally, reclassifiers drop -- most of the drop is returning them to their basic native wage index level and then they gain a bit on the way out. Special exceptions you can see lose quite a bit there and loose when we get to the end.

6 Last month we looked at this in terms of wage 7 This time we did it dollar weighted. As you can see index. 8 there are not too many extreme examples of losing or gaining a tremendous amount by moving to the new system in terms of 9 10 payments. The dollar effect is always going to be less than 11 the wage increase, the wage index change, because only part of the Medicare payment is affected by the wage index. 12 13 That's what's called the labor share and it's currently around 0.7. So we would expect a 10 percent change in the 14 15 wage index would be like a 7 percent change in payments.

One thing people are often concerned about is rural and urban and how the differential impacts play out. Here you can see that it really isn't being urban or being rural that's driving the train here. It's really a matter of whether you have a reclassification or not. Those with reclass, whether they're in urban or rural areas lose. Those without reclass, in fact, gain. So it's not really a

1 rural/urban question, which again makes sense for the 2 system.

3 Congress, one of the things they asked was 4 modification or elimination of exceptions. We think that 5 the new approach will actually eliminate the need from any 6 exceptions. These exceptions didn't come out of nowhere. 7 People felt that there was some need for some kind of 8 change. We think the new system makes those kinds of changes where needed but doesn't overdo it as the current 9 10 system does in some cases.

Hospitals that are now reclassified under the current system see a large increase relative to their preclassification wage index. So relative to the basic calculation hospitals that reclassify gain a lot. I think it's what, 8 percent or something?

16 In the new system there will be a moderate 17 increase over the pre-reclassification system. So those 18 hospitals will still gain relative to the pre-

19 reclassification system but they won't gain as much as they 20 do under the current system.

Hospitals with outcommuting and other exceptions,
under the current system there's a moderate increase over

1 pre-reclass. Under the new system they'll also see a 2 moderate increase over pre-reclass. So they will not see 3 much of a change.

4 Essentially the new county-based system 5 automatically adjusts for differences within and between 6 MSAs and statewide rural areas. That is within an MSA the 7 central county will go up, outlying counties will go down, and the same in the statewide rural areas. Areas bordering 8 9 higher wage index areas will go up and the ones not 10 bordering them will go down a bit. That will erode the 11 cliffs, get rid of many of the differences that are 12 currently fueling the need for exceptions.

Now Jeff is going to explain how this will play out in other sectors.

DR. STENSLAND: Currently, the other PPS providers such as SNFs and health agencies use the pre-

17 reclassification version of the wage index. Under the 18 MedPAC approach, we have tailored separate wage indexes for 19 each sector. We computed each sector's wage index using the 20 same basic BLS and census data. The only difference is that 21 now we weight the different occupations differently 22 depending on the index. For example, RNs receive a higher 1 weight in the hospital wage index and a lower weight in the 2 nursing home wage index.

After we went through the computations, the key question that came up this are these SNF, home health, and hospital wage indexes sufficiently different from one another to justify having three different wage indexes?

We found that all three wage indexes are very
similar. The correlations between the wage indexes are all
0.94 or higher.

10 It's important to note that we are comparing 11 workers relative wages across markets. So what we ended up 12 finding was that in markets where hospital type workers tended to receive wages that were roughly 10 percent above 13 the national mean, we also found that in those same markets 14 15 nursing home workers tended to receive wages that were 16 roughly 10 percent above the national mean for nursing 17 homes.

Because the relative wages are all so similar for the three industries, not the actual wages but the relative wages, it appears that one wage index will be sufficient. The end result will be that all providers in a county would receive the same Medicare wage index. This will alleviate the current problem of some of SNFs and some home health agencies feeling it's unfair that the hospital next to them gets to reclassify and they don't.

In terms of impact, we also looked at how payments would change for the SNFs if they adopted a new wage index based on the BLS data. As was the case with hospitals there are some SNFs that would see increases in payments under the proposed wage index and some SNFs that would see decreased payments in both rural and urban areas.

10 As this slide shows, there are almost as many 11 urban SNFs that gain as there are urban SNFs that loose. 12 However, there are more rural SNFs that gain than lose. 13 This is because rural SNFs that are located near metro areas 14 often benefit from our use of county-specific wages and from 15 the process of smoothing that cliff between the urban area 16 and the rural area. Currently those SNFs that are next to 17 the urban areas don't have the opportunity to reclassify, so 18 under the current system they don't have any of that type of 19 benefit.

20 Under the new system no one would reclassify. 21 Therefore SNFs and hospitals in the same town would all be 22 paid under that same wage index.

1 In summary, this new system would have a few advantages. First, the advantage of using the BLS data 2 3 rather than the hospital-specific data is that it comes from 4 all employers rather than the hospital only. This reduces 5 the circularity problem David talked about. Currently, if a 6 hospital is under financial pressure and restrains its wage 7 growth, that restraint of wage growth will result in a lower 8 wage index and to a degree that may reinforce the problem, 9 causing additional financial pressure. By using data from 10 all employers and not just the hospital, the circularity 11 problem is reduced a bit.

12 The new system is also less volatile simply 13 because the BLS data is averaged over three years rather 14 than being a single year snapshot. It automatically adjusts 15 for occupational mix of employees, as David has stated. And 16 the smoothing and the blending aspects of our wage index 17 make the wage index less sensitive to data errors by a 18 single hospital and also relieve some of the cliffs that 19 we've talked about.

In general, the benefits of the new wage index are all founded on the fact that the proposed wage index is more a function of overall market conditions and less a function 1 of the types of workers or individual hospital employees or 2 the types of wages that hospital chooses to employ.

The primary disadvantage is that we cannot require that hospital fill out the BLS survey. We talked to BLS and due to their confidentiality policies they would not tell CMS who responded and who did not respond to the survey even if CMS requested it.

8 In addition, some providers would face a decline 9 in their wage index if we switch to the BLS-based approach. 10 Therefore a phase-in may be necessary. For example, CMS may 11 propose not allowing anyone's wage index to fall by more 12 than the update in any particular year. That way all 13 providers would get some type of increased payments in every 14 year.

Now we'll go through the two draft recommendations.

22

MR. GLASS: The first draft recommendation is the Congress should repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary authority to establish new wage index systems.

This is addressed to Congress because we think a

change in law is needed, rather than CMS accomplishing this
 new wage index through regulation alone. The current law is
 very prescriptive.

Giving the authority to the Secretary is very similar to what Congress has done in other areas such as SNF, home health, and ESRD.

7 The second recommendation is the Secretary should 8 establish a hospital compensation index that uses wage data 9 from all employers and industry-specific occupational 10 weights.

11 This recommendation establishes that it should be 12 a broad survey of underlying wage levels rather than 13 hospital specific so it's more of an input price approach 14 and less of a cost reimbursement system, and therefore it 15 would be more appropriate for a prospective payment system. 16 We used BLS data at the MSA and statewide rural

17 level. The fixed weight to specify to eliminate the18 occupational mix problem.

Draft recommendation three: the Secretary should establish a hospital compensation index that is adjusted for geographic differences in the ratio of wages to benefits and is computed at the county level and smooths large 1 differences between counties.

2	We split this recommendation into two pieces to
3	make the method more explicit. The inclusion of benefits
4	makes it clear it's a compensation index, not just wages
5	because we discovered that there was important differences
6	geographically between areas and the ratio of benefits to
7	wages.
8	By saying it's computed at the county level and
9	smooths large differences between counties, that's kind of
10	steps two and three in our system.
11	Of course, the computation of the county level is
12	really an adjustment to the market level that we do in the
13	recommendation before this. So it's a blended system of MSA
14	and county level.
15	Draft recommendation four: the Secretary should
16	use the hospital compensation index described in
17	recommendation two for the home health and skilled nursing
18	facilities prospective payment systems and evaluate its use
19	in the other Medicare fee-for-service prospective payment
20	systems.

21 We looked at it for SNFs and home health and found 22 that there was a very high correlation. We think that

1 correlation would become even greater since what we were
2 looking at was really the BLS definition of nursing facility
3 not the skilled nursing facility that Medicare pays for. We
4 think that the correlation between if you looked at the
5 exact occupations used in SNFs would probably be even closer
6 to the hospital index than the nursing facility one which we
7 investigated. The same is true for home health.

8 We've not evaluated it for the other PPSs. We 9 suspect it would be very highly correlated for other 10 inpatient settings such as long-term care hospitals, 11 inpatient rehabilitation facilities, and psych units. CMS 12 would need to check this out for other systems like ESRD and 13 hospice.

You can see the impacts in all these cases are budget neutral. It's a redistribution of payments and there should be no impact on beneficiaries.

We'd be happy to answer any questions and lookforward to your discussion of the recommendations.

DR. REISCHAUER: It strikes me that our recommendations must have been written by somebody who practiced writing earmarks in appropriation bills. It's sort of like why don't we just say we think the Secretary 1 should accept our method because what we've done is go
2 through each component of it as if there are 50 different
3 ways of doing this.

MS. DePARLE: I had the same reaction, why don't we just say BLS. I think this is great work. We spent a lot of time. You guys spent months, I'm sure, figuring out the methodology for all of this. And it does seem that -you've described it -- we should just say do what we came up with. There's probably a more elegant way but I don't think thas to be so elliptical either.

11 MR. HACKBARTH: We can use that as a general 12 purpose recommendation. Just do it.

13 MS. DePARLE: That's our default.

14 MR. GLASS: We can certainly do that.

MS. BURKE: This is really a question for Mark. I appreciate the work that's gone into this sort of mind numbing, as wage index always is, and the fact that you looked at what the impacts are going to be. I appreciate your inclusion of that information.

20 Mark, this is really for you or for Glenn, really 21 just an interest. In the course of the conversations that 22 followed our last meeting, where we spent a fair amount of time talking about this and talking about some of these issues, I wonder what the initial reaction has been. This is a distributive issue. It's one where the Congress has historically been not shy about writing in very specific solutions to relatively unique geographic problems, literally by postal code in some cases.

7 And I wondered just what the initial response was 8 to essentially a wholesale move away from what has become 9 this sort of tortured here's the system and then here's the 10 27 ways to stay out of the system. Is there a general sense 11 that sort of like a lot of other things it is time to move 12 on? I just wondered what your initial impressions were?

13 I think the key word to focus on in DR. MILLER: your comment is tortured. I think their reaction -- I think 14 15 there's probably two words, that and distraction. So to the 16 extent that we -- as you know, we talk to the staff all the 17 time, keep them up to speed all the time. The reaction so 18 far has been, huh, this is kind of interesting. Nobody has said and we're done, we're going to do it. I don't want to 19 20 mislead you on that.

I also think there is this sense of the reclassifications system, I think it's up to a third of the

hospitals now; is that correct? People know there's this tortured process and this exception and that exception and they're just like I don't even know where we are anymore. They focused on, for example, the finding that you guys said either last time or the time before, that a third of the hospitals are being reclassed. This doesn't seem to

7 be functioning real well.

8 But nobody has thrown their arms around it and 9 said I love you, that kind of thing.

10 MR. HACKBARTH: You've got a situation where the 11 growing number of reclassifications, at one level, is the 12 impetus for change. As Mark described, people say wait a 13 second, we're sort of getting way, way deep into this.

14 On the other hand, it's also the barrier to change 15 because that's a large number of people that have a vested 16 interest in the status quo.

The only thing we can say for sure is that there were enough people interested in it that it made its way to a mandated report. As you well know, that doesn't necessarily mean anything like a majority. But that's where we are.

22 DR. WOLTER: I think this is really nice work that

you did. It must have been a tactic to send the practice
 expense chapter out first because it made this relatively
 easy to wade through.

4 [Laughter.]

5 DR. WOLTER: Just a couple things. One is when I 6 looked at the bar graph about those hospitals that would 7 have say more than a 2 percent reduction in their Medicare 8 inpatient payments, we've got almost 800 or so that are 2 9 percent to up to as much as 10 percent. I think the phase-10 in, the transition plan that you alluded to would be very 11 wise because those are some pretty big shifts for a 12 reasonable number of institutions.

I don't know if that would be important to be more explicit in the recommendation or just being strong enough in the text, but I would really favor emphasizing some kind of transition planning on this because it's going to create some planning difficulties for a certain number of

18 institutions.

And then also, on the issue of the exceptions in the reclassifications, which I think are all agree are a sign of something that isn't working well, and I certainly favor moving away from those.

But I was just wondering if, because we haven't 1 really applied this methodology yet and taken it right down 2 to the institution level, as that's done would the wording 3 4 in the chapter be something like markedly reduce the need 5 for reclassification? Do we know that this will allow 6 complete elimination? Maybe not, because that modeling down 7 at the institutional level particularly might pop some 8 things up that we don't yet understand today. 9 MR. GLASS: I think you'd probably want to start 10 with a no exception policy and then there will always be 11 pressure, if necessary, to make exceptions. But I think you'd want to start -- and that's kind of what the Congress 12 13 asked for was how do you eliminate exceptions. MR. HACKBARTH: As I read, was it you Jay, who 14 15 raised this at the lunch table, that it says no exceptions? 16 Somebody raised this while we were at lunch. 17 What I picked up on was that it says this is now the task of the Secretary to develop, implement and I assume 18 maintain this system. And what we're trying to do, I 19 20 thought, was take it out of the legislative realm and say that this is something that ought to be maintained by the 21 22 Secretary and a normal element, a normal amount of

discretion, administrative discretion, and adjustments ought to be there. I think that's inherent in delegating this to the Secretary.

But we ought not be doing rifle shot legislativechanges, I think is the message. We ought not.

6 DR. STENSLAND: Maybe one extra comment on just 7 the degree of how big the exceptions would be. Under this 8 new system everybody's wage index is within 10 percent of their neighbor. So even if you got reclassified one county 9 10 over, you wouldn't be shifting by more than 10 percent, 11 where under the current system you can be shifted by 20 12 percent by shifting over to the next MSA or outside of the 13 rural into the MSA.

DR. REISCHAUER: So we should say exceptions are only allowed if they're 15 percent or more?

DR. STENSLAND: That would solve the problem. DR. MILLER: The other thing about that 10 percent, that was a choice for the purposes of modeling, but the Secretary can choose a lower tolerance level. So if this was put into the Secretary's hands, and the Secretary said look, I'm really driving to try to eliminate the exceptions process, the Secretary could set a lower tolerance level so that getting an exception just doesn't get you that much. That's the other toggle here that's possible.

MR. HACKBARTH: Actually that was what I wanted to ask about, is how you thought about where to set that trigger, the 10 percent. Why not go lower than that? Or why not go higher? How do you even think about how to set that number?

DR. STENSLAND: I think it's what would be 9 10 tolerable to people without them getting too angry about 11 their next-door neighbor getting that much more than them, but not getting it so low. So for example, in California 12 13 you have some pretty big counties. So if you start off with a really high wage index the Bay area, if you had a low 14 15 tolerance of only 5 percent, that 5 percent could trickle way off into Nevada before you lowered down from the high 16 17 1.5 in the Bay area. So you'd have 10 iterations before you 18 got done. So we were kind of balancing those two factors. 19 MR. MULLER: Like the others I think this was 20 difficult and very enlightening work.

I must say I was puzzled by eight up there, and especially when I looked at the material that we were sent

1 in advance and also what you have on page seven.

I assumed, based on the presentation last month, 2 3 that the question you were responding to that the kind of 4 smoothing and so forth would have a bigger impact. The way 5 I'm reading this table, there seems to be a much bigger 6 impact from the use of the BLS data around the smoothing. I 7 think one of the reasons I was attracted to the smoothing is 8 that all of the kind of cliffs that we had in the current system therefore lead to all these requests for exceptions 9 10 and therefore we have one-third of the hospitals having 11 exceptions.

12 The way I read this table there seems to be far 13 more weight around switching to the BLS data rather than to 14 the county smoothing. Am I reading that correctly?

MR. GLASS: The reason for that is what we're doing is this change is relative to the CMS postreclassification wage index. And the past reclassification has all those exceptions built into it. That's why you see this big change related to the BLS data.

If we did this same chart relative to the CMS prereclassification wage index system, the basic here is what the market area values are, you'd see less of a change in

1 that first column and more of a change in the third column.

I think that's what's probably the source of confusion, is we're comparing it to the CMS post-reclass in this chart.

5 DR. STENSLAND: Just the intuitive feel that I 6 have for that first column is the big losers, the negative 7 3.6, the negative 8.3, that's largely losing your 8 reclassifications status. And the 2.1 gain is basically you 9 don't have to pay for those other guys reclassification 10 anymore through budget neutrality. So that's kind of where 11 those numbers are coming from.

12 MR. MULLER: That helps.

I'm also trying to reconcile this table that shows if I take those last two, the reclassification and the special exceptions, which are roughly 800 hospitals. If you now go to slide eight please.

I was surprised to see such big shifts based on the previous data. If I start adding up those bars like Nick did at minus 10, minus five, I start getting up to over 2,000 hospitals. The way I was reading the information prior to that is that basically the 800 that had the special big exceptions were now going to be smoothed and put into 1 getting out of the exception category.

2 So could you help me reconcile why it looks like 3 there's about 800 that have those big shifts on page seven 4 close to -- looks like 2,500 that have big shifts on this 5 one. 6 MR. GLASS: The ones shifts, the 800 just roughly,

7 the ones losing going to the system are probably the ones 8 with the big shifts we were just looking at, the 800 with 9 the big shifts we were just looking at. The ones gaining 10 would be different hospitals. And those would be the ones 11 that were neighbors to a reclassifying hospital but they 12 weren't able to reclassify. Those would be the ones you see 13 gaining on the other side.

14 MR. MULLER: It might be that middle bar minus 15 two.

MR. GLASS: Minus two to plus two is just -- yes. MR. MULLER: Obviously in the world of updates 3 percent or zero and so forth, 2 percent would be seen by many as a big shift. If in fact more of them are really clustered around zero and so forth, the politics may get a little bit smoother.

22 MR. GLASS: I think last month we had plus one to

1 minus one and that was several hundred hospitals.

DR. STENSLAND: There are some hospitals that would lose 5 percent or more that aren't currently reclassed. There are some just due to changing the way the data is done.

6 MR. MULLER: I think, in general, I think going to 7 one that doesn't invite so many exceptions is good public 8 policy. I think getting rid of the cliffs is a very major 9 point. I said I was a little surprised that there was less 10 effect of that but I think you've explained it a little bit 11 as to why that is the case.

12 I would also say I think Glen has been convincing 13 that at this point in the recommendation not allowing for 14 exceptions probably makes sense. I think, in general, we're 15 going to need some exceptions somewhere along the way. 16 Making that, as you and Sheila have said, less of a 17 political process that allows for broad strokes of the 18 Congressional pen to respond to what may be happening in one ZIP code of the country is probably a good idea. 19

But when you do something that has as big effect as the slide shows I think probably having some limited sense of an exception for where it doesn't quite apply makes 1 some sense. Exactly how to articulate that in a

recommendation without opening up the door to what Glenn is 2 3 worried about opening it up to, I'm not quite sure how to do 4 that. I think there needs to be some sense of an exception. 5 If that can be isolated in Bill's Federal Reserve, then 6 perhaps we can figure out how to do that. 7 But I think in general I really like the smoothing 8 a lot. I just have to figure out how to get this smoothing so that San Francisco hits Philadelphia. 9 10 [Laughter.] 11 MR. HACKBARTH: I think that the point that Ralph and Nick have made about transition is maybe something that 12 13 -- I know the word is in here somewhere, I remember reading it in the paper. Maybe we ought to elevate that a bit. 14 15 I remember when we did the DRG refinement 16 recommendations, it was very prominent there that we thought 17 a transition would be appropriate. I can't, off the top of 18 my head, compare the magnitude of these changes to those 19 changes, how much the dollars were shifting. 20 But as Ralph says, minus two to plus two is a significant change when you're talking about update 21

22 increases that are in the 2 percent ballpark.

1 What do you think? Let me just pause there. DR. MILLER: I think we should do that. I think 2 3 you could add a sentence or a phrase either in 4 recommendation two or three that says that the Secretary, in 5 implementing this, should have a transition to it. And you're right, it is contemplated in the chapter. We just 6 didn't elevate it to a recommendation. 7 8 I don't really care which one we do. We can just 9 make sure that --10 MR. GLASS: If we're simplifying the 11 recommendation as suggested earlier, we can do it in that 12 one. 13 DR. MILLER: If we're at that point. I didn't hear us discuss it. But if that is where we are, two and 14 15 three can become one recommendation with one additional 16 bullet that says and the Secretary should implement this with a transition. 17 18 MR. HACKBARTH: Bill, do you want to speak to the 19 formatting of the recommendation? I know that's something 20 that you had earlier expressed. 21 DR. SCANLON: Before we didn't have the 22 reclassification separate. I'm comfortable with what we're

1 doing now.

22

2	MR. HACKBARTH: We unbundled what we had last
3	time, in part because of concerns that you had expressed.
4	And now I hear Bob saying that we've got all these
5	recommendation that really can be collapsed down to a
6	simpler one or maybe two recommendations.
7	DR. SCANLON: The key ideas are the data, the
8	reclassification, and the smoothing. The smoothing is
9	really another word for redefining labor markets. That's
10	the key. The redefining the labor markets is what
11	contributes to being able to eliminate reclassification. It
12	was getting those things more explicit was where I was.
13	MS. BEHROOZI: Since I was identified as somebody
14	who gave you yet more work on this to do, I want to say
15	thank you very much for slicing the data a few more ways.
16	And actually, some more of it that appears in the written
17	materials is really helpful.
18	Over the last couple of conversations about it I
19	think a number of us have worried about the impact of using
20	the BLS, not using benefits, things like that, and
21	speculated on it. You've really provided us with enough

data to see that it's not a rural versus urban thing. It's

not significantly a regional thing, that kind of thing. It
 really is about the exceptions.

I was happy to see that the overlay of the benefits data really adjusted for a lot of the change brought about by the BLS, the use of the BLS data. So I wanted to say thank you.

7 DR. KANE: I just wanted to ask about the impact. 8 I gather that the assumption is that this will then be 9 applied to the outpatient PPS. And so, in thinking about 10 the impact, is it exactly -- I'm not quite sure whether it 11 comes out exactly the same or not. But you didn't comment 12 at all.

13 So I felt like somehow there should be some 14 comment about the implications for outpatient. And that may 15 also affect how the transition work goes. I just felt like 16 the outpatient side should be -- and I had one quick 17 question.

18 When you say that there is a change of 2 percent 19 or minus 2 percent, is that per case? Or is that overall 20 payment? It wasn't clear if it's units or total.

21 DR. STENSLAND: That's overall payments. So we 22 looked at the payments on the inpatient side in a fairly sophisticated manner and we also factored in outliers
 because the wage index doesn't end up affecting your
 outliers. It only affects either 62 or 68 percent of your

4 payments because that's the labor share.

5 So that's a fairly precise number on the inpatient 6 side that gets at all of that. And that's an average over 7 all the cases. On outlier cases, it wouldn't affect it at 8 all. On non-outlier cases, it would.

9 In terms of the outpatient, their labor share is 10 60 percent so it would be a slightly different effect. But 11 the effect would be almost the same. That distribution of 12 plus or minus 2 percent is going to be almost the same if 13 look at for overall payment as opposed to just inpatient 14 payments.

DR. KANE: That assumes the -- so when you add total outpatient to this, you think it will be the same distribution?

18 DR. STENSLAND: It will be roughly the same 19 distribution.

20 DR. KANE: Even though there may be some who gain, 21 who have a lot more outpatient?

22 DR. STENSLAND: They're all going to have the same
change in their wage index for their inpatient and their
 outpatient. So the wage index goes up by say 5 percent.
 And it's going to go up by 5 percent for inpatient and for
 outpatient.

5 For inpatient it may affect 69 percent of your 6 payments. For outpatient it will affect 60 percent of your 7 payments. So it won't be exactly the same. But that 5 8 percent shift will have a similar effect on both the 9 inpatient and outpatient.

DR. REISCHAUER: I don't know where we were on exceptions. It seemed to be that some people thought that the word exceptions should be in here. I think you said well, that would be in the hands of the Secretary, which makes me as nervous as having it in the hands of the Congress, guite frankly.

I think this is sort of a chapter about getting it right and then problems will emerge, real and imagined, which the political and administrative system will deal with. But we shouldn't open the door at this point, I think.

21 MR. HACKBARTH: I think you and I are saying the 22 same thing. I didn't mean to imply that I would say rewrite

the recommendation to say give the Secretary the authority to grant exceptions. My point was I think that's inherent in granting the Secretary the authority to create and maintain the index.

5 I would expect that as problems crop up, if they 6 do crop up, that they will use their normal administrative discretion to resolve those issues. And that's how it ought 7 8 to be done, as opposed to through the legislative process. People feel comfortable with that? 9 10 MS. DePARLE: I think the fewer areas of 11 discretion the better. And I was just thinking, you said that's inherent in the delegation of the authority. 12 13 Perhaps, but with respect to other things like DRGs, we don't, I don't think, give the Secretary the authority to 14 15 say that --

16 MR. HACKBARTH: They've got the authority to 17 create new DRGs and break them up and adjust the when they 18 think that they're not accurately paying.

MS. DePARLE: Yes, but that is, in general, on a broader scale than 18 hospitals that get chosen for the reasons we all know to get a special exception. I just think I agree with Bob, to the extent we can...

1 MR. HACKBARTH: I'm not sure it's possible to 2 write legislation that says no exceptions are possible.

MS. DePARLE: Unless the Congress expressly gives the authority to do exceptions I'm not sure -- I'm not sure I agree that the Secretary inherently has that authority on each part of Medicare unless the Congress gives it to them. That would be a good question for the CMS General Counsel.

8 MR. HACKBARTH: We're using the language 9 exception, which implies an individual hospital getting 10 different treatment, when probably the model that I'm 11 thinking of is adjustments that are not institution-specific 12 but oh, we've identified a problem. Part of the dynamic 13 that exists in Congress that troubles me is sometimes it's 14 hospital-specific exceptions.

15 MS. DePARLE: Yes, and I think --

16 MR. HACKBARTH: When you do that you're inviting 17 problems.

MS. DePARLE: Right, but to the extent that members of Congress understand or believe that the Secretary or the Administrator have that ability, they are really hard-pressed not to force it when an institution in their district or their state says we're hurt by this and we want something different. It's very hard for them to say no.
 Then you just get into the cycle and we end up with, over
 time, 30 percent of the hospitals being outside of the
 system.

5 MR. HACKBARTH: It is ultimately a political 6 system. No matter where we put it short of the Federal 7 Reserve -- this is getting more attractive all the time, 8 Bill -- it's not going to be totally insulated from 9 politics.

10 The message as I see it is that we ought to have a 11 system driven by analysis and data, as opposed to by a sense 12 of loss and injustice. And there ought to be room for the 13 Secretary to identify problems that may crop up and develop 14 systematic fixes for those, as opposed to this individual 15 hospital has got a complaint and so I'm going to give them 16 more money.

That's the ethos that we want but you can never assure that it's going to work that way. Congress can always apply pressure.

DR. MILLER: And I thought when you were saying that that when you were saying the authority is apparent, every year a notice will be put out that says this is the

1 new wage index. Everyone will comment. If there's a comment that the Secretary looks at it says oh, so we need 2 3 to adjust the wage index this way, again, it's a single 4 hospital operation. It sort of well, I'm going to adjust 5 it. That is inherent, I think, in the rulemaking process. 6 I think what we're doing is we're repealing the legislated exceptions. Of course, the Congress can always 7 8 come back.

MR. HACKBARTH: And do it again.

9

And also, as you know better than anyone in the room, through the administrative process there's also some discipline. You've got to say here are the changes I'm making and here are the reasons that I'm making them. It's not done in the back room. It's done out in the light so to speak. That also establishes some discipline.

DR. STENSLAND: Can I get some clarification for when we write this up? It sounds like the second bullet in recommendation three, that the Secretary is given some leeway on how to devise this wage index at the county level. It sounds like when you're talking about if they did exceptions, those would be exceptions for the whole country that would apply to everyone. For example, if they adjusted the county wage index in that county, everybody in that county would have a different wage index, not just one hospital or once SNF like the way it works now.

4 MR. HACKBARTH: That's going further than I want 5 to go at this point.

6 What I propose we do you do, in view of Bob's 7 comment about the packaging, is let us do some repackaging 8 and come back tomorrow for the vote so that we're real clear 9 on the language. Does that make sense? People feel 10 comfortable with that?

Before we finish this, I just had one other question.

13 The draft recommendation that we looked at last 14 time, I can't remember if it was part of the recommendation 15 was like a note at the bottom said may want to consider 16 requiring that hospitals participate in BLS.

MR. GLASS: We looked into that and BLS basically said they wouldn't tell CMS whether the hospital filled it out anyway. So it kind of would be unenforceable. CMS could say that but there would be no way to enforce it.

21 MR. HACKBARTH: I see that in the summary. But 22 you had it there last time for a reason. I assume you were 1 worried about gaming of the data by selective participation.

How do you feel about that now that you hear --DR. REISCHAUER: Don't the hospitals, in general, pay slightly higher wages than the other employers of these same kinds of labor? So if they didn't participate, they'd be shooting themselves in the foot.

7 DR. KANE: But the critical access hospitals could 8 just not participate. That's what goes on now. If the low 9 cost hospitals --

10 MR. HACKBARTH: If the low-cost hospitals in a 11 market say we're were out and Ralph, you participate for us.

12 DR. KANE: [Inaudible.]

DR. MILSTEIN: It's conceivable. I think the BLS people weren't that pleased with that idea. They like their current system where it's all voluntary. They did suggest, though, there is this thing about the hospitals paying a little more. And when there is missing data, BLS tries to input what that data would be based on the characteristics of the provider.

20 So if you are like a small CAH in the hinterland, 21 I'm not sure you would know in advance whether the 22 imputation that BLS is going to estimate what your wage 1 index is going to be is going to be any different than your 2 own.

MR. HACKBARTH: Bob just enlightened me. If you're a hospital and you say well, we've got low wages relative to the local teaching hospital, we're out. Well, if that means that the nursing homes and home health agencies are going to get more weight and they have a lower wage structure, the low-wage hospital dropping out could actually hurt the hospitals, in general.

10 DR. MILLER: They do fill when they lose people in 11 the sampling frame, they do fill.

12 MR. HACKBARTH: So this isn't a big problem.

So we will bring back a recommendation for the vote tomorrow. Good work guys. Real good work.

Next we have another mandated report, this one on pay for performance in home health. You can start, Sharon, whenever you're ready.

MS. CHENG: In your mailing materials you had a draft of the report to Congress on home health pay for performance. So this afternoon I'm going to give you just a very brief review of the material that we've developed and use most of the time to get your feedback on the content and 1 tone of this draft.

22

2	I'd also like to spend some time responding to
3	questions that you raised last month on pay for performance
4	in the context of broader challenges in the payment system
5	adjusting for socioeconomic status, extra rewards for
6	breakout or exemplary performance, and also the
7	incorporation of structural measures.
8	MedPAC has noted actually for some time a level of
9	dissatisfaction with Medicare's purchasing of home health
10	services. One thing that we said consistently is that we're
11	troubled by the lack of the definition of the benefit
12	because for our work it makes it difficult to know whether
13	patients who need home health have been denied access to it
14	because we can't identify very easily which patients need
15	home health.
16	It's also difficult to judge whether we are
17	providing it efficiently because it's very difficult to get
18	a handle on what the product is to determine whether or not
19	we're doing that in a productive and efficient manner.
20	We've noted also several times inefficiencies in
21	the payment system itself. The concern here is that adding

a quality incentive to a payment system that might already

be inappropriately reimbursing for patients and for services could lead to a perverse incentive for providers or, worse yet, could overpower the impact of a pay for performance incentive.

5 Specifically, the consistent pattern of high 6 margins suggests that the base payment in home health may 7 not accurately reflect the costs of providers and so high 8 margins may potentially blunt the impact of a reward or of a 9 penalty for quality.

We've also noted in the past the large variation in the minutes within HHRGs which suggests to us that the HHRGs, the case-mix system here, may not be accurately capturing different resource use needs of patients who look similar in the case-mix system.

Pay for performance then could reinforce the payment incentive that home health agencies have to engage in adverse selection, because by avoiding sicker patients within the HHRG not only can you enhance the profitability of that case-mix but you could also look better than on a quality measure that was giving you credit for the severity of the patient based on their HHRG classification.

22 Finally, we've been consistent in the level of

1 dissatisfaction with the link between quality and payment. This is an area where we've seen the quality measures tick 2 3 steadily upward over the last four or five years and while 4 that quality data serves an important monitoring function, 5 at the aggregate level there hasn't been much of a lever for 6 Medicare as a program to act on that. Rather quality varies 7 by individual provider and is probably more appropriately 8 measured and act upon at the individual provider level.

9 So the tone that we've tried to strike in the 10 report then is that P4P can move in tandem with other 11 reforms. Implementing pay for performance begins to make 12 quality something that we can act upon as an indicator.

The Commission also has an annual opportunity to revisit the base payment and make recommendations about changes to that. We understand that very soon a case-mix refinement proposal will be available that we can think about and see whether that moves us in the direction of greater accuracy for these payments.

Finally, there is work to look not only at home health but across the post-acute care spectrum to try to get a consistent patient classification system that would allow us to understand better are the right patients going to the

setting that's going to get the best outcome at the best cost? And so this is a CMS demonstration project, but that will help us over time understand this benefit and whether we're providing services efficiently.

5 So it is in this context then of several reforms 6 hopefully moving in tandem that we have responded to 7 Congress's mandate for a report. These are the five 8 questions that we've been working on now together for several months. We've developed principles that address 9 10 each of these questions, and we've worked with a contractor 11 to not only take these principles but also to try to work 12 them down into a model for illustrative purposes to see how 13 this all works together.

14 So we hope that this report is responsive to 15 Congress's request and really that it works at two levels. 16 At a larger level we hope that they can look at our 17 principles and how they respond to the questions that 18 they've asked us as principles not only for the design of a 19 pay for performance system in home health but also something 20 that could work across other settings.

21 And we've also presented a model for illustrative 22 purposes of one possible approach to design issues. Just

1 the ideas that I hope will be helpful and will engage in 2 some conversation in the policy world are some of the 3 features of that model.

4 We've suggested that the reward pool be funded 5 with a payment withhold. We have a measure that includes 6 outcomes and adverse events. We view statistical 7 significance to acknowledge that there's noisiness in any 8 measure, that any measure that we have here is an estimate 9 of the underlying quality of the provider that we're trying 10 to assess. And so we're using this statistical significant 11 test to set our threshold for whether we would classify you 12 as a good performer, a poor performer, or an average 13 performer.

And finally, we've suggested that you could set improvement awards at one-half the size of the attainment awards. We've discussed this at some length. We feel that both of these concepts are important and this is just one way you could strike a balance between rewarding for these two activities.

There will be no formal recommendation, so this is really the level that we hope this report will respond to the mandate at. And CMS also has a mandate they've been

1 working on pretty much under the same time frame that we've been doing our work. They're working on a pay for 2 3 performance system for hospitals on the inpatient acute care 4 side. We've spoken with them. We've had a lot of good 5 dialogue actually on their model and our ideas, as well. 6 And we've gotten some coordination too, in what we're going 7 to be saying about pay for performance and some of the 8 principles.

9 So again just to hit this at a pretty high level, 10 we've suggested that the reward pool has to be budget 11 The model discusses a withhold that is collected neutral. over time in a year one and then gets paid out after the 12 13 period of performance. In our discussions with providers 14 and the industry and stakeholders to get some feedback, 15 we've received an alternative suggestion for a system that withholds the penalty in the year after the performance 16 17 measurement and does not, therefore, disrupt the cash flow 18 of agencies that would fall into our reward or our no change categories. We can consider this alternative. 19

We have a principle about how to measure agency quality attainment. We stated that the measure should be well accepted by providers and researchers. They should

1 minimize the data burden when possible. We should be trying 2 to measure things that are under the provider's control. We 3 should seek adequate risk adjustment.

In response to our work, again in the conversations that we've had, and to CMS's work on their demonstration of a home health P4P model, home health providers continue to have reservations about the reliability and the validity of the data on which the outcomes are measured and the adequacy of risk adjustment.

10 This is in response to comments from Jennie, from 11 Nancy and others, about accounting for socioeconomic status as we measure the quality of providers. The choices of 12 13 whose socioeconomic traits, which traits, and what scales to 14 use can be challenging. Especially in home health, a 15 setting in which the characteristics of the patient's family 16 might be as important as the patient themselves, whose 17 status should be measured? The patient, their immediate family, their caregiver? 18

Must status be measured at an individual level or would an area level be appropriate?

There are also many socioeconomic trace from which to choose. Is level of education relevant, race, or 1 ethnicity?

Finally, research suggests that epidemiological 2 3 findings based on socioeconomic status are very sensitive to 4 the construction of the scale, whether you have three 5 settings, five settings, or a dozen settings determines what 6 kind of relationships you're going to find between socioeconomic status and health outcomes. 7 8 There is also some room for doubt about the 9 relationship between socioeconomic status and what you would 10 expect then of health outcomes. One recent study on breast 11 cancer mortality found higher rates of mortality among women 12 in higher SES than in lower ones. Another study found that 13 much of the relationship between socioeconomic status and health function is a function of known factors which are 14 15 measured directly and can be accounted for in clinical risk 16 adjustment, factors such as obesity and smoking. 17 Some groups feel that socioeconomic adjustments 18 could offset incentives that are inherent in a pay for performance system for some providers to offload patients 19 20 that they feel would be more difficult to treat.

21 On the other hand, adjusting for socioeconomic 22 status has the effect of setting lower expectations for

providers who are in the position to have the greatest
 impact on vulnerable populations.

3 For example, if a Medicare pay for performance 4 system were to use an SES adjustment that incorporated 5 income, it would have the effect of setting a lower 6 expectation for the quality of care delivered to poorer 7 patients. Some may view the fact that there are inherent 8 lower standards for the care of vulnerable populations to be one of health care's critical problems and the impacts of 9 10 health care conspiracies have been widely studied.

11 A pay for performance system that expects good 12 care for all patients regardless of race, ethnicity, and 13 income could be one policy tool to address the issues of 14 disparities in health care.

15 An alternative to SES-based adjustments could be 16 to allow providers to identify noncompliant patients and 17 exclude them from their data. This system is employed by 18 the U.K. in their nationwide physician pay for performance quality incentive program. A comprehensive study of this 19 20 design option was generally positive. Most physicians exempted few of their patients. There was some evidence of 21 22 abuse at the extreme. They did find a moderate correlation

between the number of patients exempted by a physician and
 their quality scores.

However, we could contemplate counterbalances as well. We could introduce public reporting of provider's noncompliance rates. We could audit providers with exceptionally high noncompliance rates. Or you could imagine a system that requires providers with a high noncompliant raid to develop and implement a plan to increase compliance among their patient caseload.

10 The next question that we've discussed is how to 11 set the thresholds for reward and penalty. Again, the principle that we've develop here is that it should be 12 13 budget neutral. So to maintain budget neutrality before you've measured anybody or determined how big or how small 14 15 the winners and losers are going to be, you can only preset one of three thresholds. You can decide what score is going 16 17 to be needed to attain the reward. You can decide ahead of 18 time how many winners you want to reward. Or you can 19 determine how large the reward could be.

20 We also stated as a principle that pay for 21 performance should, to the extent possible, measure quality 22 that's under the provider's control. One of the ideas that

we've incorporated in our model is that any measure is an estimate of the quality of the provider. And so noise in that measurement is something that's not directly under the provider's control.

5 We treated each quality score then as an estimate 6 of true equality and we bounded it by an interval so that 7 everyone was clear on what the level of confidence was on 8 our estimate and how that might vary from provider to 9 provider. We used that level of confidence as part of our 10 system.

We also thought about how to balance improvement and attainment awards. The Commission has stated as a principle that the system should include both types of rewards.

In the model we rewarded improvement at one-half the level of attainment for all levels of attainment and improvement. We added an idea that Arnie suggested at the last meeting that there might be an extra level of reward if you were a provider that was both high above the threshold and continued to improve.

21 Another alternative to striking the balance that 22 we struck then would be to suggest a different trade-off between improvement and attainment, 70/30 or 60/40, rather than the trade-off that we suggested in the model.

And finally, how to calculate a reward and a penalty. To maintain budget neutrality in the model the entire pool is spent and no more than the pool is spent. Average agencies then receive a refund of the amount that was withheld. Agencies with high attainment or improvement receive a refund of their withhold and a reward that's proportional to their Medicare revenue.

10 The model images a system in which all providers 11 who attain a high level of quality receive a reward and all 12 improvers do likewise. The percentage bonus in the model 13 then is the same for an agency that exceeds the quality 14 threshold by 10 percent as one that exceeds the quality 15 threshold by say 90 percent.

In their proposed P4P model released for comment last month, CMS contemplated an alternative to this in which there would be a nonlinear exchange between quality points and rewards so that beating the threshold by a larger amount generates a larger reward. And the other concept that they have is that it might be more difficult to attain that first bump up in quality than the subsequent bump up. So there's 1 a nonlinear exchange between points and the amount of the 2 reward. It's kind of a complicated system and I could take 3 that on question if you'd like to know a little bit more 4 about that.

5 We also included two strategies to increase small 6 agency inclusion. It's important here and in other settings 7 that we try to make this as inclusive as possible and 8 there's always a challenge to try to get a good estimate of the quality of a provider that's small. So we have 9 10 suggested two ideas. One is a voluntary quality association 11 where small providers come together for the purpose of 12 measurement. And another one that we found to be especially 13 powerful in our data is that you don't have to restrict yourself to just one year of measurement and everything be 14 15 driven off one year of an estimate. We pooled data across 16 two years and that seemed to give us a lot more bang for our 17 buck in getting a good estimate without being so big that a 18 provider would perceive that average to be difficult to move 19 over time.

Finally, we suggested that the system should be one that evolves. One of our concepts is that there should be a feedback loop in this system so that as successes and perhaps failures in the implementation can be assessed and changes can be made so that the P4P system can respond to its environment.

Also, we suggested that the measure set should expand. We contemplated adding structural measures, process measures, or measures of patient experience to the set.

So there's a recap of how I tried to respond to some of the concerns at the last meeting and also the content and the tone of the draft.

10 DR. REISCHAUER: Sharon, when you were talking 11 about the complexities of trying to do something with respect to the SES-challenged population, why couldn't you 12 just leave everything the same for them as everybody else, 13 but if an entity performs well under the standard measures 14 15 it gets paid more, even more? So there's sort of an extra 16 bonus for doing well for those patients that you think are 17 particularly difficult environmentally to deal with?

18 Would that get around the perverse incentives that 19 exist and the optics of setting a lower bar that you spoke 20 about?

21 DR. MILLER: You'd kind of have to go through that 22 exercise to figure how much more you would give. Like what would be the -- if your population has this percentage then you get this much more. It's almost like -- it's an adjustment in the payment as opposed to the measures. But to keep it a budget neutral you'd still have to go through that exercise.

6 Which is not to say no, but still you have to 7 establish what you're measuring and what the cutoff is.

8 DR. MILSTEIN: On this point, this is just FYI. 9 The current evidence on the impact of lower or higher SES on 10 quality scores suggests that its impact is primarily on 11 outcomes but not on processes. So if we wanted to make this adjustment, it should be focused on the subset of home 12 13 health measures that are outcome measures as opposed to process measures because there is not evidence that the 14 15 latter are substantially affected by SES.

MS. HANSEN: Sharon, thank you for taking this on. This is a knotty problem and the ability to get one's arms around it, because of all the complexities you cited, are something that I really appreciate.

So Bob, coming up with your thought, but yet the fact that it still has to be budget neutral. But I think, Arnie, your comment about thinking about how to look at the 1 actual outcomes. But you take a look at some of the process 2 measures, I'll tell you the reason I puzzle over this. I 3 don't have any answers.

I think this skirts the whole issue of measuring for health disparities. That's where it's just another way. How do we get to looking at some of these issues? At the end of it is, of course, the outcomes. You want the same good outcomes of adherence, for example, to certain things. So are there some process components that could be identified?

I don't think there's anything we've found, anything we've done, but there's just such a squishiness right now when we talk about how do we bridge the gap of health disparities itself? This is one Medicare provider service. It's just the ability to use the cognitive skills of trying to drill down to see if we can add to this. And maybe some of it's coming, Arnie, from your comments.

But I just would like to get a way to do this composite as we address the whole health disparities. And since home health agencies are everywhere, it is seemingly a benefit that many people use. So if we can get to it with some of these suggestions I appreciate the added cognitive 1 work that we can do on this area.

2	DR. SCANLON: Thank you very much. I think you
3	did a great job in terms of all the things that we've been
4	saying and pulling together all the material here over the
5	months. And the tone in your presentation today I think was
6	right on target. Emphasizing that and making sure we're
7	consistent this is a long chapter, so making sure we're
8	consistent throughout is an important thing.
9	Particularly underscoring that fixing the
10	underlying payment system should be either simultaneous with
11	or prior to pay for performance, because I don't think we
12	can expect pay for performance to necessarily improve
13	things. Maybe it could exacerbate things given the current
14	system we have.
15	And it may be beyond that case-mix adjuster
16	because it's conceivable that this lack of definition of the
17	benefit is really the underlying problem and then a new
18	case-mix adjuster improves things. But unless we can come
19	up with some standards for what benefits we expect or what
20	services we expect people to get, we do have this low
21	utilization adjuster, below five visits we don't think of
22	that as an episode. But we may need other things like that

1 that sets standards for the benefit.

2	I'd like to raise a couple of questions about our
3	principles. And maybe there are subprinciples and therefore
4	we haven't focused on them as much as we have but they've
5	come up in the chapter. One is about the data that we
6	should use for pay for performance. I think our overall
7	principle is that we need to be respectful and not too
8	burdensome. But in the chapter we talk about using data
9	that CMS currently has.

10 I think we should be careful about saying that 11 we're not holding that to an absolute principle because the 12 reality is we don't have enough data at this point and we 13 actually are hoping through IT that we are going to improve 14 the capacity to get sort of additional data much more easily 15 in the future and that we should be thinking about, in pay 16 for performance as well as other issues, how we can use new 17 information.

18 We're spending enough money here. It's not as if 19 we're asking for the data for free. That's an issue. I 20 think we should be a little bit careful about how we talk 21 about that.

22 Another thing that came up at one point is we talk

1 about that the measure should apply to most providers. We also talk about IOM weighing in on this issue. 2 I think 3 there's a question of where do we fit or where we sit on 4 this issue of what happens when we have pay for performance 5 measures and they really don't apply to all providers? Is 6 it incumbent upon us to have a system that is applicable to 7 all providers? Or how do we make exceptions when we have a 8 system that doesn't?

9 My sense is from an equity perspective that we 10 have to make those exceptions.

People, by doing the right thing for some segment of the population, shouldn't be penalized because of a system that we created. And the budget neutrality where we're taking money out to fund overall pay for performance potentially does that. If we think payment rates are too high we should address that by changing payment rates. We shouldn't try to do it back door through pay for

18 performance.

Also in that regard is the issuance of the small agency. I think you were going in the right direction with using statistically significant differences and trying to eliminate the noise. But it also creates an advantage for the large agency in terms of meeting a threshold. So a large agency in our model could be rewarded for being just a hair above the average, whereas a small agency has to be considerably above the average before it's going to reach that threshold since the statistical significance -- the sampling variance is a function of the size of the sample.

7 This makes it more complicated but thinking about 8 either a variable target in terms of the size of the agency 9 is one possibility.

10 The other thing, in terms of the principles with 11 respect to the measures, and this I think applies, particularly with respect to home health, is the issue that 12 13 the measures need to be comprehensive enough to capture the range of services or the range of types of patients that are 14 15 going to be served. I think one of the problems that we potentially have here is that agencies are going to not have 16 17 enough information in this process because they're serving a 18 different kind of a person. We talked about the issue of in home health potentially dealing with deterioration in a good 19 20 way is something that should be recognized and incorporated.

And we don't have things -- we haven't, in health care, thought about how to measure optimal deterioration as opposed to recovery and rehabilitation. So moving in that direction is important because that relates strongly to the whole issue of selection of patients. We don't want to create a system where there are incentives to skew your selection of the patients that you serve.

6 Those are some thoughts. I think that if we can 7 make -- I don't know whether you all agree with the 8 principles. The subprinciples I think we have. But to me 9 we've been talking about principles at a higher level. In 10 this case we were dealing with an application of our 11 principles and it actually revealed some of the nuances of 12 some of those principles. I think it's important to think 13 about them.

DR. WOLTER: That really triggered something in my mind. I thought that was well said, Bill, in terms of what are some of the subprinciples and what issues get raised. This is going against the grain, but one of the principles that I think gets us in trouble is that the measures need to apply to all providers. That's particularly true, I believe, on the physician side.

21 If you thought about pay for performance not being 22 developed around the silos of payments but rather being

1 focused on the patient, you might end up with a different 2 set of measures or a different way of looking at how to 3 design pay for performance.

By that I mean is there a subset of patients in home health who are particularly fragile or who have particular issues that you'd want to focus in on to create improvement? And that would create a set of measures around that condition and around that patient, and it would be a different thing than what we're talking about here.

10 It might also be easier to connect that set of 11 measures across silos because now you're talking about a patient with a given condition or set of conditions. 12 And 13 unfortunately that's not the direction that P4P is in right 14 It's very much designed around the current fragmented now. 15 silos and kind of designed around the providers. That's, of 16 course, who we are trying to create performance improvement 17 But it doesn't quite have the focus that might do in. 18 something different than kind of what's unfolding right now.

I think you weren't on that point exactly but I think you were really getting into some of the issues that are the nuances of pay for performance.

22 DR. SCANLON: I agree with you and I think that

we've talked about this before. If your orientation is what's the best for the program and its patients, you may come to different conclusions about how you structure things as opposed to a provider's perspective, which is to say we want to reward excellence. We want to reward anybody that's excellent. Those kind of things, when they become your principal goal, they guide you in different directions.

8 MR. MULLER: Just thinking about this last 9 dialogue, we talked a little bit about pooling here. If one 10 could pool P4P across provider types, now still most 11 incentives in the system are for the basic care and the proportion of P4P is still modest compared to the basic 12 13 payment. But one of the things, perhaps, about thinking about the point that Nick and Bill were just talking about 14 15 is whether, obviously how well you use it at post-acute, 16 SNF, home care in conjunction with institutional settings, 17 is something that we're always looking at. And obviously 18 the physician role in that can be very powerful as well.

So not to put this in this in this way, I think that's one way perhaps of thinking across the silos is whether you can do the P4P pools in a voluntary way across the various provider types, on a voluntary basis.

1 DR. MILLER: If I do one advertisement for the end of the day tomorrow, if I'm not mistaken, we have a session 2 3 on episodes of care and bringing quality into those episodes 4 of care. Those are very much condition-oriented or focused. 5 So we understand they we're out here kind of in silo and 6 payment world right at the moment, but we're also thinking about this in the back room. And we'll have our first 7 discussion about that tomorrow. 8 9 One other little advertisement, try and remember

10 some of the things we said earlier today about if you start 11 focusing, for example like we do here -- and I actually 12 forgot here -- but readmissions in SNF, readmissions in home 13 health which is part of this mix, and readmissions in 14 hospitals, you're still getting -- even though it's silo, 15 you're still getting everybody to say uh-oh, I need to be 16 thinking about readmissions.

Bob, my comment was just how to do what you were talking about. But it seemed to have killed the conversation, which wasn't the intent there.

20 DR. REISCHAUER: I thought everybody agreed with 21 me.

22

DR. MILSTEIN: Sharon, per your comment about U.K.

1 physician P4P program, there are many observers -- and I'm among them -- that regard the rate at which providers, based 2 3 on their own judgment, declare the patient to be excluded 4 from the denominator to be a problem and not a model for 5 what I would hope for in a Medicare P4P program. I'm more 6 of the persuasion that we're better off with there being 7 agreement going in as to what the bases for exclusion from 8 the denominator inclusion are, and that it not be in any way -- it not be a matter of subjective judgment by providers in 9 10 any category, even subject to some overall limit. That is 11 at least my perspective on that element of your outline.

MS. BEHROOZI: And thanks for, as people have said, putting everything together what we've been talking about. You have been a lot of reference to process and structural measures, put a lot of emphasis on it.

I would just, I guess at the risk of sounding like a broken record, I would just return to Dr. Kramer's presentation this morning and talk about breaking down the silos and focusing on readmissions where he finds in a postacute long-term care setting a correlation between staffing issues and good outcomes, particularly hospital readmission being one of those outcomes that he's looking at. 1 I think it's really worth putting some effort into seeing whether you can establish that correlation here in 2 3 home health given the squishiness of some of the -- whether 4 it's process or outcome or whatever measures -- the lack of 5 ability to audit those things. And the fact that Dr. 6 Kramer, as I said, it's providing a sort of a basis for 7 thinking maybe there's a there there and there is a way to 8 capture the data.

9 Maybe it's not about hours. Maybe it's about 10 things like staff retention. Again, in terms of an 11 accessible measure for patients. Hey, we've got low 12 turnover. It sounds like a kind of a thing that a patient 13 might want to know when selecting a home care agency.

14 MR. HACKBARTH: Okay, we need to move on. Thank15 you, Sharon. Good job.

16 Next is issues in the delivery of drugs, drug
17 benefits under B and D.

DR. SOKOLOVSKY: Good afternoon. As you know, the Medicare prescription drug benefit is administered through pharmacy benefit managers and health plans in a manner similar to drug benefits provided in the commercial market. Most outpatient drugs are provided through retail or mailorder settings. When drugs are provided in settings or
 under conditions that do not fit this model patients,
 physicians, plans, and pharmacists can all experience
 difficulties navigating the system.

Last month we reported on two such situations,
overlapping coverage of drugs under Part B and Part D, and
drugs provided in long-term care settings.

8 This month Rachel will discuss some options for 9 delivering drug benefits in long-term care settings and I 10 will present some draft recommendations to resolve some of 11 the issues created by the overlap in drug coverage.

12 DR. SCHMIDT: Last month we told you about how 13 pharmacy benefits are delivered in long-term care settings 14 and some of the issues that have come up as CMS has been 15 carrying out Part D in long-term care. We do not yet have 16 empirical evidence to know whether Part D's approach is 17 affecting utilization outcomes or quality of care for 18 nursing facility residents. Recall however that our 19 interviewees told us that they had not observed gross 20 changes in utilization, nor had they perceived detrimental effects on quality of care attributable to Part D. For that 21 22 reason we didn't think there was as yet sufficient evidence

1 to bring to you draft recommendations for changes.

2 Nevertheless, carrying out Part D in long-term
3 care has raise some important issues that we should review
4 briefly.

5 One issue relates to the quality and 6 appropriateness of drug use in nursing facilities and this 7 issue predates Part D and continues today. There are many 8 adverse drug events in long-term care settings.

Last time we talked about how CMS prohibits 9 10 nursing facilities and long-term care pharmacies from 11 steering residents into plans because of the potential for conflicts of interest. At the same time, some stakeholders 12 13 believe that Part D's approach of having enrollees pick among multiple plans is complex for this population. Dual 14 15 eligible residents are auto-assigned into Part D plans, but 16 not necessarily into plans that cover the drugs they 17 currently use.

18 Representatives of nursing facilities and long-19 term care pharmacies also told us that there's a 20 considerable administrative burden from having to interact 21 with multiple Part D plans and carry out the requirements 22 that each plan has for prior authorization and grievances,
1 appeals, and the like.

Remember that when we're talking about Part D in 2 3 long-term care settings, there are two sets of formularies 4 and rebates. One is for the Part D plan itself and one for 5 the long-term care pharmacy. CMS is very concerned that 6 long-term care pharmacies are receiving separate rebates 7 from Part D plans. The Agency thinks that this could raise Medicare program spending if, for example, a long-term care 8 pharmacy had a drug on its formulary that was relatively 9 10 high-priced and not on the Part D plan's formulary but for 11 which the long-term care pharmacy received a rebate. To the 12 extent that the consultant pharmacists who are employed by 13 the long-term care pharmacies can influence which drug gets dispensed, this situation could potentially lead to greater 14 15 use of the higher priced drug.

You can roll up all of these concerns into the general question of whether Part D's approach of using competing private plans is a good fit in the long-term care sector. Many stakeholders that we talked to said no. At the same time, CMS and others think that Part D's approach can work in this setting and past ways of doing business were not necessarily the best.

1 So one question you asked us last time was what is the range of policy approaches, what could that range look 2 3 like for delivering drug benefits in this setting? So we 4 brought back a few ideas for you to consider. We don't 5 intend for these to lead to a recommendation from you for 6 They're for purposes of discussion over time as we get now. 7 more evidence about how multiple competing drug plans are 8 working in long-term care.

9 Your mailing materials outlined three approaches. 10 The first starts with the status quo, keeping multiple 11 private plans. But in order to better ensure that plans are 12 paying attention to enrollees who are nursing facility 13 residents, the option would require Part D plans to report specific quality data. For example, indicators of patient 14 15 safety and measures of potentially inappropriate use of 16 drugs for enrollees.

This option would allow time for the relationship among stakeholders to evolve. To the extent that there is a general shakeout among Part D plans and some plans exit the market, this might address some of the concerns that we heard about administrative burden and too much complexity. But there's a lot of uncertainty about what will actually

happen here. Adding reporting requirements for this group of enrollees could help ensure that Part D plans pay attention to concerns about safety and appropriateness of prescribing.

5 Under a second option CMS would hold periodic 6 competitions, for example every two to three years, among 7 sponsoring organizations that are interested in becoming the 8 sole prescription drug plan for residents of long-term care 9 facilities in a given geographic region. If long-term care 10 residents were the only type of enrollees in these plans, 11 it's likely that the plan would pay more attention to safety and quality issues for this population, particularly if this 12 13 contracting approach were coupled with public reporting of 14 quality measures.

15 This approach would address the complexity and administrative burden complaints that we've heard about. 16 17 Payments could be structured in the same way as for other 18 Part D plans today with plans bidding and bearing insurance risk. CMS would need to verify that risk adjusters for 19 20 institutionalized enrollees are accurate in order to keep organizations interested in serving this population. 21 22 A third option is to reimburse long-term care

pharmacies directly for delivering Part D benefits. So for residents of any given nursing facility, that nursing facility's long-term care pharmacy would become their Part D provider. Unlike retail pharmacies, long-term care pharmacies already carry out some functions that pharmacy benefit management companies do, such as developing their own formularies.

8 One hurdle with this approach is that policymakers 9 would probably want long-term care pharmacies to bear some 10 insurance risk, just as all Part D plans do today in order 11 to give them incentives to consider prescription drugs cost 12 before dispensing them.

13 To meet certain regulations such as state licensing requirements for risk bearing entities, long-term 14 15 care pharmacies might need to partner with insurers to do They'd also need to develop certain capabilities that 16 this. 17 long-term care pharmacies do not now have, for example 18 information systems for enrolling and disenrolling members, submitting bids to CMS, collecting premiums, and perhaps 19 20 using utilization management tools such as prior authorization, to a greater degree than they do today. 21 22 It's not clear what effects this approach would

1 have on the structure of the long-term care pharmacy

2 industry, for example whether smaller pharmacies could take 3 on these new functions relative to larger ones.

We plan to continue work on this topic watching for evidence of how Part D is affecting beneficiaries who reside in nursing facilities. We'd like your input on what you'd need to know in order to thing through the implications of different options such as these.

9 DR. SOKOLOVSKY: Last month I reported the results 10 of interviews with stakeholders including drug plans, 11 pharmacists, and beneficiary advocates, who reported 12 instances where the overlap in drug coverage under Part B 13 and Part D created problems for them. Since then we've 14 continued to talk about these issues with physicians, CMS, 15 public health experts, and other stakeholders.

16 Interviewees agreed that since plans are not 17 allowed by law to cover drugs under Part D that could be 18 covered under Part B, decisions about overlap drugs can 19 delay beneficiary access, impede quality by affecting 20 beneficiary compliance with medication regimens, and 21 increase costs and administrative burdens for physicians, 22 plans and pharmacists. Although CMS and plans have taken many actions to ease these problems, issues remain. The most common problem continues to be determining coverage for drugs used to treat multiple conditions. Physicians also expressed concern about their ability to provide preventive vaccines under Part D. The draft recommendations we're putting before you today are intended to address these issues.

8 Let me just briefly remind you this slide shows 9 you situations where drugs can be covered under both Part B 10 or Part D. Most drugs, remember, are clearly covered under 11 one or the other program, but in some instances pharmacists 12 find that additional information is needed to determine 13 which program covers a particular drug. This slide shows 14 the four most common situations. Let me just go over one.

15 Drug coverage can depend upon when a patient had a particular medical procedure or treatment that requires 16 17 additional medication. So for example, most oral 18 antiemetics that are dispensed within 48 hours of 19 chemotherapy are covered under Part B. After that time 20 period, they would be covered under Part D even though they were still being used to treat nausea caused by 21 22 chemotherapy.

1 As many as 6,000 individual drug products may be covered by Part B or Part D depending upon circumstances. 2 3 And remember by law PDPs cannot cover a drug under Part D if 4 it should be covered under Part B. So drugs are often 5 placed on prior authorization lists. This means plans have 6 to gather additional information about why the drug is being 7 prescribed or where the beneficiary lives before they can 8 approve the drug. When this happens the prescription cannot 9 be dispensed immediately at the pharmacy. The pharmacy must 10 contact the plan. Frequently the physician must provide 11 information to the plan, and the beneficiary cannot get their medication until the prior authorization is resolved. 12 This also results in increased costs for physicians, 13 pharmacies, and plans. 14

15 So this leads to draft recommendation one. The 16 Congress should direct CMS to identify certain overlap drugs 17 and direct plans to always cover them under Part D. 18 Identified drugs should be low-cost and covered under Part D

19 most of the time.

Inexpensive drugs like prednisone and methotrexate are prescribed for many conditions. They are only covered under Part B if they are prescribed as immunosuppressive drugs following a Medicare covered organ transplant. The cost of each of these drugs is well below \$2 and it is estimated that Part D ends up covering them more than 90 percent of the time. There is a very short and identifiable list of drugs that meet the two criteria listed there. I would say less than 10 individual products.

7 Plans, pharmacists, and physicians will spend more 8 money and use more time and resources meeting prior 9 authorization requirements to determine why the drug is 10 being prescribed than it would cost plans to cover the drug. 11 And if the drug is held up at the pharmacy while the plan 12 collects more information, beneficiaries are delayed getting 13 access to their drugs and the quality of their care will 14 suffer.

Some plans told us that they have directed pharmacists to override the prior authorization and cover these drugs routinely but they are concerned about their legal liability under any future audit. The purpose of this recommendation is so that CMS can draft a regulation about what drugs should be covered under D using the listed criteria.

In order for CMS to be able to do this, Congress

1 must change the law to modify the sections that say that
2 Part D can't ever cover a drug that might be covered by B.
3 Stakeholder groups for plans, pharmacists both support this
4 solution to the problem, as do the physicians we spoke to.

5 In its guidance to plans, CMS requires all plans 6 to apply a transition policy for new enrollees who are 7 stabilized on non-formulary drugs or drugs that plans put on 8 their prior authorization list. The transition supply is 9 limited to 30 days and regular plan cost sharing applies. 10 The idea is that within 30 days beneficiaries and their 11 physicians will have the time to get a formulary exception 12 or meet prior authorization requirements or change drugs.

13 However, because again of that legal requirement 14 that plans cannot cover drugs that might be covered under 15 Part B, plans are specifically prevented from applying this 16 policy to overlap drugs. That means, for example, that a 17 beneficiary who needs an immunosuppressant to cover 18 rejection following organ transplant cannot receive a 19 transition supply while the plan determine whether the drug 20 should be covered under B or D.

21 So draft recommendation two reads the Congress 22 should allow plans to cover a transitional supply of overlap

drugs under Part D under the same conditions as the general
 transition policy applied by CMS.

3 As I said, the law again will not allow the 4 transition supply for overlap drugs if Part B might be 5 involved. So beneficiaries may wait for some time before 6 getting their drugs. Pharmacists may provide emergency 7 supplies but they will be at risk if coverage is denied and 8 the beneficiary cannot pay out of pocket. This recommendation would improve access for beneficiaries and 9 10 improve the quality of their care, and reduce risk for 11 pharmacists. Again pharmacists and PBM trade associations 12 support this approach.

13 Since in the vast majority of cases Medicare will 14 cover the drug either under Part B or under Part D, the 15 spending implications should be minimal.

Finally physicians report that coverage of preventive vaccines under Part D is problematic for them. Under statute Medicare covers preventive vaccines for influenza, pneumonia, and hepatitis B under certain circumstances. Medicare covers other vaccines under Part B if they are administered related to an injury or direct exposure to a disease. 1 For example, if a beneficiary is bitten by an animal, Part B will cover the rabies vaccine. However, 2 3 Medicare covers any other preventive vaccines under Part D 4 now. Currently, experts report that there are few 5 preventive vaccines that are being covered. Interviewees 6 mentioned that the most likely new vaccine to be covered 7 under Part D is a vaccine for shingles that was licensed by 8 the FDA in 2006.

9 However, if more vaccines become available in the 10 future, physicians are likely to have a problem billing 11 plans. Like most Part B drugs, physicians purchase vaccines and provide them in their offices but most have no direct 12 13 way of billing Part D plans. CMS is seeking to clarify how plans intend to pay for vaccines and plans have developed 14 15 some methods for direct billing, but the most common approach seems to be that the beneficiary would pay out of 16 17 pocket for the vaccine and then get reimbursed by their 18 plan. Public health agencies are concerned that these outof-pocket costs could prevent beneficiaries from getting 19 20 recommended preventive care.

21 Before the MMA preventive vaccines were only 22 covered if they were listed in statute. Congress could

simplify the process of coverage. For example, Medicare
 carriers could decide coverage based on medical evidence as
 they do other Part B services.

4 So draft recommendation three says that the 5 Congress should permit coverage for appropriate preventive 6 vaccines under Part B instead of Part D. Since physicians 7 generally can't directly bill Part D plans, they face 8 administrative barriers to provide appropriate preventive 9 care to beneficiaries. Under Part B physicians would be 10 able to administer new vaccines in their offices and 11 beneficiaries would have more access to appropriate care.

12 This recommendation would improve beneficiary 13 access and reduce administrative burdens for physicians. It 14 would likely result in some increased spending since we 15 would expect utilization of preventive vaccines to increase 16 in the future.

I would be glad to address any questions or comments you have as you work through these recommendations. Thanks.

20 MS. DePARLE: In reading the chapter, one thing 21 that I was struggling with as I looked at the 22 recommendations was what is the status of the Competitive Acquisition Program? And what impact, if any, would our recommendations have on that? Because this seems to not even mention that except maybe in the paragraph about the brown bagging there's one reference to it. I don't have a sense of whether it's taken off or anyone's doing it.

DR. SOKOLOVSKY: In terms of these recommendations
CAP really wouldn't be affected because most of this would
be Part D coverage and CAP only covers Part B drugs.

9 However, if vaccines were moved back to Part B, 10 then theoretically they could certainly be added to the 11 products that a physician could receive from CAP.

12 Currently as of actually last week, 2,200 13 physicians have enrolled in CAP which is actually a big 14 increase from the 307 in the initial enrollment period, but 15 still quite a small number of physicians compared to the 16 number of physicians that regularly treat Medicare 17 beneficiaries.

In the original sign up the most common specialties were ophthalmologists and allergists who signed up. CMS has not yet had a chance to analyze the new data so we really don't know who are the new who joined.

22 MS. DePARLE: But your analysis of the problem,

you think that the problem is widespread, the problems of the issues between Part B and Part D, and that it isn't helped at all by what's happening with the CAP program? DR. SOKOLOVSKY: CAP really doesn't affect it because they don't cover Parts D drugs anyway.

MS. DePARLE: Well, they don't cover Part D drugs but you've identified problems with Part B. So has CAP made that better or worse?

9 DR. SOKOLOVSKY: Not for these particular drugs. 10 DR. CASTELLANOS: Joan and Rachel, I certainly 11 appreciate the opportunity to talk to you prior to this 12 presentation. I think you did a great job and I really 13 appreciate the time and effort that you put into it.

May I had answer the question about CAP? CAP is effective for incident two drugs given in the doctor's office.

The vaccine issue is, I think you did a really great job on that. I really do. I think it may cost us \$50 million in one year and \$1 billion over five years, but the downstream effect in the prevention of certain disease processes and treating of that will certainly pay for itself many, many, many times over. I know I've talked to CMS and I've talked to a lot of the physicians and we really like
 where that's going. That's a real good position.

Joan, I just have some questions and maybe you can enlighten me. You mentioned this rule about the nausea and vomiting following chemotherapy where it pays for 48 hours.

6 I find that to be tremendously arbitrarily and 7 restrictive. I know we probably can't do anything about it. 8 I live in Part B and I live in Part D. And there are a lot 9 of drugs that I give that people don't get nausea and 10 vomiting until 72 hours. They come to my office. It's not 11 covered to start an IV on them. They don't have the money to buy the drugs, so these people get admitted to the 12 13 hospital and it's excess costs.

I know we can't change anything there but some of these rules are just strictly arbitrary. I'm just wondering if you could put some light on that for a second?

DR. SOKOLOVSKY: I don't think I really have anything to add to what you said except that many of these rules developed historically. The reason that the oral anti-emetics were covered at all was because -- and the only ones that are covered that I'm talking about here are the ones that directly replace infused drugs. And the decision was made, Congress made the decision that there was no point in forcing someone to get an infusion of they could take a pill. So the pills that were covered were ones that directly replaced the infused drugs. But I guess the determination was made at the time that they wanted to make sure they were really being given for nausea following chemotherapy, as opposed to other reasons.

8 DR. CASTELLANOS: Is it possible to put in the 9 report that there have been some conversations with some of 10 these rules being a little bit arbitrary and restrictive? 11 You may want to consider that.

12 Rachel, can ask you a question? One of the big 13 things that really bothered me is this issue of fraud and 14 abuse. I'm black and white on that without any question, 15 and it really bothers me.

I know it's the long-term pharmacy but is there any evidence that the physicians are involved in that? Maybe you could put some light on the fraud and abuse issue as far as the issue you talked about.

20 DR. SCHMIDT: I think what you're referring to is 21 CMS has used very strong language in referring to the 22 rebates that long-term care pharmacies receive and they've

gone as far as to say that it could constitute fraud and 1 abuse for the reasons I described earlier, the fact that 2 3 they think Medicare spending could be higher in situations 4 where a long-term care pharmacy has a drug on its formulary 5 that the PDP does not. And to the extent that consultant 6 pharmacists are able to suggest a therapeutic switch to the 7 long-term care pharmacy's drug, if there's greater 8 dispensing of that higher price drug, CMS believes that that 9 could lead to higher Medicare spending. So that's the 10 context in which they've used those very strong terms. 11 To my knowledge the physicians have not been involved in this situation. I should remind people that 12

13 what is believed is done with this rebate revenue to the 14 long-term care pharmacies is that it's used to finance other 15 services that the long-term care pharmacies provide such as 16 drug regimen reviews that are required.

DR. CASTELLANOS: I agree with you on that, but on following up on that, some of the rebates -- I mean most remains are around 7 percent. The rebates of this, I think John can tell you, some of them are up to 40 percent.

21 That's just outrageous.

22 DR. SCHMIDT: When we had our contractor do

stakeholder interviews, obviously the degree of rebates involved is highly proprietary information. However, a number of the investment analysts that we spoke with or that our contractor spoke with suggested that the larger longterm care pharmacies are able to receive larger rebates.

6 You can expect that given the setting of care and 7 the way in which care is delivered, you can probably adhere 8 to the formularies of long-term care pharmacies to a greater 9 degree than you can for PDP situations.

10 DR. CASTELLANOS: Thank you.

DR. CROSSON: If I can I want to spend a minute on B/D interaction problem that is a little different but similar to the vaccine issue which is impacting our organization and I suspect some others. I'm not sure how general it is.

Prior to Part D, we covered certain selfinjectable drugs, or drugs designed for self injection under Part B as a supplemental benefit. Particularly these are erythropoietin for pre-dialysis patients and Avanex for patients with multiple sclerosis. They are, in both cases, they're both treatments and preventive medications because they can extend the length of time before a patient needs dialysis and, in the case of multiple sclerosis, decrease
 the frequency and severity of attacks.

3 After Part D, we have not been able to cover them 4 in this way and it essentially provides really only two 5 options for this group of patients. One, that they get them 6 in the pharmacy and pay for them and then self-inject them. 7 Or they make an appointment, come into the office to 8 essentially have the drug injected by the physician and pay 9 whatever copayments are required. In either case it has 10 turned out to be a hardship for a group of patients who I 11 don't believe were the kinds of targets for the doughnut 12 hole mechanism that was constructed.

13 So we really would like to be able to continue to 14 cover these relatively narrow classes of self-injectable 15 drugs under Part D for very much the same reasons as you 16 described for the coverage of vaccines under Part B.

So where I'm going with this, since I don't know that this would add a very large financial burden and take recommendation three out of its spending category by any means, where I'm going with this is the suggestion to add a few words to that recommendation and that would be to add after vaccines "and certain self-injectable drugs" and then

1 allow that process to be worked out, to be narrowed down to 2 this type of situation.

3 MR. HACKBARTH: Reaction to that?
4 DR. SOKOLOVSKY: Me? I have a reaction. Do you
5 really want it?

6 I'm puzzled because Avanex I thought was the only7 MS drug that actually is covered under B.

B DR. CROSSON: What I'm told is that it's not, that 9 CMS has not allowed that.

DR. SOKOLOVSKY: That surprises me because before Part D I used to see that as a problem, that there were these different treatments for MS and only one could be covered under B and all the others you had to buy retail. So that surprises me a little.

As far as the erythropoietin one is concerned, I think probably we'd be a little hesitant, given all of the safety concerns out there right now, I suppose we would be really hesitant in terms of wanting to make a recommendation about that.

DR. CROSSON: This would not be designed for the patient to decide on how often. It would be under the physician's direction to allow the patient to self-inject it as opposed to have to come in and get an appointment to
 inject the drug.

3 DR. SOKOLOVSKY: In general, in theory, I agree4 with you.

5 DR. SCHMIDT: So just to clarify, this would be 6 leaving to CMS the decision of which self-injectables? 7 DR. CROSSON: That's correct.

8 DR. MILLER: One thing we can do is, given that 9 we're sort of doing this interactively, is leave the 10 recommendation is it is and raise this as an additional 11 problem after the recommendation. Just because I'm a little 12 uncomfortable putting it into the recommendation if we're a 13 little unclear on the point of where the one drug lies 14 between B and D.

DR. SOKOLOVSKY: Also, the use of erythropoietin Is so much greater than I actually think it might affect it. DR. CROSSON: I don't disagree with that, and the current data shows that it can be dangerous. But that's not the issue.

DR. SOKOLOVSKY: No, I mean in terms of spending, that it might change the spending implications because it's used so much more.

1 DR. CROSSON: Could I ask then how much time is there left before the text has to be written for this? 2 3 MS. THOMAS: So that you can see it again in the 4 meeting? Or so that you can see it again afterwards in 5 review? Because we probably will send it out to review 6 early next week and we could easily put a paragraph or two 7 in to cover this and get that to you to take a look at in 8 review draft. 9 DR. CROSSON: I'd be happy with that. I 10 understand the time problem. 11 DR. SOKOLOVSKY: Just for me to clarify in writing up, would that be in the recommendation or a paragraph in 12 the text? 13 14 MR. HACKBARTH: Text. 15 MR. BERTKO: A couple of comments, first one an 16 easy one for Joan. 17 No dispute about the recommendations, but perhaps again just something in the text to note the timing issue 18 with CMS approvals of formularies during the bid process, 19 20 please? We continually get hit by last minute or after bid changes, so that's my concern. 21 22 And then I'd go to Rachel's comment on the Part D

1 benefits in long-term care facilities and slide three with a 2 couple of comments, if you have that.

3 The first one is Rachel mentioned about a shakeout 4 coming on Part D plans for duals and low incomes who are 5 preponderantly in long-term care facilities. In fact, the 6 April 2nd rate note has changed the weighting of the 7 benchmarks and the de minimis amount. My quess is we went 8 from 2006 to 2007, from nine to about eight plans average who were getting duals and low incomes and we may go down to 9 10 five or six.

So the shakeout is going to happen by regulation,as well as by any economic forces.

The point here bring that the plans involved here the burden on the long-term care facilities is going to shrink no matter what. And they seem to be doing acceptably now. I won't speak for them at all.

17 The second part here on the additional quality 18 data, the MTMP programs are in place today to do some of 19 this. They have a dollar threshold. Perhaps you'd want in 20 the text something to say a facility type of threshold. 21 These are important people because they're expensive people. 22 DR. SCHMIDT: There is some language in the text

saying that we could have that requirements that all nursing
 facility residents are enrolled in MTM programs.

3 MR. BERTKO: Okay. And then to the second bullet, 4 the suggestion of going to a single PDP that would bid for 5 region, these are very expensive people. They are difficult 6 to deal with. My guess is you'd have some very small 7 specialty PDP plan trying to deal with this. They would 8 lose the benefit of the clout that big plans like ours and 9 our major competitors have in terms of driving down prices.

10 So aside from where the premiums are and you begin 11 disaggregating premiums so you'd see a higher premium. But 12 then on top of it, the economic forces might be you get less 13 rebates out of it, which would make it more expensive to the 14 Medicare program.

DR. MILLER: Rachel, when we were talking about this, wasn't some of the thought that you could have the specialty pharmacy then teaming with a larger insurer and that the model might get built out of --

DR. SCHMIDT: You mean the long-term care pharmacy. That's the third option.

21 DR. MILLER: Never mind.

22 MR. BERTKO: This is just a market dynamics kind

of thing. You get the biggest rebates with the most
 members.

3 MS. BURKE: Can I just ask a follow-up on that? 4 Is it your thought by raising that that we ought to pull 5 that option out? Or that in the materials that we ought to 6 reflect that those are the issues that one might want to 7 consider? Because arguably it will play out in the price 8 potentially. The question would be whether you only gave 9 them that option or whether it was among other options. 10 That you could do a full bid for a region or you could 11 choose -- depending on what the bids look like.

So I wonder, in terms of direction to the staff, is the goal to clarify what the risks might be of a direction to a single provider? And whether you envision that as being an exclusive option or one of a number of options, depending on the price points that one developed. MR. BERTKO: I was mainly raising it to clarify

18 the risks involved. This is just my observation.

MS. BURKE: I'm just wondering, for staff
purposes, whether we wanted to --

21 MR. BERTKO: Addition to the text saying this 22 might happen. 1 DR. SCANLON: I think there's also the issue of the person's perspective. Potentially, we've got them going 2 3 from Part D when they're in the community to a Part A stay 4 in a nursing home where they're now getting their drugs 5 through Part A with no co-pays. But then if we were to 6 switch them to some facility related Part D program where they had no choice, there is a third of those residents that 7 8 are going to be paying out of pocket and they would have lost control over their share. 9

10 DR. SCHMIDT: They pay the premiums and for the 11 first month they have co-pays but there's no cost-sharing.

MS. HANSEN: It's actually on the same slide. One of the things of looking at the population that we're studying over time is their cognition as a whole. Twothirds of them have some loss.

And given the idea that they might be enrolled in this MTM program, the one thing about that program, I think if it's correct, questionnaires are set out to people where they're filling out as to how they perceive this. So it seems a little oxymoronic to be sending the evaluative aspect of this to cognitively impaired people to answer telephone surveys or questionnaire surveys. So it raises to

1 me not only the methodology issue but just the general

2 consideration that that population in particular and some of 3 the dual eligibles or anybody with cognitive issues being 4 assigned to plans appropriately. But more importantly 5 probably the medications they really should be on and 6 whether these are appropriate medications.

So I have some sympathy that if the long-term care pharmacies are using some of the funds to do geriatric kind of polypharmacy review, that is a useful function for that population. And especially if their medications, for the most part on average, are fairly stable. Beyond acute episodes, this is a pretty stable base of medications.

13 I just wonder if there's another way to look at it again from a patient centered standpoint as to what model 14 15 might wrap around that that makes sense, keeps our core principles of simplicity, appropriate medication, and 16 17 accountability, and not basically keep moving them around 18 even if there's a reduction of some of the plans here. 19 I'm turning it back to that angle again. 20 DR. SCHMIDT: Those are all good thoughts. I should say about the MTM programs, it's out up 21 22 to the Part D plans to propose what exactly they're doing

right now. And although CMS reviews those plans, there's a
 lot of variability in terms of what those programs
 accomplish. Not all of them do drug regimen reviews.

So that is something, that separate requirement of nursing facilities that they conduct these things monthly may be an important thing to bear in mind. Counterbalanced against the issue that there is some concerns that CMS has about the financial relationship or the fact that consultant pharmacists are employed by long-term care pharmacies.

10 DR. MILSTEIN: At our last meeting I reference my 11 personal experience, which I think was only reinforced by 12 Andy Kramer's testimony earlier today, that this is a 13 Medicare beneficiary population that is undersupported by highly skilled and highly trained people. And for that 14 15 reason in our last meeting and today I wanted to speak in 16 favor of solutions that get us as close as possible to a 17 single consulting pharmacist that serves the facility and 18 staff and who feels personally accountable for rationalizing 19 medication use in the facility.

Accordingly, I'm biased. I favor either options two or three. This issue of quality yes, but at what price? Which is the question that I think John raised last time. 1 Should we consider the notion of options two and three being 2 subject to the cost to Medicare not being more than some 3 index of local PDPs or coming up with some way of testing to 4 make sure that the cost of that incremental quality is not 5 unlimited but that Medicare financial ability is also 6 assured while we're trying to concentrate pharmacist 7 expertise within a single facility.

B DR. SCHMIDT: Let me make sure I understand what 9 you just said. You're saying that essentially the payments 10 to a different type of or a single type of provider for 11 nursing facility residents would be subject to some sort of 12 test, maybe a local test, comparison to other payment rates 13 to plans that are serving people in the community?

14 DR. MILSTEIN: Exactly.

15 DR. KANE: Are these B and D issues, these overlaps, what's in B and what's in D, are they going to 16 17 keep recurring? Or is this sort of a shakeout of the new 18 law? Because if they're going to keep recurring, I'm wondering if the recommendation shouldn't just be we need to 19 20 figure out a way to routinely figure out these B and D borderline things, rather than the vaccines come up -- I 21 22 mean, I sort of feel like I'm designing a package here,

1 rather than --

2	DR. MILLER: The second recommendation and I don't
3	mean to jump in, but I think the second recommendation is a
4	recognition that you're still going to have to litigate
5	these issues for other sets of drugs. One way to do it is
6	to legally allow the plan to cover it for the beneficiary
7	while they're sorting through the prior authorization. It's
8	not like all these problems are solved. There will still
9	continue to be this nexus.
10	I think this is a way to keep the bene in the game
11	while the plan is sorting out the prior auth. That's the
12	best I think we've got for your issue, at the moment anyway.
13	MR. HACKBARTH: Do you want to put up the
14	recommendations on the screen?
15	On draft recommendation one, all opposed? All in
16	favor?
17	Nick and Nancy, do you want to be recorded in this
18	vote? Yes for both of you?
19	Abstentions?
20	Recommendation two, all opposed? All in favor?
21	Abstentions?
22	Number three, opposed? In favor? Abstentions?

1 Okay, thank you.

22

Welcome Jack. Good to see you again. Go ahead. 2 3 DR. SOKOLOVSKY: As you know, before 4 implementation of the Medicare drug benefit in 2006 dually 5 eligible beneficiaries who had been receiving drug benefits through Medicaid were randomly assigned to drug plans with 6 7 premiums at or below regional benchmarks. 8 In 2007 CMS randomly reassigned about one million 9 low-income subsidy beneficiaries to new plans because 10 premiums in their existing plans no longer fell at or below 11 the benchmark. At an earlier meeting Nancy suggested that using premiums alone might not be the best method for 12 beneficiaries or the least costly way to assign dual 13 eligibles and others eligible for the low-income subsidy to 14 15 a Medicare drug plan. CMS might want to consider 16 formularies and cost-sharing, as well. 17 We understand since 2006 some State Pharmacy Assistance Programs announced that they plan to use 18 19 additional criteria beyond premiums to enroll their members 20 in plans. We asked researchers at Georgetown University and NORC at the University of Chicago to study what these states 21

did and examine the potential effects on beneficiaries and

1 the Medicare programs from the methods that the states used.

I think most of you here know Jack Hoadley, Research Professor at Institute for Health Care Research and Policy at Georgetown University and one of the leading researchers on the Part D drug benefit. He is going to present initial results from this project.

7 DR. HOADLEY: Thank you. And I should acknowledge 8 there was a number of other people that worked on this with 9 me, and they are listed on the slide.

10 As Joan said, CMS randomly assigned dual eligibles 11 to qualifying plans for year one and that had a couple of particular advantages from CMS's perspective in the first 12 13 year. One was to avoid steering beneficiaries into any particular plan, and that's an ongoing concern for CMS in 14 15 how this would be done. And second, to help to stabilize a brand new market, Part D market, by guaranteeing gualifying 16 17 plans an equal share beneficiaries.

Our question really is would beneficiary assignment be more appropriate in the future, especially now that we're beyond that first year? Our key questions here, our first is a

22 beneficiary-centered approach feasible?

Second, do beneficiaries end up in plans covering the drugs that best serve their needs? Keep in mind that we're really only able to look at their current drug use in this kind of a context and that may not always be the drugs that best serve their needs. So from a data point of view, we sometimes are limited in only being able to look at their current drugs.

8 The third question, does the federal government 9 face higher cost when beneficiaries are randomly assigned? 10 I want to take a moment on this slide just to make 11 sure that you understand the context of how this plays out. If you first just look at the first column of numbers here, 12 13 the beneficiary who is a low-income subsidy eligible person, faces only minimal copayments for obtaining their 14 15 drugs. These amounts are for the full duals and they're slightly larger for some of the other duals or those with 16 17 slightly higher incomes.

18 The other important part of that column is that 19 these folks only face the same copayment for any brand-name 20 drug regardless of whether the plan designates it as a 21 preferred drug, a nonpreferred drug, or a specialty drug. 22 Furthermore the beneficiary, if the end up taking an

1 uncovered drug, they're responsible for the full cost of 2 that drug, even though they're a low-income person.

3 If you look at the right-hand side of this, you 4 see the typical plan copayments for these different tier 5 situations. And the federal government then is picking up 6 any of the difference and reimbursing to plan for the 7 difference between what the plan would normally charge and 8 what the beneficiary is liable for. So you see that the federal government then is responsible for paying the entire 9 10 difference between say a preferred brand and a nonpreferred 11 brand.

12 On the other hand, if you look at the last row of 13 this table, if it's uncovered drug the federal government is not obliged to pay the cost of that drug. So the federal 14 15 government actually does the best if the person is using 16 lots of uncovered drugs and paying for them or the 17 alternative of simply not taking those drugs. So it's kind 18 of a peculiar set of incentives that's created or a peculiar set of consequences for the federal government. 19 20 First take a look at the question of is a

21 beneficiary-centered approach feasible?

22 We took a look through interviews, as John

1 mentioned, in a number of states and let me define what we 2 mean by beneficiary-centered assignment, sometimes referred 3 to as intelligent random assignment. This is any situation 4 where beneficiaries are assigned to plans based on their 5 current drug use, their pharmacy use, or other factors about 6 their current situation.

7 We learned that about six states used some form of 8 beneficiary-centered assignment for their State Pharmacy 9 Assistance Program enrollees or Medicaid beneficiaries in 10 the initial 2006 assignments or at least, in some cases, a 11 little bit later during 2006 after the beginning of the 12 year. And some of those states are making some ongoing use 13 in some of the kind of circumstances I mentioned here.

To give a little more specificity, here are the 14 15 states that are doing this. Florida is sort of exception here because they only provided some information to 16 17 beneficiaries. They didn't actually assign beneficiaries. 18 But the other six states here all made some use of 19 beneficiary-centered assignments in their State Pharmacy 20 Assistance Programs. Maine also did so in Medicaid, and New Jersey initially planned to but ended up only doing so for a 21 22 very small group of beneficiaries.

1 The State Pharmacy Assistance Programs, in particular, had some unusual incentives to use this approach 2 3 because they were typically wrapping around the federal cost 4 for certain kinds of situations, including in many cases the 5 cost of off-formulary drugs. They realized that they could 6 achieve potential savings by assigning people to plans where 7 there were fewer cases of off-formulary drugs, and they 8 could get more savings in those states where their wraps 9 were more generous.

10 They also were interested not just in the savings 11 but also in promoting access. Some of these State Pharmacy 12 Assistance Programs also get involved with helping 13 beneficiaries when they run into prior authorization and 14 other situations, so that they found that this was an issue 15 for access.

The kind of criteria they used when they did use beneficiary-centered assignment, they always looked at whether drugs were on-formulary or not. Some states also looked at factors such as tier placement or the existence of rules such as prior authorization. Some states limited it just to brand-name drugs or made other limitations. Mostly they did look at the pharmacy that the beneficiary was
1 using, and then sometimes certain other factors were 2 sometimes used as well.

3 There were three practical considerations that the 4 state programs had to look at that we asked them about. One 5 is did they have the data that they needed to match the 6 beneficiaries' needs with plans? And the answer was they 7 had historical data to use in most all cases, so that was 8 pretty straightforward. Did they have the resources they 9 needed to conduct this? Generally, the answer was yes. 10 they found this really wasn't very expensive to do. Most 11 were able to do it out of their existing administrative 12 contracts with their pharmacy benefit administrators.

13 Did they make assignments to all of the plans that were eligible for low-income beneficiaries? Some states did 14 15 Some states used CMS-approved procedures to limit the not. 16 number of plans that they assigned beneficiaries to. 17 However, this does not seem to be something that was a 18 necessary part of going through this process. This was 19 something they chose to use for other reasons. CMS has 20 actually recognized that process in the new call letter for 2008 and state SPAPs may continue to do that. 21

22 So overall, the findings of our state interviews

were that they felt that beneficiary-centered assignment 1 could be used on a national basis, that it really was 2 3 feasible for these populations, and it really did not have a 4 major market impact. In fact, they found that the assigned 5 beneficiaries tended to line up roughly in the same kind of 6 pattern as people who selected plans themselves, the same 7 winners were winners in their process, and this really was 8 because they used a very similar process to what a beneficiary would do going on the website. 9

10 They also saw a potential for better access and 11 savings, although mostly they didn't do specific studies to 12 measure those things. They do recognize, however, that we 13 need to balance between issues of access, savings and 14 disruption for beneficiaries. You wouldn't want to do this 15 every month and move people around on a constant basis, for 16 example.

17 So the next part of our study was to ask whether 18 beneficiaries do, in fact, end up in plans covering drugs 19 that best suit their needs. We did this by taking a look at 20 three regions we selected. Take look at the plans that were 21 eligible for auto enrollment in those regions. Then we 22 selected 100 drugs that were most commonly used by Medicaid beneficiaries, and it's pretty equally mixed between brand and generic drugs. And then take a look at first the drugs that are off-formulary or subject to utilization management.

4 These are the situations where the federal 5 government would not necessarily occur added cost but there 6 may be access issues for beneficiaries. If the beneficiary 7 finds the drug is off-formulary or needs a prior 8 authorization, there might be compliance issues. They might 9 stop taking the drug. They might try to pay for it. In 10 other cases they may work with physicians to try to find an 11 alternative, and in some cases may actually get to a better 12 drug. I mean, there's nothing to say that the current drugs 13 they use are necessarily the best and the right drugs. So in some of these cases that is a good situation. Others may 14 15 find themselves taking advantage of their right to switch 16 plans.

How often do we see these circumstances? Well, of the 100 drugs -- I'm going to present one region here. Our large report shows all three regions but the patterns were pretty similar.

21 Of our 100 drugs, 40 of them were off-formulary at 22 least in one of the eligible plans and 33 of them required

prior authorization or step therapy in at least one of the plans that low-income subsidy folks were eligible for. So there is a real issue here, potentially. If you get in the wrong plan, you really could find that your drugs are not covered.

6 The next question then is does the federal 7 government face higher costs when beneficiaries are randomly 8 assigned? Here the first thing we looked at was were people 9 on the nonpreferred and specialty tiers that are generally 10 associated with those higher costs? Remember that early 11 slide I showed you. Here the beneficiary is generally unaffected by the tier placement. Their copayments remain 12 13 the same, but the federal government can incur the higher 14 cost.

15 How often does this happen? We found that 45 of 16 our 100 drugs were on a least one of the eligible plans' 17 nonpreferred tiers. When you think about the fact that 18 generic drugs rarely show up in that situation, we only looked at I think 47 brand drugs and 45 of them are at least 19 20 once on a nonpreferred tier among these plans. So this is really a real problem here or a real potential issue here. 21 22 Then we went on to look at variations in

1 copayments. Here's where you really get to the dollar impact. What we did was to look among the eligible plans 2 3 and find the minimum available copayment for each drug and 4 then compare that lowest available copayment to what the 5 copayments were for the other competing plans. We don't 6 take into account the coverage gap or catastrophic coverage. 7 We're looking one drug at a time. We're not taking into 8 account the fact that people will take a large number of 9 drugs. So this was limited in that regard.

10 But if you look on the next slide, you'll see that 11 here are some examples among our top 100 drugs of several 12 drugs where the difference in cost can be quite substantial, 13 at least \$50 higher in one plan compared to the plan where they co-pay is the lowest. You see that those differences 14 15 can get as high as over \$100, and this is for one drug for 16 one month's use we're talking about here, this is the 17 difference in the copayment.

And if you look across the broader array of drugs, you definitely can see the potential. There's a lot of detail here and there's a lot more detail in our report, but to give you a simple piece of it, there was one of the New York State eligible plans or the New York region eligible 1 plans that had 70 of the 100 drugs that were available at 2 the lowest available copayment. So if you're on that drug 3 you almost always get the lowest price and the federal 4 government's added cost would be relatively infrequent.

And yet there's another plan were 91 of 100 drugs cost at least \$5 more than in the plan with the lowest available copayment and another plan where 22 of 100 drugs have at least \$25 additional copayment compared to lowest available. So you see that there's potential for some actual higher cost to the federal government.

11 Overall what are the effects of using random assignment? Some beneficiaries in certain circumstances may 12 13 lack access to their currently used drugs. Again, it may be 14 that if they switch to the drugs the plan prefers they may 15 be in equally good or even better drugs for their 16 circumstances. They do face hurdles in staying on current 17 drugs. State governments may incur higher wraparound costs, you saw that the State Pharmacy Assistance Programs some of 18 19 them are addressing that. And the federal government may, 20 in fact, be incurring and probably is incurring some higher cost in subsidizing the copayments. This is, of course, 21 22 true both for some of the on-formulary drugs where the

1 copayments are simply higher in one case than another as 2 well as the ones where they're on nonpreferred tiers.

3 So what are the policy implications of this? We 4 found that the state experience does show that this is a 5 feasible approach that definitely could work. It could be 6 designed in several different dimensions to reduce cases 7 where beneficiaries need to use off-formulary drugs without 8 switching from their current drugs. It could be used to reduce federal program cost. It could be used to reduce 9 state cost for the SPAPs. 10

Of course, you might not get the same result with all three of those dimensions in the same plan. So there are some trade-offs. So policymakers would need to balance goals of access, goals of federal cost containment, as well as the potential for disruption. Again, you could change people every month but that would that be a desirable outcome probably for anybody other than pure dollars.

You also have implications in this for risk selection and payment fairness, and there's a whole question of the interplay between how the risk adjusters work and the role that this equal assignment was used in trying to stabilize the market in the first year. But there's a sense

1 that after the first year maybe some of those considerations 2 aren't quite as strong.

Finally, you could also think about whether this could be done in a way that takes into consideration quality or performance measures on the plans once we get more of that in place. And so things like whether plans are looking seriously at polypharmacy issues might be something else you'd also want to take into account.

9 And I would mention, as I think was mentioned a 10 little bit earlier, I think John Bertko mentioned that 11 because the benchmarks next year are changing for determining which plans are eligible, we may have more of a 12 13 situation going into 2008 and in future years than we had in 2007 where more beneficiaries in this situation may find 14 15 themselves in need of changing plans to stay in an eligible 16 plan.

Finally, I would just repeat on the next slide the limitation that we did look at each drug individually but additional analysis that could be done would try to take typical drug portfolios used by beneficiaries and give more of an overall picture of what real beneficiaries would look like in these situations and try to take into account some

1 of the trade-offs.

19

2	MR. BERTKO: Jack, I think you raise a number of
3	good issues for us to think about. I'll make a couple of
4	comments, as you probably knew I would.
5	The first is my recollection, at least in terms of
6	our dealings, is that the SPAP programs are relatively small
7	compared to the total number of duals. And so I think, as
8	you indicated, I'll rephrase it: for 2007, there were a
9	relatively small number of re-auto-allocations and new
10	entrants in here, maybe a couple hundred thousand total.
11	And the SPAPs are probably some smaller proportion of that.
12	And so the comment that it works for a small
13	number in the SPAPs is true. And probably for a number like
14	2007. In 2080 it could be between 1 million and 2 million,
15	and just the feasibility of it might be more challenging,
16	let's say.
17	The second part is to acknowledge you've got the
18	right caveat for future research and more fees here, which

But a person, and particularly low-income people here, duals, are taking a whole plethora of drugs. And when you

is I accept exactly what you said on the drug by drug level.

22 look at them a drug that might be off-formulary in a high

tier may be one, five or six are generics, two are preferred brands. And so the mix of those might be different. You almost have to do a before and after because we, at least, as a plan have had some fair amount of success A, switching to generics from brands and then switching to preferred brands from nonpreferred. So the ultimate impact before and after is probably less.

8 I'd be really interested in what your portfolio 9 would look like with -- gosh, you'd probably need a dozen to 10 two dozen what I'll call typical people with various chronic 11 conditions to see what that told us.

DR. HOADLEY: It definitely was something that we didn't have the time to do for this round but we definitely are aware of it. Many of these dual eligibles would have easily have a dozen drugs and certainly many of them with 10 or 20 drugs. There were a lot of different mixes. There would some counteracting things going on where you couldn't find a plan that has all 15 of their drugs on formulary.

In terms of the State Pharmacy Assistance Programs, I think your points are well taken. There are, I think, a total of something in the range of about a million people represented. Of course, each state is separate and

doing separate procedures. Several of the states that did this were among the largest states. And so I think the number of people that this was done for 2006 was several hundred thousand, maybe half a million people total in Pennsylvania, New York and New Jersey in particular.

6 DR. REISCHAUER: Jack, I'm sure I'm going to get 7 something wrong here because there's a lot of moving pieces. 8 But the question is over the long run, in a perfect 9 frictionless market, can the federal government save money? 10 I guess my answer would be no, except if it consciously 11 steered people into those plans that didn't cover the drugs 12 they used. But if it said well, I'm going to steer people 13 into the plans that have low copayments, as you said the beneficiary is insensitive because they have the same 14 15 payment for each one.

But what's the plan going to do? Is it going to accept a lower profit margin? Or is it going to jigger around in year two or, in my perfect market it can do this instantaneously, what's preferred and what's not preferred? When you've dumped a whole lot of people into the portion of its offering that it has the lowest profit margin on basically?

And so I think about this, forgetting about the 1 heinous policy of steering people into the wrong place. 2 3 Over all the other plans over a long period of time I sort 4 of had the feeling that the federal government can neither 5 win nor lose. Am I thinking about this wrong? 6 DR. HOADLEY: I think some of that is probably a 7 pure empirical question that we can try to get at if we look 8 at larger more real beneficiaries. 9 DR. REISCHAUER: The market aren't frictionless so 10 there will be some of this, but extracted from that... 11 DR. HOADLEY: There's certainly some sense that 12 there are some potential savings given some of the 13 magnitudes of these differences. One of the issues I think that we'd have to think about is what's the mix of 14 15 beneficiaries within various plans. There are certainly some plans in the market who's almost entire enrollment is 16 17 made up of dual eligibles. There are other plans like 18 Humana that the dual eligibles -- I don't know what the percentage is in your basic plan -- but it's really a lot 19 20 smaller. And so any kind of maneuvering that they would be doing could be potentially counter to their interest in how 21 22 they're negotiating with manufacturers or how they're out

1 there to market to non-dual eligibles were purely going.

What you are, in a sense, doing inside of most of 2 3 these algorithms for doing this is doing for the duals what 4 individuals are doing for themselves in the plan finder. 5 fact, one of the small states literally did that. They just 6 collected the information for the couple thousand people 7 they had and they just individually ran them through the 8 plan finder, a couple dozen every day until they got through 9 to the list, and they assigned them in the place that they 10 thought was the same place the person would have assigned 11 themselves, probably.

So one of the questions is so if that's the case is that same adjustment going on with the general population, if people are assigning themselves, how is that playing out and how does that just go to the overall way this market is defined?

DR. CASTELLANOS: Jack, I really appreciated yourtalk.

I know you looked at the federal government facing higher costs when the beneficiaries are randomly assigned. I'm a practicing physician and I'm going to let you know the downhill effects may greatly with added costs as a provider which is not reimbursed. I'm not sure if you've ever looked
at that or considered that.

3 DR. HOADLEY: Certainly in the sense that every 4 time a beneficiary is put in a plan with the drug that's not 5 covered or a drug that requires prior authorization, that's 6 going to have an impact on the physician as well as the individual because that's more time, it's another visit. 7 8 Some of those are reimbursed if they go back and have a 9 visit with you. But if it's just the pharmacy calling up 10 and saying hey, we're not getting this drug covered, you've 11 got to do something about it, that's obviously time that's 12 not compensated.

I think it's a really important area more 13 14 generally than just this is population is what is the 15 downstream effect of some of these changes. Even if they're 16 good changes in the end. Even if they get people into 17 better drugs, how are we adapting to the affect on the 18 physicians and the extra burden that's created out of that? 19 DR. CASTELLANOS: I'm glad you appreciate that. 20 Thank you.

21 DR. MILSTEIN: Could you clarify whether your 22 database includes information on patient diagnosis?

1 DR. HOADLEY: No. In this analysis, we are literally simply looking at the drugs and what tiers they're 2 3 on, even if we go to something more of the full portfolios, 4 we'd be talking about a person with a particular portfolio 5 of drugs and then simply looking at the relative costs of 6 obtaining those drugs for one plan versus another plan. 7 DR. MILSTEIN: This may be a self-evident comment, 8 but in follow up to Bob's input, if a subsequent analysis 9 could include information on diagnosis, it would allow 10 evaluation of different approaches to beneficiary assignment 11 taking into account not just the drug costs but also the impact of the drug diagnosis interaction on total Medicare 12 13 spending. You can't do that without a diagnosis in the 14 database. 15 DR. HOADLEY: That's certainly a very relevant 16 point. Empirically, that's a lot more challenging. 17 MR. HACKBARTH: Thank you, Jack. 18 We're on to our last item for today on hospital

19 readmissions.

20 MS. MUTTI: At the last meeting we discussed a 21 potential change to Medicare payment policy for hospital 22 readmissions and the rationale for such a policy. In the

1 course of that discussion you had several suggestions for us
2 as ways to refine our policy idea.

3 Among the ones that we heard were that we should 4 narrow the focus to select a group of conditions to focus 5 We should consider a policy that has a positive reward on. 6 for hospitals, not just a decrement or a penalty for hospitals. We should focus on hospitals not physicians so 7 8 much in this particular readmissions policy. And there was a general concern about the imprecision in risk adjustment 9 10 for this policy.

We've tried to take these comments into account and, as we go through the presentation today, I'll touch on them where I can. We'll present some new findings and a summary of the chapter.

Our intent is to continue to collect your comments and thoughts and reflect those in future drafts to eventually get it into a June report chapter.

18 Why have we focused on readmissions? Research and 19 hospitals' own experience has shown that a portion of 20 readmissions are indicators of poor care or missed 21 opportunities to better coordinate care. Reducing them 22 would improve the quality of care that beneficiaries are

getting and reduce Medicare spending. It may also begin to get fee-for-service providers -- and here particularly hospitals -- more invested in the longitudinal effects of their care, encouraging them to collaborate with other providers, and in so doing inch them more towards greater systemness, if you will, or integration.

In a sense, a focus on readmissions is the next step in a P4P agenda or a value-based purchasing agenda. And as the Commission has said before, P4P should include both process measures and outcome measures where available because they are complementary. Each has their own strengths.

13 So for this reason we are continuing to explore a 14 reward that uses an outcome measure, that is reduced 15 readmission rates.

16 The barriers to systemness or integration are ones 17 that we've discussed before. Providers often operate in 18 their own professional silos with each focused on their own 19 performance rather than the collective performance across an 20 episode of care. Fee-for-service Medicare reinforces these 21 silos by paying each provider separately regardless of that 22 coordination across providers. And generally, as we talk about readmissions today, it pays for all admissions based on the patient's diagnosis, regardless whether it's an initial stay or the same or returning or readmission for a related or the exact same diagnosis. Hospitals that do invest in reducing readmissions reap none of the reward of their investment unless they're able to fill those beds with more profitable patients.

8 So because DRG payments reward hospitals for 9 shorter lengths of stay, hospitals focus on a discharge plan 10 that gets patients out as soon as is medically appropriate. 11 Aside from moving the patient out of hospital, effective 12 management of discharge in transition is not financially 13 rewarded by Medicare.

The policy idea that we're exploring today does not change the silos, the way we pay in silos. But it would do would change hospitals' payment based partly on their ability to collaborate with other providers who can also influence readmission and work with beneficiaries, who also have an important role here, too.

Ideally we would have symmetrical incentives apply to all of those providers that are involved in this, home health providers, SNF, physicians. This topic has come up a

1 couple of times today. We've talked about home health and 2 SNF. In physicians we've talked about it when we look at 3 episodes of care, ETGs. Implicit in that idea is that 4 physicians would be held accountable for readmissions in 5 that episode.

6 So even though we continue to pay in silos, 7 aligning incentives across providers so that they share a 8 common goal should drive collaboration and increased 9 systemness.

10 The current misalignment of incentives where no 11 one is investing in preventing readmissions can lead to an unfortunate dynamic at discharge. Let's first consider the 12 13 beneficiary's perspective at discharge. It's a vulnerable care juncture for them. They may experience the transition 14 15 to home or post-acute care settings abruptly. It may be on 16 the weekends. It may be with providers or physicians that 17 they haven't worked with before in the past. Suddenly 18 they're expected to assume a self-management role that they 19 may have very much support or preparation to assume. Thev may not fully understand their needs. They may not have 20 returned to their benchmark performance and their family may 21 22 not appreciate their condition after discharge.

Further, they may not know which provider to call in the interval after discharge. It's not always clear who is informed and who's responsible at that point.

Related to that, patients may find that their
community physicians and post-acute care providers have very
little knowledge of what happened in the hospital, the
records, the discharge summary has not been forwarded to
them in a timely way.

9 So without providers focusing on transition care, 10 some beneficiaries get readmitted, perhaps unnecessarily. 11 And they may be due to medication errors, patient confusion about self-care, what symptoms to be looking for. They may 12 13 not know their end-of-life options and resort to rehospitalization as a default. There are many reasons and 14 15 we've talked about some of them before so I won't go into it 16 any further.

17 Now we'll turn to Craig.

MR. LISK: I want to move on and discuss one approach for looking at readmissions. At the last meeting we provide you with some data on overall readmission rates. But those rates also included readmissions that are unrelated to the initial diagnosis. 1 We've worked with 3M and 3M has developed some logic that allows us to identify potentially preventable 2 3 readmissions, readmissions that in many cases might be 4 preventable with proven standards of care. It's important 5 to note that although readmissions may be defined as 6 potentially preventable, it does not mean that they are all 7 preventable. Many readmissions occur even if best practices 8 are followed as a matter of course of disease progression of 9 a beneficiary.

10 The basic logic used by 3M to define potentially 11 preventable are shown in the above slide. To start, they 12 take certain conditions off the table, so they don't really 13 ever have potentially preventable readmissions. These 14 include trauma cases, burn cases, and most cancer diagnoses 15 are excluded.

The second step defines clinical attribution rules for readmissions and rules for admission patterns that do not represent readmissions. The basic rule is that there should be a high degree of confidence that the readmission is likely to be related to the initial admission.

21 Default rules are established for each pairing of 22 initial discharge and readmissions by whether they are

medical or surgical. A panel of clinicians then are used to
 define exceptions to the default rules examining every APR DRG combination that can occur for admission and
 readmission.

5 For medical admissions followed by a medical 6 readmissions, at the upper left-hand corner of the box, the 7 default rule is that the readmission is potentially 8 preventable. An example here would be a readmission for 9 diabetes following discharge for AMI.

10 There are exceptions though, these occur when 11 there are unrelated acute events. An example of this would 12 be a discharge for AMI that's followed by a readmission for 13 trauma. So that would be not considered a potentially 14 preventable readmission.

15 If we look at the top right box, we have an 16 initial medical discharge followed by a surgical 17 readmission. In this case the default position is that the 18 readmission is not potentially preventable. An example here 19 would be a discharge for pneumonia which is followed by a 20 readmission for an appendectomy.

21 Exceptions to the default rule though would be for 22 conditions where the prior discharge diagnosis was the 1 reason for surgery. An example here would be a discharge 2 for abdominal pain that is followed by a readmission for an 3 appendectomy.

Again, we show the defaults for surgical to medical, a readmission that are potentially preventable is the default. The default for surgical admissions followed by a surgical readmissions is that they are not potentially preventable. Again, we have exceptions.

9 Last month we showed you that a large proportion 10 of beneficiaries are readmitted. In the top line we show 11 you those numbers again for the 7-day, 15-day, and 30-day readmission rates. Readmission rates have also increased 12 substantially from '96 to 2005. Seven-day rates went up 0.6 13 14 percentage points, an 11 percent increase. 15-day rates 15 went up one percentage point, a 10 percent increase. And 30-day readmission rates went up 1.1 percentage points, a 7 16 17 percent increase.

I want to next, however, turn to what we see on potentially preventable readmissions, and that's on the third line using the 3Ms logic that I just explained. As you can see, these numbers are a little smaller than what we show on the top line. If we look at 15-day readmission rates, for example, 8.8 percent of cases are followed by
 potentially preventable readmission. About 78 percent of
 all readmissions if you consider all readmissions.

The last line shows spending on potentially preventable readmissions. Last time we showed you the spending on total. If we look at the 15-day numbers, we spend about \$8 billion. So if we were able to reduce the number of potentially preventable readmissions by some percentage, you'd see the approximate savings you might able to achieve on Medicare inpatient spending.

11 So how do readmission rates vary? This next slide shows the variation in potentially preventable readmissions 12 13 that occur within 15 days of discharge from the hospital. As you can see, there is wide variation. But some of this 14 15 variation is due to the mix of patients and severity level of patients treated in different hospitals. Hospitals that 16 17 concentrate on joint replacements, for instance, will 18 generally have lower readmission rates than hospitals that concentrate on cardiac care. 19

Thus, our next slide shows how hospitals' actual readmission rates differ from what is expected, given their mix of cases. This is controlling for APR-DRG and severity

level of the patients. Hospitals on the left have 15-day
 readmission rates that are lower than expected. Hospitals
 on the right have readmission rates that are higher than
 expected.

5 The expected values we use here is the average 6 readmission rate for each APR-DRG severity class of the 7 patient. Thus, by definition, about half of hospitals will 8 have readmission rates above expected and half will have 9 readmission rates below expected because that's the standard 10 that's used right here.

But if we look a certain conditions such as congestive heart failure, which we show in this next slide, the distribution of the difference between actual and expected rates of readmissions is wider than what we see for looking at all conditions across hospitals. CHF is one of the conditions with the most readmissions and potential for some reductions in readmissions with proven clinical

18 practices.

19 The average readmission rate for CHF is 12.5 20 percent but we find a pretty large proportion of hospitals, 21 20 percent for example, whose CHF readmission rates of more 22 than 4 percentage points more than expected, the two right1 hand bars.

We also find, however, that many hospitals are 2 3 able to achieve lower than expected rates of readmission 4 rates, 20 percent of hospitals are able to achieve 5 readmission rates that are more than 2 percentage points 6 lower than expected, for example. 7 If we consider practices of these hospitals, we 8 theoretically could define a new expectation of what potentially could be achieved with a goal of reducing CHF 9 10 readmission rates also for hospitals in the center of the 11 distribution, not for just that upper tail. 12 MS. MUTTI: Pioneering hospitals have found ways

13 to reduce their rates of readmissions. First, then can improve the care during the stay, avoid adverse events 14 15 during the say that contribute to post-discharge complications, and introduce standards of care that prevent 16 17 post-discharge complications. But there are other things, 18 as well. In fact, they may make even more of a significant difference than just simply improving the quality during the 19 20 admission.

There is attending to patients' medication need at discharge. One hospital system found that by introducing a

1 medication checklist into discharge packets, 30-day

2 mortality and readmission rates declined, particularly for 3 CHF and other cardiovascular patients.

4 Improving communication with patients before and 5 after discharge is another effective strategy. It can 6 involve nurse visits, and I've used that example in the 7 past. But it can also involve just a phone call or two, a 8 day, three days after discharge, to check on whether the 9 patient is complying with discharge orders, has a follow-up 10 appointment, check on developing symptoms. Some systems 11 have it so that they stay on the phone if there isn't that follow up appointment scheduled and help, in a three-way 12 call, place the call to the physician and try and arrange 13 that appointment. They have found that readmissions have 14 15 been reduced.

Hospitals that have focused on CHF might check for symptoms to do with weight, swelling, shortness of breath and pain, and with this information are in contact with the doctor and can adjust medications and avoid rehospitalizations that way. They are reporting quite large decreases in rates.

22 Others, especially with CHF patients, have the

patients call in or log into a computer system and report their symptoms on certain indicators and then nurses will monitor those responses. They will focus only on those that are having trouble. They've even be able to handle caseloads 300 patients per nurse. So that it can be fairly cost-effective if done in that kind of way.

7 Improving communication with other providers that 8 are assuming responsibility for the patient is another 9 effective strategy. According to a recent study, the 10 availability of the discharge summary at the first post-11 discharge visit appears to occur no more than 34 percent of 12 the time, hampering the quality of care and perhaps 13 increasingly readmissions as a result.

Again, some pioneering hospitals have worked toward getting discharge reports to community physicians within 24 hours, and many times they find that improving their IT systems really can help with this.

Communication to post-acute care providers is also a problem, again which can be tackled. We know of one Boston medical group that has regular meetings with SNF physicians to identify why patients have been readmitted and what they can do to prevent them. 1 So how can Medicare policy reduce the likelihood of readmission and encourage more hospitals to adopt some of 2 3 these strategies? Here we explore a two-step policy 4 approach. First, Medicare can inform hospitals, other 5 providers and beneficiaries about hospital's risk-adjusted 6 readmission rates and how they compare with their peers. 7 Many hospitals, in fact, may not be fully aware of their 8 rates, particularly the rates of readmissions to other 9 hospitals.

10 Second, after some experience with public 11 disclosure, Medicare could change payment to reward hospitals with low rates of readmission and penalize those 12 13 hospitals with higher rates of readmission. As you have 14 suggested, it may be prudent to focus this approach on a 15 limited number of conditions, at least at the outset. The narrow starter set could include those that have wide 16 17 variation in readmission rates, account for a sizable 18 portion of Medicare spending, and ideally those where 19 there's some evidence that hospitals can successfully reduce 20 rates.

In considering a target set of conditions, we've only just began to examine some possibilities. We don't

have medical staff to help inform us, but looking at the literature the best we can it seems like it might be useful to consider CHF, COPD, and CABG at least as a starter. They alone together comprise nearly 20 percent of all spending on potentially preventable readmissions as defined by 3M software, and that's looking across a 15-day readmission window.

8 Not surprisingly readmission rates for these 9 conditions are in the range of 10.7, 12.5, 13.9 percent, 10 well above the average of 8.1 over that 15-day readmission 11 period.

As Craig showed earlier, there's considerable variation. He showed it with CHF, there's considerable variation in readmission rates for these conditions. They are also ones that the literature does seem to suggest that hospitals have had some success with.

MR. LISK: This next slide shows how we might pay more for the initial admission and pay less for the readmission. Here is a concept that is basically the concept of the reward and penalty here.

If we look at the current policy, we have hospitalA and hospital B. Hospital A has low readmission rates,

1 hospital B has high readmission rates. In the end, if we
2 look at the average payment, the last column, we see that
3 their average payment per case is \$5,000 in each case.

If we go to the new policy where we pay, for example, 2 percent more for the initial admission and then we pay 24 percent less for a readmission, in this case you can see in hospital A under this system they come out ahead in terms of their average payment being \$5,035. Hospital B has a lower payment because they have excessively high readmission rates here.

If hospital B, though, was to be able to prove their performance though, that's B* in the line, they have the potential for increasing their payments. In this example, this is the example he had in your report so just a theoretical example here.

16 If they actually, because they were potentially at 17 capacity, they might actually have the ability to get some 18 new admissions that they otherwise wouldn't have had and 19 reduce their readmissions. And you see that they increase 20 their performance from the average payment going from \$4,943 21 up substantially from what they had. So by reducing their 22 readmissions they have the potential for increasing their 1 average payments.

2	MS. MUTTI: With respect to risk adjustment,
3	obviously some risk adjustment would be necessary. And
4	adjusting by APR-DRGs, as we illustrated earlier, seems to
5	be a natural starting point. Our work with 3M shows that
6	the likelihood of readmissions increases with the higher
7	severity of illness as measured by APR-DRGs.
8	Beyond that, though, some of you mentioned the
9	concern about the inability of the hospital to control for
10	all of the factors that influence readmission, such as the
11	home support environment and the fact that certain factors
12	may unevenly affect hospitals. Here we have no perfect
13	answer. This one risk adjustment seems inherently perfect.
14	We would also just point out that variation in
15	patients' home support environment can also affect length of
16	patient stay in the hospital and therefore hospitals' costs.
17	That's not currently taken into account in DRG payments so
18	we already accept some level of imprecision here.
19	One option to mitigate the concern in the case of
20	readmissions, however, is to allow hospitals to use an
21	exception policy. This is the same idea that Sharon was
22	talking about earlier in the context of home health. The

idea here is that hospitals could indicate on claims when patients did not comply with discharge instructions and have those patients not be counted in their score on readmission rates.

5 Again, if they had high and sustained rates of 6 exemptions, there would be some kind of process or review 7 for remediation.

8 Again, as she mentioned, there's an example in 9 Britain where they've used this and it wasn't abused 10 horribly.

11 [Laughter.]

MS. MUTTI: Actually, it was 1 percent of family practices reported more than 15 percent of their patients as non-compliant. So you can judge for yourself.

15 In conclusion, we'll leave you with a few questions to perhaps quide your comments. First, do you 16 17 have any questions about the payment scheme we explore? 18 Just to remind you, we laid out an approach that first 19 measures risk-adjusted readmission rates, requires public 20 disclosure of those rates, and then a year or two later includes a financial reward for hospitals with low rates and 21 22 a penalty for those with high rates.

Second, as we pointed out, we recognize that hospitals alone are not fully responsible for readmissions. Post-acute care providers, physicians, beneficiaries, and families all have an important role to play. Our approach has been to try and align the incentives.

Are there other ways that we should think about aligning incentives to reduce readmissions, is a question you might want to consider.

9 Thirdly, how are hospitals likely to respond to 10 this policy design? We have suggested that it will 11 encourage hospitals to invest in strategies that will better 12 meet beneficiaries' needs, but we'd certainly be interested 13 in your thoughts on that, too.

14 With that, we'll turn it over to you.

DR. WOLTER: This is obviously very interesting and I think certainly is an area where there's a lot of opportunity.

One of the things I wish we would do in the report, because your discussion on the silos is so appropriate, is to say that in the future we might be looking at bundling for example, Part A and Part B, of these early DRGs that we look at for readmission rates. I think 1 the more signals we give, maybe the better off we'll be.

I suppose you could think about bundling to other post-acute care sites, too. That might be more complicated, at least as an initial step.

And then, in addition to the bundling, we've talked in the past about over time maybe extending the bundle timewise out 30 days or 60 days or something like that. I know that's future work but it possibly could be referenced here.

10 I guess I'm struggling a little with the financial 11 design of this because if a best practice institution has readmission rates of 5 or 6 percent for congestive heart 12 failure, why would we subject them to some kind of penalty 13 for those particular admissions? Because I think we all 14 15 would be agreed that some percentage of the overall 16 readmission rate is related to the disease or something that's outside the control of the institution. 17

To me, it would almost be better to focus on what is an institution's readmission rate for a given condition and try to design the financial reward around those that are at best practice or, at the very least, at some sort of average and have the penalties start out in the institutions where readmission rates, per se, are higher than some mean
or some best practice.

That does get us into the issue of what you do for low-volume institutions in terms of low volumes of these DRGs.

6 My last thought is over time I would assume we might start to see more definition of what the best 7 8 practices are in terms of how patients like this are cared 9 for. And would we ever want to build into copays and sort 10 of the patient's financial responsibility things that might 11 cause them to think about choosing an institution that is a best practice in their particular problem. Which I think 12 13 over time would be a wise thing for the Medicare program to It's new territory but that would be another thing to 14 do. 15 think about in the future.

16 MR. MULLER: I think this chapter, as it's 17 evolved, hits these issues very well and so I commend you 18 for that.

I think, just following on some of the things that Nick said and you said in the chapter too, the risk adjustment is of extreme importance. Obviously hospitals that have a lot of congestive heart failure, a lot of
asthmatics, lot of pulmonary disease, are going to have
 different kind of readmission rates than hospitals that do
 more knees, rehab, et cetera, orthopedic surgery, and so on.
 So I think just echoing risk adjustment is clear.

5 I think having some kind of -- I think you 6 mentioned having some kind of documentation of process 7 measures, we're doing that increasingly on the way into the 8 hospitals. So for example, have the hospital and the physicians document the medication reconciliation or the 9 10 advice to the -- the consultation with the primary care or 11 the referring physician, the communication with the families, some kind of documentation in the record obviously 12 13 is one way of getting a sense of what they're doing around those things that are more under their control versus what's 14 15 less under their control.

16 The obvious point, the extent to which the record 17 is more electronic and there's more integration of IT, I 18 think that's a particular challenge across care systems, as 19 we've heard over and over again over the last few years.

It's hard enough to get some of that information inside one integrated system. To get it across systems is still very, very difficult. So how exactly one communicates fully and well with referring physicians or families, I
think it's made easier by having better information systems.
But still, the likelihood that those referring physicians or
the community physicians or those patient's families will
have full and appropriate access to even electronic records
is still something to be seen.

7 I have one question about whether you'd want the 8 medical errors to be in the same category as other things such as the medical reconciliation, the communication with 9 10 providers and so forth. I think my inclination is to keep 11 that more of a separate category. And whether in due time 12 CMS and others go to a different kind of payment policy, 13 especially on the errors that fall into the new terminology of the last four or five years, the never events, I might 14 15 think of separating them out in a different way than the 16 other kind of processes of care post-hospital.

I do think, just to echo again, I think the disclosure of rates is very important. I think you're obviously going down that direction.

20 So I think, in general, this has captured a field 21 that I must say as long as I've been in this I hadn't 22 thought about it as much as this chapter has caused me to 1 over the last two months. I think you've captured it quite
2 well.

3 DR. REISCHAUER: This, in a way, follows up on 4 what Nick was saying. It's two questions, arithmetic 5 questions about the example you gave here.

If I'm not wrong, hospital A from your new policy gains \$100 each on 570 patients, which is \$57,000, and loses relative to the first option \$36,000. And so in a sense it's getting paid more than it would have under current policy.

I would think you would want to set the parameters of this so that the state-of-the-art high quality hospital that Nick is referring to neither gains or loses from current policy but retains an incentive to not have people readmitted. So the gain would be equal to the loss.

MR. LISK: The goal is, depending on what you want to set your benchmark. If you set the benchmark let's say at average, average expectation first, someone who's performing better than expected will perform even better and get a reward. So you could set it up mathematically so those hospitals would end up getting a reward. And they still would get rewarded even more potentially if they 1 prevented those readmissions on an average cost per case.

They do lose the revenue from the readmission and 2 3 that's one aspect of where program savings come in. 4 DR. REISCHAUER: Presumably what we're saying is 5 some people are not performing up to standard and we 6 shouldn't be paying those ones who aren't. 7 MR. LISK: Right. 8 DR. REISCHAUER: And we're paying adequately, we 9 think, the efficient hospital. You should keep hospital A 10 harmless and, in a way, penalize Hospital B. 11 MS. MUTTI: Is this just a question of whether do you want to reward the good ones or do you want to just hold 12 them harmless? 13 14 DR. REISCHAUER: Yes. 15 MS. MUTTI: We heard some feedback from the last 16 meeting that you would like to see a reward, so we kind of 17 built our example to show a reward. 18 DR. REISCHAUER: But Nick's objection -- I mean, he shouldn't have been objection because we're paying the 19 20 state-of-the-art hospital more under your example. 21 MS. MUTTI: Right. 22 DR. REISCHAUER: But then the second question I

1 had was what if hospital B* or the readmit on hospital B* was actually hospital C? Who are you penalizing? 2 3 Earlier on you were telling us that some of the 4 readmits don't occur at the same hospital. 5 MR. LISK: What we're talking about here is really 6 -- I quess this is a mathematical example. The readmits 7 don't occur. We're still talking about potentially a 8 process that... 9 DR. REISCHAUER: You have to have some way to 10 recapture the hospital B and pay hospital C \$5,000 or 11 \$5,100. There's just a little implementation problem there. 12 MR. LISK: Basically you would still pay the 13 readmitting hospital the full rate and you would then reduce the payment for the hospital that was responsible for that 14 15 additional admission through the reconciliation process. 16 We have had some discussion about that and that 17 could be potentially handled through the billing systems at 18 CMS with reprogramming and stuff like that. 19 What I'd like to do with this comment DR. MILLER:

20 is we came to you last time with a different idea, which was 21 more focused on the hospital's particular readmission rate. 22 You had a withhold, you get it back if you did okay, and you 1 didn't if you didn't. That sort of addresses some of these
2 issues.

And then we got some feedback that said wait a minute, shouldn't you have a reward structure. So we took a shot at it.

6 Maybe what I'd like to do is can we talk about 7 both of these in the chapter as different strategies? 8 Because I think there is some attractiveness, at least at 9 the staff level, on the first idea. And then we kind of 10 turned things around in response to comments to try and 11 address this. I think in some ways we can try and talk 12 about both but maybe we could keep the first one in there.

DR. KANE: Wouldn't you want to have hospital A in your new policy have maybe \$5,100 but hospital B, because it's got a higher readmission rate to begin with, be paid less? I don't mean the average.

DR. MILLER: No, I got you. The last time we did this the way it worked, and I'll probably get this wrong, Anne, so use this time to get it all straight in your head again. Maybe I'll tell a joke or something to slow things down.

22

But last time what we were doing was saying look,

1 if we take a look at your risk-adjusted rate and you're 2 above average, we withhold money from you. You're sort of 3 in a special club, not a club you want to be in but you're 4 in. And then you withhold.

5 And so in a sense you are being paid less for your 6 admissions than a hospital that's doing better.

7 And then if you do well you can get that money 8 back. But if you don't, you don't. And so that you end up 9 paying them less for hospitals that have higher readmission 10 rates.

MS. MUTTI: Right. And those people that were really good performers, there was no penalty at all. They were held harmless. There was no withhold. They could just qo on with business as usual.

DR. REISCHAUER: The withhold also solves the hospital C problem.

DR. MILLER: Exactly. We thought it was fairlyeloquent.

DR. WOLTER: What I was trying to think of was how are the institutions and the physicians who are going to be dealing with this going to perceive a situation where they may be at that mean or at a best practice level in terms of readmission but somehow there's a perception that even with that good performance there's dollars being taken away when readmissions do occur? I think you do have to think a little bit about how is this going to be accepted and how are people going to respond to the incentives? I think there are some issues with the way this is set up, just from my standpoint.

8 DR. MILLER: Set up here?

22

9 DR. WOLTER: Yes, I think so.

10 And then there are some things we don't know yet 11 that would be kind of nice to know. Are there any 12 characteristics of those institutions that currently have a 13 mean or lower than mean readmission rates? And what are 14 those characteristics? Are they in communities where 15 there's more homogeneity of population, one language, not 16 multiple languages to deal with?

What are the challenges that people are going to face when they start tackling this? Because there are some nuances in there that I think we'll find an awful lot about if he move into something like that. But maybe there's some of those characteristics that could be mined already.

MS. MUTTI: That was absolutely on our next steps

1 for work here.

2 DR. CASTELLANOS: I'll try to make my very, very 3 brief. First of all, I appreciate the comments that you've 4 made.

5 Sometimes you have to spend money to save money. 6 The big thing here that I see is care coordination. And 7 we're not doing a very good job on that. We've learned how 8 important that is. We've seen some demonstration projects 9 in Philadelphia where nurses go out into the community, into 10 the home, where it significantly impacted readmission rates. 11 One of the things that really concerned me is that we're really talking about the hospitals. We're talking 12

13 about the physicians. But we also need to remember that the 14 patient and the family have responsibilities, also.

I fully understand that this is a very vulnerable care junction when they're discharged and you talk about improving coordination with the patient. But I have to tell you, you need to stress that to the family, too.

I really believe that it's a cultural thing, and somehow we need to stress in the report, and not put the burden on the family or the patient, but stress that they have a responsibility, too. We see a lot of patients that they caregivers are just so tired after a while, and they can't put up with it anymore or whatever, and they just bring the patient to the hospital just because they're worn out. Sometimes there isn't the capacity in a community to take care of that or capacity in the family.

I don't know how to put it and I don't want to put the burden just on the family and the patient? But they have a responsibility, too. And we need to stress that in the report.

MS. HANSEN: First of all, I just want to thank you for this next iteration of this topic. I really think that looking at the narrow diagnoses and the follow up in some of the interventions are great.

I also wanted to affirm the earlier discussion. I don't know how this could be linked, but it has to do with this whole movement to the post-acute side. Because looking at it kind of, again, however we can begin to put them adjacent to one another to take a look at that whole period of intervention and results.

21 A question to Ralph. Ralph, you indicated that 22 perhaps a separation of the medical errors there. I guess I

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don't understand really why, if we're looking at just the naked reality of the readmission period, that seems like that could be sorted out separately rather than trying to subdivide these particular diagnosis by whether it falls into the never errors.

6 So for me, I was just thinking perhaps to put it 7 together and then sort it out later.

8 MR. MULLER: I think the case that Ron just 9 referred to, the communication with not just family, the 10 physicians, the medication reconciliation, those are things 11 that are very much shared responsibilities and you can't 12 just always attribute it back to the hospital. I think the 13 errors are more under their purview and more their 14 responsibility.

In that sense, I think one can say avoid those things, but you have much more control over avoiding those things. I think the other ones go much more to the whole fabric care relationship with other institutions and so forth. I think it will get much more complicated.

As Nick said in his comment a few minutes ago, we need to understand a lot more fully exactly why these things occur, why some hospitals do better at it and so forth. 1 So I think all those other ones, in terms of communication with other doctors, with other providers, with 2 3 other institutions, with the families, with medication, I 4 think we've made a great start at this. But it's pretty 5 complicated once you start weaving your way through it. I think the error one does allow for -- it's not necessarily 6 7 black-and-white but I think it gets you a little closer to 8 that end of the spectrum.

9 MS. HANSEN: So just to clarify then, because 10 maybe my understanding is very limited on the never errors, 11 but I thought those were kind of factors that were within 12 the control or the influence of the hospital more. So 13 looking at that component and still including that, but I 14 think all these other factors are complexities of the post-15 care but I'm talking about while in the hospital.

16 MR. MULLER: Yes.

DR. MILSTEIN: I find myself fluctuating on where I land on this. But I think what I realize is that where I land on it depends on the framing. If this is framed as sort of the MMA concept of what a truly efficient hospital requires, you land in a different spot than if it falls within the P4P category. Even if you were in the P4P

1 category, there's these two different P4P concepts, one being revenue neutral and one being based on gainsharing. 2 3 So there's all these permutations. And depending how you 4 frame it, it very much affects where you come out on this. 5 I'd like to speak in favor of framing this within the MMA concept of paying what an efficient hospital 6 requires. My reasons are as follows: first, we're already 7 8 supposed to be paying for good discharge planning. While I don't want to trivialize the challenge of keeping someone 9 10 out of the hospital for 30 days after discharge, I think a 11 huge amount of the variation in 30-day readmissions has to do with the quality of discharge planning, for which we're 12 13 already paying.

And secondly, I think relative to other things, 14 15 we'd be looking to hospitals or hospital physician and other provider combinations to improve. 30-day readmissions are 16 17 relatively less challenging. This is a lot less challenging 18 than, for example, what the Medicare demo is looking for 19 Nick to do. Keeping someone out of the hospital for a year 20 after a discharge or a year, taking very high-risk patients and keeping them out of harm's way for a year, that's hard 21 22 relative to something like this.

1 That's the kind of level of effort for which I 2 think a supplementary payment or a gainsharing arrangement 3 that wasn't necessarily revenue neutral makes more sense to 4 me.

5 DR. CROSSON: I feel a little bit like the skunk 6 at the garden party, but I still have some skepticism about 7 this. I expressed it at the last meeting. I have the sense 8 that because of the complexity of this, I usually like to 9 see outcomes rewarded and then processes follow from that.

10 In this particular case because of the complexity 11 of risk adjustment, because of the issue of hospital one versus hospital two, where the patient gets readmitted 12 13 verses where the patient was admitted, the risk adjustment 14 part, I think, also amplified by the difference in the 15 country in the socioeconomic status of the patient base, which complicates the whole issue of compliance and 16 17 understanding and communication, I just have the sense that 18 for a given amount of effort that we would have put to this readmission issue if the effort were put to the idea of 19 20 bundling payments between doctors and hospitals and specifically to those processes that we know, and there are 21 22 lot of them, prevent readmission that we might get more bang 1 for the buck than trying this sort of an arcane formula.

That's just my instinct.

2

MS. DePARLE: I just had a simple question that occurred, I think at slide six. The second row there about the increase in readmission rates from '96 to 2005. I just wondered what you think is going on there and whether you've looked at those numbers arrayed against average lengths of stay over that same time period and whether average lengths of stay have declined by similar amounts?

10 And so is there something going on about decisions 11 to discharge? So you would step back even further from 12 where you are in looking at discharge planning to even go 13 back into the decision to discharge them, whether those 14 might be occurring too early?

15 MR. LISK: I have not looked at the length of stay 16 relationship. I can tell you that a lot of the increase 17 that occurred occurred within, if you see those percentage points, occurred from '96 to 2000 period on the 7-day 18 readmission window, in terms of the shorter readmissions. 19 20 During that policy we also had BBA policies implemented. I don't know what affect those might have had 21 22 on the increase.

MS. DePARLE: Well, there was a transfer policy
 that went into --

3 MR. LISK: There was a transfer policy that went4 into effect, too.

5 MS. DePARLE: -- effect that one could speculate 6 that might have had an impact.

7 MR. LISK: Although, the transfer policy paid the 8 hospitals less for shorter stays if they had shorter stays 9 and were discharged to post-acute care unless they were not 10 discharged into post-acute care.

11 But the other thing that was happening, too, is that the different payments for the SNFs and the home health 12 13 providers, some of these patients might not have gone -there was some decrease in utilization of those providers. 14 15 MS. DePARLE: But wouldn't you say that the 16 transfer policy might have lowered incentives to discharge 17 to a SNF or another post-acute care bed? 18 MR. MULLER: I have a simpler answer. 19 MS. DePARLE: Because I think it might have. 20 What's your answer? 21 MR. MULLER: The population is just much more

22 acute. The acuity of the population has gone up so much in

1 the last 10 years. We shouldn't always just think it's our 2 policies that do it.

Basically, given the advances in therapy and so forth, a lot of patients that were taken to hospitals 10 years ago aren't anymore. So the easy end -- not easy, but the less complicated patient is no longer in the hospital, they're in outpatient settings. So the average patient the acuity is up. And that's true all around the country.

9 So with a more acute population than you had 10 10 years ago, you're likely to have readmissions just out of 11 the natural progression of disease, let alone these other 12 factors that we're talking about.

MS. DePARLE: That's true, but I would be interested in seeing whether there is -- just seeing the numbers for average length of stay. Because my impression is while they haven't had the significant declines that we saw in the early period of the PPS, I think it's --

18 MR. MULLER: They've gone up again in the last few 19 years, modestly; right?

20 MS. DePARLE: It's a modest thing. But I thought 21 there was a slight decline over that time period.

22 DR. MILLER: If you look cross-sectionally at

hospitals that have high readmission rates, what do their average lengths of stay look like? There's sort of an aggregate question of what the trends were. And then also underneath it what you look like from -- I took your guestion that way.

6 MS. MUTTI: And that is part of our work plan, to 7 look into that question.

B DR. REISCHAUER: Are the increasing readmission9 numbers risk-adjusted through time?

MR. LISK: Ralph brings up a point, because what we have with 3M is the 3M logic and that risk adjustment that's built into that is just done for 2005. So that could be another factor contributing to some of that increase.

DR. MILSTEIN: On kind of a completely different 14 15 point but maybe it's a future direction out there sometime, 16 there's the readmission rate and then there's the 17 readmission rate. I think for those organizations that have 18 the ability to look at their practice, so to speak, as containing populations of patients with various problems and 19 20 who are willing to create registries of those patients and then are willing to put best practices in place and give 21 22 feedback to physicians and then have nurses and mid-levels

and others to help manage those patients, I think there's -there's probably already evidence -- but there's certainly a
high likelihood that overall admission rates are lower when
those things are done.

5 I think those are the kinds of directions we need 6 to think about going in terms of incentives and how we do 7 that needs some work.

8 Much of the infrastructure that you create to do 9 that, Arnie, would not be all be captured in current payment 10 rates, discharge planning and that sort of thing. It's sort 11 of a different sort of investment. Really there's no 12 payment for it right now in many ways.

Maybe we can think about that down the road.
MR. HACKBARTH: Okay, thank you. Good work.
We'll now have a brief public comment period.
MR. MAY: Don May from the American Hospital
Association. Sheila asked for a little reaction so I
couldn't resist standing up.

But on the wage index discussion, I think we would agree that there are real problems with the wage index that need to be addressed. We would applaud the work you've done to really look at some of the problems with the wage and to 1 put an option out on the table.

2	We have pulled together a workgroup to help us
3	look at the issue and there has been a lot of interest in
4	the work that you've done among that workgroup.
5	I just thank the staff for some really good work
6	on all of the wage index work they've done.
7	I think if we had one concern is that it's one
8	option that's been proposed. We'd like to see other options
9	that might be used as well that could be considered as we
10	start to think about this. Because this is a very
11	significant change and it has major implications for
12	hospitals.
13	I think specific to the recommendations, first on
14	the issue of a transition, we would really encourage you to
15	have specific language and appreciate the conversation you
16	had today about a need for a transition. I think specific
17	language in a recommendation would really be helpful on
18	this, given the magnitude of the change for many hospitals.
19	The second issue is on the issue for either an
20	exception or the adjustment or some need still for some kind
21	of reclassification. I think this model that you've put
22	forward would really minimize the need for

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1 reclassifications.

2	And I understand the interest in not having a
3	specific reference to it and dealing with it once problems
4	arise, and I think that's what Bob suggested. I think there
5	are reasons, though, to have some specific language, whether
6	it's encouraging the Secretary to take action when specific
7	problems are seen.
8	We haven't done an in-depth analysis for each BLS
9	market to see what that data is going to look like. And I
10	can guarantee you that once the hospitals will, the
11	providers and home health, and SNFs, will. There are going
12	to be issues that come up.
13	If you think about just one example, the hurricane
14	hit areas in the south, where a three-year rolling average
15	may not reflect what's happening today. Or areas where the
16	population has shifted significantly and the census data may
17	not make as much sense as it did before. Just some real
18	need.
19	But like you, we wouldn't want to see that
20	expanded broadly, just a need for certain types of

21 exceptions.

22 The last point on the readmission discussion,

which I find really interesting, and I think again the staff have done a terrific job looking at this very complex issue. I've been really encouraged by the comments of the Commission that say we really need to link this readmission discussion to our post-acute care rehospitalization discussion.

7 I want to throw an additional insight out there, 8 and that is that CMS is putting out some pretty restrictive 9 policies on rehab hospitals and patient rehab hospitals and 10 units, on long-term care acute hospitals, mostly driven by 11 how much does it pay to treat someone in these post-acute 12 hospital settings versus a skilled nursing facility or home 13 health agency.

What you've identified is that there are real 14 15 costs in readmissions and some of these adverse effects by 16 not having maybe the proper care either given in the 17 inpatient setting, in the acute-care setting. These post-18 acute care hospitals, rehab hospitals, long-term care hospitals may be part of a new continuum to be able to 19 20 reduce those types of hospitalizations and those readmissions. And while they may cost more per unit, they 21 22 may actually lower system costs.

And so I would just encourage you to think about those types of analyses to do in the future, as well. Thank you. MR. HACKBARTH: Okay, we're adjourned until 9:00 a.m. tomorrow. [Whereupon, at 5:58 p.m., the meeting was recessed, to reconvene at 9:00 a.m. on Friday, April 13, 2007.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

> Friday, April 13, 2007 9:04 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, Chair ROBERT D. REISCHAUER, Ph.D., Vice Chair MITRA BEHROOZI JOHN M. BERTKO SHEILA P. BURKE RONALD D. CASTELLANOS, M.D. FRANCIS J. CROSSON, M.D. NANCY-ANN DePARLE DAVID F. DURENBERGER JENNIE CHIN HANSEN NANCY KANE, D.B.A. ARNOLD MILSTEIN, M.D. RALPH W. MULLER WILLIAM J. SCANLON, Ph.D. NICHOLAS J. WOLTER, M.D.

1	PROCEEDINGS
2	MR. HACKBARTH: Good morning.
3	We're going to begin this morning with an expert
4	panel on future workforce needs for physicians and other
5	clinicians. Thank you very much for coming to meet with us.
6	This is an issue, as I was saying to some of you a
7	few minutes ago, that we keep bumping up against through
8	various doorways, and it's clearly a vital issue. Now
9	whether MedPAC can make a constructive contribution or not
10	is something that we still need to decide. But this will be
11	a very good introduction for us and we look forward to it.
12	Craig, are you going to handle the introductions
13	of the panel?
14	MR. LISK: Yes, I'm going to handle the
15	introductions.
16	The Commission, as you indicated, expressed
17	interest in examining workforce issues surrounding the
18	questions of whether or not we will have an adequate supply
19	and mix of physicians and other clinical practitioners to
20	meet the needs of the aging baby boomer population.
21	To learn from this we have a wonderful expert
22	panel here of three panelists. We're going to start with Ed

Salsberg who is Associate Vice President at the Association
 of American Medical Colleges. He is their Director of their
 Center for Workforce Studies, which they recently
 established.

5 Kevin Grumbach is Professor and Chair of the 6 Department of Family and Community Medicine at the 7 University of California, San Francisco, and also is Chief 8 of Family and Community Medicine at San Francisco General 9 Hospital. He is the Director of the UCSF Center for 10 California Health Workforce Studies.

And then finally, we will have Mary O'Neil Mundinger, Dan of the Columbia School of Nursing and Centennial Professor of Health Policy at the School of Nursing. She's also a founder of the Columbia Advanced Practice Nurse Associates.

16 So with that, we'll start with Ed.

MR. SALSBERG: Thank you. Thank you for the opportunity to come talk to you today and try to very briefly summarize the AAMC position and our recent workforce research around the supply and demand for physicians. There is a handout in your binder. The

22 presentation is a little shorter, and I'll try and summarize

1 the positions.

2	Let me say at the outset that I think that after
3	several years of studying the supply and demand for
4	physicians, there are several points that I'd like to make,
5	and again, I'll cover most of these in the presentation.
6	First, I think anyone who looks closely at the
7	evidence would conclude that the nation is likely to face a
8	significant shortage of physicians in 2020 and beyond,
9	driven by a number of factors and I'll talk about that.
10	Second, that the reality that the change in supply
11	of physicians and the distribution of physicians takes many
12	years. And so I want to be clear that when we look at the
13	supply and demand of physicians, I'm not talking about
14	today. We're really looking at 2020 and beyond because it
15	takes 15-plus years to change the supply of physicians.
16	I want to note that medical schools are
17	responding. There has clearly been a major, major shift
18	nationally and where a decade ago no medical school was
19	expanding capacity we now have the majority of medical
20	schools and osteopathic schools increasing their enrollment
21	and a discussion in many, many communities about new medical
22	schools.

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But the expansion of undergraduate medical education will really not have the impact that we've desired, which is to increase availability of physicians to serve Americans, unless there is a parallel increase in graduate medical education positions.

I want to be clear that in our recommendations to expand undergraduate and medical education and training capacity that we recognize that physicians alone are not the answer. The demand for services will far exceed the supply, and physicians alone will not able to meet that demand and we need systems reforms as well.

Some people, I think, tend to think because we've recommended a 30 percent increase they we're suggesting that more physicians are the answer to the problem. What we're saying is you need a solid core of physicians in order to meet future needs but clearly physician supply alone will not address the issues.

And then finally, the perspective that Medicare clearly has a role to play in all of this, that Medicare, as the major payer for health services and financing of graduate medical education, has a role to play in assuring that there is an adequate supply of physicians to meet the 1 nation's needs.

2	Let me quickly run through the slides that we have
3	today. First, I just want to point out that most of our
4	modeling that we've done for supply and demand assumes that
5	supply equals demand in the base year when, in fact, we know
6	that there are already 30 million Americans living in
7	underserved areas. So as we think about how many physicians
8	we need, we need to recognize that we actually don't start
9	out at a point where supply is equaling demand and that the
10	distribution issue, in fact, needs to be addressed
11	separately from the overall supply issue.
12	I'm going to throw out a lot of numbers. The AAMC
13	has additional data that we can provide you to support these
14	positions but I think these are the key driving factors in
15	terms of demand.
16	First is the growth of the U.S. population. The
17	U.S. population is growing by 25 million every decade. We
18	added 100 million Americans over a 39 year period. Clearly
19	this will be a major factor in driving future demand.
20	The aging of the U.S. population. You know as
21	well as I do that the nation's over-65 will be doubling
22	between 2000 and 2030. Why is it so important? Because

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Americans over 65 make far more physicians visits to physicians, twice as many visits, as the under-65. We know that the major illnesses and chronic illness in America is primarily affecting the elderly. And there's really no way to avoid the conclusion that the aging of the population will lead to an increase in the demand for physician services.

8 We recently did a study of clinical oncologists 9 and there it's again a particularly clear case that cancer 10 being very age sensitive, as the nation ages we will have a 11 higher incidence of cancer. We are making progress in the 12 treatment of cancer, but that means we will have more 13 survivors who need to see physicians, particularly 14 oncologists.

Lifestyle factors, unfortunately, we have that it has a major impact and unfortunately Americans lifestyle is not contributing to positive health. We believe that this will, in fact, lead to an increase in demand.

Over the next two or three decades clearly the aging of the baby boom generation not only will increase those demanding and needing services but it is a generation that has high expectations for health care. Not surprising, 1 we've invested literally billions of dollars in

2 interventions to make life better and allow older Americans 3 to live fuller lives. I would expect the baby boom 4 generation will continue to expect a lot from the medical 5 field.

6 Most of the medical advances that we've seen over 7 the past 30 years have not reduced demand for physician 8 services. They, in fact, have increased demand. But I think there has been a very positive outcome and I'm 9 10 concerned at times with those who think just because visits 11 are rising, just because more services are being used, that that's bad. We really have to weigh that against the 12 13 positive impacts of longer lives and fuller lives of 14 Americans.

15 So overall on the demand side if you look at the 16 key drivers of future demand, clearly the nation is going to 17 expect and want and need more services.

One figure that I will go into and spend one moment on is just the visit rates by age. We know that older Americans make more visits per capita than younger Americans. But I think it's clear as you look at this chart that over the last 25 years the older Americans, the visit rates have been rising. I see no reason to expect that
 these rates will reverse and begin to decline. Again older
 Americans have high expectations. We've invested billions
 of dollars in order to deliver more to them.

5 What's happening on the supply side? Several key 6 factors but one of the most important driving factors that I 7 think people often overlook is the doubling of medical 8 school enrollment between 1960 and 1980. If you think that 9 physicians generally have a 30 to 35 year professional 10 practice lifetime, that new larger number of physicians 11 produced during that period are now beginning to approach retirement. And so we forecast that retirements of 12 13 physicians will be rising from about 10,000 per year in 2000 14 to about 20,000 per year in 2020 and hence we are now at the 15 other end of that production.

And then we had 25 years of flat production in terms of MD graduates. And so what we now see is that very much of an aging physician workforce and one out of three practicing physicians are over the age of 55. Clearly, they will be retiring over the next 20 years.

21 International medical school graduates, as most of 22 you know, one out of four physicians in training, one of four physicians practicing in the U.S. are international medical school graduates. We've assumed that that supply is unlimited. I'm not sure we can continue to assume that that will be an unlimited supply. And as many of you know, there is a growing concern about the impact of the migration of physicians from less developed countries to America.

7 And then gender and generational differences. One 8 of the things that we've done at AAMC is conduct a series of surveys. We just recently completed a survey with 9,000 9 10 respondents over the age of 50 to understand what's going to 11 motivate them to retire and we're in the process of concluding a survey with about 4,000 physicians under the 12 13 age of 50 to understand about work hours and if all of the 14 anecdotes we hear about younger physicians not working the 15 same hours as older physicians are true so we can put them 16 into our forecast.

The reality is that female physicians do work fewer hours than male physicians. It is becoming about 50 percent of our medical students are now female. We do think that the younger generation of physicians will be working fewer hours than physicians did in the past but we're continuing to do that research.

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In terms of older physicians, it was a very valuable survey that informed us that physicians, based on recent activities in their plans, that physicians over 50 are likely to retire a little bit earlier than physicians did in the past or more correctly than the models assume that physicians did in the past.

7 The net result is we think that the supply of 8 physicians available to serve Americans in 2020 will be less 9 than we had previously forecast because physicians will 10 retire earlier.

And clearly residency training becomes a critical factor in the supply. What we've directed -- the AAMC logically has directed so much of its energy towards medical school expansion. The efforts on the part of undergraduate schools to expand will only have limited impact if we don't also expand graduate training.

I want to point out that after 70 years of continual growth in the physician to population ratio this growth will peak sometime between 2020 and 2025 depending upon what we do in terms of undergraduate and graduate medical education capacity.

22 The thing to be concerned about and that is sort

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of misleading here is that even though the physician to population ratio is still rising, clearly the mix of the U.S. population is changing so that the higher percent elderly, even if the population numbers are the same, would need or demand more services.

6 Again pointing out the critical factor of how long 7 it takes to train and educate a physician. I was sort of 8 taken aback myself when I realized all of our efforts to increase medical school capacity, again assuming a parallel 9 10 increase in GME, would only lead to about 16,000 more 11 practicing physicians in 2020. That's again the years to start medical education expansion, the years of medical 12 13 school, and the years of training. So it's a long pipeline 14 so again I urge you to think about what is it that we're 15 going to need in 2020, not today.

16 This is a recent HRSA forecast of the supply and 17 demand. And what you see is even under the baseline 18 scenario that we would have a shortage of 55,000 physicians 19 and it might be, in fact, as high as 150,000.

I thought this was a helpful chart to point out again the impact of the different inflows of physician and, in fact, the impact of retirement. So what you see is in 1 2006 of the 700,000 practicing physicians by 2025 that 2 cohort will shrink to about 350,000.

The current productions level, if we don't increase U.S. medical school capacity and continue to bring in 5,000 to 6,000 IMGs the number of physicians, the absolute number, would actually drop. As you can see, the relatively small impact of the expansion in U.S. medical school capacity.

9 Some recent data, and we will be issuing a new 10 report next month forecasting physician supply and demand in 11 2020 and beyond using the most up-to-date data. And we expect that there will be a shortage in the range of 60,000 12 13 FTE equivalents in 2020, growing to 123,000 in 20205. As I 14 said, even with an expansion of MD and DO educational 15 capacity, the shortage would still be significant and again 16 requires an adjustment in the delivery system in order to assure access to services. 17

Conceptually, trying to make the link between undergraduate and graduate medical education, this is the picture of medical education, U.S. MDs, DOs, and IMGs. There were about 24,000 first-year physicians in 2003. We can grow U.S. MD and DO graduates but if you don't increase
the number of residency training positions the likely outcome but not the certain outcome would be that IMGs would be squeezed out of the system. But again, you would not end up with additional physicians to serve Americans. And so it becomes critical that there be an expansion of graduate medical education in order to support undergraduate medical education expansion.

8 Let me note that the expansion at the 9 undergraduate level has not been funded in any way by the 10 federal government. These have been decisions at the state 11 and local level to expand medical school capacity at each 12 institution.

I just think it's important to also point out that America is not a physician rich country when compared to other developed nations. The reality is we have a relatively modest physician to population ratio. And even with the increase that we've recommended, and again if accompanied by a GME increase, we would not exceed the next highest country.

Finally, the AAMC workforce position, we did issue a position statement last June. The first and most prominent is an expansion of U.S. medical school capacity of

30 percent. That is roughly 5,000 additional MD graduates 1 per year. We recommended that there be an increase in GME 2 3 positions to accommodate the expansion at the undergraduate level. We recommended that specialty choice be left to 4 5 students and the medical education community. That does not 6 imply we think that the current distribution is the right 7 distribution. We just don't think that it's the medical 8 school GME lever that one should try and address to redistribute specialties. 9

We strongly recommend an expansion of the National Health Service Corps. The distribution is different than the overall supply problem. But we really worry that if we are correct and we do face a shortage of physicians that it will be the underserved communities, the rural communities, that will feel it the most.

There's no reason for me to believe that if we're short 50,000 or 60,000 or 100,000 physicians that those physicians will on their own choose to go to underserved communities. And so, in anticipation of that shortage, we think an expansion of the National Health Service Corps is critical. We also know that medical students are facing significant increases in debt and so we think that's another 1 reason to support the National Health Service Corps.

2 We continue to support increase in diversity of 3 the physician workforce.

Finally, there are some other steps that were not 4 5 included in the AAMC set of policy recommendations which 6 focused on what the medical education community can do, but 7 I think are important based on our other research. Clearly, 8 as I said, since physicians alone are not the answer we need to find ways to make more effective use of physicians. 9 That 10 includes improved information technology, and increased use 11 of health professionals other than physicians.

We have to recognize the lifestyle concerns. Our surveys of physicians about retirement show that there is a great deal of stress out there. There is concern about malpractice, there is concern with regulation.

I will tell you if you think about it, if we expect in 2020 that about 20,000 physicians plus will be retiring each year, if you can reduce the rate of retirement by one year you're keeping 20,000 additional physicians in the pool. That's equal to one year's number of medical school graduate and DO graduates.

22 So clearly, finding ways to keep physicians

working is really a very important approach that I think is
 often overlooked.

3 And then finally, I think it's critical to monitor supply and demand of physicians in the long run. You might 4 ask why should you have any confidence in our forecast about 5 the future physician supply and demand , and that we got it 6 7 so wrong a decade ago. I will tell you that I think we are 8 doing a better job at collecting data and we've thought about this a good deal in terms of medical school capacity 9 10 and GME capacity.

11 Bringing in 6,000 -- we now bring in about 6,500 IMGs a year. They are our cushion. If we are wrong, and I 12 13 don't think we're wrong, it would be far easier to reduce 14 the flow of international medical school graduates. If we're right and the demand is going to be far higher than 15 16 the supply, there's no way in 2015 you can turn around and say oh, quickly increase the number of U.S. medical and DO 17 18 graduates. It takes us too long.

19 So we're in a far better position to increase U.S. 20 medical school capacity now, even if you have some 21 uncertainties about the solidness of our recommendations. 22 And again I think our analysis is the data is pretty clear, 1 the nation is going to want and expect additional physician 2 services.

3 I'll be glad to answer questions after the other
4 presentations.

5 DR. GRUMBACH: Good morning. Thank you for 6 inviting me to speak.

7 I had to chuckle because on the way over I grabbed 8 an umbrella, and it's actually the AAMC umbrella that I got at the last national meeting of the Association of American 9 10 Medical Colleges. You may think that that was given out at 11 the meeting because the meeting was in Seattle, which is a rainy climate. I tend to think it's symbolic of the AAMC 12 13 workforce policy position that the sky is falling and we 14 need to have protection against the impending collapse of 15 the work force.

16 [Laughter.]

DR. GRUMBACH: What I'd like to do is reflect on some of Ed's presentation and put it in context because I think the key question is what are we getting for the physician supply we have now and our clinician supply in general and where we want to go with this and are we getting value for the money. 1 The first point I'd like to make is that we are 2 still in a period of over a half century of growth in the 3 number of physicians per capita in the United States. So as 4 you look forward, things start to change as you go out a 5 decade. But let's appreciate we're in the midst of an 6 unprecedented increase in physician supplies.

7 The next graph shows we've nearly doubled the 8 number of physicians -- these are clinically active physicians in the United States per capita -- in the last 9 10 half-century. Almost all that growth is explained by the 11 growths of specialists rather than generalists such as family physicians and general pediatricians and general 12 13 internists. So you could say we've actually had an 14 experiment in what do we get for increased physician supply 15 in the United States per capita. And one might question 16 whether this has been reflected in better value, better outcomes, better quality. 17

18 This is projecting forward and this is actually 19 taking some of the numbers that Ed has generated. What you 20 see in the lighter color line here is the percent growth in 21 the number of physicians in the United States and the black 22 line is a percent growth in population that's also adjusted

for the fact that we have an increasing aging population.
So this sort of builds in in the black line accounting for
the fact that elderly folks tend to use more services. But
you see we don't start to cross over this line until 2015,
so we'll have another seven or eight years where we're still
actually in a growth phase per capita of the number of
physicians, even adjusting for the aging of the population.

8 Ed's right, as you go further and further into the 9 future you begin to have to start to catch up, but there's a 10 question about where are we going with this.

Ed pointed out -- I shamelessly take Ed's own slides and present them. So Ed puts it in the context that gee, we already have all this unmet need and poor distribution of physicians and there are shortage area in rural communities and inner cities that lack physicians.

16 What I would ask is that has persisted despite the 17 growth in overall physician supply. So I'm not sure the 18 idea that passive trickle-down theory has ever really been 19 valid in the physician workforce environment, that if you 20 don't look at payment issues, you don't look at what type of 21 physicians are we training, who are we bringing into the 22 medical profession, then I think we'll never solve these 1 distributional issues.

So this gets into the whole idea of what is a 2 3 definition of a shortage or a surplus. There's tremendously, I think, muddled or lack of clarity when we 4 5 discuss these concepts. One is a sort of market definition 6 that looks at its demand, and you say a shortage is when 7 there's an inadequate supply of physician relative to demand 8 surplus and excess supply. It looks, in the United States environment, that 9 10 there's almost an endless demand if you define it merely as 11 whether people will show up and use services. In a thirdparty payment climate, where there is no direct exposure of 12 13 consumers by and large to the payment, that's part of the 14 issue. You have tremendous physician induced demand. You have the ability of this to turn increasingly into a luxury 15 16 item where more and more of the services are devoted to 17 higher and higher class of affluent person. 18 So it's very hard to say we'd ever get to a state where we'd know from just a purely market environment that 19 20 we have too many physicians because we'll almost never have a situation where we'll find unemployed physicians. 21

22 Another view of this is to look at it from a more

public planning approach, and I think maybe this is one the Commission wants to consider, which is what's a supply relative to need? Now need is hard to assess for sure. But again, if you look in a lot of the data it would question whether the population needs more physician supply.

6 So the next slide, which is point three I'd like 7 to make, is that there's actually a growing body of research 8 that shows that there's one part of physician supply that 9 seems to be associated with better population health 10 outcomes, with better quality of care, and in fact would 11 lower cost per capita. That's a supply of primary care physicians. There is now accumulating evidence from Barbara 12 13 Starfield and Leiyu Shi, from the Dartmouth Group, I think 14 Elliott Fisher has presented to you. It's been pretty consistent across these. If you look at comparing states, 15 16 comparing regions, metropolitan areas, those that have a more robust supply of primary care physicians tend to have 17 18 better things life expectancy, Medicare quality indicators 19 are better.

And then when you look at specialist supply, what you find is one thing, which is costs are higher in area that have a higher supply of specialists per capita. But in

1 fact, you don't find that outcomes are better. You don't 2 find that cancer outcomes are better, for example, in areas 3 that have a lot of cancer specialist. Dave Goodman's work, you don't find the neonatal outcomes are better in areas 4 5 that have a high supply of neonatologists. Once you get above from the lowest supply to the next area of supply, 6 7 outcomes for babies are better. But once you get to that 8 things plateau and more and more neonatal ICU units, more 9 and more neonatologists, don't seem to translate into better 10 infant mortality rates.

11 This is a slide, I don't know if you've seen this 12 before. This is Medicare data by the Dartmouth Group and 13 this compare states in the United States based on their 14 quality rank. These are very solid quality indicators. 15 These are things like do patients with heart attacks get 16 beta blockers when they're discharged from the hospital? Do 17 seniors get flu shots?

18 What you find is when you rank states on quality 19 indicators, you see a very strong relationship with the 20 ratio of generalist physicians per hundred thousand 21 population. And when you look at costs it goes just the 22 opposite way. The states that have a higher supply of 1 generalists per capita actually have lower costs for

2 Medicare expenditures. When you do these same sides with 3 the number of specialists, they go in the opposite 4 direction.

5 The fourth point I'd like to make is unfortunately 6 the foundation of primary care is collapsing in the United 7 States. This is not a problem for 2015 or 2020. This is a 8 problem now, folks.

9 So the next slide shows the number of first-year 10 family residency positions, training positions in the United 11 States. That's the top line. The second line is the number 12 of graduates of U.S. medical schools who enter these family 13 medicine positions.

You saw in the heyday of managed care there was some growth overall in residency training positions in family medicine, the number of U.S. graduates going in surged in the mid-90s. And we now today have 50 percent fewer of our medical school graduates going into family medicine than we had 10 years ago.

The same thing is happening in internal medicine. This is now looking at people as they complete their three years of internal medicine training, what are their career 1 plans. The gray bar, the first bar, is the percent that say 2 they want to be a general primary care internist. The white 3 bar are those planning to be subspecialists, and the black 4 bar are those planning to be what we call hospitalists.

5 What you can see is a dwindling proportions so now 6 only one out of five internists trained in the United States 7 says that he or she wants to go into primary care.

8 So when you project these numbers forward, and 9 this is some work from Jack Colwell at the University of 10 Missouri, if you remember that slide where I had the same 11 black slide which is increasing population with an aging factor, you see this crossover is not 2015. Right now we 12 13 are starting to see the number or the percent growth in 14 generalist physicians dropping off for adults. The green 15 line is probably the best most accurate scenario. The red 16 is what happens if nobody goes into general internal 17 medicine anymore.

18 This is not true just for physicians. Dr. 19 Mundinger will talk about some of the nurse practitioner and 20 advanced practice nurse issues but we're seeing the same 21 thing in physician assistants, the same things in nurse 22 practitioners, a greater proportion are going into specialty 1 fields. So this is not uniquely a physician issue. There
2 is really a bailing out across the professions of a
3 commitment to primary care.

Why? It has something to do with payment. 4 This 5 is the compensation of take home income of physicians by specialty. You see a family physician made about \$150,000 a 6 7 year and specialists on average made twice that. A 8 radiologist made \$400,000 a year. The growth over that 10year span was almost double for specialists what it was for 9 10 primary care. This was despite the RBRVS issues and things 11 that we attempted to do. And I think you're familiar where all of the volume growth is happening is in imaging 12 13 services, it's in minor procedures, and so forth.

14 And here's what 30 minutes of a physician's time 15 is worth based on RVUs for Medicare. Complex established 16 visit, so you have a patient with diabetes, depression, 17 arthritis coming in for a complex visit, that's worth \$94. 18 You do a colonoscopy in the same amount of time, that's twice that much of payment. And if you do a cataract 19 20 surgery, it's \$670 a payment. So if you want to know why people are becoming ophthalmologists and not family 21 22 physicians, that is one of the key answers.

I would argue to you that physician payment policy is, in fact, physician workforce policy. That you and Medicare have been engaging in workforce planning throughout the duration of the Medicare program in how fees are set, in how GME policies are set.

6 So I think most meaningful workforce policy that 7 CMS could implement would be to very actively address this 8 need to support the primary care infrastructure is the key, 9 I think, glaring problem right now on the physician 10 workforce. And that's true, I think, beyond just 11 physicians.

So I think there needs to be a recalibration of 12 13 the basic RVU for E&M codes. I think right now the most 14 critical thing one could from the Commission's point of view in CMS would be to separate the SGR formulas for E&M visits 15 16 from the non-E&M visits because all of the growth is in non-17 E&M visits. The trouble is then you try to give an increase 18 in the RVU for primary care and it gets clawed back as soon as there's an adjustment from the SGR. 19

And I'm not opposed to the SGR. I think it's reasonable to have some caps on this. But it basically penalizes primary care because there's no way to grow the

1 E&M coding system.

I would look at things like adding a primary care 2 3 coordination payment that people have proposed for the complexity of chronic medical illness problems that need to 4 5 be managed with a team approach. I would rethink the GME policies so that perhaps you give additional weight to the 6 7 direct medical education payment based on primary care 8 residents. And I think you need to be more flexible on GME because it's really hard to do ambulatory care training and 9 10 get GME support the way the payments are so locked in to 11 hospital-based numbers.

I'll close on a final anecdote. We have a family medicine residency program affiliated with UCSF in Santa Rosa, a very growing suburban and has some rural communities. The private hospital has pulled out its support for that program. That's a 30 resident program. There's another private hospitalization that is

18 actually willing to take it over in conjunction with Kaiser.
19 They're happy to have the residents come over.

20 Unfortunately, that hospital once had 0.5 FTEs of residents 21 at that hospital. So that hospital that's willing to take 22 our this program can only get 0.5 GME credits for Medicare 1 payments because they're locked into their cap there.

2	This is preposterous. I mean, there's a hospital
3	willing to do this. Medicare is right now paying for 30
4	residents for this hospital that's going to pull out its
5	support, and there's no ability to transfer that over in the
6	same region with no additional capacity in that region for
7	training to simply transfer it over because you're locked
8	into this formula.
9	So that completely undermines things like
10	vulnerable family medicine programs based in community
11	hospitals where there's a lot of instability.
12	So I think those things really need some careful
13	attention because there's some really counterproductive
14	policies in play.
15	Thanks for your consideration of these issues.
16	DR. MUNDINGER: I'm glad to be batting cleanup
17	here. We've been on the team for a long time but they
18	didn't let us get in the batting order until recently, so
19	I've got Ed on second and Kevin on first and I'm going to
20	bring them home because I've got an idea that I think can
21	solve a lot of the problems they've brought up.
22	In 1965, the nurse practitioner program came on

1 the public scene. That was the same year Medicare and 2 Medicaid were passed. These three programs have really 3 enhanced each other going forward because the kind of access that was needed in outpatient for Medicare and Medicaid 4 5 patients could not have been accomplished without the growing cadre of nurse practitioners. And certainly, the 6 7 major payer of nurse practitioners over these 40 years has 8 been Medicare and Medicaid, other than employment salaries. 9 But for outpatient care, it's been primarily Medicare and 10 Medicaid.

11 There have been hundreds of studies during those 40 years that show there is an equivalency between nurse 12 13 practitioners and physicians in the basic medical care of 14 patients in primary care. We are now at a point where 15 conventional primary care is not enough, especially not 16 enough for an aging population that's seen lots of specialists, has lots of comorbidities, has a lot of needs 17 18 where they want to be more fit, less risk-averse to the diseases that they may have to encounter as they grow older. 19 20 And this new comprehensive care is going to replace primary 21 care.

In order for us in nursing to begin to meet the

22

more extensive needs, we have switched our policy from 1 attaining a masters degree as being enough to be an 2 3 independent primary care provider to adopting a clinical doctorate. That is a policy statement by the AACM. 4 There 5 are over 200 schools that are currently in the process of 6 developing clinical doctoral programs. 20 have already 7 admitted students, some have graduated students. There are 8 over 700 graduates of clinical doctoral programs already.

In any given year up until this movement, we were 9 10 graduating around 7,000 or 8,000 nurse practitioners a year. 11 With the clinical doctorate there is a new destination in nursing. More people who would not have thought of nursing 12 13 as a career will now think of nursing as a career. So the 14 transition from masters to doctor will have not only those 15 continuing 8,000 grads a year but clearly up into the 16 10,000, 12,000, 15,000 as this new program takes hold.

17 It does not change the regulation or the rules 18 that nurse practitioners practice under by achieving a 19 clinical doctorate but the people who do go through this 20 program -- we've had three classes graduate at Columbia 21 already -- push the limits of those regulations so they're 22 much more likely to go to the extent that the law allows.

And they're going to push those regulations further. And a
 couple of those recommendations I'm going to talk to you
 about today.

So a nurse with a clinical doctorate, starts out with a college degree just like someone going to medical school, starts out with a college degree in biology or French literature or whatever it is that caught their interest when they went to college.

9 When they complete that baccalaureate degree, they 10 can choose to go to medical school or they can choose to 11 enter one of these clinical doctoral programs, which is a 12 six-year post-baccalaureate progression or four years if you 13 have a baccalaureate in nursing.

14 So it's an extensive number of years and we think that the impact of these specialty trained nurse 15 16 practitioners at the doctoral level who will be able to have 17 an education that prepares them for cross-site care, taking 18 care of patients over time in every setting, having authority and coordination skills, is going to make them the 19 20 preferred provider in comprehensive care, particularly for 21 Medicare patients going forward.

I wanted to start out just very briefly with where

I think the gaps in care are. In particular, these are the gaps in care for Medicare patients. They have more than a need to have their immediate medical condition cared for. Most of them have other chronic illnesses. They have increasing frailty. They're at risk, both by their age and their comorbidities, for serious complications.

7 We don't have a good way in our health care system 8 to help them manage those comorbidities, managed their chronic illness, know when to seek acute care, know how to 9 10 relate to all of the specialists that are helping them 11 through their many medical encounters. Many of them have families that are no longer nearby. It's not the 12 13 conventional you can move in with mom or she's across the 14 street or your daughter.

15 People are trying to manage their aging parents 16 3,000 and 4,000 miles away. There's really no system for 17 that. We don't know how to use long-term care and hospice 18 in a good way. We don't not to adopt patient values into 19 medical decisions. Compliance is a bad word. We need to help adopt new lifestyles. They're much more likely to stay 20 21 with them because they believe in it and they take the steps 22 to believe that this is what they should do, not because

1 somebody told them.

These are the roles that are inherent in what nurses do with patients. Not just those that have this extensive education. But it's part of what they do in their basic nursing.

6 If you look at advanced practice nursing, those 7 that are going to have a clinical doctorate, they're going 8 to be able to diagnosis and treat and do the things that a conventional primary care provider can do. They're 9 10 reimbursed right now by Medicare and Medicaid, variably by 11 the commercials. Nurses have you really have an ad hoc intervention with the commercial insurers to get paid. 12 But 13 we're seeing that there is a movement moving that is going 14 to take nurses to more authority, more independence.

Last year 40 percent of the states increased the independence in their rule regulation changes for advanced practice nurses. This is going to continue. We believe the most ethical way to assure that happens is to make sure that the education matches the authority.

When a nurse starts out his or her education, they start out in hospital and they work eight or 12 hour shifts. They have intimate evolving observations of patients. They 1 know the nuanced changes of care that go on with a very sick
2 patient. This kind of education is so crucial to a nurse
3 when he or she becomes an advanced practice nurse. They've
4 gone through that long period of working with patients over
5 eight or 12 hours at a time. No other profession does that.

They have learned how to look very carefully at 6 7 very small changes in condition. And when they get to an 8 office-based primary care they take that wisdom and that internalized observational skill with them. They're very, 9 10 very good at assessing when someone is maybe not coming in 11 with a totally new acute illness, but that someone is -their mental state isn't quite right. They've got a little 12 13 bit of a tremor. They don't walk the way they used to walk. 14 Things that set of lights to help early intervention with 15 elder patients even if they're only seeing them for a very 16 short time.

Advanced practice nurses with clinical doctorate are much more than physician extenders. They are independent in their diagnosis, management, prescription of drugs, billing authority. They, with doctoral education, can provide that kind of independence across care sites. But they're also people who know how to bring together family support, environmental support, community support.
They know how to use the public health system. They've
cared for patients in long-term care facilities. They've
made home visits. So they know what it takes for a patient
over time and across sites, especially frail people, elder
people, how to get the care that they need.

7 We've also had a very short talk about PAs. I 8 think basic nursing education is very, very different. They 9 care for patients in every site. They're skilled educators, 10 they're prevention specialists, they're generalists. They 11 have advanced authority and knowledge. They have an 12 independent license to bill independently, to provide care 13 independently, to prescribe independently.

And whereas nursing has its own independent area and a lot of overlap with medicine, physician assistants are within the practice of medicine. If I had been more accurate about this, the nursing circle would be much, much bigger than the medicine circle because there's many more of us. But I didn't think that was necessarily politically a good idea.

21 The special value that these advanced practice 22 nurses bring to Medicare patients is not only disease

management, especially with chronic illness, but it's also 1 the accountability and coordination for a patient over time, 2 3 coordinating with family, community, specialists, and facilitating a supportive environment to reduce their risk. 4 5 The forecast of need is what you've heard from all three of us today, much more chronic illness, more 6 7 comorbidities, lack of close family support, extended life 8 and extended frailty, and coordination of specialist care. Kevin noted that many nurse practitioners are 9 10 following the same path to more specialist care, as 11 physicians are. My experience with the Columbia Group and with the 12 schools of nursing in which I sit with the 12 13 council is that nurses, even when they go into a so-called 14 specialty practice, are providing primary care for those 15 specialty patients. I have 12 of my faculty working in the 16 heart, liver and lung transplant units at our medical center 17 and they are the primary care providers for those patients 18 for life after the transplant. So one would see that they're in the Department of Surgery in the transplant unit, 19 but what they're doing is providing primary care. So I 20 21 think we have to look more closely at the specialist 22 orientation of these nurses because if you look closely

1 enough I think you'll see that what they're doing is primary 2 care.

3 I would ask that you would consider as you open the discussion on GME broadly to consider having GME payment 4 5 for advanced practice nurses and doctoral programs who are 6 going to be primary care providers. My students at Columbia 7 in the first year of their study toward the six-year 8 progression pay \$90,000. They take 60 credits that first year. It's \$,1000 a credit. With room and board and fees 9 10 it's \$90,000. They're standing in line to come to my 11 school. They come from 22 states. A quarter of the students are from California. There's 534 schools between 12 13 New York City and California. They come because we're 14 giving them the kind of education they think they need to 15 provide this kind of care. They have debts that look just like a medical school graduate's debts when they leave. 16

And I think if they're going to be providing the care that Medicare patients so desperately need, it really demands a close look at how GME funding is being used because these people deserve it. It will bring them into these roles. And they're going to be practicing with high quality with the patients that need them. We hope you will bring fee parity up so that it's not 85 percent but 100 percent. And that you'll eliminate physician oversight. And that you'll fund more studies of outcomes because we welcome what those studies are going to show.

6 So thank you very much.

MR. HACKBARTH: Thank you. Three excellent
presentations and now we'll have some questions, comments.
MR. DURENBERGER: The first comment is to thank
you and Mark and the staff for putting the panel together.
Selecting three very good but different presentations is
incredibly helpful.

My first question relates -- and I just have two. My first question relates to whether one or more of you can tell me how many licensed ancillary health professions there are in the country today? The second part of that question is going to be why? But does anybody know the number?

MR. SALSBERG: Can you clarify when you say ancillary health professionals

21 MR. DURENBERGER: You have to help me with that 22 because I'm a layman. It's everything other than an MD.

MR. SALSBERG: If you look at the total workforce, 1 2 physicians, my recollection, are about 6 or 7 percent now of 3 all the health workers. That includes from nurses, nurse aides, physical therapists, et cetera. Again, about now 4 5 800,000 physicians and about 12 million or 13 million Americans who the Department of Labor would classify as in 6 7 the health field. And that actually includes both people 8 trained as health professionals as well as hospital workers. I don't know, Kevin, if you recall. 9

MR. DURENBERGER: I'm not looking for the numbers.
 I'm sorry, I should clarify.

How many licensed ancillary health professions are there? And if you know the answer, then my second part is why? Do you follow me? In other words, we have advanced nurse practitioner, I take it, is a licensed profession as is physician assistant, as is I'm assuming several hundred of these licensed professions in this country. Does anybody know the answer?

MR. SALSBERG: I don't have the answer. My recollection is in most states -- and licensure is at the state level -- in most states you're probably talking about 30 to 40 professions that are licensed. That doesn't mean

1 that there aren't other credentialed health professionals
2 that are beyond licensure.

3 MR. DURENBERGER: I just think it's something I 4 would like to see explored because of the productivity 5 issues. We keep seeing new categories.

6 The second one relates to the Medicare program and 7 I think Ed started out by saying the critical need for the 8 Medicare program to fund health professions in medical 9 education. I don't think anybody disagrees with that. I 10 recall at the time that we made the decision to do that 11 there was an anticipation that the private payers in this country would follow suit. Of course, they didn't. 12 And 13 then there's been a debate all the time about should we tax 14 premiums or should we tax something else.

But I have a slightly different question just to get at your views and particularly when Mary gives us the figure for \$90,000 for one year of tuition. All of you have talked about the system itself, particularly the umbrella example, and so forth.

20 Suppose the public investment in tuition, which is 21 a way of describing what it costs to go to these schools, 22 were used to finance the students as opposed to the universities, the colleges, or the other institutions
 including the teaching hospitals.

Number one, what impact do you think that might have? Are there any examples of where it is done? And do you think personally is it your view that it might help facilitate the opportunities or the capacity for education within the health care system?

B DR. GRUMBACH: That's been raised before. Should 9 you attach the payment to the individual rather than to the 10 institution? I think that's the crux of the matter. I 11 think there's pros and cons. In some ways, is the goal to 12 essentially be a scholarship type program and to defray 13 tuition? Or is it really to help the infrastructure of the 14 training institutions to do that?

15 I think the advantages, certainly it's more flexible when you attach it to the individual. The downside 16 is it creates a lot of instability. If you did it, for 17 18 example, for a family medicine residency program, I guess if we knew we would always get a certain number of residents it 19 would be a bit of a wash and it will look the same to us 20 because most of the money just goes to pay the resident 21 22 salaries we get anyway.

I think the question would be let's say you didn't 1 match so well that year, would you face potentially big 2 3 swings up and down depending if you had a few more residents this year, a few less that year. Would it take vulnerable 4 5 residency programs that are, particularly in primary care, 6 having trouble filling and almost penalize them if they 7 don't have quite the same number of people coming in? 8 So I think, with everything, there's pros and cons so there's some flexibility. Maybe that's true to the 9 10 intent but it certainly could have some destabilizing 11 factors. 12 In either case, I guess I'd ask you is what are 13 you buying for the money? What is the product you want to 14 get out of that? 15 MR. DURENBERGER: And who ends up making the 16 decision? And obviously, this is a decision that 17 policymakers, particularly those who have responsibility for 18 the Medicare program, have struggled with for many years and 19 probably haven't answered it very well. But it is an 20 important issue. 21 There's a number of ways to get at the quality or

22 the value issue. But one of them is through these people

that are lining up to go to Columbia and paid \$90,000 a year. They're making a decision about Columbia. First, they make a decision about the professions in general, then advanced practical nurse, then practice nurse. And then they make a decision about Columbia.

6 If that were made repeatedly across the country by 7 people that would like to do that, I'm just curious, and 8 particularly Kevin and your colleague, Ed, and other people who have analyzed this, would that not have an impact on the 9 10 capacity of our community systems both for residents and for 11 the basic teaching part? Would that not have an impact on capacity that would be more predictive of the needs that we 12 13 have in this country than the establishment approach we've 14 used for 100 years?

15 Maybe it's just something to think about.

22

DR. GRUMBACH: I think it depends where you target those resources. If you said we want to do it for advanced practice nurses or nurse doctorates who are going to go into family care or family doctors or if you decided we really have a need for psychiatrists and that's what we're going to fund.

But if you said just anybody who wants to go into

residency or anybody who wants to go to medical school, or anybody who wants to go an advanced practice nurse, here's the money, you're in the same quandary you're in right here, which is you put a lot of money into this with no accountability over what you're producing at the end.

To me it doesn't matter so much whether you attach it to the individual or the institution. It's what are you buying for the money and what are the products you want out of it?

10 MR. HACKBARTH: Let me ask sort of a related 11 question. I've asked some people what if we took a piece of 12 the money that Medicare spends on graduate medical education 13 to basically make it no cost to become a primary care 14 clinician, whether it's a physician or a doctoral level 15 nurse? And I've gotten mixed responses to that question and 16 how much it would affect the imbalance.

One response I've gotten is yes, that would make it very attractive. But I've heard other people, including people in the primary care field saying it's really the long-term income stream that drives the choice. It's not the front-end costs. You can make so much as a high end specialist, the educational costs really aren't a barrier 1 anymore.

Has anybody looked at that systematically? Or do you have thoughts yourself about that?

DR. MUNDINGER: We believe that those individuals 4 5 who have a choice to go into nursing after they get their baccalaureate degree to go into medicine are making a value 6 7 choice and not just a tiered choice. Those who want to go 8 into nursing tend to have values where they want to spend a lot of time with patients. They really value education and 9 10 counseling. They want to see somebody through an encounter. 11 They want to make sure everything goes well with the family. They are entering a health profession with a different 12 13 perspective. And then they end up with a skill set that 14 looks very much like what a physician has and could choose 15 to go into liver transplant and seek a \$200,000 a year 16 salary from that practice or they could choose to go into 17 independent primary care and make \$100,000.

They are making decisions that tend to lower the salary expectations. For instance, in liver transplant when they first hired the first six of our graduates they had a productivity methodology they wanted the nurses to follow. And with it would have gone a financial payment. They said 1 they didn't want it. They wanted to be able to have at 2 least a half an hour with every patient they saw. So they 3 make less money.

And I don't think nurses are any more likely to follow a poverty stream than a physician is. Nurses like to drive good cars and have nice clothes and have nice vacations and not wake up in the middle of the night all the time, too. But they also are driven by a different paradigm of why they want to take care of patients.

I don't think we're going to see a total coming together of salary expectation overriding career choice. I just don't think it's going to happen. Somewhat but not overwhelmingly.

MR. SALSBERG: I think in the long run the income of the practitioner is going to have far more of an impact on specialty choice than the funding of graduate medical education. The issue of we may think that we want more geriatricians, offering more geriatric training positions is not the answer if there is not a good delivery system and good incomes for practicing geriatricians.

21 Let me comment on the primary care piece because I
22 think they're certainly a perception in the nation that we

need more primary care physicians. And I certainly support
 the points that Kevin made about the reimbursement system
 seeming to favor specialists over primary care physicians.

But I want to be clear that the concern about shortages that we see is not just about primary care. In fact, the recent HRSA report forecast a greater shortage on the specialty side than on the primary care side.

8 If you look at the conditions that afflict the 9 elderly and the growth of the elderly, you have to be 10 concerned about the adequacy of supply in a whole range of 11 specialties that serve the elderly. We're going to need 12 urologists. We're going to need cardiologists. We're going 13 to need oncologists. There no way that we're not going to 14 need physicians in a whole range of specialties.

So I would urge you not to think about should we be trying to finagle with the GME financing system to favor one specialty over another unless we build a really solid database that convinces us that we really know what we're talking about in terms of what specialties are going to be in high demand or in shortage in the coming years.

And so I worry that this is going to be shifting and we're not going to be quick enough to identify those

1 specialties. Hence our belief that you need to look at the 2 marketplace and try and work with the marketplace more than 3 the training system.

DR. GRUMBACH: That said, I would love to be able 4 5 to tell a medical student contemplating a future career that 6 it would be a very different equation for their up front 7 educational expenses. I agree that I think it's driven a 8 lot by the life career span of compensation. But to say instead of coming out of medical school and residency 9 10 \$200,000 in debt, you'll come out \$20,000 in debt, and you 11 can defray that \$180,000 difference. That's quite a few years of post-tax income you're talking about to offset 12 13 that.

14 So I would be reluctant for the Commission to 15 leave today thinking that that didn't at least have some 16 merit, Glenn.

DR. REISCHAUER: This is a question for Mr. Salsberg and it's about the underlying methodology for your projections. What I was wondering is what kind of assumption is used about the change over time in the organization of the delivery of care that some people think that we put together inputs in a very inefficient way right
1 now and that there's some range of Jay's organization and 2 some others mixed with nurse practitioners and others in a 3 more parsimonious way.

And what if you assumed that we transformed gradually the health care delivery system to a more efficient production function? What does that imply for the need for physicians, in particular, and obviously other resources such as nurses?

9 MR. SALSBERG: A very important issue and I will 10 agree it's extremely difficult to look 15 years out and try 11 and forecast what the organization and financing of health 12 care will look like.

13 In most of our models in forecasting we will have 14 different scenarios. In the report we're coming out with 15 next month we'll have a scenario, what if 20 percent of all 16 specialty services were suddenly eliminated or we found ways to improve efficiency? What would that do to the demand for 17 18 physicians? So we can look at different scenarios. We assume that the expanded use of nonphysician clinicians, 19 20 nurse practitioners, and PAs will continue into the future. 21 I think the bottom line is that because we're not 22 assuming that the future gap that we see will be filled by

physicians there is an assumption built into our forecast that the system will find ways to make better use of physicians. And so, as I said, the most recent numbers that we're coming up with would show that if you don't change anything we'll have a shortage of about 60,000 physicians, full FTE physicians in 2020.

Our recommendations on productions adding physician supply would only meet about one-third of that. We're assuming that two-thirds of that would be met by systems improvement and, in fact, will push the system to improve. We think that you still need that core of physicians. But again I want to be clear that we're assuming that others will improve the system.

I think one of the problems with physician workforce planning in the past was sort of the assumption that because there are inefficiencies we're going to plan for a system that will weed that out.

In 1990, when we looked at Kaiser and another HMOs and said they used 25 percent fewer physicians, therefore let's produce fewer physicians, the problem was the nation didn't accept that model of care. And even though if I agree that there are inefficient and marginally effective services, I'm not sure as a planner that I would say let's assume we're going to weed them out in the next 10 years. We've been trying for a long time and I'm not sure that the concept that by keeping the physician supply very, very short we're going to forces system improvements. I think it will force some system improvements. It will also mean that there will be serious problems of access.

8 So again I think what we're recommending is some 9 expansion that keeps it tight but not so tight that people 10 won't be able to get services.

DR. GRUMBACH: The Canadian economist Bob Evans has a great quote which is stir the sugar in your tea before you add another spoonful in. And I think that has great application.

15 You have experts like Dr. Milstein and I think you 16 have the Kaiser system. If you want to say what's the 17 immediate impact Medicare could have, it would be to 18 transform the delivery of care to make better use of the 19 resources we have now. Until we start working on that just 20 talking about capacity seems to me to miss the mark. I 21 don't totally disagree that we need to invest in the future 22 workforce but we have to tackle this problem now.

1 The role of physician should dramatically change. 2 I think Arnie has this right. It will be managing a 3 population -- and it's not just about nurse practitioners, 4 physician assistants, doctoral nurse -- it's about medical 5 assistants playing a very radically different role in 6 managing populations under the supervision again of an 7 advanced nurse, a physician, and things like that.

8 There are things you could do with payment policy 9 right now that would promote and remove some of the barriers 10 to transforming how care is organized in delivery that would 11 get you much more bang for the buck right now.

DR. MUNDINGER: One thing I'd like to add into this discussion is that there are going to be 200 schools of nursing producing doctoral level and nurse clinicians who are going to out there taking care of Medicare patients. They've been authorized since 1965 to do this. The Balanced Budget Act of 1997 gave them authority in any site.

So to the extent that you look at GME as not only a payment system but as a way to assure some standards, that only certain people would be able to tap into this payment system, that there would be standards you would require in terms of education and certification to have the kind of authority that they have and which is expanding, I think GME can be an instrument of standards as well when you allocate payment.

And to the extent that we're going to have some 4 5 very high quality graduates in these programs who are going 6 to do what physicians do who have had this subsidy, I think 7 the equity of that system needs to be looked at, as well as 8 assuring that only the programs that have high quality and are going to produce doctoral level nurses who have the 9 10 equivalent skills and knowledge to care for Medicare 11 patients with high quality, that only those are included in this opening of payment if you decide to do that. 12

MR. SALSBERG: I just want to further reiterate, I think the point that was made about efficiency, do we really need more physicians or do we really just need to clean up the delivery system, I think is a critical point here.

Again, the reality is yes, we have move forward to improve the efficiency of the system. But it would be irresponsible not to also look at how many physicians we're likely to need with or without those improvements. I would like to say, and I think Kevin and I used this analogy once before, that the nation should be moving towards assuming that every car can get 80 miles per gallon. Now if you're in the business of producing oil, do you only produce enough capacity under the assumption, that in 2015 every car will get 80 miles to the gallon? I think it's irresponsible to say we're going to do that and we don't care what happens. What you're doing is forcing a crisis.

And I just don't think forcing a crisis on the
physician supply is the best way to promote improved
efficiency.

DR. REISCHAUER: But this isn't really a crisis because this is like sea level rising, it occurs very, very gradually. Incentives begin to shift. If you operate the system so that you provide enough oil for cars to continue to get 20 miles a gallon, you'll never get change.

MR. SALSBERG: Right. so you want to push the system. But again, if you need to plan, as we do for physician workforce, 10 to 20 years in advance, I don't think it would be appropriate to make the assumption that we're going to achieve maximum efficiency 20 years down the road and stop producing.

Again, I think if you look at the basic numbersyou realize that you need physician and improved efficiency.

1 MR. HACKBARTH: This is a crucial debate, which is 2 the driving force here. I don't even think that the oil and 3 car analogy is apt because the clinicians that we train 4 shape the system in a way. They shape the way it's 5 organized. They shape the expectations of patients. We're 6 not going to resolve it today, but obviously this is a 7 critical issue.

8 We've got to get through our here. Next is9 Jennie.

10 MS. HANSEN: Thank you.

I'm delighted to see all three parties represented here. And it just strikes me that the shaping of it in terms of the incentives now but ultimately this whole aspect of really being transformative. You talked about the 30 million people who are uncovered.

16 So I just wonder if -- one is going to be a broad 17 question and then one will be specific.

18 The broad question is having all three of you 19 represented here representing different domains but still 20 about the Medicare population. Is there the will and desire 21 amongst you, rather than the jockeying of whether nurse 22 practitioners or doctoral nurse prepared substitute for one group or the other. At some point, looking at the fiduciary responsibility to all Medicare beneficiaries having access to efficient care, safe care, care that is evidence-based practice, it really takes a transformative effect not just of the delivery system but frankly the leadership that all of you represent.

7 And so my casting call here is whether or not 8 there is a willingness of all of us to come to the table not to just get more here, more there. That gets to be a zero 9 10 sum thing, as compared to saying what is the core issue here 11 of serving a population that is growing and with all demographics that each of you have pointed out. But it 12 13 really is about the leadership. It's going to be eventually 14 about the faculty. It's not just the practitioner, the 15 students coming in. The students are shaped by the belief 16 system and the knowledge of all of your constituents.

17 So my question is whether or not there is the will 18 and the desire to commit to that for the Medicare and the 19 greater health care population? That's a broad question. 20 Specifically, I think the incentives that we 21 really need to put in place, the GME issue and IME that 22 we've talked about earlier is just so wrought with the

1 reality of everybody wanting to have their share, their need 2 of their share of the hospital systems and the faculty, I 3 know. Even residents that are barely making \$40,000 or 4 \$42,000. So they're not getting rich on the system.

5 But at the same time what are the incentives that 6 we can build in? I think the GME we've talked about in the 7 past having more geriatric education because regardless of 8 whether you go into primary care or specialty, it's going to 9 be an older population.

10 Secondly, the process of care which typically -- I 11 think Arnie has been one who has really pointed this out --12 it's like working in teams, using evidence-based kinds of 13 things that typically are not taught faculty. That's not a 14 specialty area.

So are we willing to pay for that as part of GME? And since chronic care is going to be the place of care, it's not always going to be in the four square of an acute care facility. But will acute care facilities be willing to give up some of that funding that they also need? Very, very tough.

21 And then also regulations. So these are some 22 issues that I just wonder from the politics to the payment. You can pay more and there's been some changes, I think we know, relative to primary care payment that's been tweaked. But not that it's enough for a lifetime of income. So there are such systemic issues. And the whole question is where is the leadership?

6 DR. GRUMBACH: Come in. I think you said it 7 beautifully, Jennie. And On Lok is sort of the exemplar of 8 how you start with what does a patient need and work 9 backwards to organize a system around that? And that's what 10 we should do. We should get rid of turf battles and our own 11 professional prerogatives and say what services do patients need? How do you assemble the right people to deliver those 12 13 services? Whether it's led by a geriatrician, whether it's 14 a nurse, I totally agree with you. I think we've got to get 15 away from our parochial interest and really think what do 16 patients need? And how do we totally be much more creative? And how do we build it into our educational systems about 17 18 really providing team-based patient-centered care? 19 I totally agree with what you said. So I'm with 20 you.

21 MR. SALSBERG: AAMC also is in the same place and 22 we're very supportive of looking at what we can do to

prepare physicians to be more in practice and collaborative practices in the future. And I think, again, I agree with the comments that you've made.

DR. MUNDINGER: The clinical doctorate in nursing 4 5 is really an attempt to do that. The additional two years 6 are very much focused on issues like -- there's an advanced 7 ethics course. There's a beginning -- we call it an ACE 8 course, assessing clinical evidence. There's an advanced 9 ACE course where we actually go to the five levels of 10 evidence and help practitioners know what kind of evidence 11 in the literature is appropriate. The designs were right, the methods were correct for the analysis that was done, for 12 13 the results that it reported, for the recommendations that 14 come out of that.

We spent a lot of time on that. A third of the clinical work in the doctoral program is in chronic illness care. So we're attempting, in our own profession, to reach that kind of transformative practitioner that was heretofore not part of the system.

20 MR. MULLER: I find this discussion fascinating 21 and I must say, sitting here at MedPAC over the years and 22 hearing the need for care coordination and what MedPAC can 1 do in terms of devising on payment bundles and other

2 conversations we have. Then I go back to my home base of a 3 big medical center where this aging population has over 200 4 forms of cancer and rise in neurodegenerative diseases and 5 everybody is specialized.

Both the science and biomedical knowledge drives you more and more towards specialization. That's where the science is going, where the prestigious is. So I have this enormous disconnect.

10 It's not just money that's driving these choices. 11 Obviously money has a big part of it. But the biomedical field is going to more and more specialization. It's been 12 13 going there for 30 or 40 years. So all the students I see 14 are going into very limited fields. It's not just 15 cardiologists anymore. We have 20 kinds of cardiologists, 16 we have 30 or 40 kinds of cancer physicians, and so forth. 17 So I would say we have the both focus on how one 18 gets better coordination in the kind of signals. Obviously

19 I think all three of you made a very good point about there 20 has to be more money in the field for primary care. But we 21 tried that 10 or 12 years ago when the general practitioner 22 and the capitation model had more control over the system

1 and that kind of fell apart so quickly.

Even the British system where they had more 2 3 commissioning by the GPs, you still had enormous influence on the part of the specialists. 4 5 So I still think as MedPAC we can focus on the 6 payment signals. But I think we should be unwise to not see 7 that the science is driving us toward more and more 8 specialization. There's an underlying force there. And 9 somehow we have to use payment policy that recognizes that. 10 But it's not going to stop it in any kind away because that 11 thrust is there. 12

So I commend you all for looking in this direction and I do think as a payment commission obviously the signal that we can send the most directly as the signals on payment policy.

If one, with a magic stroke, could flip the chart that Dr. Grumbach had it on on the payments for primary care versus specialty, if one could flip that magically overnight -- and I'm not saying anybody could -- that still wouldn't totally change the supply of where people go. So I think we have to keep focusing, as Mary and the rest you talked about, on an increased supply.

And getting people who understand the kind of case management of care. As Mary said very powerfully, it's understanding the whole family, the social environment and so forth. We don't teach people that well how to do that. And maybe nurses might be a better way of looking at that than physicians are at the moment. There are obviously fields like family practice that do it quite well.

8 But I think we shouldn't go away from this 9 thinking that this is just a matter of payment policy. The 10 science is driving all the specialization and it's going to 11 continue to drive that.

MS. BURKE: I think a fair amount has been said. I want to thank the three panelists, as well. I'm particularly pleased to see Mary here, a colleague of longstanding.

To Glenn's point, I don't think we're going to solve these issues today. But I'd like to suggest the following, that I think there are both short-term and longterm issues here that we all are struggling with, not the least of which is whether Medicare, in fact, ought to play a role in the financing of medical education. We've clearly begun to alter that role in the last few years and we may

well alter it more fully going forward in terms of GME and
 IME.

3 But setting aside the very, very long-term for the moment and many of the issues others have raised, I think it 4 would be quite helpful, Glenn, for the staff, in 5 6 anticipation of further conversations, to follow up and make 7 sure that the Commission -- for purposes of short-term 8 issues -- examines a bit of the questions that Kevin raises 9 in his bullet points about the current weighting and also 10 the current method of payment policy in terms of how we 11 structure it given what we know to be the changing nature of the location of training. 12

13 The fact that, in fact, many are moving out of the 14 traditional clinical teaching facility, academic medical 15 center, both for purposes of the kind of thing that Mary 16 very appropriately raises but Kevin notes as well in terms 17 of these relationships with hospitals that are 18 nontraditional in the sense of what we understood to be the 19 sort of academic home.

And as training moves out, I mean I, in fact, did some of my training at SF-General in one of the clinics there but also in a clinic that was located in downtown San 1 Francisco, nontraditional settings at the time, less

2 nontraditional today where we know people are moving out of 3 clinical boxes into community-based care. But the system 4 hasn't really followed that in many ways except in the very 5 opportunities that Kaiser and others who do a different kind 6 of payment system.

7 So I think it would be helpful if the staff were 8 to help us understand the nature of what occurs literally today, how it has in fact or what it does in terms of 9 10 depending on where you are, whether it impairs relationships 11 that will allow this transition to occur over time and make sure we have a good grounding in that beyond the sort of 12 13 bigger political question should Medicare pay for financing 14 medical education or not? Or expand it to include nurse 15 practitioners and others where we have traditionally not 16 done so?

So again setting aside the big issue over the long term, the whole question of the future, I'd like for the Commission going forward to have an understanding of what, in fact, occurs today? How are we inadvertently either encouraging or discouraging this transition to different methods that are, in some cases, more productive, certainly 1 more responsive to patients and where they want to be 2 treated and cared for then we have in the past?

3 It has some of the concerns around things like 4 home health where if it occurs out of the box we get nervous 5 because it's not as easily defined. And this is one of 6 those situations where it is occurring in settings that are 7 not as traditional for us. But in some cases they are and I 8 think some better sense of that would inform all of us 9 looking at this longer question.

10 So I would ask that perhaps some thought be given 11 to that in the future conversation so that everybody 12 understands these two points that Kevin raises.

13 The only other thing was really just a passing 14 interest. The discussion, Ed, on the part of the AAMC in 15 terms of where the workforce is coming, I'm just interested 16 in understanding how many FMGs are U.S. citizens? How many 17 of the folks coming back into the country that we believe to 18 be foreign medical graduates are, in fact, U.S.?

MR. SALSBERG: Currently, of the 6,500 IMGs each year, about 1,500 are U.S. citizens. Those are those coming back that passed the USMLE test and get the ECFMG certificate. Based on the number applying for ECFMG certification, my current estimate is that about 2,500 U.S.
 citizens are going abroad each year to go to medical school.
 The vast majority of those are going to schools in the
 Caribbean and we do have data on that and can provide you
 with more information if you'd like.

MS. BURKE: You mentioned just in passing, you didn't raise it in your comments, but this question of, in fact, the brain drain out and whether we're pulling people in and then failing to send them back to their home countries, I think is a legitimate question.

But this whole question of how many slots are available, what the nature of the slots is, what's happening in terms of admission rates, I think in part gets buried a little bit by a lack of understanding of who some of the IMGs are, why they're going out, who's coming back in.

I think the sort of comment you made on your paper but not in the text or in your comments, and that is the options for assessing medical schools outside of the U.S. What do we know about the quality? What do we know about that process? But what does it say about the fact there are people going out? Is that a quality issue or not? Again, not to be answered today but I think just

an interesting question as we look at the long-term source
 in terms of providers.

3 MR. SALSBERG: We think it's a very important I didn't focus on it today because it seemed less 4 issue. 5 directly related to these issues. But certainly important to the medical school capacity if there are large numbers of 6 7 Americans that want to go to medical school and are unable 8 to get into the U.S. schools and are now going abroad, I think it is an indication that we have a responsibility to 9 10 expand undergraduate medical education and provide them with 11 opportunities. Especially since so many of them are coming back into the system in any case. 12

And we are concerned about the accreditation or lack of a systematic accreditation process or assessment process of those schools. And there is some activity going on to see if that can be developed, particularly within the Caribbean community.

MS. BURKE: It's also an interesting question in terms of geographic distribution. I have some vague recollection of getting a sense of the number of physicians in the state of Kansas working in Osawatomie. There is a particular characteristic to where people go when they come

back, who goes there and why. I think it's an interesting 1 2 question in terms of our long-term strategies and the use of 3 nurse practitioners and others, where they have opportunities. As Mary suggests many of the states are, in 4 5 fact, expanding that to address a real long-term need of 6 people committing to a community, staying in the community 7 and not just doing these quick turnaround things, get me 8 back in, get me settled and let me move on. So I just wanted to understand it. Thank you. 9 10 DR. GRUMBACH: Just one quick comment, Sheila. 11 I think the first point you made is really fundamental. I think the question for the Commission is is 12 13 graduate medical education payments from Medicare, is it a 14 medical education policy or is it a hospital subsidy policy? I think the enacting legislation had more to do, frankly, 15 16 with subsidizing teaching hospitals for costs associated or 17 case-mix or the fact they're taking care of more indigent 18 and disadvantaged patients, frankly, than it was explicitly a policy about medical education. 19

I think you would have to tackle that question if you're going to come up with a rational answer to your first question.

MS. BURKE: Trust me. There's been not an insignificant amount of conversation on exactly that point and there are interesting views and historical perspective. But you're right.

5 DR. MILSTEIN: If we, meaning Medicare and the 6 private sector and Medicaid workers comp, actually succeed 7 in creating our goal, which is a payment system that's much 8 more sensitive to value received by the beneficiary, one of the consequences you can reasonably expect is a much faster 9 10 evolution in the production function that optimizes that 11 value. You're going to see a much faster evolution of the so-called price performance frontier. 12

What are any of your thoughts on how we might build a much more flexible use of Medicare -- I should really call it clinical education dollars -- in order to motivate clinician educators to be able to adapt much more agilely to emerging workforce strategies that one can see as one watches the evolution of the production function and the production function that leads to highest value?

I'm envisioning the rate of so-called knowledge turns in the optimal production function of health could begin to speed up quite a bit. How do we go about using what medical education dollars we have in Medicare to sort of fund -- I guess I'm repeating myself -- but a much agile approach to adapting to a much faster change in the optimal production function?

5 DR. MUNDINGER: I hope I understand your question, 6 but I think what we can do in nursing is work with the 7 population of those who are already RNs, who already have a 8 baccalaureate degree, who have not gone on for the next four 9 years to get a masters or a doctorate because they don't 10 have the money to do it.

11 Their graduate medical education, if you will, has to come from after-tax dollars when they write a check with 12 13 a lot of other priorities. We know that there is a 14 widespread belief that there's a nursing shortage in this 15 country, that there's somewhere like 150,000 open hospital 16 positions that can't be filled. There are over 500,000 17 nurses with current RN licenses who are not working in 18 nursing. We don't have a nursing shortage. We have a 19 shortage of good jobs at the basic level for which they're 20 prepared.

21 And if they want to go on and prepare for a 22 position that's more attractive, more authoritative,

something along the lines of primary care the way they're 1 talking about it today, they are ready to go within two 2 3 years post-masters these people can achieve a clinical doctorate and be out there in full scope primary care. 4 5 So the longtime wait for such wonderful practitioners is not an issue in the nursing world. 6 7 DR. GRUMBACH: I think, Arnie, it's driven much 8 more by the actual practice. Medical education is usually the lags and it's going to be the force for change. If you 9 10 provided the incentives for delivery systems to start to 11 adopt innovations, that would drive what the preparation is, in many ways. And I think teaching environment is almost 12 13 the last to adapt. 14 So I think you'd want to drive it at the

15 systemwide level and then build in the flexibility so you're 16 not handcuffing what can be done in the training rather than 17 thinking you can drive it through the training system. So 18 it is all stuff Sheila was talking about, getting people out 19 of the hospital in the training setting and into these 20 settings.

21 You can try to regulate gee, everybody has to have 22 teamwork courses and things, but I think that's sort of

artificial. I think it's much more where the system is going and can you unleash the restrictions to allow training programs to be flexible enough to say gee, we actually don't want people to be in hospital so much. Let's get them working in an ambulatory care setting.

DR. MILSTEIN: But how do we modify our Medicare -- I'll call it hopefully clinical rather than medical education policy to motivate the current people who are educating our clinicians to be much more flexible?

10 DR. GRUMBACH: By vote, I would do, frankly, 11 outright essentially grants to training institutions and that you have criteria about who's going to get the money 12 13 which is based on what are the programs like? What are they 14 producing? And how do they organize their programs? It's 15 not just anybody's who's got a resident or whatever, here's a check per slot. It's here's a program -- I'd convert it 16 17 were to a Title VII type grant mechanism. That's the way I 18 would do it.

MR. SALSBERG: The difficulty, of course, is that there are 8,000 accredited residency programs. And so to try and assess each one of those I think would be extremely difficult. But I would agree that the Title VII, while

relatively small when it was fully funded at \$300 million and now at only \$150 million, relatively small. But the concept was can we stimulate innovation and develop models including of medical education, PA education, nursing education. Nursing his Title VIII. But there is a real role for that type of grant program separate from the basic funding stream.

8 DR. MILSTEIN: I agree with and the answers sound 9 right to me. But can you give me some basis for optimism as 10 to how this might actually work within institutions in which 11 the leadership is primarily dedicated to categorical

12 education within today's existing definitions of health care 13 professionals?

14 MR. SALSBERG: There are some demonstration projects and programs underway, particularly around 15 16 collaborative care, that the AAMC has been involved in with 17 some foundation support. We've also been working on trying 18 to improve -- one area that more needs to be done and a lot 19 is being done is the use of new technologies in medical 20 education and training. We're really on the verge of some 21 drastic improvements with computerized and advances in 22 technology.

So it may be a series of grant programs and 1 2 dissemination of projects to help spread that more rapidly. But there are others at AAMC who are far more 3 knowledgeable than I about medical education reform and 4 5 improvements that we might want to bring into the dialogue 6 to say well, what can be done on the payment side to help 7 promote those educational reforms? 8 MR. BERTKO: A quick comment first, and then a question possibly for Kevin and Mary. The comment being 9 10 that I will confirm from our data that your slide about 11 provision of care at what I'll call lower cost her episode from primary care is evident on the private sector, as well. 12 13 The question is for us to think about -- you 14 mentioned bonuses for care coordination as being apart. For 15 us, what should we think about the size of the bonuses that

16 would be effective?

And secondly, I'll put it this way, kind of along Arnie's, what value, what services should we buy for those kinds of payments? I view that both in the APNs and the generalist side.

21 DR. GRUMBACH: I think you want accountability for 22 any bonus payment you give in coordination. So I would not

just -- I would again say -- partly I would base it on what infrastructure do you have? Do you have teams? Do you have group visits? Do you have care managers, health education, promotores?

5 So I'd look at it partly in sort of the Donabedian 6 structure/process/outcome. Partly you could qualify if you 7 can demonstrate the structure, if you had electronic medical 8 record. If you can demonstrate you have a registry for 9 chronic care patients.

10 So I would think about some structural things 11 because I don't think it should all be on the outcomes or 12 the performance side. But if you demonstrate you have some 13 capacity you're entitled to that. Or if you can show you 14 will invest in that over the next one or two years, that can 15 justify some of the payment.

16 And then I would build it into some of the pay for 17 performance around then how are you doing both on process 18 and outcome measures?

19 I think every bit helps. I think particularly if 20 it's coupled to some of the infrastructure. Ralph touched 21 on some of it. There's a whole culture that drives some of 22 this. There's some of the take home income. Some of it is just the sheer I'd love to do better chronic care but I don't know how to do it. I don't know how to get the right electronic medical record. I don't know how to be able to hire the right person. So some of that stuff built in and say if you will hire somebody who knows how to do chronic care self-management, here's some payment that can go to that.

8 I think the most intriguing version is what Grohl 9 [ph] and Bob Berenson just came up with an article in the 10 Journal of General Medicine which is almost taking 11 capitation without any of the downside risk it used to have 12 and say patients have to register. I think that's another 13 thing. And I don't now in your program maybe there's an 14 explicit.

I would do Medicare start thinking about patients have to register with a medical home. And again, it doesn't have to be a family doctor. It could be a home that provides -- again, you could stipulate what services have to be provided to qualify for a medical home and that people actually register not with a gatekeeper model but that there's clear accountability.

22 I'd start to think about some of those mechanisms.

DR. MUNDINGER: If the new primary care is more 2 3 than diagnosis and management, and it really has a lot to do with not only patient specific coordination of care but 4 5 family and social resource development, the case management that Ralph was talking about, they can be fairly easily 6 7 listed as components of the payment system that you're 8 devising. And the provider, whether it's through hiring a 9 chronic care manager or a registry. There are a lot of ways 10 to meet the needs of reporting that this is happening. But 11 redefining primary care as more comprehensive care is probably the way to start. 12

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13 DR. GRUMBACH: The final thing, it's the whole 14 non-encounter-based payment so that increasingly I think 15 we'll move to e-mail management, medical records a patient 16 can access on the web, and I think telephone follow-up. Ι 17 think, frankly, the fee-for-service system needs to be 18 rethought, whether we go completely to more capitated or 19 some model. I don't know if you're paying for some of those non-visit encounters in your program and things, but I think 20 21 that has to be factored into it, that it can't be driven 22 just by face-to-face encounters as the source of a practice

1 revenue.

2 DR. KANE: I'll be brief. Sheila actually brought 3 up a lot of the questions I had.

I guess the one thing that still sticks with me that I wonder what you have to say about this is I saw a presentation once on the Ross Medical School which is one of the Caribbean medical schools. And it's much cheaper then the U.S. medical school by a lot. When you say \$90,000 for the first year of tuition.

I'm just wondering what would it mean to adopted their mode of training? I think it's just the first two years. But it's definitely cheaper. What would the implications be for medical schools if, in fact, they adopted the Caribbean mode for those first years and the nurse's didn't have to pay \$90,000?

16 What are we giving up and what are we gaining, I 17 guess, by the rather large cost differential.

18 MR. HACKBARTH: It would be a lot more fun for19 sure.

DR. KANE: Actually, it looks like it's not much fun. You get a suntan, but you're in a big barn and it's really not that much fun. DR. MUNDINGER: The \$90,000 is the first year, the first introduction to nursing, when we're pushing everything into 12 months, 60 credits. Because they're so eager to get into their graduate level education. So essentially this isn't even something we would expect MedPAC to look at. This is their basic nursing education to get them ready for their graduate studies.

8 The point I was trying to make is -- and \$1,000 a 9 credit is kind of the way private schools do things so it's 10 not out of line if you look at \$30,000 for room and board 11 and fees for 12 months, it's because you've got 60 credits 12 in there.

But the point is they are so eager to get into the graduate level training which is -- it's 45 credits and it's over two years. It's not the same annual expense that that first year is. But they're so eager to be in this world of primary care they're willing to do this.

DR. KANE: I think my question is more related to whether there might be cheaper ways to do this overall, but the \$90,000 did catch my interest because it seems like a lot. so maybe it's more the traditional medical school training.

MR. SALSBERG: I think you're right, it is more the traditional medical school.

3 My understanding is most of the schools in the Caribbean have sort of pegged their tuition to the U.S. 4 5 tuition. So from the student's perspective it is not a 6 cheaper education. They pay significant amounts of money 7 for even the third and fourth year when they're doing 8 clinical training in sites that are frankly unregulated by anyone in the U.S., although some states do have some 9 10 provisions.

11 We should be clear that most of the new medical schools in the Caribbean are for-profit. Ross is owned by a 12 13 company that is traded on the stock market, the New York 14 Stock Exchange. There are legitimate questions about the 15 role of for-profit education. Many of you know that 100 16 years ago America really abandoned for-profit medical 17 education. We have a pretty clear standard setting process 18 through the Liaison Committee on Medical Education and the 19 American Osteopathic Association in terms of osteopathic 20 education.

21 We have tried to identify -- and again this is not 22 my area of expertise -- but I know that we've really tried to identify what does it take to become a physician, to become a well-qualified physician? We want all of our graduates to be well-qualified, regardless of whether they're the top student or the last in terms of their standing in their school.

6 So we do have some clear and strong criteria. Can 7 a for-profit medical school in an unregulated environment 8 produce well-qualified physicians? Yes. But we, again, 9 really believe in the value of the accreditation system that 10 we have.

11 Having said that, that doesn't mean that there aren't things we should be looking at in medical education 12 13 to see if we can do it better and less costly. There are 14 people thinking about this and the question of whether the 15 four years of medical school and then three to seven years 16 of training is the best way, is there some way to reduce the 17 time? Is there some way to use new approaches to medical 18 education? Again, we do spend a lot of time though saying 19 what do you needed to be a well-qualified physician? Ι think that's the core that's been driving us. 20

21 And so while we should look at innovations, I 22 think we're still going to remain committed to what's the

1 basic core education that every physician should have.

2 DR. GRUMBACH: I think your question is a good 3 one. For Medicare it's a little tougher to get a role in 4 the pre-doctoral education, let's say in medical school. 5 But here's a very concrete example.

6 California has decided we need to expand our 7 capacity for medical schools, legitimately. We're really at 8 the bottom of the nation in terms of medical students per 9 capita. And a very wise decision was made to build the next 10 UC Medical School in Riverside, which is a real underserved 11 growing area, lots of Latino population. So I've been doing 12 some consulting with them.

One of the things is don't necessarily think you then want to build a big academic medical center as the core of your medical school. How would you do a community based medical education program that is not built around an inpatient institution?

18 So those are the kind of questions that I think 19 some policy could be brought to bear to think about not just 20 replicating the kind of traditional hospital-centric 21 training environment.

22 DR. CASTELLANOS: First of all, I really

appreciate this discussion. I happen to be a physician myself. There's been a lot of great comments made and I don't want to repeat them.

I wish Karen Borman was here. Dr. Karen Borman is a head of a residency program in Mississippi. I've had a lot of talks with her privately concerning the workforce issue, especially as it applies to general surgery.

8 Ed, I think you hit the nail right on the head 9 when you said this isn't a doctor problem. This is a whole 10 system reform problem that we need to do. We not only have 11 to think of physicians, primary care and the other 12 specialties, nursing, but we need to think the whole system 13 together.

As I said, I happen to be a surgeon, too. But when I'm in the operating room, if I don't have good OR techs with me, if I don't have surgical people with me, if I don't have the radiology support, I have nothing. The chain is as strong as the weakest link.

So we need to think of the whole system.
I know we are a payment policy committee, but I
think throwing money at somebody is not going to attract
them for what we want. I think you hit the nail right on

the head. Why people go into the fields, whether it's in nursing, whether it's in primary care, is a value choice. If you're going to throw money at a primary care doctor to get them to get up to do primary care, I think you're using the wrong incentive.

I think what we really need to do is improve thewhole system of delivery of care.

8 I'm just saying this because I made an observation 9 and it may be a good observation or it may not. When the 10 three of you started it was like you were adjusting for 11 positions. Until you made some beautiful comments concerning patient care and why we're here to take care of 12 13 the patient, you all came together and said you know, you're 14 right, that's what we're here for. We need to work 15 together.

What I see in the medical community -- and I'm not just saying physician community -- is a bunch of us jousting for position. That's not where we belong. We belong here to try to change the system so we can provide the very best care to the patient at a reasonable cost.

I really appreciate your comments. Thank you.
DR. CROSSON: Again, my thanks. I think you all
1 did a really good job of bringing up the important questions 2 very clearly and efficiently, and that's helped the 3 discussion.

I just want to reiterate, I think, one thing that Kevin said and that is that Medicare can have a role in transforming the delivery system. I think we believe that on the Commission.

8 We also, I think, have the understanding that 9 something about payment policy with respect to physicians at 10 least and probably with respect to physicians and hospitals 11 together, is the key to that.

We've also noticed somewhat more recently that the communication of that is somewhat more complex than we would hope it would be but we've really just begun that work.

We're also concerned about workforce issues, but particularly concerned about, I think as was mentioned, the current shortage of primary care and that, as I was talking to Kevin before the session, is an immediate problem for us in California and for even our organization, which is relatively attractive to primary care physicians.

21 So we are looking for levers. I think we are 22 going to be looking for levers in the short term to try to

do something about that. We have had some progress on that 1 2 in the last year or so. Specifically though, Kevin, I 3 wondered if you could expand -- you've done that a little bit -- but if you could expand on your final bullet point, 4 5 which is about flexibility in GME training policies and ambulatory training. What specifically are you thinking 6 7 there? And is there something in the relatively short term 8 that could be done?

9 DR. GRUMBACH: I think there's some immediate 10 things around it's really uncoupling the formula so much 11 from it being driven by the number of inpatients, whether 12 the ambulatory training site has to be under the 13 administration of the hospital organization. I believe 14 that's a limitation right now.

15 So that if you work at Family Medicine Clinic at 16 San Francisco General Hospital, that counts as sort of your 17 time contributed to the GME count. If you go work at 18 Mission Neighborhood Health Center, which is a community 19 health center down the street, that time would no longer be 20 credited as part of the GME FTE counts.

21 So it's things like that, to say if the residency 22 has a relationship with an organization that's a great training site, particularly for ambulatory care, that's not administered by the hospital organization, that shouldn't be penalized. I think that's a very immediate decision that could be made in some of the policies.

5 What I talked about in Santa Rosa, with the 6 ability to transfer slots, particularly in primary care, if 7 a residency program is losing the sponsorship of one 8 hospital -- and I'm facing this in Salinas, another critical 9 area of family medicine program. That county hospital may 10 close and there's a private hospital or a district hospital 11 that may take it up.

12 So I think those are two really concrete examples. 13 Being able to transfer GME FTEs when a hospital pulls a 14 sponsorship out of a residency program, and allowing credit 15 for ambulatory care activities outside the sponsoring 16 hospital organization.

17 Does that help?

18 DR. CROSSON: Yes.

MR. HACKBARTH: Okay, thank you very much.
Excellent job. We appreciate your spending time with us.
We are now going to take up an issue from
yesterday, namely the hospital wage index recommendation.

You will recall that at Bob's suggestion we did
 some reformatting of the recommendation.

The reason for the pause is that we had a couple of commissioners rush out of the room. I don't want to do the vote without so many commissioners here. So we've got another short item here, the review of the physician letter. Let's do that first. I'm sorry, guys. Let's do that first and then hopefully we'll have the rest of our commissioners back.

10 Thank you for your flexibility.

11 MS. BOCCUTI: I'll make this very brief.

Each year we're required to conduct a technical review of CMS's estimate of the upcoming update for physician services. So this presentation is really going to summarize what's going to appear in the June report as an appendix.

Just keep in mind that this technical review involves an examination of how CMS has calculated the update numbers, it's not a payment adequacy evaluation which is what we do, of course, in March for each year.

21 The bottom line, which we'll get to of the 22 technical review, is that CMS has really used the best information available and that the figures that they produce are consistent with recent trends. Moreover, even if CMS's estimate changes between now and the fall it's extremely unlikely that the update will be anything other than the maximum reduction permitted under law, save of course statutory changes.

7 So just turning to the numbers, looking at the 8 target growth rate as determined by the SGR, CMS is required 9 to examine changes in four factors when determining the 10 target spending growth. The four factors are the 11 productivity adjusted input prices for physician services as 12 measured by the MEI. That target rate gives you an 13 allowance for inflation.

14 The real GDP per capita, which is a 10-year moving 15 average, and that gives the target rate and allowance for 16 volume growth.

17 Then you have the enrollment in fee-for-service 18 Medicare and that gives the target rate an allowance for 19 fluctuations in the number of fee-for-service beneficiaries. 20 And then you've got spending attributed to changes 21 in law and regulation. That gives the target rate an 22 allowance for statutory or regulatory changes that would 1 affect physician spending.

2	As you can see, the MEI and the GDP have positive
3	impacts on the target rate and the enrollment and law and
4	regulation changes have negative impacts. Considering these
5	four factors, the target growth rate shown by the yellow
6	line there on the bottom comes to 2.2 percent for 2008.
7	Please note that the percents in that right-hand
8	column are not added. Rather they are converted to ratios
9	and multiplied.
10	If you carry that yellow line to this slide,
11	you'll see that the target spending increases in yellow have
12	been below actual spending, in red, since 2001. In previous
13	years, CMS has provided MedPAC with helpful type of service
14	volume analyses with its updates.
15	This year, however, CMS did not include such
16	analyses in its letter and indicated that it does not yet
17	have these preliminary numbers, nor have they been able to
18	analyze revised numbers for 2005 which they typically do.

19 So CMS's preliminary volume estimates that they 20 have given us in the past have been very helpful because 21 they give us a heads-up when we start to do our analysis 22 next year with the full claims data, so we'll be able to do 1 that next year in full but we don't have a heads-up right
2 now.

Looking at this slide, when we shade in the area between the actual and the target, you can see that that spending is essentially in that shaded region. So that is the cumulative amount that we've gone over over the past years.

8 When you sum that up, that affects the update 9 adjustment factor which we present on this slide. That's 10 the second step of the formula. Because of the cumulative 11 spending differential the update adjustment would be 27.7 12 percent, about, if not for the statutory maximum placed on 13 the formula.

14 In other words, the formula allowed the cumulative 15 overrun to be corrected or grabbed up say all in one year, 16 then the update would be around at negative 27.7 percent if 17 not for that maximum amount.

However, because the 7 percent maximum limit is placed on the formula, the final update for 2008 has to be estimated at about 5.1 percent.

Again, just as before, these numbers are converted to ratios and multiplied so they're not added. That's why 1 the 5.1 looks a little funny.

2	The take home point here is that CMS's update
3	estimate is extremely unlikely to change without a statutory
4	override because the cumulative difference in actual and
5	target spending is so large that we've gone well beyond the
6	maximum reduction permitted under law.
7	I can go on to do the last two slides that you
8	have in your handout but I think in the interest of time
9	I'll take that on question, if you like.
10	So then that would conclude.
11	DR. REISCHAUER: I guess what strikes me on page
12	two is how big the change due to law and regulation is for
13	this year. I mean, 1.5 percentage points. Do you have any
14	sort of
15	MS. BOCCUTI: That's actually one of the slides I
16	skipped because I thought there would be some questions but
17	I'll review that quickly since you asked.
18	There is a net reduction overall. So if you look
19	at slide six, you'll see. I can just go over that.
20	There are some increasers and some decreases. So
21	with reductions, if you just look at those first few
22	bullets, the one that I think has the biggest effect is the

one related to TRHCA, the Tax Relief in Health Care Act that 1 was recently passed. And the conversion factor bonuses is 2 3 what really makes the relative difference between what was in 2007 and what's in 2008. So then the expiration of the 4 5 GPCI floor comes into play there because the TRHCA law extended that provision. So it expires now in 2007. So in 6 7 2008 you're going to see a decline for that and then the 8 physician scarcity bonus also expires.

9 So those are the decreasers and they overwhelm the 10 positive which are down below. Would you like me to review 11 those?

MR. HACKBARTH: Other questions or comments?Okay, thank you very much.

Okay, now we'll turn to the wage index vote.
MR. GLASS: Returning with recommendations as
modified from yesterday, the first and third are the same.
The second combines the old second and third and adds a
phrase about transition.

19 So recommendation one is the Congress should 20 repeal the existing hospital wage index statute including 21 reclassifications exceptions and give the Secretary 22 authority to establish new wage index systems.

The new recommendation two is the Secretary should 1 2 establish a hospital compensation index that uses wage data 3 from all employers and industry-specific occupational weights; is adjusted for geographic differences in the ratio 4 5 of wages to benefit; is adjusted at the county level and 6 smooths large differences between counties; and is 7 supplemented so that large changes in wage index values are 8 phased in over a transition period. 9 That last phrase was added. 10 Three is unchanged. The Secretary should use the 11 hospital compensation index described in recommendation two for the home health and skilled nursing facility prospective 12 13 payment systems and evaluate its use in the other Medicare 14 fee-for-service prospective payment systems. 15 MR. HACKBARTH: Questions, comments, 16 clarifications? We've discussed the content. Ready to 17 vote? 18 All in favor? 19 I even warned you. 20 MS. BEHROOZI: All together or one by one? 21 MR. HACKBARTH: We ought to do them one by one. 22 Good point. Thank you, Mitra.

All in favor of recommendation one? Opposed?
 Abstentions?

3 Okay, recommendation two. All in favor? Opposed4 to recommendation two? Abstentions?

5 And recommendation three, all in favor? Opposed? 6 Abstentions?

7 Okay, well done.

8 We are now to our last session on resource use and 9 quality measurement.

10 MR. BRENNAN: Good morning everybody.

11 Today I'd like to give you a brief update on some of our ongoing research on resource use and quality. As you 12 13 know, most of our work to date has focused on resource use 14 measurement. However, in order to be truly effective, any 15 system that compares physicians needs to incorporate both resource use and quality metrics in order to ensure that low 16 17 resource physicians are not stinting on care with potentially negative ramifications for beneficiaries. 18

You might remember that last year we conducted some parallel analysis to our episode analysis using some claims-based quality measures developed specifically for MedPAC. They were called MACIE indicators.

Today, I'd like to present some simple results 1 from a recent analysis conducted for MedPAC by Ingenix, the 2 3 makers of the ETG software, utilizing another software tool known as EBM Connect. EBM Connect software runs in tandem 4 5 with ETG software using the same set of claims to analyze 6 quality measures. We ran the same 100 percent sample of 7 claims from our six MSAs that recently featured in our SGR 8 report chapter. 9 I'd like to note here that EBM Connect is not 10 strictly speaking episode-based. It's more of a population-11 based measurement tool, but it can be used in conjunction 12 with episode-based analyses. 13 And finally, I'd like to acknowledge the help of 14 both Megan Moore in some of this analysis, and also the 15 folks at Ingenix, Dan Dunn and Sherry DiGiovanni. EBM works by comparing medical, laboratory and 16 17 prescription drug claims to evidence-based best practices. 18 In our analysis these measures applied to approximately 37 medical conditions, although I'd like to note here that a 19 more recent version of the software can now measure 20

21 evidence-based best practices for 52 conditions and a future 22 release will be able to measure 63 conditions.

The EBM measures are developed in one of two ways. 1 The first way is published specifications from NCQA or the 2 3 American Medical Association, et cetera. And the second is they take treatment quidelines from the specialty societies 4 5 and then, in conjunction with an expert clinical panel, for ones that can be converted to some kind of claims-based 6 7 measurement, they developed algorithms based on the 8 specialty-sited treatment guidelines.

9 EBM analysis can be used for a variety of 10 purposes. Some of you might remember last year we had some 11 folks in from an IPA in Rochester and they were using EBM Connect. One of the ways in which they were using it was, 12 13 for example, to remind physicians with diabetic patients if 14 they were not administering the requisite number of A1C 15 tests or LDL tests within a given time period. The results 16 from these analyses can then be aggregated to a patient, physician, or system-level in order to get an idea of how 17 18 people are doing on these quality measures.

19 It's important to note here though that with the 20 data that we have available to us in Medicare at the moment, 21 we're unable to measure all of the available EBM measures. 22 As I mentioned in my previous slide, EBM uses medical, lab,

including the results from lab tests, and prescription drug
 claims. Lab test results are currently unavailable on
 Medicare claims, although the Commission did recommend in
 March of 2005 that lab claims should start to include test
 results. We're not there yet though.

6 Drug claims are also currently unavailable in 7 Medicare, although with the Part D program entering its 8 second year we're hopeful that claims will be available soon. However, because of the structure of Part D, it's a 9 10 voluntary program, we are never going to have drug claims 11 for everybody in fee-for-service. That's something that we're going to need to think about going forward. I'm going 12 13 to show you a couple of slides that show the importance of 14 having drug claims for measuring some of these things.

What's the impact of not having lab results or drug claims on the number of EBM measures that we can measure in our data? Well, what we did with this table is we rather crudely divided into medical, lab result, and drug. Medical, really what that means is EBM measures that can be analyzed with the A/B data that we have. So it includes some lab work and things like that.

As you can see, not having lab results or drug

claims has a fairly large impact and we're currently only 1 able to measure slightly less than half of the available EBM 2 3 measures. 8 percent of EBM measures rely on lab results and 45 percent of EBM measures rely on drug claims. 4 This 5 underscores the critical need to get Part D drug claims as 6 soon as possible so we can start to incorporate those into 7 the analysis and get a fuller picture. Of course, it's also 8 important not only from a quality perspective but it's 9 important from measuring resource use, too, to get the 10 dollars associated with those drugs into the episodes. 11 You can also see that there's variation across conditions in the number of EBM measures that we have. 12 13 We've just picked a sample of conditions here, sort of 14 ranging from conditions like atrial fibrillation, where we 15 can only measure 13 percent of the available quality 16 metrics, up to stroke where we can measure 71 percent of the 17 available quality metrics with the data that we have. 18 Despite these limitations, we wanted to show some

results to you. Again, just taking a moment to orient you to the table, starting at the left we have the condition in question. I'd also like to stress here that there can be multiple measures for each condition, and that's what the second column shows us. It shows us the number of measures
 for each condition that we can measure using our data.

3 The third column indicates the number of quality opportunities for that condition. These should not 4 5 necessarily be viewed as either episodes or people. Just to 6 give a simple little illustration, let's say that we had 20 7 diabetics in our universe and there were five diabetes 8 rules. That would mean that there would be 100 total 9 diabetes quality opportunities. To take that a step 10 further, to give an example for the final column, let's say 11 that four of those diabetes rules had perfect compliance and the fifth had zero compliance, the overall compliance rate 12 13 would be 80 percent.

So as you can see, there's a good deal of variation among conditions in the compliance rates, ranging from a low of 44 percent for cervical cancer screening to a high of 95 percent for low back pain. Diabetes, which we're going to look at in a little more detail in the next table, has a 66 percent overall compliance rate.

20 So generally speaking, there's a fair bit of room 21 for improvement on a lot of these measures if the goal is to 22 get to 100 percent or as close to 100 percent as possible.

1 This table presents a more detailed look at 2 diabetes and you can see how results on multiple rules 3 aggregate into an overall score for diabetes.

You can also see here that not all diabetics are 4 5 subject to every diabetes measure. There are 214,000 6 diabetics in our sample. For example, you can see that only 7 213,000 qualify for the retinopathy rule and 65,000 8 qualified for the nephropathy measure. The reason for the retinopathy is that if you're blind already you're not going 9 10 to be screened. And nephropathy has a slightly more 11 complicated screening process but it involves people over 70 aren't eligible for this particular measure. 12

Also people with existing kidney problems. There
will be different populations eligible for all these types
of measures across all conditions.

In conclusion, I'd like to stress that this is a preliminary look at the data and we'll be back with more in the fall, hopefully looking at physician level quality scores. Obviously, as drug and lab claims become available, our ability to use this tool will only be enhanced.

21 For today and in the future, we'd like you to 22 think about how Medicare might use measures like these and

1 under what process should measures be adopted or developed.

2 We'd also like you to think about the implications 3 of not having prescription drug data for everybody in fee-4 for-service and the effect that that might have on our 5 ability to measure and compare.

6 And then finally, finally I wanted to just draw 7 your attention to some ongoing research issues for 2007 in 8 this general area. We're going to be looking at exploring alternative attribution methods. As you all know, we picked 9 10 an illustrative attribution method for both the June report 11 and the SGR chapter. What we'd like to do is delve a little deeper there, look at episodes under which single 12 13 attribution might be appropriate versus multiple 14 attribution, maybe explore different thresholds, counting 15 more than E&M dollars, for example accounting all dollars. Because really when you get down to it, in thinking about 16 17 P4P, obviously attribution is fairly critical.

We're going to continue looking at some of the per capita versus per episode issues that have cropped up over the past 18 months. We have a series of site visits planned to various areas to determine ways in which physicians have successfully been brought into the quality and efficiency measurement process. There are examples where private sector insurers have tried it and it's gone less than well, and there are examples where private sectors have tried it and it's going fairly well. We just want to see on a more qualitative level what drove those differences in physician acceptance of these measures.

And then finally, we're going to be exploring a little more ways in which this information can be reported to physicians and/or beneficiaries, ranging from simple things like what kind of information should be presented say in a one-page summary to we also have the ability now to view some of these results in an online tool with sort of an easy drill down and things like that.

So with that, I'd be happy to take any questions that you might have.

DR. WOLTER: This is a great direction, I think, and obviously as we have more robust information it allows us to create some changes.

One thing I'm wondering about is in the direction of this work if we should look at collaborative approaches with providers that are already doing this on their own and vendors. Because there are some good organizations now that are capturing all of this data as they're building their electronic medical records. As we want to build these databases that sort of public/private -- you're suggesting it in a way -- approach to making sure that we kind of build the right databases could be really useful.

In my organization, we could provide you all the diabetic data, including the medications and everything because it's being built into the system now. So there's a lot of that data out there in pockets. And how could we create some collaborative approaches?

11 Then I would also connect this a little bit in my mind to where do we want to go? When we heard the 12 13 presentations on workforce this morning, one of the themes 14 was medical home and the infrastructure within that to 15 manage patients. To me that's very much about putting this 16 type of data together so that we're starting to manage populations. I really think connecting this work to that is 17 18 very important.

I also think it's very important to connect this work to our desire to incent changes in the delivery system. I think we have to start being more relentless about that. So when we do site visits to physicians we really should include two organizations in which physicians practice
 because ultimately we need to use this kind of database
 development, I believe, to create organizational approaches,
 team approaches, to how we take care of patients.

5 We say we want to do that but we tend to slide 6 back to, I guess, taking this kind of approach and just 7 looking at it in terms of the current silos of care. So 8 those would be my hopes as we move forward with this, which 9 is a great project.

10 DR. KANE: I have two issues. One is actually 11 that we bring up the private sector and go to the providers to work with them. But particularly where we're missing 12 13 information at times, wouldn't it be useful to work with the 14 under-65 plans who are trying to work with their -- I know 15 there's an issue now about combining Medicare data with non-16 Medicare data. Especially if you're going to get down to 17 the physician or even the system level, wouldn't it be great 18 if there could be some kind of effort to collaborate with 19 the private sector, particularly since we're missing pieces 20 that they may have that may help us see more than we're 21 going to be able to see with our own data.

22 The second question I have is if we make a

1 recommendation in March of 2005 about laboratory claims 2 including test results, can someone explain to me the 3 process by which that might actually happen and how long 4 that might take?

5 MR. BERTKO: Can I do that? The process lab tests 6 come from a variety of sources but the statewide reference 7 labs are now -- at least in our system -- comprising between 8 40 and 60 percent of the total claims coming in. And as 9 part of our contracting agreements with them, we get that 10 appended to the administrative claims data just as a few 11 extra fields.

12 Presumably in Medicare we could require the FIs to 13 do virtually the same thing.

In contrast to some other things, the stuff is already in electronic format, appending four more fields -pick a number -- to the fields is a manageable process. And again, subject to the same thing that Niall said, you wouldn't get it on everything but you could get it on a really large sample.

DR. KANE: I understand how you might do it, and I guess my question is when we make a recommendation CMS obviously has to do it. And my question is how long does it

1 usually take for a recommendation like that to get put into 2 the fiscal intermediaries practice plan so they actually ask 3 for it?

I'm simply still recovering from the experience of asking for uncompensated care data, which we still haven't been asking for. So when we ask for something like this how long do we have to wait to get it?

8 MR. HACKBARTH: Until they decide to do it, I 9 guess is the answer.

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10 [Laughter.]
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DR. MILLER: Those conversations have been somewhat -- we haven't had them recently but back when we were working on it we obviously had the lab folks in in detail and all of the different large chains and different groups and all of that.

To John's point, they indicate that they do have electronic systems for billing and for the test results. Now they said there was great difficulty in bringing these two streams together, which we also knew that in the private sector some people had required them to do it. And so we thought it was something that could be overcome.

22 But it is, it's just a matter of will and

1 adaptation.

MR. HACKBARTH: In fairness they do, as we've 2 3 discussed so many times, have a whole lot of demands being placed upon them and maybe not always adequate resources to 4 5 the task. So my response is a bit glib. 6 DR. SCANLON: There is another aspect of this 7 which is the issue of HIPAA and what people at one time 8 thought HIPAA was going to produce, which was going to be some uniformity in terms of submissions. The kind of 9 10 experience we have now with John, you're getting that 11 information, Medicare or not, is repeated across other payers as well in terms of differences in information. 12 13 The idea of moving towards a more uniform 14 information would be something that would both help programs 15 manage and sort of assist providers a lot. So there's a 16 bigger picture here too that goes beyond Medicare. 17 MR. HACKBARTH: John, did you have a question? 18 MR. BERTKO: Part of it is a comment first, and then a couple questions for Niall. The one is I am a big 19 20 fan of administrative data used for these kind of purposes. 21 It's got some limitations, as I'm sure Arnie and others 22 could say. But it's out there and it's fairly

1 comprehensive.

2	Niall, on your comment about the Part D only for
3	part of the population, clearly that's the case. But
4	particularly for people in the employer benefits type
5	retiree drug subsidy folks. But it still strikes me that
6	well over 20 million people who are A/B members in
7	traditional Medicare also have separate Part D plans. That
8	would be a lot of heavy lifting to pick up and assess all of
9	that.
10	But the sample size is approaching 50 percent or
11	so which would teach us an awful lot about it. And

obviously one of the things is we've asked questions about how does fee-for-service Medicare compare with Medicare Advantage in all of its forms? This would seem to be a really great opportunity.

I'm always hesitant to endorse a particular
software vendor or something like that but again, back to
Bill's point on standardization, if this thing were viewed
by staff and us as adequate -- not perfect -- maybe we
should go ahead and say that. Would my side of the industry
do something that MedPAC said to do? Probably. I hate to
speak for more than one company, but it strikes me as a

1 pretty good thing to do.

22

more for the public, I think.

Was I correct on saying my 50 percent or so would 2 3 be about fair? MR. BRENNAN: Yes, most likely. We're a little 4 5 spoiled in fee-for-service because we have everybody on the 6 A/B side and we don't have everybody on the D side. so it's 7 not an insurmountable problem. You do have a significant 8 chunk of the A/B population. 9 But you're right, you lose the MA plans obviously 10 and you lose the employer subsidy people, and the people who 11 have chosen not to sign up. MR. BERTKO: The last thing is just to give you a 12 13 little bit more homework, we've worked with Beth McGlynn at 14 RAND and the attribution rules on this between individual 15 providers, which we went through more or less on the 16 efficiency measures, and teams that are affiliated providers 17 are even more complex in the way that you think about them 18 and how many providers are attached to a particular measure. 19 So you may want to talk to that group if you 20 haven't already. 21 DR. MILLER: Just one clarification and this is

I don't think we would ever get to a point where we would endorse a specific software product. But what we would do is say such a thing needs to exist and then Medicare would go through the process, like it always has with any of its grouper softwares, where it would develop it and then put it out. That would be more the path that we would go.

8 MR. BERTKO: Thank you.

9 DR. MILSTEIN: A couple of informational items and 10 then a question.

First, I think if we're going to consider moving ahead with suggesting that Medicare at least ask the reference labs, if not the individual physicians who are billing for laboratory tests, to expand the number of fields so we can get the test results. As long as were at it, there's no reason not to do the same thing for hospitals.

Almost all of the hospitals have automated lab results reporting systems. And so many of them are moving toward those being HIPAA compliant. And so the incremental work associate with that would be, from a Medicare administrative point of view, would be small to essentially go both at the same time. And it would enable us to, in a much, much more refined way, begin to answer some of the questions we struggle with as we try to think about rationalizing inpatient and peri-inpatient payment policy. The granularity and the level of confidence we'd have in our information base would be substantially better.

7 The second point is in terms of Nancy's suggestion 8 of collaborating with private-sector payers that have already accumulated a lot of claims data. There are a 9 10 number of states where it would be -- and in the private 11 sector they do have at least the Rx data in most cases and in some cases the lab values as well. There are a number of 12 13 states where this would be easy to initiate because the 14 private sector has made a lot of progress.

In Massachusetts, for example, six of the seven biggest plans have already aggregated their databases and are using them for similar analyses. The analyses could be ever so much richer and beneficial to Medicare if we could find a way of taking advantage of that.

The third point is if we're going to, as part of our discovery process, talk to physicians about what approaches to measurement and reward might be meaningful to

1 them, I think at the same time let's also talk to

2 beneficiary leaders. Because they are the other potentially 3 important users of this database.

And as one begins to poll American consumers, 4 5 Medicare beneficiaries and others, with respect to their 6 attitudes toward issues of performance measurement in health 7 care, whether it's physician denominated or otherwise, it's 8 clear that their perspective, especially with respect to the question of the minimum threshold of validity before they 9 10 want to be able to see the data is not identical to 11 physician perspectives.

12 If you think about some of our thoughts in prior 13 reports on the Medicare program thinking through how to 14 better engage Medicare beneficiaries in appreciating and 15 making decisions based on differences in value is on our 16 list, as well. And so I would hope that we wouldn't only 17 focus on the physician constituency in our discovery process 18 but also the consumer constituency.

Obviously, not all consumers have sophisticated thoughts on some of these measurement issues. But the leaders of organizations like Consumers Union, Consumers Checkbook, they have had a chance to think through pretty

carefully as to what would work for their constituency. 1 Finally the question, I'm sorry for the long 2 3 intro, but could you just briefly give us a preview of current staff thinking on what different approaches you have 4 5 in mind for testing as you think about integrating per 6 capita and per episode based approaches to judging physician 7 efficiency and quality, especially for chronic conditions 8 where, as you so well demonstrated for CAD, using a per episode based view only might not be sufficient? 9 10 MR. BRENNAN: A couple of points. Just to clarify

11 on the site visit aspect, we're not just going to talk to 12 physicians. We're obviously going to be talking to insurers 13 and hopefully other players in the area to get a full 14 picture or all sides of the story.

15 Regarding your question, our thinking is still at 16 a fairly early stage. It could range from something as 17 simple as saying your per episode results are this but your 18 per capita results are this, and your per capita results are 19 higher because your episodes per beneficiary are higher than 20 your peers. That's like one simple way.

21 Another way, and we haven't done any data analysis 22 around this yet, would be to try and come up with some kind 1 of an adjustment factor or something like that.

But we're still at the early stages so we're just 2 3 thinking through. Mark can probably --DR. MILLER: That's precisely what I was going to 4 The only thing I would also say is I don't think I 5 sav. would leave the impression yet that this is a problem for 6 7 all chronic episodes. When Niall went through it he kind of 8 ran across this situation for one. 9 MR. BRENNAN: Most pronounced for CAD. 10 DR. MILLER: Most pronounced anyway. And I know 11 this issue has been brought up and talked widely about okay, this means episodes don't work. I think that's way 12 13 overstating -- I don't think you're saying that -- but I 14 think that's way overstated. I think it still needs to be 15 worked through and thought through. I think the issue is 16 definitely there, sort of what kind adjustment would you end up or what way in reporting the data you would do in order 17 18 to correct for it. 19 DR. REISCHAUER: Niall, a question about the other side of the coin. This is about quality, and are you doing 20

22 of other stuff, too, which maybe has low or no value. We

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the right things? The question is are you doing a whole lot

1 don't really have diagnosis associated with these

2 opportunities, do we?

22

3 MR. BRENNAN: Yes.

DR. REISCHAUER: We do? Because if you do, you could then run through the other things with the same diagnosis but are not on the list of, in a sense, preferred opportunities to get some kind of feel for relative efficiency.

9 MR. BRENNAN: And in a way that's the goal, and I 10 know there's been some discussion in the past that obviously 11 you want process measures and outcome measures. But right 12 now we have more process measures than we have outcome 13 measures. And there may be a correlation between process 14 measures and resource use because to do something involves 15 using RVUS.

I guess my thinking on it has changed a little bit over the last couple of months in that a lot of these specific quality measures are actually fairly low resource use things. They're getting a test on -- or whatever. So they actually have a fairly small impact in terms of overall episode costs. You can have two physicians

who are meeting -- like they're both giving the recommended

1 LDL tests and the doctor visit every six months and the A1C 2 test. And then physician one, it's a well-managed patient 3 and that's all he does, assuming you've adjusted for risk 4 and all those things.

5 And physician number two, it's not just one 6 outpatient visit, it's come back and see me in a month, come 7 back and see me in a month, even if the test results are 8 fine.

9 So when you can marry that, so they've got the 10 same quality score but there's going to be a difference in 11 resource use and you can maybe point to that.

So that's where I think this can be useful.
MR. HACKBARTH: Any others? Okay. Thank you,
Niall.

We'll now have a brief public comment period. As always, I'd ask you to first identify yourself and your organization and keep your comments to no more than a couple of minutes.

DR. RICH: My name is Bill Rich. I'm Chair of the RUC and I'm the Medical Director of Health Policy at the American Academy of Ophthalmology.

22 I'd like to address the two parts of your agenda

1 today, first the manpower issue; and second the issue of the 2 SGR. And frankly, there are closely related.

As far as Mr. Salsberg's presentations, I think Dr. Reischauer expressed some of my concerns. After being involved in manpower issues from '78 on, I think we make a huge mistake in our society when we try to use very static approaches to an incredibly dynamic changing issue.

8 I think that, frankly, the current shortage now is 9 leading to innovation, leading to models that Dr. Milstein 10 has talked about because we've had to become more efficient 11 to provide this care. And frankly, just throwing more 12 bodies out there thwarts that innovation that's going on now 13 and does not address maldistribution.

14 Secondly, if you look at the specific issue with primary care, it's obvious we have a growing crisis in our 15 16 country. But it's not strictly economic, as Mr. Muller 17 pointed out. Manpower is basically a combination of 18 economics, demand for a job, and you need happy heroes. You need a lifestyle that fits your personal needs of your 19 20 family and is intellectually stimulating. And frankly, just to throw money at it has never really been the issue. 21 22 However, there are some issues specifically with

primary care that I think it's within the purview of this
 group to address.

When you look at RBRVS, we've kind of done our job. Major procedures since the first five-year review, cataract, total knee replacement, pick one are down 46 percent.

7 E&M services are up 84 percent. But why hasn't 8 the income changed? The income has not change because 9 there's no way that you can increase your productivity in a 10 general internist or a family practitioner's office. In 11 surgery, we've been able to move from the inpatient to the outpatient and dramatically increase our productivity 12 13 despite cuts per procedure and actually had an increase in 14 income.

15 With the current evaluation and management 16 guidelines, which restricts and demands face-to-face time, 17 we are not going to be able to address this. Primary care 18 cannot change their productivity no matter what model is 19 adopted, whether it's advanced nurse practitioners, more clinical assistants, more family docs. They cannot change 20 21 their income unless we do something to enable them to 22 increase their productivity through more innovative models 1 of delivery of care.

And frankly, the biggest problem is the issue of 2 3 the SGR. We've dramatically increased in the last five year review, 33 percent increase in work for primary care. 4 That 5 should have translated to a 16 percent increase in revenue 6 for 2007. What happened? With the SGR and the failure of 7 the administration to adopt the recommendations of the RUC 8 and MedPAC on utilization for imaging and things like that, their total increase was only 5 percent. So we can only do 9 10 so much with RBRVS but we have to look at how SGR has 11 dramatically cut and the failure to implement the recommendations of this panel and the RUC on practice 12 13 expenses has really dramatically diminished. 14 The system is trying to address the reimbursement needs of primary care. But it can't be done in a vacuum 15 16 without looking at other payment policies. And specifically 17 the SGR. 18 With the work adjuster and the SGR, what should 19 have been a 16 percent increase ended up at 5 percent. So I 20 encourage you to look at the issues of talking with CMS to 21 enable them to increase -- not matter what model is involved

22 to provide primary care, and it has to be more diverse than
1 it is now -- to enable them to change the regs to they can 2 increase their productivity.

3 Frankly, unless the SGR, no matter what we do with manpower, we're not going to see any changes in primary 4 care. Because they the ones that are getting killed. It's 5 a blunt instrument across all services. Primary care isn't 6 7 going up. Major surgical procedures isn't going up. 8 Imaging and testing is. And yet with that thing we're crushing down the area where we have unmet need and demand, 9 10 primary care, general surgery, vascular surgery.

11 So thank you for your time.

MS. FISHER: Karen Fisher with the Association forAmerican Medical Colleges.

I just wanted to add a point of clarification or a point of information concerning Medicare policies in ambulatory training.

The Balanced Budget Act of 1997 did provide that non-hospital sites could receive -- and Nancy-Ann knows this -- could receive Medicare direct GME payments directly. The issue is that in order to receive those payments they had to incur the costs of the training.

22 The information is that most non-hospital sites,

hardly any, took advantage of that provision. I think there was one at the time and it may have pulled out. The reason that we understand it is that they had to incur all of the direct training costs but under Medicare's policy both for inpatient and outpatient, Medicare only pays its share of the costs.

So a lot of these settings were saying where do we make the gap? If we only get 30 percent of our total direct costs, whose going to make up the gap? And of course, that's a difficulty.

11 The other issue is for some of these settings, 12 too, they don't have large Medicare shares. So they may 13 only have 10 percent on Medicare share. So again they have 14 to incur 100 percent of the costs and they're only getting 15 10 percent of reimbursement back from the Medicare program.

We do think there are issues associated with Medicare and its role in ambulatory training and would love for the Commission to look at that. The Association has been working closely with the family practice physicians because of current Medicare regulations that we believe are inhibiting the ability for residency training to occur in ambulatory sites.

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The accrediting bodies have a lot of information on the books and there's a lot of training that's going on in these settings but I think it would be useful for the Commission to look at what is Medicare's role and what are Medicare regulations doing to either enhance or inhibit the ability of this training to take place. Thank you. MR. HACKBARTH: Okay, we are adjourned. Thank you. [Whereupon, at 11:38 a.m., the meeting was adjourned.]