MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
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9:49 a.m.

COMMISSIONERS PRESENT:
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MITRA BEHROOZI, J.D.
ROBERT A. BERENSON, M.D.
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GEORGE N. MILLER, JR., M.H.S.A.
ARNOLD MILSTEIN, M.D., M.P.H.
WILLIAM J. SCANLON, Ph.D.
BRUCE STUART, Ph.D.

AGENDA PAGE

P R O C E E D I N G S

MR. HACKBARTH: Okay. I apologize for the late start. Thanks to those of you in the audience who have come to see us work.

With this session, we now leave what has preoccupied us for the last couple sessions -- namely, updates to the various payment systems -- to talk about a set of interesting and challenging policy issues. On today's agenda, we have got shared decision-making, benefit design, improving quality and efficiency in hospitals, in-office ancillary exception, and GME. And my head hurts already thinking about it, but they are obviously all very important issues and things that we have touched on in the past, and I hope to make some progress towards recommendations on some of these.

First up is shared decision-making, and, Joan, are you leading the way?

DR. SOKOLOVSKY: Yes. Good morning. This morning we're going to focus on the beneficiary with two presentations. First, Hannah and I are going to look at the role of shared decision-making. And then in the next session, Rachel is going to talk about benefit design.

It has been a year since we last talked about shared decision-making, and at that time, I described how it works. Today I just want to remind you of what it is. Shared decision-making is a process that involves giving patients personalized information about their condition, possible treatment options, and the probabilities of benefits and harms for those options, and then allows the patients to communicate to their physicians how they value the relative importance of the benefits and harms, and then the patient can participate with the physician in decision-making. For example, breast cancer patients learn that there is no difference in survival rates for lumpectomy versus mastectomy but that there are other tradeoffs with both procedures that they should consider. Shared decision-making includes the use of patient decision aids, and these are tools that give patients objective information on all treatment options for a given condition.

Shared decision-making is not appropriate for all decisions. You obviously cannot use it in emergencies or when the medical evidence is unambiguous. It is used most often for preference-sensitive procedures when medical evidence suggests that there are several possible treatment

options. The goal is to reduce unwarranted variation by ensuring that the procedures are chosen by informed patients who value their possible benefits more than their potential harms.

Let me just quickly go over our key findings.

Proponents of shared decision-making argue that it can help beneficiaries take a more active role in their health care. To better understand how it works, staff made four site visits and conducted numerous interviews with individuals employing the programs and companies that produce the materials that are used shared decision-making.

We found potential in the model but also some conditions that must be met before shared decision-making can be widely employed throughout the health care system.

First, physicians must support shared decision-making, and for that to happen, it must not interfere with office work or add to the time they have available to see patients.

We found that it is more easily incorporated in specialty care when there is a discrete, time-sensitive decision that a patient must make. However, primary care physicians as a group express support for the idea.

To be successful, a program must use objective, up-to-date, and easily understandable patient decision aids. Clinical IT is important to find patients at the right moment to make a decision and to make it simple for physicians to prescribe the decision aid.

Now Hannah is going to talk to you about the beneficiary need for better communication about their health needs.

MS. NEPRASH: We know that beneficiaries face challenges when making health care decisions. Compared to their younger counterparts, they're more likely to be poorer, less educated, cognitively impaired, and faced with multiple chronic conditions. They're also more likely to have low health literacy. This is defined by the IOM as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."

Research indicates that health literacy declines with age and is lower for certain segments of the population including the elderly, Medicare or Medicaid recipients, racial and ethnic minorities, and low-income adults.

One factor that contributes to low rates of health

literacy is the inability to understand the meaning of numbers, which leads to confusion about the risks and benefits of health care procedures and, in turn, affects how patients make decisions.

Many patients especially don't understand the difference between a relative versus an absolute risk presentation and are more likely to view a treatment alternative positively if the benefits are expressed as a relative risk reduction. So, for example, saying that a cancer screening test every two years will reduce the chance of dying from that cancer by one-third over the next ten years is a relative risk presentation. And the equivalent absolute risk presentation would say that the same test will reduce your chance of dying from that cancer from around 3 in 1,000 to 2 in 1,000.

Low health literacy affects health outcomes. After controlling for demographic and socioeconomic factors including income, numerous studies show that elderly adults with poor health literacy were more likely to be in poor physical and mental health; knew less about their chronic disease; were less likely to receive preventive care; and were hospitalized more.

Additionally, some of the literature finds a reduction in racial disparities for the use of preventive services when you control for health literacy.

So if health literacy is the ability to obtain and process health information, patient activation is the capacity to self-manage one's health and one's health care. An active patient is more likely to receive preventive care, implement healthy lifestyle changes, adhere to treatment plans, and ask questions about his or her health care.

Like health literacy, low-income and minority populations are less likely to be active patients, but ongoing research indicates that patients can become more active through tools like shared decision-making. Some studies suggest specifically that minority and low-income patients can become more active, making them more engaged participants in their health and health care decisions.

A more active patient may be a very good thing for both patient and provider, who may not always exchange necessary information during an office visit.

Researchers at the University of Michigan surveyed patients and providers to assess their rankings of key facts and goals for 14 treatment decisions. When providers were

asked to choose the top three things patients should know about chemo and hormonal therapy for breast cancer, not one selected side effects or risks; whereas, almost one quarter of patients expressed wanting to know about serious side effects of the treatment.

When patients and providers were asked to choose their top three goals and concerns for the same 14 treatment decisions, they identified very different goals. Providers had a tendency to cluster around only a few goals, such as keeping the breast and living as long as possible for breast cancer decisions; whereas, patients were more diverse in their goals.

I will turn it back over to Joan.

DR. SOKOLOVSKY: Shared decision-making programs that try to bridge this disconnect are expanding, but challenges remain significant. Initially, programs began at academic medical centers, but currently there are many demonstrations going on at community based clinics. The highest adoption rate has been at breast cancer centers where 50 centers are actively distributing the aids and have programs built around them and a number of others are considering it.

When we asked how the programs are working, we have some evidence, not enough. Results from 55 randomized controls found that patients using shared decision-making with decision aids consistently show more knowledge of their condition, they are more actively engaged in their care and have a more realistic idea of the likely outcomes of treatments. They are more likely to choose less invasive options. Cost implications are difficult to come by. In the Group Health demonstration project, which I reported about in your paper, after one year, they found a 10-percent reduction in knee replacement surgery, a 20-percent reduction in hysterectomies, and no change in hip replacement rates.

Surveys have shown that physicians generally have a positive attitude towards shared decision-making. For example, one survey of orthopedic surgeons found that the majority thought shared decision-making was an excellent or good idea. The most important benefit they cited was that it increased patient understanding of their condition and the potential treatment options. But few had attempted to implement it within their practice. They reported that the most important barrier was the fear that it would take lots

of time and interfere with their work flow.

Similarly, in a national survey, 93 percent of primary care physicians said shared decision-making was a good idea, but again named lack of time with patients as the main barrier to its use. We found that with most current programs, there were physician initiatives, but that didn't mean that the physicians were involved in the day-to-day operations of the program. In fact, our interviewees repeatedly told us that programs could only work if they could fit into the way physicians practice. If the program created more work or interrupted the work flow in the office, it was unlikely to be widely adopted.

Physicians are not equally receptive to shared decision marking. We found some evidence that physicians in high-volume specialties are more receptive. For example, orthopedists were high adopters in a number of practices. They found that it resulted in fewer patients who were poor candidates for back surgery or knee replacements and that patients had more realistic expectations about treatment results. So this is some information, but this is something we would need to look at more closely.

Physicians often stress the importance of

implementing shared decision-making in primary care, but the difficulties are significant. Specialists are more likely to have a limited number of decision aids to prescribe for their patients. Primary care physicians deal with a wider range of issues. For example, program organizers at Massachusetts General Hospital identified 22 decision aids that are available for use by their primary care physicians. And the physician is less likely to know before a patient visit exactly which decision aids would be appropriate.

Secondly, patients may find decision aids provided by specialists more salient than decision aids used in primary care. Specialists prescribe decision aids at a time when the information is most useful to patients -- before meeting with the physician to make a treatment decision, for example, on cancer treatment or back surgery. The physician can then spend more time with the patient answering questions and discussing the options and less time explaining the basics of the diagnosis and treatment options. On the other hand, patients may not be willing to invest the same amount of time to understand the advantages and disadvantages of different cancer screening options. Specialists are also more likely to get the results from a

patient's use of shared decision-making, so there is more of a feedback loop there.

I want to talk about some potential policy options.

Patient decision aids are the foundation for shared decision-making. They present the risks and benefits and help patients understand how likely it is that those benefits or harms will affect them. They can be written, web-based, or video. Some are multimedia, combining many ways of presenting information, including video clips of patients who have used the information and how they made their decisions.

In 2003, an international collaboration of researchers, practitioners, patients, and policymakers from 14 different countries began a consensus process to develop quality criteria for decision aids. The criteria, described in your mailing material, also include a checklist to see whether a particular aid meets the criteria. Decision aids have multiplied in recent years. More than 500 aids have been identified including at least 200 that meet at least one of these criteria.

Those involved implementing programs stress the

need for national quality standards for decision aids. A national standard supported by Medicare would establish the framework for shared decision-making based on objective, timely, and comprehensible material. It also would help consumers identify materials that are based on accepted clinical evidence.

So one policy option for you to consider today is to have the Congress require the Secretary to establish standards for decision aids and accredit aids that meet those standards.

Information technology is also important in facilitating the use of shared decision-making. It allows program organizers to track patients who could benefit from specific aids. It allows physicians to order aids by clicking a button on a patient's medical record. It minimizes the steps needed to disseminate aids. And sometimes it tracks patient response to the aids. We have yet to find a practice-wide program without a strong IT infrastructure.

As a result of the ARRA, providers will be receiving about $36 billion over the next six years to encourage the adoption and use of electronic health records

that meet criteria for meaningful use. The Health IT Policy Committee -- a federal advisory board that makes recommendations for meaningful use -- included provider access to patient-specific educational resources in everyday language. However, when CMS issued its proposed rule on meaningful use, patient education capacity was not included.

Development of shared decision-making would be facilitated if the Secretary requires systems to add this criteria in their final rule. And I did just want to add that this is not only about shared decision-making. For example, the current criteria say that lab values have to be available to patients on their electronic health record, but without the patient capacity, the physician doesn't have any easy way of letting the patient understand what the lab value means, which could lead to a fair amount of panic and perhaps unnecessary doctor visits.

I would like to conclude the presentation now, and we welcome your discussion.

MR. HACKBARTH: Thank you, Joan, Hannah.

I'm really delighted that we have this issue on the agenda. When I was at Harvard Vanguard -- this was probably around 14, 15 years ago now -- Dr. Al Mulley from

Mass. General came and made a presentation to our clinical leadership on this subject, and what he said still rings in my ears. He presented this as an ethical imperative, and his argument was that there were many medical services for which the right answer was entirely dependent on the patient's preferences, their assessment of risks and benefits and how they valued different potential outcomes, and a system in which that was invested in the physician without any systematic effort to bring the patient into the discussion was, in his view, an ethically flawed system.

And then he went on to present evidence that when patients are engaged in a systematic way, in fact, they do make different choices than patients left to their own devices might make. And so this I think is a very, very important topic.

Okay. We will open it up for Commissioner round one clarifying questions. I would ask that Commissioners really discipline themselves. I have had several Commissioners come to me and say, you know, "A lot of the round one stuff is really overly broad. I'm patiently waiting and people are basically jumping the queue by not following the ground rules of round one. So round one

questions are simple, clarifying questions: "What did you mean by X?"

With that as a preface, we will start over here with Bruce.

DR. STUART: I just want to echo what Glenn said about the importance of this chapter. Not only is the subject matter important, but the way you presented it is really good.

My question is on Slide 4, and it is the last point about relative versus absolute risk. I will betray my views on this in terms of this is a personal bete noir, but there is a comment that you made and a like comment in the text that indicates that individual patients respond more positively to relative risk than absolute risk. And I think I understand why: because relative risk looks big when absolute risk is small. Is that what you meant by this? Or does it take into account the level of absolute risk?

In other words, relative risk to me doesn't mean a thing unless you know what absolute risk is. If absolute risk is high, then relative risk is important. If absolute risk is really low, then relative risk is really misleading.

MS. NEPRASH: You've characterized it perfectly.

The example I presented about the hypothetical cancer screening with the relative and the absolute risk reduction, the equivalent presentations, was also presented to patients, and overwhelmingly, when it was as relative risk reduction, they said that they would opt for that screening versus the equivalent absolute risk reduction.

DR. MILSTEIN: Could you clarify whether the current physician payment system does or does not expect as part of the payment that physicians have done a thorough job of explaining to patients the pros and cons of a therapeutic option? In other words, is this something that is already expected as part of the definition of what we are paying for in the fee schedule but it is not happening? Or is this something that wasn't contemplated when the physician fee schedule was put together?

DR. SOKOLOVSKY: I don't know if there's a specific component in the fee schedule that would reflect that, but there is the issue of informed consent, which is something that, in fact, we were thinking that we would bring to you in April, which is definitely something that before a procedure is provided.

You always, including at the dentist, sign an

informed consent rule, and some of the issue here is: Is it really informed consent.

DR. MILSTEIN: My question was a little unfair because it wasn't -- it is embedded in this, but there may be someone else on the staff who can answer.

MS. BOCCUTI: I think there is a way that you can bill for some extra time. I think Kevin has left the room, or maybe Karen -- so there are ways. Now, it doesn't mean -- you know, if the patient needs extra counseling, then there is a code that you can do for that one. It is face to face, and you can add on to your visit. And there are other ways for visits to be accounted for, not just by it is one code but you can have sort of add-ons. But it is not specifically one for shared decision-making.

Karen, did you --

DR. BORMAN: [Shaking head negatively.]

DR. BERENSON: Basically the definitions of office visits have -- and there is now -- I am sure you have heard about these documentation guidelines at what has to happen. They are focused on history, physical, and decision-making, sort of the doctor's decision-making. In those circumstances where counseling makes up more than half, what

I believe is the guidance, of the time of the visit, that can be the dominant reason for the code. So there is no expectation that shared decision-making will happen. The focus is really on doctor stuff. Some of us think those definitions, maybe it is time to relook at that. But for those physicians who want to engage in shared decision-making, there is this approach that you just heard about which permits them to bill a higher level than they can justify simply by the history, physical, and decision-making activities that they engaged in, if that makes sense.

MR. GEORGE MILLER: I also want to echo your comment at the beginning of the session about how important this issue is. And I guess my question dealing with the question about health literacy and tying that to health disparities, and if you were able to show a correlation between the health disparities and health literacy and how those may tie together, this may lead to, I guess, a round two question, really, and I apologize if I have strayed into the weeds about that issue.

MS. NEPRASH: What I mentioned refers to a few studies that have looked at regional and ethnic disparities in the use of especially preventive care services. And when

the researchers can adjust for health literacy levels -- which is usually based on two specific tests of health literacy -- those disparities are much less significant.

MR. HACKBARTH: Okay. Other clarifying questions?

DR. KANE: Is there a distinction between shared decision-making and patient education? I mean, I am wondering which one we are really talking about here, because your example about a patient getting a lab value and needing to understand what it meant is not really necessarily a decision so much as just understanding. So I am guessing you are talking about the broader topic, but I just want to clarify which topic you really are --

DR. SOKOLOVSKY: In that situation I was talking about the broader topic, but it is the same criteria in meaningful use would facilitate both.

DR. BERENSON: You talked about and in the paper specifically mentioned that researchers in the field stressed the need for national quality standards for decision aids. I am a little nervous about going down the road of a national accreditation program for decision aids. But do we have any examples of misleading decision aids, you know, proprietary-induced decision aids that are moving

people into a certain direction that might not be viewed as fair and balanced?

DR. SOKOLOVSKY: There's so many examples, I don't exactly know where to start, but one thing I can say is during the snowstorms I spent a lot of time watching local news; many, many commercials which end with "and call us," your pharmaceutical company or device manufacturer, "for a discussion guide that you can take to your physician."

MR. HACKBARTH: Further clarifying questions?

MR. KUHN: Joan, a quick question. You had mentioned the various modalities that are available -- you know, web-based, video, I assume one-on-one. Is there any research that shows that one is stronger than the other in terms of impact with patients? I am just curious what is working best out there right now.

DR. SOKOLOVSKY: There are a number of studies that try to get at that, but they are too small, I think, for you to really draw any conclusions from them.

MS. HANSEN: Yes. On page 4 -- excuse me, 5, the whole aspect of the people who are at risk perhaps in making these decisions, and even though you found a couple of studies that show that even with more challenging

populations, you can reduce -- basically have the decision-making a little bit more effective.

My other question is I notice that more community health centers are now beginning to take a study of this. Has there been any research that has come kind of from that grouping of providers?

MS. NEPRASH: I think it's still a little bit too early. You know, we're aware of a few studies that are going into community health centers, and especially taking advantage of the time in the waiting room to use decision aids to boost -- you know, to make these patients more active, to help brainstorm questions for them to ask their physicians and ways for them to become more involved in their decisions. But results are still coming in. So I am happy to stay on top of that and get back to you when we know more, but that is a promising area of research.

MS. HANSEN: I would appreciate that because so much of some of the issues that evolve come from the factors listed on your Slide 5, you know, which is really a bulk of characteristics that people have relative to their comprehension.

DR. SOKOLOVSKY: My sense was that this is kind of

the cutting edge of where they're going right now, looking to do things. But one other thing we saw recently, there are some decision aids now that are meant to be used with caregivers. For example, we saw a really good one on fall prevention for the frail population. It's meant for the patient and their caregiver to watch together.

DR. DEAN: Is there any index or clearinghouse or any place where the available decision aids have been sort of cataloged or put together where people can go to look for these?

DR. SOKOLOVSKY: There is an organization in Ontario that does catalog the decision aids -- I can actually send you that link, if you would like to see it, and you can see what's up there -- that meet some minimal criteria before they will list them there. But, yes, there is a catalog, and I would say it's an ever-growing catalog.

MR. HACKBARTH: Any other clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Let's move on to round two comments beginning with Karen.

DR. BORMAN: Just in terms -- there was a lot of this information that was very good and very nicely put

together. I have two sort of question and comments. One is, in the materials, you talk about the University of Michigan study and what came out of the encounter with the physician -- the shared decision that was initiated by the physician. And we say that for every intervention examined, discussions with the provider tended to emphasize the pros over the cons and involve a recommendation about what the provider thought best.

I am going to leave aside right now the pros over the cons piece, because I think that is problematic, but that notion that involves a recommendation about the provider thought best, to my mind, the way this is written, it sounds a little bit pejorative about the recommendation, and frankly, your doctor should be making recommendations. They need to be well structured, well thought through, objective, evidence-based recommendations, but what I think we have something of a problem with is that we oftentimes aren't making a recommendation.

And so I would like to see us maybe rethink or reword or do some wordsmith some in that way to get across the concept that we think a recommendation that is based on good background is, in fact, an appropriate part of the

doctor-patient encounter, or physician assistant or whomever, but that it is a proper part of the encounter, and this just has a little bit of flavor of suggesting otherwise, which I doubt is what you meant, but that was one.

And then if you could help me understand, because I understand, I think, what health literacy is and I can bring up lots of patient connotations in my mind about low- and high-literacy patients that I have dealt with. The activation part and the linkage to the literacy part is where I am struggling a little bit, because you mentioned that something -- it almost sounds as though you are suggesting that an activated patient compensates for less literacy without becoming more literate, and it just seems illogical to me that if you have somebody who is activated or becomes activated, that in order to meet the definition of an active patient, almost by definition, they are becoming more literate. Is that -- or have I misinterpreted?

MS. NEPRASH: I don't think you have misinterpreted. There is a little bit of research that looks at patients with low health literacy, and if they are

scoring high on patient activation measures, they are asking questions and may be more likely to adhere to treatment regimens, and so they are compensating a little bit for the health literacy. But I am not sure I would say that there isn't a change in their literacy. Does that help?

DR. BORMAN: What I am trying to envision is it almost sounds in reading the chapter that you could be very activated but very low health literate, and I am just having a little trouble envisioning what that patient is who is very engaged and does these things and who is low literacy. It is almost like we are judging the quality of what they know, which I think goes way beyond what we can measure.

DR. CHERNEW: Like Grandma.

MS. NEPRASH: I will go back to the text and work on clarifying that.

DR. BORMAN: Okay. There you go. Okay.

DR. STUART: I would like to follow up on my first point here. I know there is other research on absolute versus relative risk, but the concern that I have in terms of presenting it in somewhat neutral fashion is that we know that providers, some providers give risks in relative terms because they know that that looks like the impact is bigger

than the absolute impact is. In fact, they know that if you gave absolute risk differences, that patients would behave -- would respond differently than if you do it in terms of relative risk.

So what I would like to see here is some statement to the effect that if, or when risk-based information on benefits and harms is provided to patients, and if it is provided in relative terms, it is also couched in absolute difference terms. And there is research supporting that. So it is just saying -- this sounds like a little part of a much larger picture, but when you really get down to it, almost everything that you are talking about in terms of shared decision making, choice A, choice B, you can frame in these terms. Physicians and researchers have traditionally used this metric of relative risk and I think that it is problematic mathematically, but even more importantly, I think it is problematic because it could be misused to promote services that have relatively low value.

DR. CASTELLANOS: First of all, I appreciate you bringing this up. I think it is a pertinent topic. Like Glenn stated this morning, this is not a new concept. This has been something that has been emphasized in the medical

community for a very long period of time. And as Karen said, perhaps because both of us are surgeons with informed consent, this is something we commonly try to do as best as we have with our limited knowledge.

I think that another place this can be put is in our recommendations in graduate medical education, that this be emphasized.

Like Bob, I am a little concerned about where we are going with this, especially where you suggest perhaps this policy, the Secretary could incorporate it into a meaningful use criteria. You know, I am worried that we are getting another Medicare bureaucracy, increased costs, increased lawyers to review, more costly, et cetera.

Perhaps we could do something like a Good Housekeeping Seal of Approval type of process rather than trying to really get it down and dirty.

MR. BERTKO: First off, it is a nice chapter and I'm all in favor of shared decision making. I mean, how could anybody not be, right? Then comes the cynical comment, which is this seems to be, by itself -- I am looking at page 11, Slide 11, and the recommendation that the Secretary establish standards as being an ineffective

standard -- it strikes me as we are pushing on a rope. Glenn, you gave the example at Harvard Vanguard, you were in a capitated health care system, and so your system had a direct advantage to doing this. In fee-for-service Medicare, what is the advantage for the individual fee-for-service physician? Relatively little.

And there's a second part of this and it's the pushing on a rope of getting consumers activated, beneficiaries activated. I think you guys made mention here of one example where there's a cash incentive for some group of patients. Wasn't that in the background literature? So, I mean, do we need to have more investigation of that to get beneficiaries interested in doing this?

I think what I am suggesting to be a little bit less cynical is that we suggest more research on the best ways to get this done as opposed to saying, just do it, because the "just do it" part says, oh, sure, let's all walk more. Let's travel less. For my taste, let's fly on airplanes less, things like that, all well-meaning thoughts that don't happen automatically.

DR. SOKOLOVSKY: I actually thought we were being much more conservative than you are being here, because we

weren't saying just do it. We were saying, okay, let's put standards in place, like have NCQA have standards. As I said, there's a lot of work for that already. But there are programs that do incentives, but I feel like we could say that -- particularly in fee-for-service -- that there was enough infrastructure to say, okay, let's make incentives and people will go do it.

MR. BERTKO: Okay. So incentives in the -- or rather, standards in the absence of incentives, I think, are weak or ineffective, and perhaps we should think about other things. I mean, everybody has heard about Safeway and what they have done with their employee population, the guy there who has been dramatic in his getting that message out, whether it is accurate or not. Do we need to have more research on whether the incentives work and how big the incentives should be and whether there should be incentives on this side? I just, again, don't want us to suggest doing things just for the sake that they sound good.

MR. HACKBARTH: Can I just pick up on that for a second? So you used the term there should be standards. That can be interpreted in a couple different ways. One type of standard is, it's a regulatory requirement. You

can't do it if you don't do it this way. Another approach is a purely voluntary accreditation, the Good Housekeeping Seal of Approval model. Which of those do you have in mind?

DR. SOKOLOVSKY: The second.

DR. MILSTEIN: A couple comments here. I mean, it's important to realize that the -- for me, I think it's useful to realize a couple things. Number one, patient activation and shared decision-making are not one in the same. Shared decision-making is a form of patient activation. Maybe on another day, in another session, we should discuss patient activation because there's actually some reasonable research in credible scientific journals that suggests that, especially Medicare patients, live longer if activated. It was the Caplan-Greenfield paper, and that's sort of a technology, a method of producing health care that is documented, but for obvious reasons has not been rapidly taken up like perhaps a biomedical technology innovation might have been taken up. But it is a basis of improving value, in this case, longevity for patients irrespective of their baseline level of health literacy. So it is a separate topic.

Now, with respect to this particular form of

patient activation, shared decision-making, I think that when Medicare was initially laid out and as it's been refined along the way, one of the areas that has not been kind of well conceptualized is whether or not Medicare ought to be paying for services that would be unwanted by an uninformed -- that would be unwanted by an informed beneficiary. That is really what this is targeting, because there's a certain percentage of Medicare services that if the patient were to be given a well-structured opportunity for shared decision-making, they would not want.

The review article by Annette O'Connor that I believe was cited and suggests that across, I think, 50 such studies in various countries, predominately the U.S., it turns out that patients, when they go through this process, decline what their doctor recommended about a third of the time. I think that's the mid-point. And so that's a fairly substantial fraction of decision-making-relevant services that are currently being delivered that would not be wanted by a well-informed patient. That's a lot of money.

I don't know how the -- I'm not sure that the original definition of medically necessary, or when Medicare wants to pay for services ever thought about this, but for

me, one of the other options on the board besides the ones we've talked about is to basically say, it's not covered. It's not a covered service if a shared decision-making aid that has met a certain standard for its scientific and decision-making merit is applicable and was not used, because then we essentially -- there's roughly a one-third chance that Medicare would end up paying for a service that, had the patient been well informed, they would not have wanted.

So add that. This is not something that I think that Congress, if they had a chance to think about, would want to be paying for, because of these things that an informed patient would not want, but a lot of patients are not informed.

And the last comment is in terms of thinking about how we might go about, irrespective of which tool we pick, you make it a requirement to be a participating provider, you make it a voluntary Good Housekeeping, you incorporate it in P4P, you know, there's two ways of going about that. One is essentially you go through a certification process to say whether or not your method of making sure patients were well informed before they came to a decision were good

enough.

Another that I know that has been developed, I have heard presentations of in various settings by leaders in this area like Al Mulley, is a notion of just on a sample basis actually testing beneficiaries with respect to what did they understand on the eve of proceeding with the procedure, because that, separate and apart from telling you whether or not the structural elements of the decision, shared decision process were good enough, it actually tells you, at the end of the day, did the patient make the decision with a reasonable understanding of the risks and benefits of treatment A versus whatever was the alternative treatment. So another way of going about it is not a certification process but rather a random sample, sort of a survey of patients on the eve of these procedures to see whether they did or did not grasp what the pros and cons were of the treatment they were about to embark on versus the alternative.

So I think it's three somewhat distinct points.

MR. HACKBARTH: Could I just ask for a clarification on the first one. So the first point, as I understood it, was a policy option is Medicare shouldn't pay

unless an appropriate shared decision-making tool was used, and the important thing is the tool was used, not what decision the patient made, but their use of the tool.

Now, the way I interpreted what Hannah and Joan were presenting was a conservative sort of first step. A first step that might lead to that ultimate approach would be let's get certified decision-making tools in wide use. Am I interpreting your approach correctly?

MS. NEPRASH: Yes.

MR. HACKBARTH: Okay. Arnie?

DR. MILSTEIN: That, I completely agree with that. That is a contrast with what I suggested. And I will say that one of the -- in broad brush, one of the things that I think is relevant to this discussion but relevant more broadly is the weight on the side of supplying services is not subject to any kind of conservative approach. There is very little regulation once a -- on certain service volume. I mean, we don't do well on that. And so when we have methods or techniques that weigh on the other side in terms of balancing against service volume, the danger of always proceeding in small increments is that we never are agile, fast, and strong enough to offset the relatively non-

conservatively ramped-up forces in favor of service volume.

MR. GEORGE MILLER: I want to thank Arnie for his points, because I hope that will help, at least in my mind, frame my comments. I'm in favor of the first bullet point on the standards for decision, particularly around the notion that I raised earlier concerning disparities in health care. In my mind, I think making those standards for decisions aids will be important to address that issue. But like Bob and John, I don't believe there needs to be accreditation for those standards. I think the statement needs to be made they should be part of a process, and as Arnie well described, that if one-third of folks if they are fully informed may not choose to have that procedure done, then Medicare would not pay for that. I strongly support that notion.

But just to reclarify the point, I don't think an accreditation body aids or serves the purposes well. I think that that conversation between the physician, it does deal with the informed consent, have a meaningful discussion, and I like the concept of testing afterward, before the procedure, did they fully understand, and that would lead to -- in my mind, it would lead to a better

understanding and would help to eradicate some of the disparities, which is my major thinking about how this would possibly affect disparities in health care in a very pronounced way.

DR. KANE: Yes. I mean, I'm very supportive of this notion, although I'm a little daunted by the challenge of the comprehensibility of a lot of these types of things. I'm just wondering if there's a way to think about how the program itself might target where it's really important to have these types of decision aids. I mean, I was just looking, glancing at the article you left us about copayments and hospitalizations, and obviously some very poor choices were being made there where health plans increased copayments for outpatient visits, and so patients said, okay, I won't follow up on my hypertension, diabetes, or my MI, I will just sort of hope it doesn't happen again, and they end up being hospitalized more.

So clearly, there's some poor decision making going on, particularly around when there's financial incentives that make people make poor choices. So I'm just wondering if there's things we can't target.

And the other one that comes to mind would be end-

of-life care, where there's clearly a lack of family provider and patients' willingness to go through the understanding of the options in a timely manner before it's too late. So the whole idea of what are your -- and I know this is a sensitive subject, but there's really a need for some sort of a tool that helps people through those choices and that really reflects what they most want and value as opposed to what maybe even their family member wants and values.

So I'm just wondering if there could be some priorities or targets, because otherwise, this is a huge subject. And then if you were going to then tack on something like, we won't pay for that unless you have done this, then it would relate to driving programmatic goals for Medicare rather than just this broad, wide open, you know, any kind of education counts-type thing.

DR. SOKOLOVSKY: Let me just say two things about that. One is in Minnesota, they are considering legislation. They have identified 14, I believe, preference-sensitive decisions, and within the State Medicaid and State employers-employees health plan, they won't pay for those procedures unless the shared decision

making has, in fact, happened.

DR. KANE: And that is being driven by public policy makers saying, these are the important areas, whereas this is a -- I mean, I just think this is very big and I am just kind of overwhelmed by the possibilities, whereas I think there are some real program areas where we know that the patients and their families are not making the best decisions, and maybe even the providers need a little education and maybe that should be articulated or made -- if we are going to try to go this direction, that there should also be an effort to create a priority list.

DR. SOKOLOVSKY: And then the other, in response to your other comment, there is an advance directives shared decision-making tool and it is one that's one of the ones most popular for primary care doctors.

DR. KANE: And should we try to make that a requirement at some point, at some stage of life or some -- I don't know. I mean, again, thinking about how can we advance program goals with these aids as opposed to just saying they are a great idea and they should meet certain standards.

DR. BERENSON: Yes, just a couple of points to

follow up on my technical question that I asked about standards. I haven't come to a conclusion of where I come on this. The problem I'm having is that there are literally hundreds of thousands of communications a day between doctors and patients and in no way do we have standards for those communications. There is the direct-to-consumer advertising which would not meet the standards that you would lay out for decision aids, and yet we are going to pick this sort of subcategory and have standards. It just seems sort of the tail wagging the dog kind of thing. I am not necessarily opposed to it. Maybe these are discrete enough and maybe we can make an advance in this area even if we can't do anything directly in all those other areas, but I would need to be convinced.

I also would want to explore the question of why we would necessarily need the Secretary to direct that there be an accreditation as opposed to the market asking for an accreditation to happen, which is what typically happens when NCQA or somebody else finds that there's a demand for an accreditation, but maybe again there is a reason in this area to do it. I just would be asking those kinds of questions.

I guess that's the basic point I wanted to make.

DR. CROSSON: So I think one of the questions that I would ask myself, and it ties back to what Glenn first said, and I think Ron said the same thing, these tools have been around a long time. This way preceded pay-for-performance and many of the other ideas that we have talked about here, and sort of the question is, well, so why is it that 15 years later, we are actually talking about how can we get this tool employed?

And as I look at my own organization, I have to ask the same question. So as I look at the pattern of quality improvement activities that have taken place in that 15 years' movement towards patient safety, preventive medicine, early detection of disease, focus on better outcomes, process improvement in the hospital, all of these things have just sort of moved along.

This one has been relatively slow in my own organization. I talked to Matt Handley from Group Health, who was the physician who spearheaded this, and said, you know, you have done a great job with this. So what do you really think? And he said, I tell you, we got this done but it was very hard, because even in our setting where there is

no negative incentive for the physicians, we continually deal with the fact that many physicians really believe in what they do, and so they have sort of an underlying resistance to saying, gee, really, we ought to go through this process to sort of second-guess what I think ought to be done as a physician. I am not saying they are right. I am just saying there is a human element to this that goes beyond financial incentives and I think that may suggest that this ought to go in -- if we really want to push it, it may need to go in one of two directions.

I also had, about a year ago, a session where I brought together leaders of group practices, both prepaid and fee-for-service, and employers, large employers, to talk about what would be areas of common interest, and I had prepared this issue as one of the major discussion points, and it kind of just laid an egg. I was really kind of taken aback that what I would view as progressive group practice leaders are kind of looking aside and down at the table and saying, well, you know, this is kind of hard to do. And even the employers were saying, gee, I'm not sure really our employees would like this.

So there's a lot of sort of passive resistance to

this that belies the value of it, and I think -- so where that takes me is that maybe, if we really believe in this, either we're going to have to ramp up incentives for the patients, the carrot thing, or go down the direction that Arnie said, which is to progressively build it someway into the regulatory environment or the incentive environment in such a way that it overcomes that resistance.

This is not -- I'm not saying that physicians are opposed to this or that it's principled resistance or even strong resistance, but that there is a human element here which transcends incentives that I think has made this rather slow to progress.

And just one last point on the standards thing. I think the other point to make in terms of the feasibility of this is that you can't sort of just do this one time. I mean, the elements that go into, for example, in situations where there are many different modes of therapy, the evidentiary-based changes frequently and the relative risks and benefits of these things change. So you would need not only a body to do this once. You would need somebody, some set of people to be updating it all the time to make sure that it continually reflected the evidence.

MR. HACKBARTH: Let me just pick up on that. I referred to Harvard Vanguard's looking at this. Our clinical leaders decided not to do it, and it wasn't because they were in any way philosophically opposed. In fact, it struck all the right chords philosophically for our clinical group. We had a couple of our departments look at the specific tools that were being proposed by Al Mulley, and the way they looked at it is, if we are going to do this, this really needs to be integrated into our practice. It is not there is a library of tools that patients are referred to and then they come into the office and we tell them something completely different. It has to be part of how we practice medicine so there is a consistent message delivered to the patient.

And trying to get to that point is just a huge undertaking. There were disagreements about how some of the evidence was presented and it just sort of died of the weight of trying to integrate it into our practice in a meaningful way, despite all of the philosophical belief in the approach.

MR. BUTLER: So one more comment on the provider focus versus the consumer focus, which was kind of a theme

that has been picked up and, I think, a way -- it applies, by the way, not just to this, to other things like, say, medical homes. We give money to the provider side. Why don't we incentivize the consumer to participate?

So if you look in the private insurance side, major employers are increasingly activating their employees through financial incentives. It starts with the risk assessment online, then you get your cholesterol checked, and then if you have a chronic illness, if you engage in the program, and it goes on and on. I think it's starting to show some results.

And so how we get Medicare beneficiaries similarly incentivized, I think it doesn't address the narrower shared decision-making around specific, you know, targeted areas, but it does activate the enrollee in a broader way.

And I could even say on the last issue of the IT, why just do the stimulus dollars? Why don't you reward the consumer who picks a physician who provides direct online access to their health records? And it is a different -- somehow economically different. And that would further incentivize those offices to provide that service, not just by the government providing dollars for putting it in place,

but patients would pick you instead of somebody else.

MS. HANSEN: Thank you. I appreciate a lot of the specific examples that have come along with this second round of comments. Directionally, you can probably anticipate that I like the direction of this, but I see how large a topic this is. And then when I think about the incentives of places that are actually set up to do this, if we could go to Slide 11 for a moment -- oh, sorry, I meant Slide 7 -- I think what the hard work is that Jay brought up, and I think why Harvard Plan didn't do it, is the last bullet which says that patients and providers identified very different goals.

And my sense is that when physicians are moving in a direction of evidence-based practice and the latest things that come up, oftentimes, that doesn't translate necessarily to the goals that the patient might have. And then when the research that comes out that if given the choices, perhaps even with whatever the evidence has that the patient selection may be different and reducing to one-third of those choices, that sets up a real tension as to whose decision trumps, the standard of quality that would be measured here.

So therein for me lies a nexus of the tension of do you weight the consumer-beneficiary decision after knowing the relative risk and decision-making but have some incentives at the same time to pick the best evidence-based provider in, say, technology or something like this? It requires a different profile.

And then an outlier comment that I have, that I'm always curious that when we have another body of work of the most efficient providers for best value, the work that was done, like how did they do that, the group of you who worked on that. How does that correlate to anything here, if at all? But it is just like there are bodies of work of where it is the best quality, best value. Were there any considerations of how the beneficiary progressed in that? And it is just another cross-tab of thinking about this issue.

But I think part of the difficulty is, ultimately, it's both the technical knowledge and the beneficence value that comes from the part of the provider-physician, and whereas the patient-beneficiary appreciates that, but still may have other options even with the given information. And I don't know how we weight that in deciding what the

ultimate best and right decision is. So it's like you have two different things going on. Patients want something different despite the information that is provided, or even with the information that is provided.

So again, I may be making this more complex, but it just strikes me, why is there that resistance? Certainly, a 15-minute office appointment doesn't allow for this kind of work to be done.

DR. CHERNEW: So as you might imagine, I am very supportive of this and I think it is brilliant to have this followed by the next chapter. I think that is great. So I very much like the idea of consumer decision stuff.

That said, I guess I'm a little skeptical about involving more government role, bureaucracy in here, although I do believe that there probably are some select areas where one might be able to -- if one picked up. So one question I have which I'll let you get to in a minute is how many clinical areas do we really think are clean enough that one now has the ability to say something about both what a balanced and accredited decision aid is, and we could do something stronger. Now, maybe we could have more over time and maybe I would be supportive.

But what I am worried about is there's a lot of value judgments. If you look on page 24 at the list of things that is what makes this accredited, good, is it balanced, it's very hard to figure out. I imagine we would have a problem with any for-profit entity trying to promote this, right? But I can just see with the orthopedic surgeons we have a decision aid and the decision aid cuts out a third of back surgeons. We have decided it is unbalanced, and someone else thinks no, but who is going to decide? And then you have the specialty groups, which are kind of now like the decision aid rucks, that are putting together their decision aids as to what happens and how we manage all that, and it just strikes me as a challenging endeavor.

I am even worried, just taking the very simple example which Bruce gave, which I agree with completely, incidentally, about the relative versus absolute risk and how to deal with that, but there is a fair bit of, say, Amos Traverski evidence that people down-weight absolute risk. They underweight low risk differentials more so than they might if they were, quote, "rational" in the way people make decisions.

And it's not that I want to have a debate about relative or absolute risk, both of which I think are hard, as much as I am worried that the implementation of an accreditation, Good Housekeeping, other sort of seal puts the government or CMS in a position that no matter what they do, they are going to be inevitably seen as driving clinical practice one way or another.

So while I am very supportive, as our health affairs paper said, about better education around end-of-life care, I would run to the hills if there was a government-sponsored end-of-life -- or maybe government accredited is not the same as government-sponsored, so I understand the difference, but still, I would be scared, really personally, to have to defend what might come out of a decision aid if the various sides disagree about how one gives this type of information.

So while Al Mulley, who taught in the same course, I have a lot of respect for how this bubbles up in organizations like Harvard Pilgrim or in other places, I am really very supportive of these things, I think before one moves forward to have sort of an official Federal role in this, one really has to be careful as this could be

perceived, in fact, maybe correctly, but in any case, perceived -- I will stick with that -- as a step towards suddenly influencing the practice of care in a way that might be opposed by relevant, although perhaps biased, constituents.

So I think it requires a lot of thought and caution before one moves forward unless we take particular clinical areas where we say, this is an area where we think the evidence is so good and the problems are so bad that we could do a good job of that. And that is my biggest concern.

MS. BEHROOZI: I think that -- sorry. A lot of what I wanted to say was said before, but now, Mike, you make me want to say a lot more. I think that there really has been quite a lot of work done around these areas. You've got states mandating -- right? -- that decision aids be used, and these decision aids, they're not just -- you know, they've been around for 15 years or more. There are recognized organizations, bodies that have various advisory committees that, you know, are vetted up, down, every which way, and the point is that they're most effective when there isn't a right answer. They're most effective when

information is all over the place, and they're most effective when the entity giving the information does not have skin in the game. And I think that is what we are -- oh, sorry, the slide is not up now, but that is what we're talking about when we're talking about accrediting these things. It's not this is the right decision aid but, rather, this decision aid tells you there is no right answer. And, really, the process that I was most impressed with -- I attended one of the site visits with Joan and Hannah, and what I was really most impressed with was the elicitation of the patient's own values.

We contract with Health Dialog for our nurse helpline, so we have a lot of those decision aids available for our members, but it's not connected to, you know, the clinician. It's that the members can get it themselves. So I've seen some of them, and they're very good and they're very helpful, and the information is out there. And, by the way, I would rather get information about whether to get -- you know, how often to get a mammography from that kind of a presentation than this sort of shrill backlash after the recent controversy or, you know, evidentiary findings about frequency of mammograms. I'd rather have it presented in a

dispassionate way all in one place, these are the two sides.

Screenings I recognize are not as easily -- it's not as easy to implement these things with respect to, you know, the kinds of standards that Arnie is talking about where you wouldn't pay for something unless the process had been gone through. But, anyway, so I think it's important that we do this because we are talking about giving people information, and to step back and say, well, it's just too complicated to figure out what's the information to give them when there has been so much development of the information in this area and it is about there being no right answer.

We say all the time, IOM, everybody says all the time, among other things, care should be patient-centered. That's what this is. And as Arnie says, we don't want Medicare dollars going for things that patients ultimately don't want. So I think one of the things that I would suggest in the paper is to stress how these tools assist physicians in doing what we think they ought to be doing. Whether that's expressed by way of the fee schedule or not yet, I think it should be more expressed that these are things -- or it is sort of implicit that these are things

that we want providers to do, and these are tools to help them do it, and do some of it outside of that 15-minute consultation so it is not a burden.

Now, I recognize that just because I say that doesn't mean physicians are going to accept it and, you know, think that, okay, well, there's one patient who wants it so I'll do it because she said so. But I think we do have to start with national accreditation so that it's elevated to a level of recognition, and hopefully acceptability, and then provides a foundation for doing things like setting requirements.

One other thing that I would add in terms of, you know, the negative incentives or the reluctance of physicians, one thing that is mentioned in the paper is that in Washington State, where they have implemented legislation on shared decision-making, it includes legal protections for physicians who engage in shared decision-making, which makes a whole lot of sense, right? When somebody is really informed and has really made the choice, the physician is entitled to that protection, and that might provide a little more incentive for physicians to get on board.

DR. DEAN: Well, Mitra just made most of my

points. I would take a little issue with what Mike said for the very reason that Mitra just raised, that these are very difficult, complex decisions, but the proponents of the procedures, for instance, they're not going to be timid about the validity of what they promote, like Bob said.

And so I think as hard as it is, these decisions are going to get made, and I think as a public body or whatever our role is to try to be sure there is some balance there, as hard as that is -- and it's terribly hard, and it's controversial, and we are going to make mistakes and all that stuff. But I was going to raise the issue of the whole liability implications of this. I don't know if that came up in your research, and maybe it's not developed enough, but it would seem to me that that would take away a lot of the fear that drives a lot of physician behavior if they had that protection to know that this individual really was informed and that the validation of that comes from the fact they went through this process, not just because I told them that about the risk, because we know that's not a terribly valid thing.

So, you know, it probably maybe is too early to make that judgment, but it would seem to me that that would

be a powerful force.

DR. SOKOLOVSKY: My plan was to hit you all with that next month.

[Laughter.]

DR. DEAN: Just one quick thing. I ran across one of these decision aids, and the complexity of this -- this is in a completely different context, another activity I'm involved in, and I thought this was really a good decision-making aid. I sent it to Joan, and she thought it was terrible. And it has to do with, you know -- it's just a comment on how complex this process is.

MR. HACKBARTH: Okay. Well, we've got something short of a complete consensus on how to proceed here, but I do think we have the beginnings of at least some constructive thoughts about how to proceed. So we'll have more on this later. Right now we have to press ahead with the next item on our agenda, which is improving Medicare's benefit design.

DR. SCHMIDT: Joan and Hannah talked about giving beneficiaries a more active role in their health care through information. I'm going to talk about beneficiaries' incentives for using care and how they may be affected by

benefit design.

The Commission has been evaluating fee-for-service Medicare's benefit design for several years now through illustrative cases of redesigned benefits and an expert panel about value-based insurance design that included Mike Chernew before he was a Commissioner. And last year, Chris Hogan of Direct Research analyzed the effects of supplemental coverage on Medicare spending.

We are talking about it again today because this is an important and complicated topic. Where possible, we have rough estimates of spending and the distributional effects, but note that these are subject to change.

The Commission devotes a lot of attention to reforming providers' incentives through their payment systems, but improving incentives for beneficiaries may be just as important to address long-term goals for the Medicare program. Changes to the fee-for-service benefit could offer an opportunity to make Medicare's benefit package better for individuals who have very high health care spending and cost sharing.

For the long term, Medicare needs to be transformed to improve incentives for delivering and using

high-value care. Given the program's problems with financial sustainability, it's likely there will need to be changes. For example, we may need to consider whether Medicare's benefit design should be different for future cohorts beneficiaries. We may want to discuss ways of introducing management tools into fee-for-service Medicare. As we develop a better understanding about the relative value of alternative treatment options, we may also want to explore value-based insurance design, matching individuals' cost sharing to their clinical needs in order to encourage them to use high-value therapies. In this session, we will focus primarily on approaches for redesigning the fee-for-service benefit and for redefining the role of supplemental coverage.

The structure of Medicare's benefit has shortcomings in coverage that leads most beneficiaries to take up secondary insurance. This chart is just to remind you about the distribution of supplemental coverage in 2006 among all Medicare beneficiaries. About 91 percent had supplemental coverage and 9 percent did not. Employer-sponsored coverage was the most common type, followed by individually purchased Medigap policies, private Medicare

plans, and Medicaid.

When looking at how beneficiaries use Medicare benefits, there are two different sets of incentives to consider. The first is their decision between enrolling in a Medicare Advantage plan or in fee-for-service. In the commercial world, when a consumer has different options for health insurance, premiums can act as a signal of the breadth of coverage and provider options. For example, we usually expect plans with relatively tight networks of providers to have lower premiums.

In the Medicare program, premiums are not a good signal of information. In fee-for-service Medicare, there is one benefit design, a uniform Part B premium, and patients may choose among any willing provider. In the Medicare Advantage program, premiums have been artificially lowered because of how the Part C payment system operates and the use of rebate dollars. So in the choice between fee-for-service Medicare and MA plans, premium signals that consumers typically use to help them make choices do not help very much.

The second set of beneficiary incentives deals with behavior at the point of service, which can be affected

by cost-sharing requirements. The amount that a patient must pay at the point of service can sometimes affect whether she chooses to seek care in the first place, which provider she sees, and which treatment she uses. There is an extensive literature showing that cost sharing can affect the use of both necessary and unnecessary care, and we don't want to discourage necessary care. Trying to encourage the use of high-value care is the great challenge of benefit design.

Last year, Commission-sponsored work shows evidence that when elderly beneficiaries are insured against Medicare's cost sharing, they use more care and Medicare spends more on them. That analysis found some notable patterns. For example, having secondary insurance was not associated with higher spending for emergency hospitalizations, but it was associated with 30 percent to 50 percent higher Part B spending for services such as minor procedures, imaging, and endoscopy.

Looking within each category of supplemental insurance, paying little out of pocket seemed to be associated with higher Medicare spending. The analysis suggests that if supplemental coverage did not fill in as

much of Medicare's cost sharing, the structure of fee-for-service cost sharing could be used to help beneficiaries choose high-value care.

Another part of last year's analysis found that lower-income beneficiaries are moderately more sensitive to cost sharing than higher-income ones. One would expect filling in Medicare's cost sharing to be more valuable to low-income people, and it might have a stronger effect on their willingness to seek care.

In general, the analysis found that when either lower-income or higher-income beneficiaries had supplemental coverage, their Medicare spending was higher than individuals without supplemental coverage and similar income. However, the presence of secondary insurance had a moderately stronger effect on Medicare spending for lower-income beneficiaries.

The Commission has explored problems with traditional Medicare's benefit design. The fee-for-service benefit alone does not provide financial protection against very high levels of out-of-pocket spending. Compared with other types of coverage, Medicare's benefit has a high inpatient deductible and low outpatient deductible. These

features lead to a highly concentrated distribution of Medicare's cost sharing.

The one form of supplemental coverage that is available to all elderly Medicare beneficiaries -- individually purchased Medigap policies -- are often expensive, with administrative costs of 20 percent or more, and premiums for them can vary a lot.

The most popular types of supplemental policies fill in nearly all of Medicare's cost sharing. By effectively masking price signals at the point of service, supplemental coverage may affect beneficiaries' choices related to care -- whether to seek it, which provider to use, and which therapy to use.

Short of the long-term changes that I alluded to earlier, we may want to take some incremental steps to begin changing beneficiary incentives. The aims of these nearer-term measures include:

Out-of-pocket cap to reduce beneficiaries' financial risk. Above that cap there could be nominal cost sharing, as in the Part D benefit. At the same time, set limits on supplemental coverage so that Medicare's cost sharing could discourage beneficiaries from using lower-

value services. Since low-income beneficiaries are moderately more responsive to cost sharing, design assistance with their cost sharing that does not deter them from using higher-value care.

Move forward with the Commission's recommendations on comparative effectiveness to establish an independent public-private entity that would produce and provide information to compare the clinical effectiveness of services with their alternatives.

And another aim may be to begin examining ways to use information and financial incentives to encourage beneficiaries' adherence to high-value therapies.

You can think of the next several slides as a thought exercise that goes through pieces of potential changes. These are not mutually exclusive. They lead to a combined illustrative package. We are presenting them over a series of slides in order to help us the distributional effects.

Consider the effects of adding an out-of-pocket cap to fee-for-service Medicare. We will look at some specific dollar examples in a minute, but the general points to take away are it would provide some relief to

beneficiaries with the highest cost sharing and also tend to lower supplemental premiums for many beneficiaries.

Medicare would start paying for some of the costs now covered by secondary insurers. Since beneficiaries who have Medigap policies pay the full premium for the supplemental benefits of everyone in their insurance pool, including some with high Medicare cost sharing, all beneficiaries who have Medigap policies would see lower premiums.

The downside is that simply adding an out-of-pocket cap would lead to higher Medicare spending at a time that the program already has problems with financial sustainability. It would also lead to somewhat higher Part B premiums since B premiums are set as a percentage of Medicare spending for Part B services.

Having no more cost sharing above an out-of-pocket cap could lead to somewhat higher utilization. One way to counter this might be to follow Part D's example. It has an out-of-pocket cap, but above that cap beneficiaries still pay some nominal cost sharing.

To give you a sense of the magnitude of spending involved, here are data from CMS that show the distribution

of Medicare cost sharing in 2008. This reflects what beneficiaries owed providers, but in most cases, their secondary coverage paid for much of this. Most people did not pay these full amounts out of pocket.

Forty-two percent of beneficiaries had less than $500 in Medicare cost sharing, and on average, they each paid about $250, so that would basically cover the Part B deductible and the 20-percent cost sharing for several office visits.

At the other end of the spectrum, 2 percent of beneficiaries accrued $10,000 or more in Medicare cost sharing, with an average amount of more than $15,000 a person. Hospitalizations tend to drive this amount of cost sharing. These are beneficiaries who likely had several hospital stays during the year and probably had to pay the Part A deductible several times, along with Part B cost sharing for physician care in the hospital as well as for their office visits.

Since a lot of Medicare's cost sharing stems from having a hospital stay, I should point out that this distribution is just for a one-year snapshot. In any given year, about one in five Medicare beneficiaries has a

hospital stay, but over several years the odds of having one or more hospital stays go up considerably. For example, among beneficiaries who were in Medicare in 2004 and were alive in 2008, about half had a hospital stay at some point over that five-year period. So an out-of-pocket cap could have benefits over time for more people.

As an example, in the year 2008, if Medicare's benefit had capped cost-sharing liability at $5,000 per person, about 6 percent of beneficiaries would have been affected if they owed $5,000 or more in Medicare cost sharing. But many other beneficiaries who owed less cost sharing would still have benefitted because their premiums for supplemental coverage would have gone down.

In the case of people with Medigap policies, a rough estimate suggests that, on average, Medigap premiums would have been about 15 percent lower, or about $300 in 2008. However, specific effects on Medigap premiums would depend on the specific pool of people covered. It is less straightforward to quantify exactly what would have happened with other forms of supplemental coverage like employer-sponsored retiree plans and Medicaid.

Under this example, beneficiaries would have owed

at least $10 billion less in Medicare cost sharing, so Medicare program spending would have been higher to cover that expense. Part B premiums would also have paid for some of this additional benefit, an increase on the order of $4 a month.

Now consider adding both an out-of-pocket cap and a combined deductible that applies to both Part A and Part B services. Today Medicare has a high inpatient deductible, about $1,100 -- exactly $1,100 in 2010, and a relatively low outpatient deductible, $155. By comparison, one combined deductible that applied to both inpatient and outpatient services distributes cost sharing more evenly over the insured population. It's the approach used with many commercial policies.

Because of concerns about the added cost of providing an out-of-pocket cap, let us assume that we need to set the combined deductible at a level high enough to keep Medicare program spending the same. But we just saw that the costs of providing an out-of-pocket cap are pretty high. The example I gave of a $5,000 out-of-pocket cap was $10 billion a year for one year. If we made no other changes in Medicare's benefit design, all beneficiaries

would need to pay a relatively high combined deductible to pay for the additional capped benefits.

In our example from 2008, Medicare beneficiaries would have had to pay a combined deductible on the order of $950 to cover the additional benefit cost. Again, remember that as we project to future years, the size of the deductible would be larger. This is an example for 2008.

These two illustrative changes would still provide cost-sharing relief to the sickest beneficiaries, and since we designed this to be budget neutral, Medicare program spending wouldn't change. The Part B premium would probably go down a bit. If Medigap policies were allowed to fill in the combined deductible, the average premium across all Medigap policies would probably remain about the same. Adding an out-of-pocket cap to Medicare would lower supplemental costs, but covering the combined deductible would raise them, perhaps netting out.

It may seem counterintuitive to let supplemental coverage fill in the combined deductible, but I'll come back to this in a moment.

There are important downsides of these two changes to consider. First, obviously, the combined deductible

amount is pretty high. And, second, we need to be concerned about how beneficiaries who do not have supplemental coverage would react to this combined deductible. We already know that these individuals use less care on average, and the worry is that they would use even less necessary care. And this is a very important concern to bear in mind as we go through this thought exercise.

One way that could help to lower the combined deductible while keeping an out-of-pocket cap involves an excise tax on insurers with supplemental policies that fill in most of Medicare's cost sharing. Only applying a tax to these types of policies serves several purposes.

First, the tax would help in part to recoup some of the additional Medicare spending associated with that more complete coverage, and it is similar in the approach used in Part D where beneficiaries who enroll in plans with supplemental benefits must pay additional premiums for their higher use of services.

Taxes would be paid by Medigap insurers directly to the Medicare trust funds through the same Medicare administrative contractors that already process claims. Presumably, insurers would pass an excise tax along in the

premiums of those more complete plans. In turn, this would provide incentive for beneficiaries in those plans to voluntarily consider other types of Medigaps that have lower premiums but require paying more of Medicare's cost sharing. Policymakers may want to also consider giving policy holders a one-time option to move into Medigaps that are not subject to the excise tax on guaranteed-issue basis.

This slide shows the distribution of Medigap policies in 2008. Plans C and F are the most popular with a combined 55-percent market share. They cover both Medicare's Part A and Part B deductibles.

Plan types K and L are newer standard policies that cover part of the Part A deductible, none of the Part B deductible, and have lower premiums, but so far not many beneficiaries have purchased them. Not many at all.

This summer, Medigap insurers may start marketing new plan types M and N that also essentially trade off more beneficiary cost sharing for lower premiums. Plan N will use co-pays for office visits and emergency room use.

If there were an excise tax only on Medigap policies, it probably would not raise enough revenue to lower the combined deductible that we have been talking

about by much. If the tax were applied only to those Medigap policies that cover both the Part A and Part B deductibles, a 10-percent excise tax might raise on the order of $1 billion per year. With that amount of revenue, a redesigned benefit could still have a $5,000 cap, but it would still also require a pretty high combined deductible to remain budget neutral. The revenue would probably lower the combined deductible by less than $50.

If the excise tax encouraged beneficiaries to move into the newer Medigap policies that require paying more of Medicare's cost sharing at the point of service, that could lower the growth in Medicare spending and, in turn, more of those resources could be used to get to a lower combined deductible.

A legitimate question is why let supplemental coverage fill in a combined deductible. It is inconsistent with the idea that we want less masking of price signals at the point of service.

Well, another approach could be to simply restrict supplemental insurers from covering the combined deductible. It would lower program spending considerably, but analysts have raised this idea for a long time, and it has never been

well received, probably because beneficiaries tend to like Medigap Plans C and F a lot. So in our thought exercise, we have let supplemental coverage continue to fill in deductibles, but also included the excise tax as a way to encourage beneficiaries to move voluntarily to some of the newer plans that have a bit more cost sharing.

Another variation would be to make all supplemental insurance subject to an excise tax, not just the ones that provide first-dollar coverage. So, for example, the excise tax might apply to all Medigap policies, not just the C and F plans. This would potentially provide more revenue that could get to a lower combined deductible, but it would not necessarily encourage beneficiaries to move toward the newer plans that have more cost sharing. Maybe a little bit on the margin.

We have focused on Medigap policies, but another approach would also make employer-sponsored coverage subject to an excise tax. How complete is the coverage offered by employer-sponsored plans? For many years, surveys have shown that employers often include cost sharing in their retiree benefit packages, but it's unclear whether these cost-sharing arrangements apply to all retirees or primarily

those who are in younger cohorts.

A few years ago, Actuarial Research Corporation analyzed 2005 data from the Medical Expenditure Panel Survey for the Commission, and at that time about 20 percent of beneficiaries with supplemental coverage through an employer had no out-of-pocket spending other than their premiums. The retiree plans paid for their Medicare cost sharing.

In other Commission-sponsored work that used 2005 data from the Medicare Current Beneficiary Survey, 50 percent of fee-for-service beneficiaries with employer-sponsored coverage paid 5 percent or less of their Part B spending out of pocket.

To summarize, we have discussed adding an out-of-pocket cap to the fee-for-service benefit in order to protect the sickest beneficiaries from very high financial liability. However, unless we made other changes at the same time, Medicare's program spending would be quite a bit higher. We discussed how adding a $5,000 out-of-pocket cap in a budget-neutral manner would require a relatively high combined deductible, for 2008 on the order of $950. Additional measures could help to lower that combined deductible somewhat.

For example, we discussed an excise tax on insurers that offer supplemental plans that cover nearly all of Medicare's cost sharing. The tax revenues alone might not lower the combined deductible by much. However, if they encouraged beneficiaries to move into newer Medigaps that require the policy holders to pay more of Medicare's cost sharing, this could also free up resources to lower the combined deductible.

There are other issues that we will continue to explore. For example, there may be other ways to change the fee-for-service benefit design, making cost sharing more uniform across all types of services. For future cohorts of beneficiaries, Medicare's benefit design may need to be restructured in a different way, and their options for supplemental coverage may need to be different as well.

We can explore using pilots or demonstration programs to try out new approaches with supplemental coverage. For example, we might want to encourage new types of Medicare SELECT plans, Medigap policies that charge lower premiums or provide premium rebates when beneficiaries use network providers. So far, these have been limited in scope, only establishing networks of hospitals, not

physicians. Insurers might be more interested in establishing physician networks for SELECT products if they shared some of the savings from doing do.

Another topic that could be the subject of a pilot or demonstration is value-based insurance design, perhaps by tailoring Part D cost sharing requirements to individuals' clinical needs, and this would be an opportunity to test whether value-based insurance design could help to achieve lower Part A and Part B spending.

The overarching goal of this thought exercise is to make the fee-for-service benefit a better benefit. Changes could improve the benefit package for those beneficiaries who today have repeated hospital stays and face unlimited financial liability under Medicare's cost-sharing requirements. But at the same time, we would need other reforms that affect a broader number of beneficiaries in order to avoid worsening the program's financial sustainability. Changes from the status quo are very difficult, but they could potentially encourage beneficiaries to choose higher-value services.

For your discussion, I'd appreciate hearing what additional analysis you'd like us to pursue and what

direction you would like to take.

MR. HACKBARTH: Okay. Thank you, Rachel. Like Mike, I think the juxtaposition of this with the preceding session on shared decision-making is good. In fact, from time to time I think that what we need is sort of a thematic report, like a June report that is about different ways that we might seek to engage patients in promoting a high-value delivery system. You know, 90 percent of our conversation focuses on how we pay providers and all that, and clearly that's important. But I think also engaging patients in that effort is equally important. In fact, my fear is that if we neglect that piece of it and we just change what the providers do and patients are not involved, you set up, you invite a backlash, much as we had with managed care in the 1990s.

So I am glad we are starting to take a look at some of these patients issues. They are, however, complicated issues, and, you know, for example, the issue about the effect of increased cost sharing on low-income beneficiaries is a very important issue that I worry about.

Okay. We will start over on this side this time. Let me see hands for round one clarifying questions.

MS. BEHROOZI: Hi, Rachel. I'll save my response for what you said about the juxtaposition of sessions until round two, but just on Slide 9, the people with the highest spending, the sickest beneficiaries, take the last two sections, I guess, the 4 percent and the 6 percent. Of the total Medicare beneficiaries, you told us that 9 percent have no supplemental coverage. Do you know what that figure is with respect to that 6 percent?

DR. SCHMIDT: No, I do not. I know it is a higher proportion. The pie chart I showed you actually includes MA, and if we just looked at fee-for-service, it's maybe 11 percent do not have supplemental coverage. And it is higher yet within those highest spenders, but I don't know the exact number. I can look into that more.

DR. CHERNEW: When you calculated the excise tax for your examples, how does the magnitude of that compare to the spillover of the supplemental policy on the fiscal liabilities of the Medicare program? Do you understand the question? I just wasn't sure if the excise tax was having beneficiaries pay more than what they were costing the whole system in extra use or less.

DR. SCHMIDT: It was considerably less. I gave a

hypothetical 10-percent excise tax taking into consideration political problems associated with having a tax.

DR. CHERNEW: But if you were really going to charge them the full amount that buying that policy cost the Medicare program, it would be more.

DR. SCHMIDT: Considerably more.

MR. HACKBARTH: How much more?

[Laughter.]

DR. SCHMIDT: Way to put me on the spot. If we used the estimates that Chris Hogan came up with last year, it was getting close to 100 percent, 75 percent tax, which seemed like something that was completely infeasible.

MR. HACKBARTH: [off microphone] Other clarifying questions?

MR. BUTLER: This is obviously very specific to Medicare in this country, but I am just curious. Is there absolutely anything to be learned from other countries that cover large populations that have tweaked with economic sharing, you know, for the beneficiaries? Do we know of any data that would help, what has happened in other areas?

DR. SCHMIDT: I frankly would need to come back to you with a little more look at the literature before I could

answer that well, but I am happy to do so.

MR. BERTKO: Peter, I would only offer that having read a couple of the recent books on it, it actually goes in the other direction, and the protections for people that are critical care users are generally much better, that is, co-pays on drugs and other kinds of things drop to zero after some -- and I'll use the words "out-of-pocket limit" gets hit. So it is in the other direction.

Of course, their payment rates are so much lower that they can have lower out-of-pocket's compared to our payment rates for the same level of services.

DR. KANE: I am just curious to know what kind of -- does Congress or anybody now regulate the Medigap policies beyond -- I know they specify the different benefit levels, but can they --

DR. SCHMIDT: Oh, yes --

DR. KANE: Is it already pretty much something easy to do to go ahead and start configuring, reconfiguring the Medigap and the employer-sponsored plans?

DR. SCHMIDT: It's a very complicated topic you raise. There are a series of reg -- the Federal Government has set standards for what the policies might look like, and

there's also medical loss ratio standards that the insurers need to abide by. They're regulated by each state in addition. If you were to make changes to the structure of these, certain bodies within the Congress would need to pass laws that would ask the National Association of Insurance Commissioners to set up changes to those standards. In fact, some of that is contemplated in the Senate health reform bill, I believe.

DR. KANE: How about the employer-sponsored plans?

DR. SCHMIDT: The employer-sponsored policies are regulated in a different manner. Many of them are under ERISA so they're not subject to the same types of regulation, state level. And it's also a different set of entities within the Congress that would be acting on that.

There might be a tie-in to Medicare that's mentioned in the mailing materials with respect to Part D, the retiree drug subsidy, where many employers continue to provide primary prescription drug coverage and receive a subsidy from the Medicare program. So there is a link there that one might possibly use.

MR. HACKBARTH: Just to follow up on what you said about the employer-sponsored, they are not regulated by the

State insurance commissioners. They are covered by ERISA. On these issues of basically benefit design, I think that means that they are largely unregulated. There are no federal standards in lieu of state regulation. This is basically entirely up to the employer on advice and counsel of their consultants and health plans.

DR. SCHMIDT: [off microphone] Correct.

MR. GEORGE MILLER: A question on Slide 5. You mentioned in your presentation that with supplemental coverage Medicare spending increased about 30 percent, if I remember correctly. Do you know how that may be broken down by physicians and specialties? Do you have that stratosphere? And does it slope up just like -- and Bob -- well, I guess not Bob, but a presentation earlier by the Urban Institute. Or do you know?

DR. SCHMIDT: In some of the work that Chris Hogan presented to the Commission last March, he had some fairly detailed tables about differential effects across types of care and settings of care and the like. In general, the existence, the presence of supplemental coverage is associated with greater use of specialty care, of certain minor procedures, of imaging. I'm happy to show you the

tables from his work again.

MR. GEORGE MILLER: Yes, thank you.

MR. BERTKO: Okay. Two questions or comments. The first one is on nine, and I think I know what you have done, Rachel, but I wanted to be certain. I interpreted this as this being the cost sharing for Parts A and B without any D types of things in there.

DR. SCHMIDT: That is correct.

MR. BERTKO: Okay. So just for everybody to know, there are a very small subset of people that would shoot into that $10,000 or more coverage due to high-cost biologics and others. The rest of Part D, I think, would only modestly bump the number or the percentages upward a little bit. And I think everything we are talking about here in terms of redesign is only on the A-B coverage and not on the D coverage.

DR. SCHMIDT: That is right. There are some difficult challenges --

MR. BERTKO: Yes.

DR. SCHMIDT: -- associated with thinking about how to combine A and B and D, given that we use stand-alone prescription drug plans.

MR. BERTKO: And if the Chair lets me, I won't offer an opinion, but I would like to offer another option to your options slide, if we could, if we can go to that one. And I will come back. I will save my other comments for two.

So here are potential improvements. I would offer a different one that I think could be, at worst, cost neutral, and at best, cost savings, and that would be an out-of-pocket cap with minimum cost sharing on all Medigap and retiree types of things. And so I'll just now, if you let me, make a minor editorial comment that we know the cost of the out-of-pocket cap is the $10 billion from Chris Hogan's work, which seemed to be the amounts recoverable, or actually, I should say, excess demand within the neighborhood of $40 to $60 billion out of Part B on the 100 percent run-up, if I recall that number correctly, and minimum cost sharing, such as $5 PCP, $25 specialty, $100 emergency room might slow that down remarkably.

DR. SCHMIDT: So can I just make sure I understand what you are saying? So rather than trying to change the combination of supplemental coverage and the Medicare benefit, you would just change the structure of the Medicare

benefit?

MR. BERTKO: No. It's the supplemental coverage, and the recovery part of that. So I would do one thing to the current Medicare coverage, that is, only put an out-of-pocket cap on it, because I believe your comments about the combined deductible and the problems with access to professional services are very big. And then, secondly, I would save the money by putting in minimal cost sharing on all supplemental coverages. I think it's conceivable, at least, I'll look for your reaction and the panel's later, on the fact that that could easily recover $10 billion and might recover $20 or $30 billion in terms of reducing the induced demand from zero cost share supplemental coverage.

MR. HACKBARTH: Okay. That's a thought-provoking round two comment.

MR. BERTKO: Sorry. [Off microphone.] I'm bottomed out.

MR. HACKBARTH: Ron, and then Bruce.

DR. CASTELLANOS: In the material you sent to us, you talked about select networks for physician services. How does that differ from basically the MA plans?

DR. SCHMIDT: You mean the Medicare Select

policies, those plans? They are Medigap products, so they operate in the context of fee-for-service Medicare. And generally, it includes a network of hospitals at this point. It does not tend to include physician networks.

DR. CASTELLANOS: [Off microphone.] I think in the material, at least how I interpret it, you are thinking about developing a network just for physicians.

DR. SCHMIDT: Well, the notion was to maybe do a demonstration to see whether any insurers that are offering Medicare Select products would be willing to take on the added costs of setting up a network of physicians if they perhaps shared in some of the savings that the Medicare program might accrue from having network providers. That is the idea.

DR. STUART: I'd like to echo what Glenn said about the importance of this chapter. I think you've got a great start and I have some suggestions for expanding this in my round two comments.

In round one, as you know, a year ago when Chris Hogan was here and I had questioned some of the estimates of induced demand and price responsiveness, and I just looked at the face sheet -- now, obviously, I have not had a chance

to read the article that all of the Commissioners were given, but it's instructive, and if I do some back-of-the-envelope calculations, what I come up with is an estimate that for every ten percent increase in price, you would get a one to two percent decrease in use of ambulatory services and hospital services, which is, by the way, spot on with what the RAND Health Insurance Experiment came up with.

And so my question is, if you were to use the elasticity estimates that are implicit in this article, would that have changed your estimates about the impact of raising the -- or combining the deductibles?

DR. SCHMIDT: Let me again qualify that the estimates here are really rough ones and do not take into account the thought of higher inpatient utilization, which is suggested by this Travetti article.

DR. STUART: To just take one half a minute, that would mean, then, that your estimates assume that there is no price responsiveness, that that would not have a behavioral impact.

DR. SCHMIDT: At this stage, but --

DR. STUART: At this stage. Okay.

DR. SCHMIDT: -- it was to give you a basic

understanding --

DR. STUART: All right. Okay. Thank you.

DR. SCHMIDT: -- but I plan to come back with more.

MR. HACKBARTH: Okay. Round two? Mitra?

MS. BEHROOZI: We've had some discussion about this before, Rachel, so I'll be brief. Your work is very thoughtful and thorough. I appreciate that.

I still have a question about why this topic links together protecting the highest spending beneficiaries with so-called the incentives at the front end. It's a laudable goal. I absolutely don't want the sickest people to go bankrupt because of circumstances beyond their control. But even if it's ten percent of that six percent of fee-for-service beneficiaries, that's 0.6 percent of fee-for-service beneficiaries that we should do something for. But to wrap that in, to take the cost that mostly is being paid by Medigap insurers, frankly, and put it at the front end, leaving aside the fact that you're assuming that much of that will be covered by Medigap insurers anyway, I have a real objection to doing more of that, to loading more costs up front, which I've expressed before, and I'll just say a

couple of things about that.

I think that the -- I know there are a lot of economists here. I don't operate as an economist.

DR. CHERNEW: Yet.

MS. BEHROOZI: Yet, he says. Oh, I'm getting farther from it, actually.

It's not first-dollar coverage, and I know this is really swimming upstream and my fins and tails and whatever are getting all shredded going up against that stream, but it's really not first-dollar coverage by itself that's the culprit. It's the lack of management. It's the lack of the ability to have any other levers to control behavior. And so we use dollars as a mechanism for controlling behavior. It's a cost shifting, really. It's a proxy for management.

If everybody were in the same economic circumstances and made their decisions on a fully-informed basis, as we talked about in the prior session, then okay, fine. I guess we could just revert to an economic model and assume that people would make economically rational decisions that aligned with clinically rational decisions. But where people have different perceptions, even, of their own ability to afford things, whether they think they can't

afford it or whether they think they can afford it, they're not going to make clinically rational decisions. If they think they can afford the extra imaging tests and the full-body scans and all of that stuff, that's not a clinically rational decision, right, and that's more spending for the Medicare program, just in the same way that it matters -- and so I care about that from the Medicare program's end.

But I also care about the beneficiaries and, frankly, the Medicare program, who aren't poor enough for Medicaid, may not even be, on the face of it, poor, but live in a high-cost area, have lots of people they are helping, you know, pay the rent or whatever, who feel like they can't afford the costs that are shifted to them.

So ideally, to drive the most clinically appropriate behavior, it seems to me that we should be imposing costs where a particular choice is not of clinical value, right? That's the kinds of things that we've been talking about in lots of different ways in different types of topics that we cover, and that's what I was saying, Glenn.

I would add to your comment and others' comments about how this topic flows so well from the shared decision-

making topic. I would have put the value-based design at the other side of it, because that, to me, is the beginning of the approach to how to really get people to -- to support people in making clinically rational decisions.

And just on the last point, so we have talked about cost shifting generally, but I would say that deductibles are the bluntest, crudest form of behavior modification via dollars. John's point about more targeted types of copayments, I can live with. I still don't think it's as effective as management, because like I said, the $25 copayment for a specialist for somebody who thinks they can afford it, they'll go to six of them. So it doesn't necessarily effectively manage. And somebody else who really needs to see an endocrinologist won't go.

So I really have a strong reaction, I think, to the notion of even if it's true that we don't have a lot of other levers right now besides dollars, I really object to it being in the form of deductibles.

MR. HACKBARTH: Let me just pick up on Mitra's comment for a second, and I want to get Rachel to help us out with some of the existing research on this topic, and then I want to ask Mitra a question to better understand her

point on the research.

Of course, one important piece of research on this is the RAND Health Insurance Experiment, and my recollection of the RAND findings were that cost sharing mattered. There were significant reductions in utilization, as Bruce was saying.

A second finding was that there was a reduction in both appropriate and inappropriate services in roughly equal measure. In other words, faced with cost sharing, people weren't saying, oh, I am just going to get rid of the inappropriate stuff. They were unable, pretty much, to distinguish between the two.

A third finding was that for most of the population in the experiment, the fact that they couldn't discriminate between appropriate and inappropriate didn't seem to affect their health status.

But the fourth finding was that the exception to that was for low-income people.

DR. SCHMIDT: Right. It was, in particular, low-income and people in poor health.

MR. HACKBARTH: Yes.

DR. SCHMIDT: That combination. They tended --

they had lower blood pressure levels in the existence of no cost sharing. That was the clinical measure they looked at.

MR. HACKBARTH: Yes. Yes.

DR. MILSTEIN: Glenn, you need to recognize the RAND Health Insurance Experiment was for under-65 people.

MR. HACKBARTH: Yes.

DR. MILSTEIN: It was not -- and I suspect that people over 65 have a different elasticity of demand.

MR. HACKBARTH: But it may also be that the potential risks are greater for the over-65 than for the under-65 population covered in the experiment.

So now I wanted to ask Mitra my question. So what I heard you express concern about was across-the-board cost sharing, as exemplified by a big increase in the deductible. But I thought I also heard you say you have less problem with it if it is, for example, cost sharing -- you pay more for a service of unproven value. If you choose the new drug that hasn't been proven to be more effective, you ought to pay significantly more for that. Did I hear you correctly?

MS. BEHROOZI: That is an example of how to target cost shifting so that you are incenting behavior in a clinically rational way.

Can I just say something about --

MR. HACKBARTH: Yes.

MS. BEHROOZI: I am sorry. I forgot to mention -- actually, Bruce mentioned it -- the recent New England Journal article on a study done at Brown University only among Medicare Advantage beneficiaries finding changes, increases in copays-where the copays already existed, it wasn't a matter of going from zero to something, which John has told us has a dramatic impact, but it was from something to something more -- yes, reduced outpatient spending, but there is some evidence that of the reduction of appropriate care because they actually indicate that there was an increase in inpatient utilization -- an increase in inpatient utilization -- and they extrapolated that they think that the increasing cost to the plan is $24,000 for every 100 health plan enrollees.

Rachel and I had some discussions about some issues that may not -- that may undermine some of the findings here, but I actually am rereading it and I am feeling like it says a lot that we hadn't looked at before, particularly in terms of Medicare beneficiaries and changing copayments, not adding copayments, certainly nothing as

dramatic as going from a $150 deductible before you get any coverage to $950 of deductible before you get any coverage.

DR. CHERNEW: So I want to echo even more strongly how important I think this issue is, and apart from any of the details, which I will say something about in a second, I think it raises a fundamental question about the role of patients in the future of Medicare as we address the Medicare problem.

And the question is, in part, do we sort of balance the back and reform Medicare simply on the back of providers through various payment rate reforms, or do we include patients in some way to deal with this, and how we deal with that is a challenge.

My one broad comment is, going forward, of course, in a broader thematic view, the interaction of these two things matters. So one could envision a system where you have very strong payment rates. Then you might not need all these same consumer incentives, although you do have the conflict that patients want this and they don't have to pay and now you have clamped down on the providers. So there is room for a lot of thoughtful work, not just about the role of the patient incentives, which we don't talk about as

much, but also how that interacts with all the things we've said on the payment side, because they're not mutually exclusive. I think that, broadly speaking, is a really important thematic way to go for big picture issues.

On the specific substance, let me say first what I think the status quo is, because the status quo, in my opinion, is not the pictures that you showed up there. The status quo for people who retire ten years down, maybe less, is going to be substantially less Medigap coverage, whether it be Medigap coverage because premiums have risen. Employers, I think, are pulling back dramatically. I was with Paul Fronstin the other day who said that in our work we are doing with the Urban Institute, we should assume that in third years, no one gets employer-based coverage. And now people say, what about public employees? Well, that might lag a little bit.

But for the most part -- and as it happened, the next day, I went to the benefits committee that I just was appointed to with my employer, and I won't say the details of that, but I might be upping some of my savings.

[Laughter.]

DR. CHERNEW: Because, essentially, some of the

promises -- I think if you look actuarially at some of the promises that were made by employers to individuals are not tenable. And we can pretend they're tenable by looking about what's going now, but my opinion is they're really not.

And then if we reform Medicare Advantage, which we've discussed in a way that I think is reasonable, I think you find that Medicare Advantage as an outlet to a way to get this coverage will be less generous than it may have been in the past, because right now, we are spending a lot of money to get some of these gaps filled in that way.

So my view is the status quo for many people that I know is that it's not as generous a picture going forward that it is now. So when we talk about reforming it, we can't talk about reforming what it would look like today, and it looks like we're making things a lot worse for people by putting in a deductible or all this, which I understand. But it might be the case, and I won't go so far as to say this, that, in fact, some of these things are going to look a lot worse for individuals and we really need to think about how to do that.

And the big challenge that I think is raised here

extraordinarily well is that we have to balance our desire to maintain access to the things we think are of value and discourage access to the things that we aren't. We want to make that overall, and it has very strong implications for issues related to disparities.

One of the challenges that I think arises in all of the work that we do is how to think about it in the following way. Mitra's comment, which I am supportive of, is we would want to charge people more for the things of lower value. What I think is actually more likely to happen, whether we want it to go this way or not, is we would see coverage deteriorating in various ways and we have been struggling very hard to at least try and carve out those areas that we know are high-value to protect them. We don't know what they all are.

So the status -- we've only argued for lowering barriers to high-value things, but that's against the backdrop of coverage getting a lot less generous by and large, and I think even if the Medicare benefit doesn't change, I think beneficiaries are going to perceive the Medicare benefit as becoming less generous over time. And I think through the benefit package structure, we have to

think about how to manage that, and one way could be through solving all the problems with physician payment changes, and that solves the cost problem, we can keep copays down, but I'm not sure how well that will work. And I think that interplay is why the beginnings of this chapter, which is one that I hope gets revisited, I think, is going to be fundamental.

MS. HANSEN: Well, I cannot be more articulate than I think both Mitra and yourself combined here. I do think that there's the immediate term, the design, as well as looking at the trajectory of what's coming down the pike, and I certainly have brought that up with kind of the growing older population who will actually use more services regardless at the moment of this design.

But I do think that in the interim period, the blunt instrument factor of the $950 on the front end, especially for a group that I've oftentimes also spoken about, is this less than Medicaid population but at great risk, is something that we should think about.

I think perhaps just as a backdrop of pure economic dollars, I think I've raised this, also, but if we just also think of the context of the typical Medicare

retiree and what their normal income is. So we can talk about absolute dollars, but what percentage does that affect their total ability to manage their costs so that we get also a full or constant picture of the impact to the system, the Medicare system now, the Medicare system in the future. But the concomitant erosion that will occur with the absolute dollars, what in future dollars, what that is, let alone today's dollars, where half of the Medicare beneficiaries live on probably less than $22,000 a year for everything.

So those are the things. I just wanted to have that robustness of that picture painted.

DR. SCANLON: I would just sort of add sort of my sense of the importance of this, and I think that we really can't think of Medicare as insurance unless it's got some catastrophic protection. And that, I think, just leads to the point of thinking that there has to be a cap of some sort, a cap with some nominal cost sharing sort of beyond that certainly is a reasonable thing.

It also seems, and it's always been the case, that it makes no rational sense to be heavily subsidizing an insurance product for the beneficiary population and

simultaneously allowing for supplemental coverage which is adding to the cost of that insurance product. So taking some steps with respect to supplemental coverage, I think, is very important, and not just Medigap but also the employer. Even though the employer coverage may be withering, it's there now for the time and it's there. We shouldn't be incurring those unnecessary costs.

The thing I would stress is that we really have to take into account what Jennie raised the issue about, sort of the portion of the beneficiary population that is lower income. And defining things in nominal terms, either a deductible or some copayment, I think misses the point that for some people, those are very big numbers.

We have the Medicare savings programs that cover cost sharing up to poverty, okay. Poverty is about $11,000 or $12,00 for an individual, $15,000 for a couple. Those people in poverty, they have a very different -- are just above poverty -- they have a very different sense of what these dollar amounts means. So I know it's much more complicated to think about defining a program with income tiers, but it's something that we, I think, can't avoid when we talk about improving the Medicare benefit.

DR. CROSSON: Yes. First of all, I agree with Bill. I think we've talked about the need for a catastrophic cap for some time. It seems to me that the idea of someone covered by Medicare going bankrupt because of out-of-pocket costs is something, if we can do it, we ought to try to prevent.

Among the options, the one that we have on the table that causes me the most heartburn, like some others, is the combined deductible. So, I mean, for most Medicare beneficiaries in the average year, that results in an effective deductible for outpatient services of $950, which is a lot, and it's a lot for certain populations, as I think has been brought up.

So I have sort of a specific question. You mentioned earlier that in the bill that passed the Senate, the health care reform bill, there are some provisions that are directed at trying to change the allowable benefit structures in the Medigap policies, presumably for the same reason of reducing program costs. So I guess my question is, could we look at -- and it may be or may not be by the time we look again that something may have happened along those lines and this could be along the path of becoming law

-- would it be possible to look at projections of whether those provisions, if passed into law, would allow, without dealing with the combined deductible piece, would allow for a catastrophic cap either at the $5,000 level, which costs $10 billion, or solving half the problem, at the $10,000 level, which appears to cost $3.9 billion a year?

DR. SCHMIDT: Let me say what those provisions are and then I'll get to your specific question. As I read the Senate health reform bill, what it contemplates is as of the year 2015, standards for Plans C and Plans F, which are the most popular types of Medigaps, would need to be revised by the NAIC to incorporate nominal copays for office visits. I think they're on the order of $20 or so is what's contemplated for office visits for primary care, somewhat higher for specialty care. I think it's kind of left a little unclear exactly what those levels might be. And also emergency room visits.

One thing about those provisions is that it would affect people who are just now becoming elderly, entering the Medicare program and contemplating the purchase of a Medigap. It would not affect the stock of current folks in the Medicare population. They would be grandfathered,

presumably, and could keep what they have. So the savings initially from having those in place presumably would be relatively small.

There is some out-of-pocket cap that might be provided with that, but I would suspect it is pretty high. Over time, the savings relative to a world where those Medigap policies did not change would grow, and presumably that would pay for more. We could try to do some projections if that would be helpful.

DR. CROSSON: One point of personal privilege. Becoming eligible for Medicare and becoming elderly are two separate things.

[Laughter.]

DR. SCHMIDT: Forgive me.

MR. HACKBARTH: But the Senate health reform bill only addresses prospectively Medigap. It doesn't do anything with ERISA, exempt employer --

DR. SCHMIDT: Correct. It is only with Medigap.

MR. HACKBARTH: Okay.

DR. BERENSON: Yes. I will share everybody else's view that this is very important and I like the direction of where your proposals were going and, essentially, let's get

a real stop-loss and catastrophic coverage and then create incentives for people not to buy first-dollar supplemental but to face some cost sharing. This article gives me some pause and I'm going to have to understand it a little better.

I'd make two points about why at least my going-in view -- two points that haven't really come out. One is implicit, having to do with value-based benefit structure. Virtually every discussion I have about medical homes with people trying to figure out how to encourage beneficiaries to participate but not lock them in or assign them into what appears as a gatekeeper, the glib thing is, oh, we'll just waive their cost sharing, to which I glibly respond, they don't have any cost sharing, at least 90 percent of them don't. So there's right now some real practical issues around trying to promote certain kinds of behaviors because everybody has first-dollar coverage.

The second point I would make, which hasn't come up, is an issue around the beneficiary, the beneficiary's family, and fraud and abuse or mistakes. In my own situation, I will recount this, my mother died a few years ago. As part of her acute illness, she had a transfer from

a hospital two miles away to another hospital and there was, after months of going through things, I found that there had been a supposed helicopter moving her from one to the other at $6,000 when, in fact, there was no helicopter. It was simply an ambulance. And I had no reason to -- I mean, it was all paid for. The hospital billed. Medicare paid that. It got transferred over to the Medigap insurer that paid the rest of it, and I sat there saying, I really need to look into this, and yet I haven't still. I will, now that I am saying it very publicly here.

[Laughter.]

DR. BERENSON: So one thing I believe they do in France, where people, at least for physician services, people do have first-dollar supplemental coverage but they have to pay the copayment in the office, see what they're being charged, and then on the back end collect, I just think we need to think of -- I know AARP over a decade ago had a whole campaign about sort of being part of and ability to care about bad billing, whether it's intentional, fraudulent, or whether it's a mistake, which I would hope happened in this case. It's hard to imagine how, exactly. I do think there is a reason to have -- I mean, it's an

aspect that I think -- and anything you can find about what sort of behavior change happens with patients and their families as they have to face bills, even if they're not ultimately liable for the cost, but sort of how the bills move, how the claims move, I think would be helpful in this discussion.

DR. KANE: Maybe a finder's fee for finding fraud in the bill?

I just wanted to support the concept of having all of these numbers presented as a percentage of household income and not necessarily just as -- there's actually two people involved here, too. It's usually not just one beneficiary. I mean, a lot of these people are couples, and so you multiply that by two on household income, not just one. I think that would help us get a better sense of how powerful some of these things are to families.

And I guess I don't quite understand -- it would be helpful to get a sense of how the Medigap policies value, because they're doing catastrophic, aren't they? Some of these Medigap policies have a catastrophic --

DR. SCHMIDT: Well, some do, and they effectively are picking up all of the cost sharing, so --

DR. KANE: Just actuarially, what does that mean to them? And I guess how would that -- it's a little hard to understand how you value the catastrophic coverage in terms of -- I know there's a certain amount, but does it all -- do people also end up using more services when they have catastrophic coverage?

DR. SCHMIDT: Yes, they do.

DR. KANE: So that's not in here yet?

DR. SCHMIDT: That's not in there yet.

DR. KANE: I just find it really hard to kind of follow this in the little pieces when there is a big behavioral effect that could also swing in if you start putting in catastrophic coverage. And then how would you offset those costs?

DR. SCHMIDT: Right. And, again, we hope to come back with more detailed information for you.

DR. MARK MILLER: But you also said in your presentation that you could use the Part D construct, where once you hit the catastrophic cap, there's still at least some nominal co-payment that stays in place. You did say at least that much.

DR. MILSTEIN: I support all the prior comments

about the notion if we want to have a reasonable chance of closing the so-called value gap, you know, that we've got in the health care system and in Medicare, we probably need two engines, you know, operating the provider side of it and the patient side, and you want both to be value-seeking in their orientation more than is the case now.

That being said, I think, you know, it's funny, we have certain metaphors for what's difficult to do, and, you know, John was saying pushing a rope uphill. I think we'd probably put in that came catalog of metaphors applying a 75-percent excise tax to Med. supp plans.

[Laughter.]

DR. MILSTEIN: That's probably harder than pushing a rope, but, anyway, so I think what it really boils down to is what we want is we'd like to within reason and within what is reasonable to expect of Medicare beneficiaries to have beneficiary incentives to make higher-value decisions and engage in higher-value behaviors. That is the overall concept. And then you sort of say that then raises two questions that were in some ways answered in various ways by some of the prior comments.

One is which behaviors and decisions would have

the most leverage on affordability and quality. You know, I think the choices look something like this: First of all, treatment options, you know, which treatment option. That's sort of what we've done with drug formularies, right? And that certainly could be extended to non-drug treatments.

But people who catalog cost-effectiveness and/or comparative effectiveness studies say that we have a little bit of building to do before that -- the cupboard is not as full as it would need to be if we wanted to have a big impact. So for the time being, that's a little bit challenging.

Second is self-management behaviors, you know, engage in various programs to reduce your health and, therefore, health cost risk. That is, I think, a little bit more challenging in the Medicare population than it is in some of these pilots in younger populations. But also my sense is the evidence doesn't suggest that that is a big opportunity to lift value in the Medicare population, more than has been recognized in the past, but it's not a big number.

Then last is, I think, something actually we've talked about before, which is choice of higher-value

providers. Now, there's a behavior in the decision where I think there's reasonable evidence you could get a pretty big lift, and where value is defined as we have defined it here in the past.

And so you say, well, what -- then I think to myself, well, you know, what mechanisms. Well, you know, one would be the GAO mechanism that was advocated in a couple of their reports, which is if we do have evidence that there is a subset of physicians that are way off the market in the Medicare program with respect to their resource use, that is, unfavorable resource use, and hopefully measuring, you know, available measures of quality, one idea would be to say, well, let's have more favorable -- you know, lower patient cost sharing for patients that agree to select among physicians that are not in the -- I think the GAO words for this was "distant outlier" category. That is one option.

Another would be to tied this in with our mainstream recommendations and say, look, if a beneficiary is willing to select an accountable care organization or an accountable medical home that is taking accountability -- I mean, not just upside but downside accountability for

moderating, for improving value by lowering the spending trend and improving quality, then they should get some kind of a benefit incentive.

Now, in terms of what incentives you offer, that's where I think we probably -- I wish we had more research on, you know, what the relationship is between certain economic incentives and certain people's behaviors, particularly in a way that is kind of sensitive to people's income and education levels. But if we're going to talk -- if what's on the table is, you know, establishing or much better out-of-pocket protection or better deductible, you know, my intuition would be that's something we haven't -- it might be something better fit for the non-affluent Medicare beneficiaries, and we do have some precedents in the federal programs for giving a little bit more of a benefit or having -- to people of lower income or asking people at higher income to pay a little more. That has begun to creep into the Medicare program, and that could be, if you wanted to moderate the need to raise taxes, you know, to give rewards in the form of lower -- introducing maximum out-of-pocket and lowering deductibles, we might want to start with people, you know, who are below a certain income level.

MR. HACKBARTH: As is often the case, Arnie, I really like the way you framed that, and you did something I was trying to do, but not nearly as well as you did it.

You know, these are tough decisions about increasing beneficiary cost sharing. This isn't the first time we've looked at this, and people haven't exactly run up and grabbed it and embraced it as the way for Medicare to go. And that's because there are a lot of legitimate issues about its impact on the Medicare population.

It seems to me that maybe if, as opposed to just latching onto this and pursuing it to its end, whatever that might be, if we first said here is the array of tools that might be used to engage patients and try to do some assessment, like Arnie suggests, you know, here are the high-leverage, high-value, and how this fits in that framework and compare it to other opportunities, I think that might be a fresh approach to it and potentially a more compelling approach, both maybe for people around this table and for the Congress. So thank you, Arnie. I like that framing.

MR. BERTKO: So I am now going to take my opportunity to opine a little bit, keeping in mind my --

MR. HACKBARTH: You did that already.

[Laughter.]

MR. BERTKO: No, and I've got more opinions than that, Glenn. Come on. But I'll try to be quick. So recapping here, a $5,000 out-of-pocket, $5 primary care, $25 specialty, $100 emergency room visit.

The first comment here is this is urgent, we need to do this without grandfathering.

The second comment is -- and I'm going to go towards your comment you just made about increasing cost sharing. The answer is, yes, you're increasing cost sharing, but, secondly, you're not going to really affect beneficiaries very much because the cost of their Medicare supplement premium will come down almost as much as the cost-sharing difference. And if you recall, like Medicare Advantage, except it's worse with Medicare supplement, you're paying $1.40 out in premium to get $1 worth of cost-sharing benefit back, because the loss ratios are in the 65- to 70-percent range. So with everything that moves around, it reduces the premiums.

MR. HACKBARTH: On average, but there's still a different distribution of those costs.

MR. BERTKO: That is a true statement except that the way the premiums are calculated, they come down, on average, and they come down for most people. So 93 percent of Medicare beneficiaries see a doctor a couple times a year. It's very few who have no encounters whatsoever, and the cost sharing for the catastrophic portion affects everybody who's got a Medigap coverage.

The second thing here is that this is actually -- you like to look for things which have a two-fer or a three-fer effect. This one has got at least that many. So it would -- as Bob said earlier, for medical homes, accountable care organizations, and medical management -- Mitra's question -- you need to have some way to affect cost incentives and channeling so it works there, management tools. Value-based insurance design or whatever you're going to do on that, whether you stick to small stuff like diabetes management at the start or expand to other things later, you've got to have these things so you can say, oh, yes, we went from here to there, and you can't go from there to plus money on paying that.

Then, lastly, this actually has some ability, possibly, to reduce the demands on the Part A trust fund

because if you can reduce emergency room admissions, you can also reduce admissions to the hospital which then affect directly the Part A fund, because hospitals -- and I don't know if Peter would agree with this wording, or Herb, but they harvest admissions out of the emergency room, for better or worse. And if we can keep people going through a less acute care for these kinds of little-acuity conditions, then that would be great, too.

So I think --

DR. KANE: John, what's the "this" again?

DR. MARK MILLER: Can I just --

MR. BERTKO: The $100 per admission co-pay rather than zero, which says go see your primary care or specialist before -- rather than checking into the hospital to be treated.

DR. KANE: But a $100 co-pay [off microphone].

MR. BERTKO: Yes. Separate, outstanding, can't be waived, or filled in.

DR. MARK MILLER: So what John is saying -- and this is to connect to his last couple comments. I am sorry. The first ones that he made and then these, and just to kind of pull some of this together because I think you were

moving fast, and I am sorry, I'll be as fast as I can.

So you're saying, all right, let's drop the deductible idea, let's go to a cost-sharing idea, and he's giving examples of cost sharing for an ER visit, a primary care visit, and a specialty visit. And these are co-payment amounts, $100, $5, and $25. Just talking, right? That kind of thing. At the same time, as a catastrophic cap, correct?

MR. BERTKO: Correct

DR. MARK MILLER: Okay. So that's the approach instead of a deductible and catastrophic cap, you have this cost sharing through arranged visits with a catastrophic cap. And then what I think some of your other comments were, from the ER you might get a secondary effect of fewer hospital visits. And then he was also saying to Bob's comment over here that then you could say to the beneficiary, I will relieve or not relieve you of these things in order to incent you to go to an ACO or a medical home, just to connect that dot.

And I had just one quick question. And you're also saying for Medigap and why the premium falls is Medigap cannot fill these.

MR. BERTKO: That's right. Medigap would be --

this would be minimum cost sharing. Medigap couldn't pay for it, which brings down Medigap premiums, and because of the 140 percent or $1.50 to pay $1 in claims, it doesn't close it all the way, but it will be a near dollar-for-dollar reduction. More cost sharing lower premiums.

DR. SCHMIDT: Could I ask John a question here? That is, this notion of having the co-pays, would that just be on Medigap policies? Or are you envisioning employer-sponsored care plans?

MR. BERTKO: Well, Medigap I am certain has the big bang. You mentioned, I think, in your presentation that 20 percent of retiree health care have this. I would put it in there as well. I would also consider an income-related one for Medicaid in much the same way. But, you know, again, this is a straw man. Everything is subject to looking at.

DR. SCHMIDT: Right. The reason I raise that is that the cost of even a $5,000 cap, I gave $10 billion, which did not have a behavioral effect and was for 2008. It would be more money in future years. And I'm wondering if just, you know, a change to the Medigap population alone would be enough resources to pay for that.

MR. BERTKO: Given your numbers and the size of the population covered by Medigap, namely, 25 percent of it, I think the answer is yes. But I'm aware at least of only one instance -- and this is by anecdote -- of where some retiree health coverage with near 100-percent coverage was twice the AAPCC-induced demand. And so, yes, it would have an effect on that. I would do it everywhere that it made sense.

MR. HACKBARTH: Okay. We're down to our last few minutes here.

DR. CASTELLANOS: It's very difficult to follow John. I live in the real world. I'm a practitioner, and I'm just going to talk about some -- as a urologist, I feel somewhat impotent when I bring up my comments.

[Laughter.]

DR. CASTELLANOS: I do want to mention that cost sharing really does affect the real world. You know, we can criticize the RAND study because it is below 65. We can criticize the Brown study because it only was MA patients. But in the real world it affects, and we do need to do something about increasing the barrier for the treatment of unnecessary services. And we certainly need to do something

about lowering the barrier for the necessary services.

Cost sharing does make a difference, and I think it's important to put -- I think the beneficiary needs skin in the game. I'm sorry, but I think they need skin in the game. We need to protect some of the high-risk populations, the people in poverty, the ethnic minorities, and the catastrophic sick patients which we call the train wrecks. They really, really need help.

And, lastly -- and Arnie opened up the issue about higher level of providers -- the provider needs tools, just like Glenn said. We need comparative effectiveness, and we really do need tort reform. I have a patient who came in the office Monday that didn't need a CAT scan and didn't need a bone scan, but her comment was, "I have insurance and I demand it, and if there's something wrong, I'm going to come back to you and I'm going to sue you." I need some protection.

DR. STUART: I know that woman.

[Laughter.]

DR. STUART: No. I'm not going to repeat all this. I think there's a broad consensus, and I think that looking forward in terms of what the insurance market will

look like is the way to go.

There's a danger, I think, in saying, well, Medicare is behind the 8-ball because it doesn't have a combined benefit with a single deductible and coinsurance feature. I think we understand that. But if you read the trade press, everybody is looking at value-based designs. I saw the results of a survey of insurers and self-insured plans that said that 30 to 40 percent either had some element of that now or were planning it next year. So this is something that's happening right on the -- it's happening, and it would be useful to have that summarized in the chapter. And it would also be useful to have -- now, I have no idea of this. Maybe John or Jay know how many Medicare Advantage plans are using some kind of value-based technique. But I think that that would be useful.

But I think that Mitra is on to something in terms of, you know, it's not just economic incentives that matter here. And, in fact, if you look at the value-based design, what you'll see is that the programs that are touted as being the most effective are ones that combine some form of disease management or behavioral modification together with the change in price. Those are the ones that really move

behavior. And so it would be interesting to see the extent -- it would be interesting to talk about that because I think that utilization management is a really important element of this.

Then I will end by saying, although I recognize that we will never learn anything from the French, that the French do do one thing that is designed to reduce unnecessary costs, which is to charge for no-shows to physicians.

MR. HACKBARTH: Okay. Thank you, Rachel.

* We'll now have a brief public comment period.

[No response.]

MR. HACKBARTH: Seeing none, we will reconvene at 1:15.

[Whereupon, at 12:23 p.m., the meeting was recessed, to reconvene at 1:15 p.m., this same day.]

AFTERNOON SESSION [1:17 p.m.]

MR. HACKBARTH: Okay. Yes, we still have guests filing in at the back, but I think we'll go ahead and begin with our introductions.

We are scheduled in this session to run till 3:00, and we'll have to adhere pretty tightly to that, and I ask that commissioners help in doing that because, as you know from looking at the agenda, we've got quite a bit after this scheduled for today. So it's important that we stay on time.

We will, as we usually do, have the two rounds of questions and comments, and I'd ask people again to be very disciplined in round one. Limit yourself to clarifying questions only, and I've asked our presenters for their help in that.

Anne, do you want to do the intros?

MS. MUTTI: Sure. Today, we have two hospital leaders to discuss how they've improved care at their hospitals and how they have done, as well, serving a diverse population. I will introduce them in just a moment, but first wanted to remind you of the context for this discussion and give you a sense of our work plan in this

area.

This panel discussion emanates from our work on considering whether Medicare can do more to accelerate quality and efficiency improvement. We've been focusing on what we're calling Medicare's quality infrastructure, and to date we've held an internal panel on this issue back in October, and we've had two public discussions with you -- one in November about technical assistance and what Medicare's role is in that, and then back in January we talked a little bit more about technical assistance and then also conditions of participation.

Overall, our logic for taking on this topic has been that Medicare has a responsibility to both motivate and support quality and efficiency improvement. To motivate improvement, MedPAC has recommended numerous payment changes including pay for performance, penalties for high rates of readmissions, bundling, medical home, and we've also recommended public reporting of quality data.

But it may be that payment incentives and public reporting alone are not sufficient to induce the magnitude of change needed. Support may be needed to enable the full spectrum of providers to respond to these incentives. Some

providers may simply not know how to improve, and some may face particular challenges. Also we wanted to consider other levers Medicare has to motivate and support improved performance, and here we have focused on conditions of participation and whether they could be leveraged more to accelerate improvement.

With respect to technical assistance, we've raised several questions and possibilities for change. Among them are: Should technical assistance resources be targeted to low performing providers or communities? Here we've talked about the wide variation in quality of care. And we've also talked about how targeting assistance in this way could help address racial and socioeconomic disparities in the quality of care since low performing providers tend to serve a disproportionate number of minorities and economically disadvantaged people.

We have also asked who should provide the assistance? Currently, Medicare contracts with quality improvement organizations, QIOs, in each state to provide assistance to providers. Interviews with stakeholders and research have raised questions about the efficacy of this program. Also, in the last decade, more private sector

organizations have begun offering technical assistance. So an alternative to consider, to the current structure, would be to allow more types of organizations to participate as technical assistance agents, and these could include exemplary provider organizations functioning as mentors.

And lastly, what type of assistance is needed? Is it process reengineering? Is it building relationships between providers? Should we also consider providers' need for Medicare data, particularly across episodes? And this may be critical as providers try to reduce their readmission rates and avoidable emergency room visits.

With respect to conditions of participation, we have discussed creating voluntary higher standards for providers. Higher standards could provide additional motivation for high and middle performing providers to continue to improve as they seek ways to distinguish themselves in the marketplace. Another option is to create mandatory outcomes-oriented standards for select procedures, akin to the current requirements for transplant centers. And lastly, the COPs could be expanded to require efficiency improving activities and updated to increase the chance that adherence really results in measurable quality improvement.

To help you determine if this discussion of policy options leads you to a recommendation, Hannah, John and I will continue to research the issues surrounding them, including the ones that you've brought up over the last couple of meetings. But we also wanted to work to provide you a provider's perspective, and that's what leads us to today's panel discussion.

I also wanted to let you know that we're complementing this panel with our own more in-office and site visit conversations with providers, now and also through the summer. In the fall, we'll report back to you on our findings and continue to address any questions you may have. Our thought, subject to your feedback, is that we will have an initial discussion of these issues in this June's report to Congress, but we will make no recommendations.

So now let me turn to the panel. We are very fortunate to have Dr. Philip Mehler, Chief Medical Office from Denver Health, and Dr. Ron Anderson, President and CEO of Parkland Hospital in Dallas, to talk with you today. You have their bios, so I won't use the time to introduce them other than to say that both organizations have been widely

recognized for their commitment to quality while serving a diverse population and have been mentioned specifically by a number of commissioners as organizations we can learn from.

I think this is likely to be a broad conversation, touching on a variety of issues, but for your reference this is a list of some of the topics that we've asked them to address. I won't read it. Instead, we'll just go straight to the panel, and I believe Dr. Anderson will be starting us off.

DR. ANDERSON: I'd like to thank you for inviting us here. We have a lot to detail in 12 minutes, and I'll slip through some of these slides and leave them for you to review, trying to get to the questions and answers where really the meat is usually there.

But we are a safety net hospital in Dallas. We fill a lot of gaps in trauma, for example. I know Karen Borman was one of our trauma surgeons here, and we still miss her. And we do about 16,000 deliveries for babies per year, and about 55 percent of the doctors in Dallas actually trained at Parkland. So we fit a lot of the needs for the community as a safety net.

And we have a very diverse population, very

heavily minority population. That has changed, more toward Hispanic than African American, over the years I've been there. I've been CEO for 29 years.

This is a very busy hospital. It's the busiest in Dallas County, and you see the growth that's occurred with population growth in every place except the ED. In the ED, you actually see a reduction. As the population virtually doubled from 1980 to last year, we actually decreased from 182,000 visits really to 130,000, and that's because we've put clinics out in the community where the patients live and provided a really better mousetrap and instituted a medicine model called community-oriented primary care.

We have built our surgical volume by building day surgery, those kinds of things -- just constantly growth. We're like an HMO except you can enroll on December 31st with a gunshot wound. So it doesn't -- always open.

This is an important slide. It's one of the keys to where we've been successful. In community-oriented care, we've gone out into the community, working with the community, trying to manage the in-betweens -- between our hospital, between our primary care, the sub-specialty areas, but also where people actually live, trying to work in a way

that they might actually be able to help care for themselves, decrease demand. And that's by going out and doing the public health work to determine what's going on in the community, developing interventions with the community's participation, doing the interventions, looking at the results, giving it back to the folks that are there, having them comment on that, and then doing a continuous quality improvement program.

We're located throughout Dallas County, but if you know Dallas County, we're located in the low income areas with now 11 health centers, 8 women's clinics. Oftentimes, they're conterminous. We go to schools, homeless shelters, and basically try to de-emphasize the hospital if we can, but do a lot of things in nontraditional settings.

We've had a program called the Cancer Prevention and Intervention Program where we've done low or no-cost mammography. Just to show you what's been accomplished there, in green, those that are screened, their state of presentation -- his is work done by Marilyn Leitch and Skip Garvey, two surgeons in our place -- and those that didn't screened prior to the provision of free and low-cost mammography.

So sometimes it turns out to be much cheaper for us since we're the insurer of last resort, like Medicare, many times. We're caring for a population, oftentimes Medicare, Medicaid or charity. It's to our advantage to spend the money and to take the barriers down and get the people cared for.

We do a homeless outreach program to 28 homeless shelters, 6 of which are mainly focused on domestic violence. That's also saved us quite a lot of money.

And we've had an outreach program for 30 years in prenatal care. We now deliver prenatal care to 98 percent of the women who actually come to Parkland to deliver. You can see the results are a reduction by almost two-thirds in stillbirth, neonatal deaths, intracranial bleed and days in the NICU. So it saves us a lot of money. When we're asked why we provide prenatal care to undocumented women, the economic argument outdoes everything, but the humane argument should.

This is a look at disparity. We're doing some work also looking at African American infant mortality. You can see we've brought it down nearly to that of the Caucasian population -- again, nothing you could turn on a

light switch with, something that took many years to develop. Even if you provide incentives, you have to gain the trust of the community, and you have to go out there in the vineyards quite a long time. I think you hear similarly from our colleagues at Denver, that this really is not just a light switch situation even if you give us incentives to do so.

This is my Jaw of Life chart. It shows that as we increase the amount of prenatal care, we decrease prematurity. Prematurity, as you know, in the United States is going up. We actually have seen a reduction over the last 20 years, and again this is something that many public systems might be able to teach the private sector. We think it's important.

We were gifted the jail, so we used it for public health intervention. We screen tuberculosis, sexually transmitted diseases. We try to work on care management of mentally ill patients. Sadly, we have 1,400 inmates a day out of 6,000 or 7,000 that are mentally ill, and care management for those is really important. Otherwise, they'd just through a revolving door and cost a lot of money.

These are some of the things that we're actually

doing, and we're trying our best to kind of do outcomes research to see where we're going, and that's important.

We own our own HMO which has over 50 percent of the market. That's to help us integrate care as much as can and do care management.

We now have over 4,500 children in an asthma program. We've decreased hospitalizations by over 50 percent, ER visits by over two-thirds at our children's hospital, and so this care management actually works very well.

I'm going to quickly go through the trauma portion of this and the prevention that we do to emphasize the need to go upstream, to recognize as a payer of last that we want actually to intervene early, take all the barriers down that we can, to try to have an impact that we want. And we've tried to shift our paradigm toward integrated preventive health care and promoting financing that makes sense, that doesn't discourage prevention. You know now if we prevent something in a fee-for-service model, we actually lose money and revenue? That's a fatal flaw.

We want to equip people, so they'll be able to be motivated and have the skills necessary to help with self-

management. And we make prevention an element at the very crossroads in the health care interactions that we have, and we think chronic disease management, where maybe 10 percent of the patients cost 90 percent of the money, is where we ought to really be focusing a lot of our attention.

I want to go over now to where we've worked in quality, where we've been. We were proud to be Parkland. We had no clear method of measuring quality. We had no ability to basically determine if we were actually achieving what we wanted to. We tended to be siloed in departments, and we had great individual effort, but no systematic approach.

We are in a journey, and we are working with people like IHI. We're working with UHC to compare ourselves to our cohorts. We worked with the Texas Health Foundation, the agency in Texas that really works with this, on things like one-day admissions. But mostly, we've worked with outside private groups to try to catch up with where they're at, and so that's, we think, very important to do.

But we also had to change our own board. Our board had played a lot of attention to fiduciary responsibilities, but we have to convince them that quality,

safety and access is a fiduciary responsibility. They made a safety and quality committee basically parallel to the finance committee. They spend as much time on that, and so from the very top of a governor-appointed governance board we started paying attention to that.

The medical school has paid more attention to it, as they've owned their own university hospital and had to. But we used to assume that we were good because we were the medical school's hospital. I would never assume that; we never would.

But these are some of the things that we did to raise consciousness, to really put in a system of accountability, to actually put in rewards to the physicians for achieving goals in quality, and looking at outcomes more and more, and not just throughput. Too many places look at throughput. They don't go ahead all the way and look at outcome, and I think that's an important thing.

So now where we're currently at is organizational analysis, trying to provide right care at the right time and the right place, trying to look at prevention and look at quality improvement programs.

We have a program on readmission for congestive

heart failure. We found that the biggest reason for readmission is socioeconomic, not a physical finding, not a laboratory test, not an injection fraction study. It's the fact that they lived in a poverty area, and they're more likely then not to have the support they need from social services. So we try to identify those on the day of admission, and then by the time the patients get out, get them into a primary care home, have them seen within a week or two because most readmissions occur before the patient is actually even seen, and to try to have that sort of embracing service with social services, dietary and other people there to help them.

I think that's very important, but that's not right now recognized by CMS -- no social severity of illness. We look at medical severity, but I think we need to migrate toward social severity and understanding that.

But the power of the electronic medical record and being able to do outcomes and be able to hold us more accountable, hold ourselves accountable I think is very, very important, and we spent over $70 million in the last 5 years. That's one thing I'm worried about with public safety nets. Many of them, particularly rural hospitals,

don't have the ability to do that, and that's going to be a very important place for you to provide some support.

We redesigned our own ED, and we cut dwell times in half by doing systems engineering with an MBA MD person who we've trained.

We also decreased left without being seen, from 2 years at 15 percent, to 3 percent or less and actually found that those people who left weren't less sick. They basically were sick because our admission rate has gone up as we had more of them stay and be seen and the throughput. So they weren't non-sick people who were just coming there. But I think the biggest key is if you provide another place for people to go, like the clinics we do and walk-in clinic that sees 300 people a day, they will use those in lieu of the emergency room, and you can be quite successful.

But the biggest thing I think is we need to add to our extensive primary care systems a care management system and disease management system, and those things together we think will have the kind of impact on outcomes that we're seeing in some isolated models. We'd love to see some of the models and projects funded. They're really important to try, and I think we'd learn a lot from each other and then

disseminate the information.

Again, I'd like to thank you, and I'd be open for questions later. Thank you.

DR. MEHLER: Likewise, I'd like to thank you for inviting Denver Health to share with you some of the things that we've put in, in the last few years.

I apologize, I got a cold yesterday on the way here.

Very quickly, I'm going to go at it a little bit different than Dr. Anderson, but this is Denver Health very quickly. Similar to what he said, it's sort of the right care at the right place at the right time. So you see there the main medical center, Denver Health Medical Center, which is a 500-bed, Level 1 trauma center.

But the key to our success I believe, over the last five years, is really the fact that: We have public health integrated within Denver Health Medical Center. We have nine federally qualified health center to provide primary care. We have our own HMO. We have Denver Cares which is a non-medical detox, so all these patients that used to come to the ER are now taken to this other facility and detox over there. We have correctional care. We also

have school-based clinics which allow us to take the care to the students at the place that they are, rather than having them come down to the hospital. And then we run our own 911 center.

But the two keys I think, and the takeaway messages, are that: We have an employed physician group. We're a closed medical staff. We employ all our physicians, and by doing so it really gives you leverage to effectuate care versus having private docs come into your hospital.

Then, similar to what Dr. Anderson said, we've invested over $300 million in the last 10 years into IT. We have a fully developed CPOE model, other IT advancements. The combination of the employed medical staff, HIT and then having an integrated system with an extensive array of health centers across the community has allowed us to achieve the success we have.

We care for over 150,000 individual patients. One in four patients gets their care at Denver Care. About 40 percent of Denver babies are born at Denver Health, 35 percent of Denver's children use us, and we actually take care of, through our trauma mission, patients from every Colorado county.

Who do we serve? Well, we really serve a vulnerable people. This makes it tough because there's unlimited demand for services and they don't have, as Dr. Anderson said, a lot of the ability to take care of themselves when they get out of the hospital. So you have to be creative in order to effectuate good outcomes and prevent readmissions.

We take care of the poor. We have a large non-English speaking population, high-risk pregnant women, victims of violence. We take care of a lot of homeless people, public inebriants.

Chronically mentally ill is a big challenge for us at Denver Health. There are very few psych beds within Denver right now. There are only about 50. Five years ago, there were three-hundred psych beds. That's one of the biggest challenges going forward is the ability to integrate mental health within the acute care model because if they're not adherent to their psych issues, they're not going to be adherent to their medical issues.

We also take care of prisoners and victims of infectious disease.

Similar to Dr. Anderson, a very ethnically diverse

population: 52 percent of our patients are Hispanic, 13 percent are African American, 25 percent are Caucasian.

We have provided over $4 billion in unsponsored care in the last 20 years. Almost 50 percent of our patients are uninsured. We only have 10 percent of the beds in Denver, but we provide over 40percent of the unsponsored care in the Denver metropolitan area, and despite those challenges we've remained in the black every year since 1991.

We go beyond the uninsured. We're the major Medicaid provider for the state, which is important for us as a source of income. We're the major provider for CHIP. We have an increasing role in Medicare. About 14 percent of our revenue comes from Medicare. We're the busiest trauma center in the state. We're a major correctional care provider. And we have a number of competitively won grants of about 20 million for disaster preparedness after 9/11.

Despite the challenges of taking care of a poor population, we have been very cost efficient. Our charges are some of the lowest of any peer metro Denver hospital in 25 of 35 categories that are looked at.

We were number 4 out of 102 hospitals and

university health consortiums for length of stay divided by total expense per hospital discharge. For 2009, our admissions were 7 percent over budget, but despite that fact our average length of stay actually fell from 4.6 to 3.8 days. And, as you know, even a 0.1 decrease in your length of stay is very substantial.

Despite taking care of a vulnerable population, our readmission rate vis-a-vis UHC is in the top 10 percent of all UHC hospitals.

Very quickly -- I'm sorry if you can't read this well -- these are some UHC data that would support the fact that we've really gone on this quality journal over the last few years and have really had terrific results. This shows our O/E ratio in the top third of the slide there, and, as you see, our observed to expected mortality ratio for our total inpatient is 0.53 -- so, a 47 percent decrease risk of dying from similar illnesses when you come to Denver Health despite the protoplasm that we take care of at Denver Health.

These are some data from the American College of Surgeons looking at all the trauma centers across the country. I don't know who the other people are, but Denver

Health is the little green dot all the way on the left. We had the lowest mortality rate for any major trauma center in the American College of Surgeons survey that was published last year.

Then UHC does a quality and accountability aggregate where they look at a number of things. Shown here, Denver Health for the last year was number 1 out of 106 hospitals in UHC despite the fact that we're taking care of a vulnerable population, and for 3 out of the last 5 quarters we've been number 1 in UHC in that regard.

So when you sort of distill that down on why there's such a very important, compelling reason to try to improve quality, basically as a result of these, about 133 patients did not die as expected, which is a huge, significant outcome. And we're not talking about end-of-life issues and hospice patients; these are patients that come in with typical medical illnesses.

Similar to Dr. Anderson, we believe one of the keys for improving quality and where there needs to be a lot of focus is on the outpatient. As you know, as a country, we spend about $700 billion a year for inpatient care, but about two-thirds of the dollars we spend are actually for

outpatient care.

In the rest of the country, about 34 percent of Americans have their blood pressure controlled, so about 70 million Americans have hypertension. At Denver health, almost two-thirds of our patients have hypertension controlled. This then results in you have less admissions for stroke, less admissions for heart attack, et cetera. So focusing on the outpatient arena in addition to the inpatient arena, in an integrated system, is one of the keys for success.

This is something sort of hackneyed, but it's something we're proud of. You know hand hygiene has been talked about. It seems real simple, and it's sort of, you know, just do it. But we really struggled with this, and until we put in programs. I think the important thing that we did here is that we don't want to blame people, but we want to hold them accountable. When you have a surgeon that keeps going into the room time after time, something needs to be done in that regard. We actually put in an online system where anonymously people could report people that they saw not complying with hand hygiene, and I think that was one of the reasons we were able to get up to 90 percent.

Our ICU bloodstream infections due to catheters, which is a huge waste of money to treat these infections, just by putting in simple checklists and by putting in a central line insertion cart in all of our ICUs, we've been able to decrease our ICU central line infections markedly -- similarly with regard to ventilator associated pneumonias, by putting in the bundles which are so important and sort of learning from other industries that have been successful, like the aviation industries where you have these simple bundles, where you have these simple checklists, and using those and enforcing them and then, perhaps most importantly, putting these data up in the ICU where you're transparent and you're compared to the other ICUs. Doctors tend to be competitive, and that's what drives change, I think.

So our quality journal in 2009, we won the NAPH chair award, which is the highest award that they give for quality. This is related to a program that we put in. We didn't go with the flow with regard to rapid response teams, which I don't believe makes sense in teaching hospitals. I think what you've got to do is get the residents to the bedside and empower the nurses to call when they think a patient is starting to become unstable. We put in our own

program that integrates the residents into the program.

The message here is I think you've got to know the literature. You got to be willing to say we don't agree with sort of the trends out there, and for our hospital this sort of makes sense in order to sort of reduce the inexorable decline that some of these patients are on.

We have docs that are on the advisory committee for NQF. We have a couple docs that are on the JNC 8 committee. We've been involved in the HIT Senate committee because of the investment that we've made in HIT.

We've published a lot of our things, and I think that that, being an academic medical center and trying to predicate theory on evidence-based medicine, is the way to go. We don't tolerate sort of Gestalt and this is anecdotal. We really try to say what's the evidence and let's effectuate that evidence.

I really think the investments that we've made, we've tripled our infection control staff in the last couple years -- significant expense, but I think that the return on that investment is key because infections continue to be a big issue in all acute care hospitals.

This is just a letter about the clinical triggers

program that we put in for the rapid response. Again, the message there is to be brave enough to say that what everybody is doing may not be right for your hospital and be willing to try something a little bit different.

Another key thing was being transparent with our quality. Initially, we had a quality scorecard that we started about four years ago that was tallied and sent out. The real big thing that we've done now is that we now have a new electronic interface with a data warehouse. It took about six months to develop.

But the key point here I think, which drives quality, is you have to be able to drill it down to the clinic, and you have to be able to drill it down to the physician. We don't believe that physician-related data should be de-identified within the hospital. We want to compare it to the peers in a non-punitive manner and use this quality scorecard on a regular basis, given to the leaders and the physicians of the hospital to drive quality.

So this is just a quick snapshot of it, but basically for all of our outpatient indicators -- diabetes care, hypertension care, et cetera -- we have drilled down to the physician within Denver Health. Again, since we have

an employed physician staff, you can really drive change by having these data available.

Another thing that we've really tried to do is to integrate LEAN within Denver Health, and that's a big message that Dr. Gabow, our CEO, really wanted me to impart here. We've been on this journey with regard to LEAN. LEAN traditionally has been a process measure for finance and other things. I said to Dr. Gabow a couple years ago, I really think that we can use LEAN theory in clinical.

Actually, one of the things that we've applied LEAN to is reducing hospital readmissions. We deal with the same issues that Dr. .Anderson. A lot of these determinants are social determinants. They're not due to the usual things that you'd think, and therefore you have to be creative in order to reduce these readmissions.

One of the things that we've really invested in is to very much augment our UM staff in the hospital, by having more nurses that are there at the time of discharge, by having a discharge lounge where again the medications are gone over with the patient. You get the patient out of the bed, you move them to a different unit, and you reinforce the fact that they need to be taking these medications.

This is the number you need to call when you're having a problem. And we also get them an appointment in primary care at the time they're leaving the hospital, rather than relying on chance where they have to make the appointment on their own, which doesn't seem to work.

Another big issue that we're worried about at Denver Health is this whole issue of abnormal results. We know that what drives a lot of lawsuits are tests that were ordered and nobody followed up on them. This, we're also using LEAN technology in order to improve our abnormal results tracking.

We're also endorsing the Global Safety Score that a lot of hospitals are using across the country right now. It's a group of measures that really indicate there was a bad outcome in a patient, and you simply add these up and continue to track them. So, rather than looking at just an individual one or two indicators, you have this Global Safety Score which is really a surrogate. Is quality in your hospital improving?

Another big issue is to take quality out of the department of safety and quality, and diffuse it into the different departments across the hospital. You have to

engage the physicians and the nurses and the social workers in quality. One of the big challenges is how do you pay for the physicians who are generally seeing patients or doing procedures. We need to give them salary support in order to engage them in quality. Simply to have a top-down approach doesn't work. You have to engage the different departments, and we believe in that, and we've done creative things within every department to have a quality champion that helps us effectuate things, but also creates things within their departments that other departments can learn from.

So, in conclusion, Einstein said, you shouldn't use an old map to explore a new world. We think that we have a new map at Denver Health, and again I think the keys that have been able to help us drive quality across the hospital have been the employed physician group, the integrated system, our investment in HIT and then being creative, similar with our clinical triggers program versus a rapid response team, and similarly with regard to other programs that we've put in that may be a little nontraditional, using LEAN in the clinical arena, being willing to take those leaps to effectuate good care for the population that has a lot of social issues going on and

makes it hard at times to really get good care for them.

MR. HACKBARTH: Thank you -- two great presentations and right on time. It's really appreciated.

So we begin with round one clarifying questions, and let me kick that off with a question for Dr. Anderson. Could you talk a little bit about how your medical staff is organized? Dr. Mehler emphasized the importance of a salaried medical staff.

DR. ANDERSON: We're similar to being salaried in the sense that we have the University of Texas Southwestern Medical School, and we're a closed faculty. We spend about $120 million a year on faculty salaries, and we also pay for the house staff which are our employees. So we work very, very closely with them.

And for many years, before they had a university hospital, we were the university hospital. Now they have their own university hospital, but we tend to have Parkland doctors, and they tend to have university doctors. So it's very much, except they're not our direct employees.

This is a better model -- direct employment -- I'll tell you, because there are many other things in an academic setting too, that people have many masters.

They're trying to publish. They're trying not to perish, and that sort of thing. So it is tougher to get them to focus.

So we've hired some doctors that focus on quality, who work directly for me or our employees. We've had to supplement that to get where Denver Health because they have the people directly employed. So I think the directly employed is a better model.

MR. HACKBARTH: So let me start over on this side and see hands for clarifying questions.

DR. MILSTEIN: Why isn't the distribution of performance closer to yours? In other words, what is it that makes it so hard for other organizations to do this?

I mean we hear a lot from other organizations saying give me 20 years and a lot more money. Why are you able to do it now, deliver these results now, and not have any particular major subsidy to do it? What's the difference here?

DR. ANDERSON: I can tell you part of the difference is leadership. Patty Gabow and Dr. Mehler and others have really had a lot of leadership in there. We've had leadership to try to do some of this.

But I think it's also been a drive. It's a culture -- something we've wanted to do a long time because we were the payer of last resort. We had limited dollars, but open enrollment. We had a vulnerable population. And if we save money, it's not like Kaiser. If it's enrollment, I save the money, I get to keep the money.

Actually, if I save money by keeping people healthy, I create new capacity, and other people come and use it. There's always a backfill in public hospitals. So it's actually a disincentive sometimes. Like in Canada, they bed-block mainly because they don't want new patients necessarily.

We do. We want to actually show better value by being better stewards, and that's been something that's been rewarded for a long time.

But I think it comes down ultimately to leadership and also incentives, and we don't have an incentive to use more. We have an incentive to get better outcomes.

DR. MEHLER: I would basically agree with Dr. Anderson. I think the only additional thing is that there's an urgency when you're a safety net hospital. I mean things can go bad, and a second payer's sources can change, and so

there's an urgency really to do things.

I think the other thing is that because we're lucky to be an academic center -- all of our physicians have an appointment at the University of Colorado with the same criteria for promotion as a doc at the university -- we really try to effectuate outcomes that are predicated on evidence-based medicine. We push that throughout the organization, and we push that with the residents, to say what are the data to say that what you're doing is the way to go in medicine. That combination of the urgency, the academic model and the integrated system I think is what drives it.

DR. GEORGE MILLER: Thank you. Both presentations were outstanding. I really appreciate your being here today.

I'd like to focus my question to both of you about disparities among minority populations and what you've done and what you can see that could be used in a broader sense, to other organizations, from your learning and your understanding and the outcomes you had from them.

DR. MEHLER: I think one of the things that is key that I really did, I was the Chief of Medicine at Denver

Health for about 15 years, and I still see patients on a regular basis and love doing it. I think one of the keys is that you have to have a provider staff that's diversified, and we take pride in the fact that we have a number of African American physicians, a number of African American nurses and a number of Hispanic physicians. I actually employ two full-time Russian-speaking physicians, who trained in Russia and came to the States because there's a huge Russian population in Colorado. So to be culturally sensitive, you have to have a provider staff and a work staff that's also diversified.

In addition to that, we've actually done outcome studies trying to look at our outcomes in our different populations, and our immunization rates are actually -- if you're an ethnic minority, actually our immunization rates are actually better. However, we recently discovered that our lipid control was actually worse in our African American population, and so we're figuring out how we can do better in that regard.

But I think the key is to have a workforce that's ethnically diverse.

DR. ANDERSON: George, I also think you have to

have people interested in doing studies. It's like the alcoholism; you have to recognize you have a problem, and if you recognize it and you see it. Like in the cancer study I showed you, where we decreased from 50 percent in Stage 3 and 4 down to 8 percent, we did that basically because we knew there was a problem. Inherently, we saw it. Our doctors said, what can we do? We tried to develop something to address it and do outcome studies.

We're looking at GI studies in black males right now and getting colonoscopy out. There's a huge, huge issue, but we can prevent that cancer if we find the polyps and remove them. Finding a way to do that may require out-of-the-box thinking. We may have to use different approaches to colonoscopy or virtual colonoscopy or some other way to do that.

If you reward folks for doing the studies and for presenting them, many medical schools haven't thought this is real science. Honestly, if it's not sub-cellular and mitochondrial, it's not real science. This is where we can translate science at the bedside or at the community side quickly, and I think really get impact and payback rather substantially. So I think you've got to reward it, but too

many schools have not paid attention to the social determinants of health.

There's a recent article by the Blue Ridge Association about the value of social determinants of health and why medical schools should be teaching about this. You know that deals with social justice issues and racism and poverty, and that's huge.

Graduating from high school may be the most powerful thing you can do for your lifetime, for your health. So we work with the schools to try to get these kids to graduate.

Those are the kinds of things that you have to have the bigger, broader view. Instead, our health system has been more of a sick system instead of a health system.

MR. HACKBARTH: Clarifying questions?

MS. KANE: With 30, 40 percent uninsured, what are your major sources of subsidy for those patients?

DR. ANDERSON: At Parkland, we get about $400 million a year from the local government, from taxes. We get DSH and UPL, about $170 million which is incredibly important, and we worry about that all the time. But we do $575 million in charity care cost. So out of, well, a $1

billion expense budget, basically charges don't mean anything. We all know that.

We just look at the expense budget side, but we get about 38 percent of our money from local taxes, but our charity care burden is about 50 percent. So I've got to make that up like any other business, and that's why DSH and UPL have been so incredibly important to us.

DR. MEHLER: Similar to Denver Health, DSH and UPL are very important to us.

We've realized in the last couple years that we need to increase our commercial business a lot more, and so we put in very unique programs, using the terrific medical staff that we have at Denver Health. So, for instance, I have a small program at Denver Health. I've been interested in for about 25 years in the medical complications of anorexia nervosa. So I have a small program, a six-bed unit at Denver Health, that I re-feed people that weigh 30 and 40 pounds, from across the United States. All those people are insured. If we can increase our commercially insured population by 1 percent, that's $17 million to Denver Health.

So we have challenges. We have UPL. We have DSH.

We have Medicaid/Medicare. But we've also realized that we can't continue to be the old Denver General that people knew from 40 years. We changed our name. We've really tried to compete, and by improving our facilities at Denver Health, we've been able to attract more commercial patients which are very important to us.

DR. BERENSON: Just following up on the payer mix issue, Dr. Mehler mentioned that I think Medicare was 14 percent of your revenues. Could you, Dr. Anderson, tell me what it is at your place?

DR. ANDERSON: It's in that range, about 10 or 12 percent, and most of the Medicare business we have are crossover patients in Medicare and Medicaid. So they're actually our target population, and they're the poor. I mean that's typically the population.

We're finding more and more it's very difficult for people to get Medicare, a new provider, and so actually we're getting more Medicare business. It's growing because private sector doctors are not accepting Medicare. So we see that as a new population we may have to gear up to do. We have a very busy geriatric program.

DR. BERENSON: Is that the same situation in

Denver? I've actually heard that Denver is a particular problem of Medicare patients finding doctors. Is that what you --

DR. MEHLER: Absolutely. The medical community has disembraced that population. In fact, in Colorado Springs, which is the third biggest city in Colorado, none of the sub-specialists there will take Medicaid as a source of payment, and so we found that our Medicare business has gone from single digits up to 14 percent over the last 4 years. We actually view it as an opportunity for us. Especially if we can get them enrolled in our Medicare Select, our own HMO at Denver Health, it actually makes money for us.

MR. BUTLER: Okay. So I'm going to borrow a little bit from a topic we're covering later today -- graduate medical education -- because you both have referenced it.

So, for Ron, you've been there a long time, and you've seen your program increasingly embrace the community-oriented primary care. So first, my question would be to you. How have you aligned, or how have you adapted or not, the GME program to be a facilitator or a supporter of the

GME?

And Phil, on your side, you've got a little bit more inwardly measurement, LEAN process. How is that filtered or integrated with the graduate medical education training? Are residents getting LEAN techniques taught and so forth?

So, same question but kind of different, how do you adapt or use your GME programs in the quality improvement processes?

DR. ANDERSON: Thank you, Peter.

We have our COPC doctors, who work out in the community, are our employees. The medical school said they really didn't want to go there back in the nineties. Some have gone there. Pediatrics has gone there. Family medicine has gone there. OB/GYN went there in a big way many years ago.

But my own department, internal medicine, was very traditional. They didn't want to go off campus. You know doctors can't go off campus. Something bad may happen as you travel from the medical school. You know.

However, we have a new General Medicine Director, Ethan Halm, who is very interested in this and wants to do

population-based studies. These are wonderful opportunities, laboratories, I mean to understand the public and population-based medicine. And we have a school of osteopathy in Ft. Worth that wants to send their students. So I'm using them to leverage my medical school, to say, why don't you really look at this? This is a wonderful opportunity.

In regard to learning about quality, access, safety issues, the compliance issues in the hospital, these students oftentimes are turned loose on the public without having any knowledge at all about what they're going to do when they go into practice. We're trying to expose them, but right now it's again more the hospital pushing it. At the medical school center, our curriculum is so full, and it is full. But it was said once, we had the best residents in the world, and after you retrain them they're even better.

DR. MEHLER: At Denver Health, specifically in regard to your questions, we have the chief residents from all the major services participate in a LEAN event, what they call the Rapid Improvement Event. It's a weeklong event to address a clinical issue -- so, the medical chief resident, surgery chief resident, OB, Peds and psychiatry.

We're a very inbred program, so a lot of our docs actually have trained at Denver Health and at the University of Colorado. So if you expose them to this way of doing things as residents, then when they become your faculty it's easier for them to integrate into what they do.

I think the biggest challenge right now with GME and everything is some of these mandates about the work hour restrictions, which I think the evidence sort of supporting them is somewhat tenuous, and it's really creating havoc within the hospital because of the handoffs that have to happen and the shift work that has to happen.

I really worry that the next generation of physicians, we have to rethink how we're training them because in my humble opinion it's way different than it should be right now, and I'm not sure there's a lot of evidence supporting it. So just like I promote evidence-based medicine, and my docs on the medical staff, I think that we need that with regard to graduate medical education.

MS. HANSEN: Yes, this is in relationship to the Medicare population that you both serve, and, Dr. Anderson you brought up that you have a robust geriatrics program. I wondered if you could talk about that a little bit and

whether or not we have something focused on that. I'm thinking about measures since outcomes are so critical in your commitment, the use of ACOVE measures, the acute care of vulnerable elders in hospitals.

And then just you mentioned using a team of people, that is nurses and social workers, to work with the physicians. So I'm just curious about that whole part because we've talked about that in the past here. How do you get to that point?

DR. ANDERSON: We, like I think Denver General, see -- the Denver Health hospitals see actually the Medicare population as an opportunity for us. We get a lot. We have the largest house staff training program in Texas. So there would be some incentives for somebody because Medicare is a good payer from the educational point of view. A lot of other people in Texas, Medicaid doesn't help us with education and that sort of thing. So it's important for us to look at that.

But it's also the underserved. Who is our underserved population? We have 400 elderly minority patients in a swath where there are no clinics in Dallas, which is less populated, that we actually do home visits

for. We go out and we take people from geriatrics to do home visits. You don't really know your patients until you go in their home type of thing.

The central campus, where we do the evaluation for, say, Alzheimer's or where they do the very long tedious evaluation which isn't paid for very well, that's always cross-subsidized.

But then out in the community, we try to get doctors interested -- family medicine and internists -- in geriatrics because we're not going to have enough geriatricians. We have three on the family medicine faculty. We have about seven on the internal medicine faculty. But we're training fellows in everything, but that's still not enough to really do anything. We have to get added competence and get people to want to do this.

I think connections to nursing homes that has been done in Wishard in Indianapolis, where they actually covered nursing homes from the academic setting. Some of the care in some of the homes are not very good, frankly. So I think we could integrate a lot of that better.

And some of the managed care products that are coming out in Texas are looking at how to deal with the

people who have the high burden of illness, and so I think this is a population we're pretty good, and we can actually care manage those people and really given an opportunity. So we see that as a calling.

Thirty-eight percent of the Texas doctors take Medicaid, and probably sixty, seventy percent will take Medicare. It's a problem that we see coming, and we think we have to get ready for it, but just a tsunami in aging. So if we don't prepare for that, we're going to miss I think the real public health aspects of this.

But we're looking at PACE as well. We're looking with the Volunteers of America. They're doing PACE programs. That's not our core competence, to do all the social services they do, but it might be that we would provide the medical care and basically use a PACE model, which we think is probably one of the best models.

MS. HANSEN: The question of metrics for the ACOVE, do you do that in the acute facility as part of your quality measures?

DR. ANDERSON: Yes. Yes, we do.

MR. KUHN: I know, Dr. Anderson, you said your statement about the importance with your governance of the

quality effort. Could you tell me, and also Dr. Mehler, about how much time do you spend at a typical board meeting on quality issues, and what particular metrics are the most impactful or the board members find so much useful in terms of viewing what you're all doing in performance in this area?

DR. ANDERSON: I think the numbers -- sometimes we used to say statistics in public health were the human tragedies with the tears washed away. We actually sometimes bring patients to talk to our board, not just the good ones, but we also present seminal events, never events. We're trying to make that more transparent instead of behind closed doors, which is always the liability the lawyers want you to do.

But we also use the same sort of bundles and scorecards, and we've actually -- my incentive salary is tied to quality.

But we used to spend half the time on finance, and now we spend about a third of the time on finance and about a third on quality and access, and about a third on compliance and other issues and strategic planning. It's much more balanced than it was.

But when you look at people who get appointed to public hospital boards, I mean a lot of them are bankers and a lot of them are people that are very substantial folks. We had recently our chair as an African American woman is a nephrologist trained at Parkland, and I can tell you that she wants to focus on quality and on disparities and other things.

I think that really matters, who is on boards. But people tend to do, on boards of hospitals, what they do in real life, so to speak. So, if it's all bankers, it's going to be mostly about that. So I think we have to start enriching these boards, and we need to educate them about governance.

If it doesn't start at the very top, but it also has to start with the medical advisory group, and they need to be an empowered group of physicians. In academic medical schools, a lot of times it's the chairs who control, and basically they're in their little silos. So we've had a terrible time trying to go from a medical advisory council to a medical executive council where the doctors at the front, on the line, are actually empowered to make change. Sometimes it's been a peculiar thing to watch because that's

what we need.

We need doctors at the front who are actually doing this every day, to be involved in fixing this. They come and make reports to the board, and we identify projects. We celebrate projects that have been successful. We also talk about ones that weren't successful. You learn as much from failure as you learn from success, but I think the key is you've got to be willing to talk about it and put out and make it transparent, as you go down to the individual doctor level. We're trying to get to the point where we can go down to the individual doctor level, so that we can do that, not in a punitive way, but in a way where we can open this up as much as we possibly can.

But every one of our meetings, we'll have all those bundles. Whether it be pneumonia or bloodstream infections or other never events, they're all displayed basically on something that a lay person can follow.

DR. MEHLER: I think it's really the same thing at Denver Health. I think across the country the sort of mantra of board on board is where everybody is going, that it's not only a financial, but it's also a quality fiduciary responsibility.

In addition to that, some of the things we do at Denver, similar to what Dr. Anderson said, is we always have two physicians as part of our board members, and one comes from the dean's office at the school, and one is from actually the private community.

In addition to that, we encourage the board members to round with us in the hospital, and I think that that's very important, so that they understand the challenges that we have. So, when I attend on the medicine service, which I have for close to 30 years, every day that I'm attending there's one of the board members there that are rounding with me. The patients love it, and the board loves it, and the staff love seeing them there which is important.

We also, on the day of our board meeting, we have what's called the EQAC meeting which stands for Education and Quality Assurance Committee, which is a board committee that reports directly to the board. And similar to what Dr. Anderson said, we review all sentinel events that occur.

Actually, one of the key things that have been very good over the last couple years is they want us to report on sentinel events follow-up six months later. Show

us what's happened to prevent it the next time. So we do a root cause analysis. They want the outcomes from that root cause analysis presented in six months to show what Denver Health has done to try to prevent that sentinel event from happening again.

I've been involved in the administration of Denver Health for many years, and there's clearly been an evolution. None of this stuff used to be discussed in a board meeting, aver the last number of years it's probably a quarter or a third of what we do at every board meeting.

MR. HACKBARTH: Other clarifying questions?

Okay, let's go to round two, and I'll kick off round two.

So both your organizations are exemplary in terms of quality, efficiency, population health, and you both work in environments where the resources don't come easily because of the populations you serve, among other factors. So what we're looking for -- we often hear in particular from institutions that are challenged in that way, in terms of resources, that, well, we want to get better, but it's really hard for us.

So, if you were on the other side of the table, in

thinking of, charged with the responsibility of saying, here are the policy levers that could help other institutions achieve what we've been able to achieve, what sort of policy tools do you think ought to be looked at?

One example, just my question may be too abstract, is obviously a part of the Medicare program is the QIOs, and there is a notion that we provide resources to the QIOs, and they can help institutions get better. Do you make use of that resource? If not, why not and what other tools do you think might be better than QIOs?

DR. ANDERSON: We used the Texas Medical Foundation and worked with them because we had problem with single-day admissions. Part of it was we had no beds, and patients were under observation. We created a better way to handle that, but we concurrently review every admission. So now we actually solved that.

But a lot of times our physicians weren't caring about reimbursement. They weren't getting paid more. They were worried about the patient going home. They were worried about a homeless person who couldn't get outside care, I mean didn't have the resources to get home care. So they would put them in for social admissions, those kinds of

issues.

It's hard to know that the doctor is working in good faith, and then you may be punitive if you don't -- you may have penalty if you put the person in. So we've actually admitted some of those people and just don't charge for them. We just don't submit a bill because we think it's protecting the patient. So we've had to accommodate some of that.

But I think the work with IHI, I like their rapid -- they have rapid implementation program you can sign up, and we've done palliative care and things like that with them, where you really see something come out. I will tell you it's much more effective than what I've seen done even with committees and people working in good faith with the CIO. So a lot of people are going private.

What would I say to other people who tell me that we can't be as good as you are or whatever? That didn't happen overnight. It happened. It's a journey. Don't let perfect become enemy of good. That's part of the problem.

And it would be great to set up an incentive program that people get better, and as they get better they get incentivized to get better because sometimes they can't

jump a canyon in one jump. I mean they're going to have to go down the canyon and climb out the other side, and that's what they're afraid of.

I see this in Texas all the time at the rural hospitals. They just don't know. There's a huge digital divide between what they can do with information systems, for example. So they're almost waiting for some new technology. Instead of cable, we're waiting for a cell phone, and I don't know if that's coming.

In the public hospitals, I'd hate to see you lower our standard, so that we can basically limp along, and we'll be okay, and we'll get paid for mediocre care. You ought to challenge us to provide the best care we can, and we can.

But I would say on the other side we may have actually done a better job than some other places have done in the private situation with our patient population, and I'd hate to penalized because my patient population is sicker or poorer. I see a lot of times people don't understand the socioeconomics of the patient population we're dealing with, and the constraints, and I think that's why we need some studies on social severity.

DR. MEHLER: I think very similar to what Dr.

Anderson just said, it has been a journey. It's nothing that happens overnight. But I think really the message has to be to everybody also out there, if two safety net hospitals can achieve this level of quality, then what's wrong with everybody else, and why can't you do it? I think that has to really be a message that gets out there.

In addition to that, I think that to say woe is to me because I'm strapped for resources, I think you really have to look from within and say, where is there waste? There's a lot of waste that happens in hospitals.

As we all know, the incentive systems are misaligned right now, and we have to figure out in order to do evidence-based care and not care that just I sort of feel like doing today. The way to do that is to give concurrent, timely, peer-reviewed feedback to the docs, to say, if the other docs in your clinic are achieving 60 percent hypertension, why are you are 30 percent here? And I think that that's very important in order to drive care.

In addition to that, I think the way that you sort of tell people how you can make a difference out there is to really emphasize the fact that you have to understand that most of the medical costs are actually in the outpatient

arena. Certainly, we spend a lot in the inpatient arena. But getting to integrated care systems and getting to the medical home, the true medical home that everybody agrees makes sense, in a way, that integrated system is a way to achieve good results. When you have fragmented, open medical stats where you don't control a lot of those things, it's difficult to get your arms around it.

MR. HACKBARTH: Okay, let me see hands.

DR. BORMAN: I wonder if each of you could touch on two things that I think you both have experience with. One is if you were challenged to identify some metrics that would represent quality educational processes, because you're both important elements of university teaching programs, academic medical centers, things that you, for example, some of the achievements that you have, can you relate those to things that could be measured as the quality, that reflect the quality of your education programs as play out in your health systems? That would be one.

Are there some things that if we measured you on, you would do well, and we would want to be able to apply those same metrics to other. They're achievable with the right kind of systems that include graduate medical

education. So that would be one. Are there any metrics like that? What should they look like?

And then secondly, the notion of, and I want to emphasize at least from my knowledge of at least one system at the table here, that they've both I think underplayed a lot the leadership contribution to what has happened in these two places, and they both need to take a lot of credit of that and others in their system they share that with.

But thinking about that, how would you recommend, for example, is there a way that we can use the Parklands and Denver Healths as intentional mentors and resources for other like places? And not necessarily even like. Ron, for example, you invoked the multiple rural hospitals in parts of Texas. How can Parkland be a mentor and aide to them, and how can we potentially help you be that through federal programs?

So those would be my two things. That is what are quality education metrics as it plays out in your very good systems, and then how would we utilize programs like yours? How do we actively mentor others to achieve where you are?

DR. ANDERSON: I think in the past we have had a very good residency program, very competitive. We have

measured it basically as deans of medical schools would measure it. You know, how well did we do the match? And we get the best residents in the country and those kinds of things and that sort of business.

I think a lot of times the best doctors are not necessarily some of the folks that are the highest ranked, although we are still looking for that. But I'd like to see how many people actually go out into areas where they really make a difference. We are trying to get some people to study systems to look at, you know, comparative analysis, comparative effectiveness, look at some of the research programs that really we need to help answer the problems that face Medicare and others. And we do not see enough of that kind of research. You know, the type of funding that might come from that kind of study and see house staff go into those kinds of things, you know, in an academic discipline, how many go out and do that, and what type of impact do they make.

I have been on programs where we have a local mentor and we have a national mentor with young faculty. For example, they leave from our house staff and join us. I think that is a very good way to go. We did that in

patient-center care, a study on patient-centered care. I think we need to do that also in this evidence-based work looking at quality but also looking at the other issues that make our systems function better. Evidence-based policy, if we believe in evidence-based medicine, we ought to be doing evidence-based policy. And I think that would be good to see if we have some -- we don't have to have every house staff come out.

Ultimately, you have got to be clinically competent. You have got to be really clinically competent and learn how to think so that you can face the new challenges that come out. I think that is one of the things we are known for, is we didn't just teach you facts. We teach you how to think and how to solve problems. But I would like to see those physicians actually become part of the change leaders that are out there, and many times they just want to go practice medicine and that is the end of it, that is it, and citizenship is not the issue. And that is okay, but I would like to have some who really enter this arena. This is a battlefield where we need their talent.

We also now are already mentors to many of the systems. We have had over 30 countries come study our

community-oriented primary care, many other health systems who have come to look at it, and I know they go to Denver. We have a system that works, but we invite them all to come. We are working now with the Center for Primary Care in Atlanta, and we are going to doing a COPC symposium this fall and look at -- you know, basically you need more than primary care. I have been in that and really pushed it. But poor people need access to some specialty care. They need access to integrated care within the hospital and back out again. And you need every place basically to be on the same agenda and working toward the same thing, and people do not get to see those systems. We love to mentor folks, but we also love to learn from others. That is an important part.

It would be great to have some pilot projects and have a national group of maybe 10 or 12 hospitals like ours who agree to participate in a rapid response research project, for example. Some of those things have been done. AHRQ does some of those. HRSA does some of those. But I think those are the kinds of things where we might be able to look at a national perspective very quickly. IHI does this. How can we rapidly deploy something that would affect

policy in two years instead of waiting 10 or 15 or 20 years? I think that would be -- most of us would be glad to do that, I think.

DR. MEHLER: We don't actually have our own residency. All of our residents come from the university. So one of the markers that we use that sort of we are doing a good job is that when the university tries to pull them back, the residents revolt and say, "We love being at Denver Health." And so we use that sort of as a marker that, you know, we're giving them a good education there.

But I would flip that around a little bit, and I think that in the 1980s and 1990s we gave residents too much independence. So when I trained at Denver Health in the late 1970s and early 1980s, we ran the hospital. We defended Denver at night. And I think we need to take that back, especially because of the work hour issues. I think the attendings have to be involved on a daily basis.

When I used to attend on medicine, I had to write a note one in four days, and that was it. It was easy to be an inpatient attending.

I think that because residents are students at the end of the day and their training is much more fragmented

than it was years ago, I think that we have to impel the attending physicians to take ownership of their service in order to impart the quality to the residents more than we used to because now I think that their care is so fragmented and their training is fragment that if you do not do that, I think you are really apt to have bad medical outcomes. And one of the reasons that we have been on this journey and have been successful is we have done that. We mandate that there is an attending note every day. Regardless if you are a high-priced neurosurgeon or an internist or whatever you are, you have to see the patients every day and write a substantive note in the chart.

And so one way that we measure that is we started to do pro-fee billing, which we never did before. Physicians never had to document anything. Now they do. And we follow their earnings that come out of that as a marker of how much are you involved in the patient care. So I think we need to really drill that into all hospitals.

In addition to that, as Dr. Anderson said, we have a LEAN Institute at Denver Health where we have a lot of countries come in and sort of learn how we have integrated LEAN into the clinical and into the hospital arena, and that

has been good. But we'd love to see Medicare do some demonstration projects with regard to accountable care organizations. We really think that we are poised at Denver Health to do one of these studies because we have the integrated system.

As Dr. Anderson was saying, I think, before we started today, if you have a number of private docs that sort of come in three times a year in your hospital, how do you divvy up those dollars from an accountable care organization? But when you have an integrated system with primary care and ER and all the components that we do at Denver Health, I think that we'd be able to demonstrate for you all a way to make this happen and to promote this idea that really if you want to change quality in organizations, you have to have these integrated care delivery systems.

DR. CASTELLANOS: First of all, we really appreciate you being here, and the comments were right on line.

Glenn asked about policy tools. Karen asked about what other tools can you do, like systems. I happen to be a urologist in a community, and we don't have an academic center. The closest one is 150 miles away. We are on a

fee-for-service model. We're not on a salary model. We're totally fragmented. We don't have integration. We're just beginning to get HIT in the hospital and in our community. We don't really have strong leadership. In culture, we compete against each other. We are competing against the system.

There is a lot of distrust. My population is 73 percent Medicare, and because of what just happened with the cuts on Medicare and the insecurity that we have on whether we are going to get funded or not, it really makes a big difference on who I hire and what I hire, whether I buy HIT, whether I do this, whether I do that. So we have a different community, but we still want to get better. We still want to get where you are.

We do practice evidence-based medicine. We do have the incentive to get better. But we don't have the academic model, we don't have the leadership, and we don't have the culture. Where the hell do we go now?

DR. ANDERSON: Sometimes not having the academic model may not be, you know, as much of a burden as you think. I love what I live, I suppose, but, you know, sometimes it's very difficult also in an academic model for

people to pay attention.

There's an old statement that a guy told me years ago when I went into academics, he said, "You have to learn how to be selectively irresponsible to make it and to become tenured," because you can't pay attention to everything.

Well, we're asking people to pay attention to everything. We really are. There are ways to create review groups. There are ways -- we're looking at some public hospitals in Texas in a study called Tex-HIT that Ruben Amarasingham did looking at the digital divide between public hospitals, private hospitals, teaching, non-teaching, and rural-urban. And, you know, it was really, really bad if you were in that rural hospital, non-academic affiliated and that sort of thing. You're waiting for that new technology to come.

But there are some, you know, maybe portals we're looking at on the Internet where we could actually reach out on the Internet and provide a portal for people to come in. And we met with a granting agency yesterday to try to explain how we could actually, you know, serve as a portal to help using our base, our investment, to have other people get in through an Internet connection. It has not been done

anywhere, but we need to study that because there is a huge, huge need out there to standardize.

We talked a little bit, Philip, about the waste. Waste is something -- we always talk about fraud and abuse when we're angry with the industry and we want to see change. I've watched it throughout administration after administration. I am far more worried about variation, and variation that cannot be explained, and it just costs a ton of money within communities and also across communities. And we have this example in McAllen, Texas. I think I know what the diagnosis is. They're for-profit, position-owned, equity-owned situations. There are no public, no nonprofit, et cetera, et cetera. And so, you know, it doesn't take rocket science to figure out why utilization levels might be really high.

But I think there are ways that we could reach out, and maybe on a regional basis. Texas has seven medical schools. Could we regionalize? One of the things I was going to speak to, we are a regional trauma center, but we're locally funded. We take care of people from a huge, huge geographic area because we are capable of doing that, a burn center, maternal-fetal medicine, neuro intensive care,

et cetera, those kinds of things, sophisticated cancer care. How could we work with those folks who are not close to an academic center and be assistive to them without stealing their patients? You know what they are afraid of, is if they ever send them to us, they go into a vortex and they never come back.

And so what we have to do is become serving leaders and send those patients back home when they can be cared for back home. And so I think that we need to work those things out on a regional basis, and right now we are living with policies created in the 1950s, county-based finance systems that make no sense at all. We need to at least have regional finance systems, or the Federal Government or someone else saying let's use the resources we already have, the medical school, to become regional centers, and let's reward them for reaching out and taking care of people across their jurisdictions.

And I think particularly in things like surge capacity, there is no business model for us to create surge capacity, but we need to for the security of this country, for H1N1, for SARS, et cetera. What could you do to stimulate this through the existing resources and task them

with helping others and task them with being mentors to the rest of the system? You know, we can create a virtual network pretty easily without ownership, and the technology is there.

DR. MEHLER: I think a couple other ideas, and certainly I do not by any means have all the solutions to that. But I think that providing data to the private folks in the hospital I think is very important. So why does Joe Blow have a readmission rate of 4 percent and yours is 11 percent? Why is your blood use twice as much as someone else in the hospital? And figure out systems that could provide credible data in a concurrent and timely manner I think is important across all facets of medical care.

In addition to that, if you look at Eric Coleman's paper that was published in the New England Journal about six months ago looking at readmissions in Medicare, it's fascinating when you look at some of the small print in that study, but 50 percent of the patients that got readmitted within a month were actually readmitted for medical reasons, not surgical reasons, in the surgical population. To me, I think that we have to be more integrated within hospitals, and we have to stop these silos, so I am a medicine patient,

I can't get the surgeons involved, and vice versa.

There was just a study published in the Archives of Internal Medicine this month that looked at ICU outcomes to say for hospitals that don't have a lot of intensivists, how can you achieve great outcomes? And the key there was a multidisciplinary team to effectuate care.

And so I think that we have to -- at Denver Health what we have done -- and I have a couple scars on my back from this. We put in mandatory consults. If you have staph aureus bacteremia, you get an ID consult. I don't care how smart you are. I don't care how many of these you have taken care of. Because we published a couple studies on this showing that care, as Dr. Anderson just alluded to, was very varied across providers. You can't have that. There's one way that you take care of staph aureus bacteremia. There's one duration of therapy that you need for them.

And so I think that we have to be brave to say that there are certain conditions when you need a specialist involved and you can't be out there on your own. Whether you are in at Denver Health, whether you are in a private hospital, I think you need to have systems of care that ensure that the patients are getting good outcomes and you

don't have a cowboy out there who is sort of doing it the way he has done it for 20 years but nobody sort of holds accountability there. And I think the more that we have systems through CPOE that put in guidelines, so when you put in an order for a CTPE, it says have you calculated a Well's score to make sure this person is likely to have a DVT or a PE.

As you know, CTPE's are being used way, way too much in the United States right now, creating health issues with lymphoma and other issues, but just waste of care.

What we have done is we have embedded rules in CPOE that you have to answer the rules in order to move to the next step, and that's important. If you make it part of the work flow, even in private hospitals or public hospitals, that then drives care if it is evidence-based.

MR. BERTKO: First, let me be the next among -- it's great to hear success stories from you guys and your leadership teams. The question I have is: If you were sitting on this side of the table, how would you get the attention of the other hospitals around? And I'm guessing that you guys have constant financial pressure from your funding sources. What we find, at least, at Medicare

hospitals is that they frequently have pretty good revenue streams from their private payers. And what would you have us do or what would you do to get people in your peer hospitals to act a little more urgently on these quality issues?

DR. MEHLER: Well, I think that the key is transparency of data. I think that we have the power within IT now to give good data back to people, and I think we have to have transparency across health care systems. And I think that that is what is holding us back in many places. In many hospitals you have no clue, really, when you drill down as to what's going on.

And so if I was sitting on the other side of the table, I would say that if a safety net hospital like Parkland or Denver Health have been able to achieve this phenomenal quality success and this creativity, there's no reason that people that have commercially insured patients can't achieve it.

But more importantly, as Dr. Anderson also said, data, you need data, and you need to have transparency in health care so that there is nothing hidden. And regardless of your standing in the community or who you are,

everybody's data is out there. And we talk about it at the Med Staff Executive Committee, and if there is an outlier -- we have moved too far. We say no blame, no blame in medicine. But we've gone too far. As Wachter and Pronovost have really promoted, no blame is fine, but there's got to be accountability. And the way you get accountability is by having credible objective data that are shared and that you hold people accountable for. That to me is the key.

DR. ANDERSON: I'm actually, as a disclosure, on the board of the American Hospital Association, and as I've gone around and looked at a lot of the hospitals and visited, I've got to tell you, most people are very -- they're good people of good will who want to see things better. They want to align with their doctors. Sometimes the doctors don't want to. There's not that ability to align as much. There's a lack of trust. But they're basically good people, and I think we could harness a great deal of good will that is existent in the profession and the industry if we actually also try to recognize that we all need to be on a journey to get better daily.

There is an Indian proverb that says it's not noble to be better than another man but to be better than

yourself yesterday. And if we look at that and we are trying to improve all the time, and we put incentives up there for improvement, some people are going to start at a different place, but you don't want them to say, "I can't get there." You know, "I don't want to jump rope, put the rope on the ground, I'll step over it." No.

I mean, we have got to set some standards. We've got to try to move toward the incentives. But I would reward people actually for moving in the right direction and giving doctors an incentive to align with their hospitals toward that direction instead of seeing themselves oftentimes in competition.

But, you know, when the business model prevails and the doctors have the day surgery center across the street and they're competing with the hospital, and they give the hospital the really sicker patients, we see stuff like that all the time. It's hard to compare, you know, what's happening in one setting versus another because of financial incentives.

I would like to see us be able to neutralize those and to put the patient first, put the outcomes we really want first, and put them out from in front of the people to

get them. And there are people who've done it. I mean, everybody has role models, and I won't hold us out as a role model. We still have a long way to go to be where I think we ultimately can be. And so we would help other people go down the road, but we also need to improve. And I think that is the important thing, because none of us have arrived. I don't know any place in the country, no matter -- we'll hear Geisinger mentioned, and you'll hear, you know, Virginia Mason. Everybody writes the stories. They have not arrived either. They are all on a journey. But they're starting at different points in their journey. So I would encourage people to get on the road, if you will, and have incentives for them to do it.

You know, there's a lot of people who worry about punitive, they're worried about the stick and they want the carrot all the time. You're going to have to have a mix of both.

DR. MILSTEIN: A couple questions. First, I think probably everybody here would agree that with your first prescription, the way to achieve this is through exceptional leadership. But if you think about the words "exceptional leadership," it's not a nationally scalable concept, right,

because of the exceptions. I think in most industries the exceptional leaders are the ones that the rest of the industry learns from. That's how it works. In the very competitive industries, everybody else learns very quickly or they're out of business. That's not, you know, in a somewhat less competitive hospital and doctor industry, you know, you don't have that going. And so we then, you know, turn to the problem of, you know, granted, our society needs people like you who can discover, you know, the better, cheaper ways of delivering health, but then we have to -- then what do we do for everybody else?

I think you've already actually done a terrific job of giving us some ideas on that, and I think the nature of the prior questions really, you know, I think, aligns with what we know about innovation adoption. That is, if you can make them more observable, it's easier for unexceptional people to copy them. And I think things that you're already doing such as, you know, setting up the LEAN institutes and allowing people to sort of come on site and kind of see, hear from peers, you know, who are in the same job that they're in how it's being done and how it really is feasible could really make a difference.

But thinking about how you might, you know, speed the rate of spread it seems to me does really on the tools that you mentioned earlier about, you know, you have to think about can you do this by tele-video consults with those that are really, you know, succeeding; how do you do it so it doesn't require people getting on an airplane and flying to Denver or Dallas, which is obviously a barrier for a lot of clinical teams.

So my question is: Are there some things that, you know, could be done to aid and abet that would be -- you know, while we're waiting for the technology to put in place to allow any clinician to tune into your best clinical teams, you know, is there something we could do? I'm thinking about in the early era of utilization review, Milliman and Robinson put out a set of so-called, you know, length-of-stay guidelines that had actual -- some suggested inpatient clinical pathways that would get you, based on what the exemplars had done, you know, a shorter length of stay, better -- not so much better outcome, at least a shorter length of stay.

For those organizations like yours that have really been working on this for a while and have, I think,

very advanced notions as to what the best clinical pathway might be for X, Y, and Z -- maybe you don't have, you know, A through Z, but for many things -- is there an opportunity for that to be kind of bundled into the -- I'll call it the inpatient or in the case of, you know, chronically ill ambulatory care, kind of, you know, version of the M&R guidelines that would essentially make it even more easy, you know, for people who are -- who don't even know about what you're doing to essentially replicate what happened with the M&R guidelines where you have, yes, it's a cookbook and, yes, it would take medical leaders to figure out how to adapt it to institutions and then populations in different circumstances. But I think anything we can -- what are your thoughts on how we get this stuff spread more quickly? Because, you know, exceptional leaders like you are few and far between in the industry.

DR. ANDERSON: I've been an educator all my life in the medical school and still see patients and all that, but, you know, sometimes education is not the answer. I hate to say that because you really think that that's all you need to do, and I really want to continue that. But sometimes you have to put hard stops in with explanations.

So it's not necessarily cookbook medicine, but a CPOE will tell you what medications you can use and, by the way, this one is extremely expensive and this one is generic now and quite affordable for your patients. And so, you know, what is the difference? You can get the more expensive medication, but you have got to explain yourself. And we put in some hard stops that you can go around, but you have got to explain yourself, and you're subject to peer review.

I think sometimes it's that kind of behavioral change, so behavioral interventions may be actually as important as educational interventions, and so a mix of those things. But there are programs available in the CPOE approach to algorithms and that sort of things that help you standardize care and help you force out variations. That's really ready now. Many of the ambulatory settings and that sort of thing, you know, HEDIS recommendations and things. We're measuring more process than outcome. We're going to have to evolve to get outcome. The process in the meantime may be where people need to start.

DR. MEHLER: In addition to that, I would just say that the whole science of quality assurance and quality improvement I think is pretty young, and I think it's not

well developed quite yet. It would be an interesting that I've thought about a couple times, is that an organization like UpToDate, which really all the residents breathe when they're in the hospital, there's no UpToDate on quality improvement in hospitals. What are the bottom-line things that work that improve quality of care in hospitals? It would be neat to have the leaders of quality in the United States get together and work with UpToDate to put in programs that are updated every quarter that say this is the latest and greatest with regard to improving patient safety across the hospital. So I'd like to see that go in as a way to do it.

The other thing is that, as you know, after the studies in the 1990s that proved if you give a patient a beta blocker after a heart attack, you improve their survival. We know that it took 15 years to get docs to prescribe beta blockers. It doesn't make a lot of sense.

And one thing we struggle with at Denver Health -- and I would really echo what Dr. Anderson said. We're not nirvana. We have a lot of improving at Denver Health. We're doing a good job, but we have room for improvement. And if you don't believe that, you're in trouble. You

better get off the boat when you get too cocky about those things.

But I think that we all have guidelines. I was just talking to Dr. Anderson's CMO over the last few days. He and I have become buddies. And, you know, one of the big issues, we all have policies and guidelines and care practices, and you go there and there's thousands of these. But what we need is dissemination. We need dissemination committees in hospitals and medical communities to say this is what's out there, now let's figure out a way to get the information to the providers and to the bedside. That's what I think is lacking.

So in response to your question, how do you speed it up? We need to spend as much time on policy and guideline development. We have to spend an equal amount or perhaps more time on disseminating that information in an efficient manner.

MR. HACKBARTH: Let's just do a time check here, George. We have just about 20 minutes left here. Can I see hands of how many people are in the queue? So we've got six at least. If you will be quite disciplined in your question asking, I'd appreciate it.

MR. GEORGE MILLER: Okay. I will be very brief. And I really appreciate both of you being very, very candid about where you are and where you need to be. That is also an admirable trait.

I would still like to go back to my first question about disparities of health and how you deal with that and how you feel we, as a policy-making organization, can help deal with that issue nationwide, or if there are things that we can do, or if there's something unique.

And I'd also like a response concerning accountable care organizations and the quality metrics that you would recommend we have if we go that step further. I think Dr. Mehler mentioned about accountable care organizations and bundled payments, how we can make sure that all Americans receive the same standard of care, no matter what their ethnic background is or social background or if they're poor or rich. How does that work from a policy standpoint?

DR. MEHLER: You know, I think the whole issue of comparative effectiveness, which in the Stimulus bill there's going to be a lot of dollars for, we need those answers right now. As an example, we really don't

understand hypertension in the Hispanic population. Those studies have never been done. We understand some things about African American hypertension, a little bit about Caucasian. We know nothing about Hispanic hypertension, really, what kind of pathophysiological basis is it.

One thing that could be done is making those studies and sending out RFAs and those kind of things to really promote health disparity research. Certainly, there are some. There are dollars out there right now and I think we've got to get the word out about them. But trying to make that a bit easier to get that funding, I think is an important way to get at ethnic disparities to really answer some of these questions in regard to really how we're going to make things better for the ethnically diverse populations that we take care of.

The second question that you had was with regard to -- it slips my mind.

MR. GEORGE MILLER: [Off microphone.] About accountable care.

DR. MEHLER: I think the metrics have to be really more in outcome than in process, and I think that's one of the big problems right now, the way we incentivize things.

So if you get an A1c in a patient, you meet the standard, but that to me is not the issue. It is really what have you achieved with regard to their A1c or their blood pressure, not that you have them on an ACE inhibitor, but what is the hard outcome, and I think that we need more and more metrics that really look at health outcomes rather than just process measures.

The other thing that I think we have to be careful of is that people quickly learn how to game those systems. And so if you have a doctor who has dropped a person's sugar from 300 to 150 but the target is 140, he gets nothing, but the person who takes a person at 150 and drops them to 130, they get the carrot, we have to be careful of that. So I think we have to incentivize both outcomes, but we also have to incentivize delta change, and in the vulnerable populations, that's very important. If I take someone who had no health care for the last ten years in my system but I can't achieve blood pressure control after six months and you penalize me, versus someone who has an insured population, I think that's going to create more disparities and more cherry picking, which is not good.

DR. ANDERSON: I think that's an important issue,

about the cherry picking. I'm on a committee on disparities at the AHA and they're really focused on this issue and one of the big fears of some of the folks in the private sector was that if we really focus too much on these people, we will avoid the population. If we are paying for outcome, one of the bad things about outcome might be, I will just avoid sick people, and that's a big issue.

I look at disparities as deferred maintenance on people. It's like slum lords. We have people who have lots of things that have accrued over time. You don't really fix them right away, but you have got to get better and you have got to get better. Sometimes, generationally, you have got to get better. And you have got to then focus.

But being Baptist, you will understand this, George, you folks, but I always say, I don't want justice, I want mercy. And when you say, I want to get equal treatment, I would argue with you that equal treatment is not necessarily true. You may want more treatment, and people want equity when in public health it may not be equity. A statistician is a person who will get you drowned crossing a river of average depth of three feet. There are holes in the river that are eight feet deep and what we have

to do is go work on those holes and work on the disparity issues.

If we're going to really change our numbers as a nation, and part of our issue is because of disparities, this nation doesn't look as good as other nations, and we have the best sick care system in the world -- we have a bad health care system -- and if we focus on disparities, our numbers would come up remarkably.

So I think for a while, we need to intentionally go after these issues with some veracity, and so I think for a while, it may not be equity. It may be more than that.

DR. KANE: Well, I have two questions, but you don't have to answer both of them. Actually, one is how -- you mentioned that the one reason your results on diverse populations was good is that you had a diverse medical staff, and so a question to you maybe is how did you achieve that?

And then the second question actually is to Dr. Anderson. If you were to retire sometime in the near future, what would be the characteristics of your successor and how have you ensured that that person will be there when that time comes?

So maybe start with the first one about how do you achieve a diversified medical staff. What do you do different, because I know it's really hard to get a diversified faculty, so I'm just wondering how you do a diversified medical staff.

DR. MEHLER: Well, I think one of the things that does that is community-oriented primary care. When you have the health care system in the communities, then oftentimes people that grew up in those communities are the ones that come back to your hospital to practice. So we have a number of doctors at Denver Health that grew up in inner-city Denver and they want to come back to their communities. If we didn't have an integrated system, if we didn't have community-oriented primary care, they'd have no reason to come back there.

Number two, we try to figure out ways to incent them to understand the sort of sacred mission of what we do at Denver Health. So when I was Chief of Medicine and I was trying to recruit people, I would tell them, this is what I can do for you to study this issue in the culture that you come from. So when I hired those two Russian physicians, I said, we have a captive population of thousands of these

patients. I'll give you interpreters. I'll do what we've got to do. And we published off of that population. So when you can tie the academic mission in with the clinical mission, it's a way to get them there, as well.

And then the third issue is I think that your reputation sort of drives it. If they in the community and nationally you're known as a Mecca with regard to health care delivery, then people want to come to you and so you try to, therefore, when you have a lot of people that are knocking on your door for jobs, you try to make sure that you're doing a good job in getting an ethnically diverse provider and nursing staff.

DR. ANDERSON: Our medical school next door, as Karen will attest, there are not as many women as there ought to be. There are not as many minorities as there ought to be. It's a wonderful medical school, one of the top 15 in the country. But success oftentimes blinds you more than failure.

In my COPC, the 150 doctors I have, half are women and half are ethnic minority, and part of the same reason that Philip talked about, people want to come back and serve their community. I have been accused of hiring

missionaries, and I will plead guilty, because you can get something done. But I'm hiring doctors who understand that we've got to work with entire patient populations and stewardship is about not just putting everything with one person where you don't know if that's going to help, you know, but that dollar can be used down to take care of other things going on in the community.

They like the model. COPC attracts them, because primary care is very difficult to attract people to right now. You've got to have some way to show outcome and my life makes a difference, and I think that's important.

Now, as far as my replacement, there are lots of people that would be loving to find that out --

[Laughter.]

DR. ANDERSON: -- but let me say, I have got three people internally at the very top, and one is the CFO, one is the COO, both have run private hospitals, who came over because they saw something happening at Parkland, and I asked them to because I had helped train them years ago and said, I want you to come back and do this. And then my Chief Medical Officer is a previous Chief Resident who went off someplace else for 20 years and I went and asked him to

come back.

I have three other outside names of people I have been impressed with that I have on my board, so they will have outside and inside, but they will choose my successor, not me. I'd love to see it be a physician who gets it, who understands that we're taking care of people. That is what this is about. But, you know, it can also be a very good finance person who will have an empowered CMO model. And I think that's really critical.

Do you have both components focused on that, and that's important, but not for just when you retire. That's for also if you don't make it to work the next day. I mean, the succession plan is really for if you die, and I've had that happen to me, and that's one reason we've really got a lot of depth in my organization because my number two guy died and I didn't have a succession plan in place for that. So I got to do his job for two years and mine. I didn't like that.

But I think it's hard to find replacements for people, because Patty will retire at the same time I do. She had been one of the people I would have gone to steal, you know what I mean? And if I were a board person, because

you like to find people who get it. But some of the CMOs that are behind them, I think, are the people who will take our place. Motivation and serving in leadership is what I look for more than I would look for brilliance. Persistence is more important than brilliance.

DR. KANE: Great. Thanks.

DR. BERENSON: quickly, agreeing that we want to get to integrated care and payment models that support integrated care, are there any immediate things that Medicare could do the way Medicare does business in its current payment models that could happen tomorrow that would make your lives easier, would promote the integrated care that we're talking about, in DRGs, fee schedules, anything like that? Does anything come to mind?

DR. MEHLER: You know, I think one thing that ought to be looked at, which may be a conundrum we don't want to talk about, is sort of the doughnut in Medicare D. I mean, I think there's pretty good evidence that when people hit that, their adherence to medical regimens goes off, and because most of the people that are in that have chronic illnesses, they don't suddenly not need their medicines at that point.

I really think that those value-based insurance programs where we don't have any copays for things that have been proven in evidence-based to be efficacious, that's the way to go. So, as you know, Pitney-Bowes has really been a leader in that regard, so basically they don't charge for mammograms and they don't charge for pap smears. It makes a lot of sense. The ROI on that is pretty substantial.

So I think it's a combination of figuring out that there are things that clearly have been proven to be effective, but in our populations, people have a limited amount of dollars and they're either going to spend it on food or they're going to spend it on health care, and ultimately, we're still going to have to take care of them tomorrow because we're the provider of last resort. So I think there have to be creative ways to think about some of the impediments that in the end will cost us a little money, but I think ultimately will save us money.

DR. ANDERSON: I think that we've set the system up in a zero-sum sometimes in policies. And in fact, if five percent costs 50 percent and ten percent costs 90 percent -- and you hear these numbers batted around -- focusing on those really sick patients and paying for care

management, paying for the wrap-around services, paying for the things that we could do as a capitated model if we were in charge for all that.

Many of my Medicare patients, as I said, are Medicaid patients, as well, and they're very poor. We, for a while, we don't charge them -- with Medicare, we didn't charge them because they qualified for charity. We still had to go through all of the same policy things to be sure that we weren't trying to entice people to come to us who can't pay. I mean, it was really kind of a crazy thing, you know, that we might be doing something that would entice people to use our services and increase admissions. We don't make money on them.

So in a fashion, what could we do to do some demonstration projects on that ten percent that cost so much? Almost anything else we do with the people who don't use very much won't cost hardly anything compared to these folks that we're really not focusing on to maybe do more for, we might do more for, but in an ambulatory setting outside the hospital and their quality of life would improve.

And I think palliative care is very important.

Somewhere at the end of life, we've got to deal with our -- yes, we can do something, but should we do something? We are going to have to have that discussion as a nation, because sometimes we're very meddlesome and we're mischievous with what we can do and not answer the question should we or not. And I think there are enough patients that don't want us to that we don't have to worry about the ones that want everything done. I mean, that's not the issue ordinarily.

So I think we're going to have to be thoughtful about how we deal with things that are marginal value that just don't yield good results, and we think everybody should have access to everything. I don't think we can afford that, but we ought to be scientific about it and evidence-based about it and do no harm if we can't do good.

MR. HACKBARTH: Okay. We are down to our last few minutes.

DR. CROSSON: I will be brief. I just want to add my praise as a physician for not only the presentations, but the work that you both have done. It's just extraordinary.

I want to take one second to see if I can paraphrase a bit what you've said, because the question on

the table is what can the Medicare program do, which is admittedly about ten to 15 percent of your revenues, respectively, to help promote quality and efficiency, and what can we learn from the work that you've done, and I think what I heard in here was that the Medicare program could do a lot of things, but they're relatively indirect. They all involve helping shape the environment in which the work that you do takes place.

For example, supporting integration, which in different ways for each of your organizations is important. So work we've done, for example, policies that we've discussed about reducing regulatory barriers to physician-hospital integration, promoting bundled payments as an incentive to integration, accountable care organizations, and the like, I think are in that category.

And helping to promote incentives, both to your institutions and potentially incentives directly to your providers, that drives things in the right direction -- pay-for-performance, and particularly, I think as was noted, paying for outcomes as opposed to paying for process -- and in so doing also being sensitive to the necessity to risk adjust those systems for the kinds of populations that you

all deal with.

What I did not hear was direct Medicare help to your institution or other institutions in quality improvement, for example, larger investment in the QIOs. Now, maybe that was just a deafening silence, but I think it's important to have you say, is that what you mean?

DR. MEHLER: I'd like to -- so we haven't had a lot of interaction with the QIO in Colorado. They're a good group. I know a number of the doctors that work at CFMC, but I can't tell you directly that they've had a big impact on quality at Denver Health.

I think that one thing that we'd love to see Medicare really think about is the core measures that are coming out and them really being evidence-based. They've come under a lot of heat, as you know. There's been unintended consequences because of some of the core measures, specifically the pneumonia ones. And as Dr. Anderson alluded to, that many of the things that really determine how our patients do are not the usual things you'd think about that we measure.

There are rumors that the core measures are going to go up in number significantly over the next few years,

and as a hospital, we really struggle with that. It takes a lot of resources and it's not clear to me how many of these really impact care.

So I would love to see for Medicare going forward that there's perhaps additional deliberation on the core measures that we currently have and ensuring that the new ones that come out are really evidence-based. I think you can effectuate more -- you know, there's this whole concept of improvement fatigue and initiative fatigue. There's just too many things that we have to do right now and I think we just have to be a bit more selective in trying to promulgate the ones that have the most substantive return to really improve care.

The QIO issue, maybe some of those dollars could be diverted elsewhere to try to effectuate some of that within the hospital, to effectuate good quality.

DR. ANDERSON: You know, I guess instead of looking at the QIO, I've looked at the IOM and some of the studies they've done on outcomes and looking at chronic disease models and which ones we can have big impact on -- there are about 20 that cost a fortune -- and how we can actually do care management and those kinds of things.

We've looked at the private IHI and the rapid implementation. We've looked at UHC and others who have done comparison so we compare ourselves on that grid with our cohorts, but we've done one or two projects with the QIO in Texas. And we see it a lot of times as looking at the finance side instead of the true quality side as much, I think, or we're trying to deal with the fraud and abuse aspects of things instead of how do I really move this field forward.

And so I think we've looked other places more than we've looked at them. Even though they're very good and I don't think anybody doubts their good faith and that sort of thing, they're good people, I don't know if the focus -- AHRQ, HRSA, some of the ones that have had demonstration projects, they tend to be more meter movers than I have seen the State's QIOs be. That's my perception. I may be wrong.

MR. BUTLER: One quick direct question. We've looked in MedPAC at the relationship between financially-stressed hospitals and the profitability in Medicare and shown that there's something like ten percent of the hospitals that are financially stressed that actually make a 0.5 percent margin. So how do each of you do on your

Medicare margins?

DR. ANDERSON: We lose money on Medicaid, which is a big part of our business, and obviously the self-pay. I think that we're doing pretty well on Medicare. People say they lose money, but when they lose money, they're looking at fully-loaded charges. As we start to build a new hospital, which we're going to build one with 38 percent more capacity, take care of more of the charity load in that community, and you've got new capital costs, because we were debt-free, that profile is going to change. But we were debt-free in an old 1954 building. We were making a margin with Medicare, principally because of the add-ons for medical education and being the largest residency program in Texas.

But the fact that there were Medicaid and Medicare patients, you also then had train wrecks, I mean, people that cost a fortune, and the DRG doesn't even begin to touch those folks. So to a degree, we've seen that high-risk population -- that's one reason we try to do the care management we're trying to do, because those folks can really be a huge, huge hit on you. But if you just looked generally across the board, I'd love to have just a routine

run-of-the-mill Medicare patient instead of the Medicare-Medicaid crossovers. I would hope I could make money on those, actually.

I heard a statement the other day at a board meeting that the tenant had actually said as a corporation, they were trying to figure out how to make it work on Medicare alone because of the payer problems without reform. If reform doesn't come, what are we going to do? And everybody in the room moaned. I mean, everybody moaned except the public hospitals who said, it may be an opportunity.

[Laughter.]

DR. MEHLER: We do okay on inpatient Medicare. We do very well on Medicare HMO products. Our own Medicare Advantage product, we do very well on. We make actually money on Medicaid, again, in an HMO model. We feel that that's the way to do it. And we have passive enrollment in Colorado, so if you don't sign up for a Medicaid program, you get passively enrolled to Denver Health, and that's been a very significant financial boon for us.

On the outpatient arena with Medicare, we sort of break even, perhaps, but we don't make money on our

outpatient. But we believe ultimately our outpatient business saves us money because they don't end up in the ER like Dr. Anderson was saying.

MR. KUHN: To the point that Arnie asked earlier and Dr. Mehler answered in terms of dissemination, I remember a fact I think I read about a year ago where it said for every dollar spent on patient safety work, maybe less than five cents were on dissemination or bringing that information to the bedside. I hope I'm wrong on that number, but it's disproportionately skewed against the dissemination of the information out there.

But the one question I had for both of you, but particularly Dr. Anderson, you raised the question earlier or the issue earlier about social severity or maybe even a poverty index. Can you tell me, have you seen any proxies out there that would make sense that we could look at, and if so, how would you use that or how would you see that effective for institutions like yours or others across the country?

DR. ANDERSON: It might be as insensitive as a census tract or a ZIP code. One of the studies we are doing on congestive heart failure readmissions, there was one

public housing project, and if that was the one that came up, the chances of them being readmitted were very high. But there are other things. If you have a married couple and you just lost a spouse, for a period of time, we know that they're at higher risk and that sort of thing.

But looking at the simple things like income and disease burden, comorbidities, I mean, we looked at that for the health outcome, but I think it's also important for the social severity. I mean, do they have the resources they need to get the care they need, you know, access to social services.

We do a lot of our tax dollars, we use them to provide wrap-around services because that keeps you out of the hospital. And so there used to be a guy out in Santa Clara Valley who was a hospital administrator there that came up with the term Social Severity of Illness Index when he was Chair of the National Association of Public Hospitals, and we've all looked at that. But something simple like income, family size, education levels, and poverty area.

We have some areas in Dallas, West Dallas and Cadillac Heights, where the people for years were exposed to

lead smelters and vermiculite, which is a form of asbestos, and it's in the houses, it's in the attics and everything else, and we looked at cancer rates in those communities. So there's an environmental component, too, of people -- particularly poor people, people of color -- who have been exposed to that element. And I can tell you, that makes a huge difference on burden of illness.

And so we don't have a good index right now, but that's the thing. We need resources to help us determine what's a simple thing that could be easily measured on admission.

The young man that's doing research for us says, let's do it on the day of admission. If we wait until the time they're being discharged, when we're moving them out in 3.8 days, it's too late. We haven't gotten things done for them. So we try to identify them day one, and that's the kind of research, I think, that's really important for us to determine.

MR. HACKBARTH: Others?

Okay, not too bad, a little bit behind schedule. Thank you very much, not just for your contributions to our deliberations, but also for the exemplary model you provide

for American health care -- really terrific work that you do.

DR. ANDERSON: Thank you.

MR. HACKBARTH: Okay, our next session is Services Provided Under the In-Office Ancillary Exception.

Ariel, here's what I think we'll do on this. We're about 10 minutes behind schedule, and given that we're not contemplating recommendations in this area I think I'd like to see if we can pare this down just a little bit. What I propose to do is limit the commissioner participation just to clarifying questions for this particular presentation, and that will allow us to get back on schedule and hopefully finish on time today, so whenever you're ready.

MR. WINTER: I'll try to pare things back in my presentation as well.

MR. HACKBARTH: Okay. Thank you.

MR. WINTER: Good afternoon. I'd like to begin by thanking Hannah Miller for her help with this presentation.

During this cycle, we've been discussing the in-office ancillary exception to the Stark Law and exploring strategies to address concerns raised by the growth of

ancillary services in physician's offices. Our goal is to include a chapter on this topic in the June report, but with no recommendations.

In today's session, we'd like to focus on various policy options, some of which you've seen in prior meetings. Depending on your discussion and feedback, we could pursue recommendations for the next cycle of meetings beginning in the fall. I'm going to skip over most of the background material in the interest of time, but it is included in your paper.

Over the last several years, there's been an increase in imaging, lab tests and physical therapy provided in physicians' offices. At Peter's request, we examined the share of Part B payments for different specialties that come from ancillary services. We found that ancillaries, particularly diagnostic imaging, accounted for a significant share of Part B revenue in 2008 for several specialties, and there's more information about this in your paper.

In a proposed rule, CMS asked for comment on whether certain ancillary services should no longer qualify for the in-office exception such as services not needed at the time of the patient's office visit, to help with

diagnosis or treatment, but CMS has not yet followed up with a specific proposal.

At our last meeting, we were asked to provide more information about self-referral of radiation therapy and outpatient therapy, which includes both physical and occupational therapy. I'm going to first talk about radiation therapy provided under the in-office exception. This occurs when physicians other than radiation oncologists refer patients for radiation therapy provided in their offices.

Medicare paid just over $100 million to specialties other than radiation oncology for radiation therapy in 2008. This was an 84 percent cumulative increase from 2003, but these specialties' share of total radiation therapy payments stayed relatively small between 2003 and 2008 at about 5 percent. This was because there was rapid growth in overall spending on radiation treatments.

Outpatient therapy is covered by the in-office exception when a physician orders therapy that is provided by therapists employed by the physician's group. Therapists employed by physicians may provide therapy incident to a physician service or may bill Medicare independently.

Therapists who bill independently are called therapists in private practice. The distinction is that incident to services must be supervised by a physician who is in the same office when the services are delivered, whereas therapists who bill independently do not require physician supervision. Many physicians may prefer that a therapist bill Medicare independently because there's no requirement for physician supervision.

Now let's take a look at the data on therapy spending. These pie charts show the distribution of physician fee schedule spending for therapy services in 2003 on the left and 2008 on the right. Overall, spending grew from $1.4 billion in 2003 to $2.2 billion in 2008. The share of therapy services furnished incident to a physician service fell by nearly half from 30 to 16 percent. At the same time, the share of services delivered by physical or occupational therapists in private practice grew from 70 to 84 percent.

These changes could reflect a policy clarification by CMS in 2003 which said that therapists could be employees of physician practices, but still be considered therapists in private practice. Unfortunately, Medicare claims do not

indicate whether therapists in private practice are employed by a physician group or practice separately from a group. So we are unable to estimate how much of the money spent on physical therapy was related to self-referral.

Here are a range of options we could consider to address concerns about in-office ancillary services based on your comments from prior meetings and staff work since then. We have separated radiation therapy and outpatient therapy from diagnostic tests based on a concern expressed by several commissioners that self-referral of therapeutic services may have a greater impact on treatment decisions than self-referral of tests. The first column shows potential strategies for radiation therapy and outpatient therapy, and the second column shows potential strategies for imaging and lab tests.

I won't go into much detail on the final policy, the payment accuracy option, which is the last one your slide, because there is separate work going on in this area. The reason we included it here is because the rapid growth of ancillary services, along with the use of new technologies, raises questions about equity and accuracy of physician payments.

I'll first talk about the set of options related to outpatient therapy and radiation therapy. The first approach would be to exclude these services from in-office exception based on the rationale that physician investment in these services may skew clinical decisions about the treatment of patients. There may be a concern that this change would inconvenience patients by forcing them to receive care in hospitals. However, patients would still be able to receive outpatient therapy from therapists in private practice who are not employed by physician groups. In addition, patients could continue to receive radiation therapy from freestanding radiation oncology practices.

This change would not affect providers who primarily serve rural beneficiaries because these providers have a special exception from the self-referral rules. However, this change would limit clinically integrated groups that treat a wide variety of cancers using a range of modalities including radiation therapy. For example, a medical oncologist would no longer be able to refer patients to a radiation oncology who is in the same group, for radiation therapy.

Under the second option, radiation therapy and

outpatient therapy would be excluded from the in-office exception unless the practices were clinically integrated. What we're trying to do here is balance the risks of higher volume that are related to self-referral with the potential benefits of a clinically integrated practice such as comprehensive and coordinated care. A key issue, of course, would be how to define clinical integration, and there are several ways you could think about this, but one idea would be to require that each physician in the group provide a substantial share of his or her services, such as 75 percent, through the group.

Currently, groups can contract with or employ specialists on a part-time basis to perform and supervise ancillary services. For example, a group can set up a radiation treatment center and contract part-time with a radiation oncologist to perform and supervise the radiation therapy.

It's important to point out that even clinically integrated groups have an incentive to drive up volume under the current fee-for-service payment system. Eventually, the payment system will need to be changed to hold providers accountable for cost and quality.

Now I'll move on to talk about imaging and lab tests. Under the first approach under these set of options, diagnostic tests would be excluded from the in-office exception unless they are usually provided on the same day as an office visit. One of the primary justifications for the exception is that it enables physicians to make rapid diagnoses and initiate treatment during a patient's office visit. As we discussed at the last meeting, there's wide variation, and now frequently different types of tests are furnished on the same days as an office visit.

An important issue under this option would be defining which diagnostic tests should be covered by the exception. One option would be to set a numeric threshold for how frequently tests should be provided on the same day as an office visit in order to be covered. Another option would be to only cover tests that do not require advanced scheduling. And with either approach, there would be significant implementation challenges.

A second option for imaging and lab tests would be to exclude them from the in-office exception unless the practice was clinically integrated. We presented the same option for radiation therapy and physical therapy, and the

issues are the same. So I'm going to skip over this and move on to the next slide.

The third option would be to reduce payment rates for a task performed by self-referring physicians. Studies by the Commission and other researchers have found that physicians who furnish imaging services in their own offices refer patients for more imaging than other physicians. In addition, research by OIG has found that patients of physicians who owned clinical labs receive 45 percent more lab tests than all Medicare beneficiaries, on average. The objective of this approach is to recapture some of the additional Medicare spending that is associated with self-referral of diagnostic tests while continuing to allow physicians to provide these services in their offices.

A couple of policy design options to think about would be whether the policy should apply to all diagnostic tests or a subset. Reducing payments for all tests would be simpler to implement, but it would affect many more providers as well as many more services. Alternatively, this policy could be limited to high-cost imaging services and lab tests, or tests that are not commonly performed on the same day as a visit. Another issue would be how to

determine the size of the payment reduction.

So, to sum things up, we describe several options to address concerns related to in-office ancillary services. We'd like to get your feedback on which of these strategies, if any, we should consider making recommendations on in the future. Our plan is not to include recommendations on this topic in the June report, but we could consider a recommendation during the next cycle of meetings and reports.

MR. HACKBARTH: Okay, thank you, Ariel.

We have, let's see, 25 minutes for commissioners. What I'd like to do is let's go through a round one, and then if we have any additional time we'll try to squeeze in a few more substantive comments, but I really do want to finish at 3:45.

DR. STUART: This is probably just my naivete, but I'll ask it anyway. It strikes me that somewhere there must be a way to do bundling to handle this. Is this something that makes any sense and have you looked at it?

MR. WINTER: It's something on our longer-term agenda, both packaging which refers to increasing the size of the payment for services performed during the same

encounter by the same provider, which is frequently done in the outpatient department, as well as bundling which would involve a payment that includes multiple encounters, perhaps by multiple providers.

We've not done a lot of really in-depth work this area. There is, of course, the recommendation the Commission made to begin experimenting with bundling for services around admission. But in terms of specifically outpatient services or conditions that tend to be treated more in the outpatient, more outside a hospital, we've not gone very far in that direction, but it is something on our agenda, and we mentioned it briefly in the March report.

DR. CASTELLANOS: I guess my clarification is that I think this is a very important subject and to have to limit it because of time constraints I don't think is appropriate, and I don't have any comments.

MR. HACKBARTH: Rest assured, Ron, that we will not move ahead on any recommendations until we have the appropriate discussion. So I'm sympathetic with your concern.

Others clarifying?

MS. KANE: Yes, have you looked at all at the

difference in ordering patterns when a physician is employed by a hospital that encourages them to use, you know? I mean I've heard that one of the reasons you employ physicians is to capture their ancillary volume. Then the one question is: Are they also encouraged to order more tests in an employed situation?

I guess I'm not sure that this is any worse when the physician owns the equipment than when the physician is employed by an entity that also stands to benefit from tests. Just, have you looked at the ordering pattern differences, if any, between these?

MR. WINTER: We have not. It would be a great question to look at.

I'm not aware of a way to identify whether physicians are employed by a hospital based on Medicare claims data. There might be other data sets available which identify whether physicians are employed, and we can look into that.

One thing I want to point out is that there is an exception in the Stark Law for physicians who are employed, and there is the entity that employs them theoretically is not supposed to be linked, is not supposed to link their

compensation to the physician's referrals for diagnostic tests and other ancillary services covered by the Stark Law. So there may be ways to get around that, but that's sort of the technical rule.

DR. BERENSON: I'm interested in the integrated group issue, and I understand, as Glenn mentioned last time, it would completely interfere with the whole business model of an integrated group to sort of prevent a self-referral. And at the same time I agree with what you said up there, which is in a fee-for-service world it's not at all clear that we're getting anything other than lots of volume from integration.

Do we have an ability to actually look at utilization associated with patients getting care in integrated groups compared to non-integrated groups, maybe through some attribution model? I'd like to know more about what behavior we're seeing currently in thinking about how we would approach this problem. I mean is that something we could do?

MR. WINTER: We can think about -- I would want to talk to my colleagues like Christina, who have done work -- looking at, with claims data to look at multi-specialty or

integrated groups and see if what we could come up with claims data. It would be difficult because we only have a share of their business. We don't have the private payer.

DR. BERENSON: That's why it would have to have kind of attribution model that we had some confidence in. I'm not saying it is, but I'm just troubled by sort of this broad exception, and yet I don't have an alternative to it.

MR. HACKBARTH: I would say there are integrated groups, and there are integrated groups. If it's a group that is purely fee-for-service and just has everything in one place, you may get a use pattern that is very similar -- a high use pattern, that is. On the other hand, if you have a group that is largely capitated, they might have a very different pattern. And it's a continuous variable. The degree of capitation can be anywhere along a wide range. So I'm not sure that it's a meaningful category, integrated group, or not.

DR. BERENSON: Well, I was going to suggest that if we had the ability to do it, then we would compare the integrated groups that are predominantly capitated and those that are all or predominantly fee-for-service. If we had the basic methodology, it's something we could do.

Obviously, well, if it's capitated, even in fee-for-service Medicare we wouldn't necessarily know how to attribute.

MR. HACKBARTH: Okay, any other clarifying questions?

MR. BUTLER: So we've discussed before things like flagging the high utilizers if you could and then maybe having starting with preauthorization, particularly for some of the major imaging. Are we dropping that as a strategy or just not on the table today?

MR. WINTER: That's sort of up to you all to decide. We didn't bring it forward this time based on we sort of went through the comments we got from the last couple of meetings, and tried to figure out which were the most, which options had the most support among the majority of commissioners. We could certainly work that one back in if that's what you want us to do, for the chapter in the future.

MR. BUTLER: I just thought we, especially some insurance colleagues around the table, like John, said this actually works in imaging. So I would like to see it as an option. It's not too hard to impose compared to some of the

other things that really are difficult to get around the ownership. This is not a simple thing.

MR. WINTER: Just to be clear then, so you're asking us to look at both flagging the high utilizers but then subjecting them to some kind of prior authorization method.

MR. BUTLER: I think that, yes. Then the average Joes get off, you know. You're not burdening them with a lot of bureaucracy for now. You're just trying to get the low-hanging fruit, if you will, and putting a process that might work.

MR. KUHN: Ariel, you had the one slide up here, and maybe I missed it, but it showed the significant drop of incident two services for therapy and a big gross-up of activity in terms of physical therapy services. What was going on at that time for that big change to occur?

MR. WINTER: In 2003, CMS announced a policy clarification which said that therapists could be in prior practice, meaning they don't require physician supervision, but still employed by a physician group. So, until that point, I think it was unclear whether physicians could do that. Or if they wanted to bill for physical therapy, they

would have to do it on an incident two basis, which meant they would have to meet all the supervision requirements which are more onerous than when a therapist bills independently in private practice. That could be influencing the shift we're seeing from incident two to therapists in private practice.

MR. KUHN: Thank you.

MR. WINTER: It's hard to disentangle the factors.

DR. CHERNEW: I just want to make sure that I'm right in my assumption that the basic cost analysis would be the same. In other words, we don't think that it's cheaper for the physician necessarily to provide in-house versus refer out. So we don't think there's a meaningful cost difference.

This is really just essentially the patient gets a big benefit. It's like lowering a co-pay, if you will. They don't have to travel. So they use it a lot more, and a physician gets a bigger incentive to refer to it because they get more money, but it's not a cost issue.

So, if we were to adjust the fees, my point is right now they're paid the same, right. So, if we were going to adjust the fees, if they cost the same, someone is

going to be paid more generously than others because we think the cost is the same.

MR. WINTER: Right, that's true. We think the costs are the same, but it could be that the self-referring practices because they could have the potential to drive up volume more than a provider that depends on physicians for referrals. So, if they're more efficient, that would lower. That would spread their fixed costs over more services, and that would reduce their cost per service, but we've not been able to look at that analytically.

DR. CASTELLANOS: Can you clarify that answer? I thought his question if he refers out, the costs would be the same?

MR. WINTER: I thought the question was is the cost the same for a self-referring practice, let's say doing imaging, versus a freestanding center doing imaging? Are the costs the same?

My point is if one setting can achieve higher volume than the other, per machine, then they could spread those fixed costs over more services and therefore have lower cost per service.

DR. CHERNEW: And you couldn't tell which one was

which because the one that's getting referred to could be like a hub. So the physician office might have a smaller set of patients to do the scheduling --

DR. CASTELLANOS: How about if it was referred to the hospital?

MR. WINTER: Yes, right, that can work both ways. That is the entity that's non-self-referral, that's not self-referring could have higher volume than the self-referring entity, but it could be --

DR. CASTELLANOS: The hospital wouldn't have higher costs.

DR. BERENSON: Or if not higher costs, we pay them differently, more or less, and that's the point I think. I mean that's what the cardiologists are now complaining about. If we reduce the fees for nuclear imaging tests in the office, then refer everybody to the hospital, and we'll pay five times more is what the allegation is. So the question, I think it's an important issue.

What's that?

DR. CASTELLANOS: And the co-insurance.

DR. BERENSON: And the co-insurance goes up.

MR. HACKBARTH: We still have about 15 minutes.

Ron, do you want to use some of that?

DR. CASTELLANOS: Just, my points are this is a terribly important issue, both from a patient viewpoint, a care continuation and coordination viewpoint, a cost viewpoint not just to the patient, but to the Medicare system. I just think we just need to really look into this.

Jay and myself briefly talked about this out in the hall, and I have a lot of concern because I think the system has some merit, but there is just no question that in my opinion that there's abuse also.

As Arnie said last time, he said, you know, there's 90 percent of the doctors are doing what they think is appropriate, that they think is right. They're doing the best thing for their patient and best thing for the community. Yet, 10 percent aren't, and you don't want to throw everybody under the bus.

MR. HACKBARTH: So where does that leave you in terms of policy response? From that, do you conclude that we ought not do anything at all, or would you lean to any particular option that Ariel laid out, or is there some other option that strikes you as a better choice?

DR. CASTELLANOS: I think we need to look at the

options, but I think we've already seen one option that does work. It's an option that you've used, and I've heard it discussed previously -- reimbursement on the procedure. Make it appropriate to the procedure. Don't pay, like we have done sometimes, excessively. Make it appropriate.

MR. HACKBARTH: Yes. So let's just pursue that for a second.

To me, sort of the worst case is that somebody goes out and buys a very expensive piece of equipment, and then once they've got it in place the economics are I ought to use it a lot because that gets me down the cost curve. I spread the fixed costs, and that's where you have sort of the most toxic incentives at work. So, what, if anything, can you do to deter people from maybe making the investment?

It seems to me that if you price, set the unit prices at a level that you have to have a substantial volume to achieve, you may at least deter new investments. The ones that are already in place, that's sort of like water over the dam. But if you're really pricing down the cost curve, that may deter people from buying new pieces of equipment.

DR. SCANLON: I agree with you, but it's this

question of how far down the curve do you go because you have to get to this point where you're getting closer to that incremental cost, so that they're not going to be able to spread that much of their fixed cost -- because if we really believe that there's this potential for abuse, that we can sort of order more of these kinds of tests, as we move somewhat down that curve, the response will be, for the existing owners, well, I can make this back by increasing the volume even further. And then other people can see this and say, well, that's a viable business model too. There's that problem.

The other issue is as you're moving down towards trying to get to this incremental cost it's incremental cost at what scale, and what are going to be the implications of that for convenience to patients in terms of access in different areas, because if you get it to the point where you're only able to share, spread a little bit of the fixed costs through any individual service. So, therefore, you have to have really significant volume. You got to have a really large population in order to justify the service. There's where you're going to get into the resistance because you're going to hear from the medium-size and

smaller communities, you're shutting us out of the service.

DR. CROSSON: Well, I mean I was thinking along the same line. I mean first of all what we have here is a problem that I think we all recognize is real and a whole set of solutions and everyone has them has a significant problem associated with it, either conceptually or in terms of trying to visualize how it would be implemented, and I'm not sure I have a perfect one.

But I wondered whether or not we could think about combining the idea that Peter brought back, or that John had discussed initially, and that is to try to focus on those providers, those situations which appear to be problematic based on some statistical analysis. Then, in that situation, you could do different things.

One would be to do preauthorization. That happens to be something I don't particularly like because I don't think it's that effective.

But another thing you could do in those cases would be in that situation then, once some threshold had been passed, would be to apply marginal pricing. After a while, providers would know, gee, if I get to this point and fall off the cliff, then the economics of using this piece

of equipment dramatically changes for me. So I better be sure that I don't do that -- just a thought.

DR. BORMAN: I think one of the other pieces that doesn't exactly fit in these very specific options will relate to potentially episodes of care and bundling some of these services -- that, for example, if the point of a visit relates to establishing a new diagnosis of CHF or reassessing it or something, there's so much money that allows you to evaluate that through some bundle of tests. If you want to do it through nuclear plus this lab test, great, or if you want to do it some other way, but there's sort of a limit.

And Nancy and I talked a bit about this earlier today, and I think particularly for the four or five kinds of high-volume diagnoses that we could identify some things where perhaps that's an alternative to this because this is fraught with all these risks that we've identified. I think out of all the things we've talked about, what Jay articulated and what was brought up about let's focus on the outliers, I think that's always a good beginning strategy, and I think it's something that perhaps we could do fairly quickly, initially perhaps non-punitively and then ratchet

it up.

But I think another way to come at this would be from the direction of frequent diagnosis, tests and test-related bundles, that maybe in the end that's where the bigger savings are achieved.

And there's more autonomy to local circumstances where, particularly in the smaller community setting, maybe you can work it up by X. You don't have Y available, and so you utilize the resource you have. But you're not either advantaged or disadvantaged, and you're not required to have every kind of equipment in order to get all those returns.

DR. MILSTEIN: Yes, I think Ron makes a good point. I think I'm the one who suggested just reduce the payment rates for self-referring.

I think Ron's point is a good one. You wouldn't want to penalize providers that were self-referring, but who were doing so in a responsible manner. So the question is: Is there a practical way of defining the term doing so in a responsible manner?

I go to two different spots. One is to think about sort of two. You can say, well, it's an algorithm that basically says is the provider self-referring, and then

if you are you're in a different bucket than those who aren't.

Then the next point in the algorithm might be something, is this provider part of an especially cost-effective, high-quality delivery system? If the answer to that is yes, then they're dropped out of the presumed guilty group.

I think about this because I think when we heard the Virginia Mason presentation -- it was three or four years ago -- one of the points they said is as they began to innovate they realized that for low back pain getting the physical therapy, their own physical therapy, involved within two hours is really the way to get much more efficient outcomes.

That's why I think having an initial screen of, yes, they self-refer, but we have evidence that they're exceptionally efficient, using the measures that we will inevitably have to come up with as we move to accountable care organizations, et cetera.

Then the next thing I would ask because I don't want conscientious good stewards, who happen to be owning their own equipment and self-referring, caught into this

penalty net. But say they don't qualify for that, but it seems to be it would be possible to sort of calculate the rate, maybe on some kind of case mix-adjusted basis which they are using, whatever it is that they are self-referring to, relative to the ambient rate in their communities that providers who are using that test, who don't self-refer, who are using external.

If there's no delta, which in the case of practices like Ron, I would expect there would be much of a delta, then no penalty. But for those that failed both of the tests, that is their overall care is not exemplary in value, and (b) they indeed are using the ancillary service at a case mix-adjusted rate that is in excess of their peers in the same community, in the same geography, on some kind of a reasonably -- case mix adjustment would get refined over time. But on a case mix adjustment basis, that's where I think an automatic payment reduction would feel better to me than just doing it across the board, which was my inclination last time.

MS. KANE: When it's a hospital outpatient visit, they go into a whole other mode of bundled payment for ambulatory service, the APG.

MR. HACKBARTH: Not so much bundled.

MS. KANE: Some of it's bundled.

MR. HACKBARTH: They go into a different payment system.

MS. KANE: But doesn't some of that include some bundles of services that naturally occur together, and I guess how different is that from what we're talking about? I don't really have a good feeling for what types, how those things are completely different.

I mean in other words, if the same patient with the same problem went to a hospital outpatient department for a bundle of services, they'd get paid on an APG rate for stuff that went with that visit. But when they go to the doctor's office, they get that visit unbundled. I'm just wondering what's the difference in how those are structured.

MR. HACKBARTH: Ariel, if you want to address.

MR. WINTER: So the APGs have a higher degree of packaging, particularly because of changes made in the last couple of years, than physician fee schedule services. So, as a couple of examples, if you get some kind of surgical procedure or other procedure in the outpatient department, certain imaging procedures that are done at the same time,

like image guidance, like if you're doing a biopsy and you need some kind of imaging service that helps guide the needle, that's packaged into the main payment, as well as radial pharmaceuticals. So if you're doing a nuclear medicine study, the radial pharmaceutical that's used, that's packaged into the payment rate in the outpatient side, whereas on the physician fee schedule side those things are still paid separately.

So there's a greater degree of packaging on the outpatient side, but it doesn't go so far as to include MRIs and cat scans that are associated with a treatment for a migraine headache or a knee injury, that sort of thing. It doesn't go that far yet. They've expressed some interest in expanding the bundles to include more things, but right now they're sort of including things that are done, that are integral to the main procedure, that are done during the same encounter, same day, that sort of thing.

MS. KANE: So, if an outpatient came in and said, I think I've sprained an ankle and needed an x-ray or something, that wouldn't be bundled?

MR. WINTER: That's paid separately, currently. The x-ray would be paid separately from the visit.

DR. MARK MILLER: [off microphone.]

MS. KANE: Yes, that's too bad.

DR. DEAN: I guess some of this leaves my head spinning, trying to figure out how we can ever get the prices right. It seems to me that one of the things, one of the troubling things to me in the whole health reform issue is there's been very little attention to the amount of money we're spending on administration of all this system, and these kinds of processes seem to me will only aggravate that.

And it seems to me we just have to move toward paying for episodes of care and let the decisions as to what is appropriate be made at a local level based on given a certain package of money, like our previous panel. These guys had a certain amount of money to work with. It was clearly limited, and they figured out a way to do it -- obviously, something that's very admirable and inspiring.

It seems to me that we need to take that lesson and say, we're spending way too much money on counting beans, and we need to give certain amounts of money. I realize it's not easy and it's a big shift, but instead of getting in these fights about whether that scan was

appropriate or inappropriate because on the front line it's hard to make that decision sometimes. So, anyway, whatever.

MR. HACKBARTH: Well, I think over the course of the many discussions we've had of this now, I think there's broad agreement that ultimately the best solution is to move to broader bundles of payment, get away from fee-for-service. These issues are a byproduct of fee-for-service.

But that in itself is not something that's going to happen overnight. It's got its own set of complexities that we talk about in other conversations. So what we're trying to do here is focus on steps that we might take in the interim before we arrive at that promised land of more bundled payment.

I think your point is well taken. While you're working on the interim steps, you need to be very conscious of the amount of resources required and the complexities and the potential inequities. You can get yourself all tied up in knots trying to operationalize halfway solutions. I very much agree with that.

DR. CHERNEW: Do we have a sense of how much money is on the table? If we actually knew and we could get it all exactly right, if we were to make one of these changes,

how much are we talking about?

MR. WINTER: It's very difficult to say. I'll go back to the example I gave about physical therapy, where we don't really know how much of that is driven by or related to physicians employing therapists. And even if we did, there have not been many studies looking at what's the induced demand effect when physicians employ therapists versus referring to them independently.

There's a lot more work done in the area of imaging, but there the estimates vary widely depending on the methodology and the types of conditions, the types of imaging modalities and those sorts of things. So it's difficult to come up with a precise estimate.

We can try to think about in terms of imaging. We can probably get a better sense of how many dollars are being spent for services that are being delivered in physician's offices. We can come up with some estimate of that and get that to you in the future.

DR. CHERNEW: We had a debate, a discussion a while back about the depreciation rules and the number of hours for big types of equipment and stuff and various ways, and we had a recommendation. Am I correct that that

recommendation ended up not being implemented or was implemented, then it was repealed?

MR. HACKBARTH: It was the hours of use.

DR. CHERNEW: Right.

MR. HACKBARTH: The assumption that goes into the practice expense calculation, how many hours is the equipment assumed to be in use?

DR. CHERNEW: Right.

MR. HACKBARTH: Ariel, why don't you say what the status of that is.

DR. CHERNEW: You were going to raise that?

MR. WINTER: We recommended increasing it, right, to roughly 90 percent of the time, and that was adopted and implemented by CMS beginning this year. It was also in the different health reform bills.

DR. CHERNEW: [off microphone]

MR. WINTER: I believe that both bills would increase the assumption. I think the Senate bill would have done it more slowly and phased it in and would have done it in a non-budget-neutral way, whereas CMS did it in a budget-neutral way, so the dollars stay within the physician fee schedule.

DR. BERENSON: But I think they got to a different place. I don't think they got to 45 hours. I think they got to something less, 75 percent. They got to a lower number.

MR. WINTER: The Senate number, the Senate bill. But CMS went to 90 percent. They adopted our recommendation.

MR. HACKBARTH: And that is in effect now.

MR. WINTER: It's in effect now, yes, for advanced imaging, for MRI and CT and PET.

MR. HACKBARTH: I don't think of pricing it more aggressively, moving down the cost curve, as necessarily a punitive thing. I see that as sort of a prudent policy to do, independent of self-referral.

We're going to have to bring this to a close for today. Thank you, Ariel, and I appreciate your being a good sport about the shortened time.

Next is restructuring medical education funding.

[Pause.]

Okay. We have allotted two hours for this, and the reason for that is that if we are to have recommendations on GME for the June report, we need to have

our final votes, obviously, next month. And so that is our task for today to decide what, if any, recommendations we wish to bring back next month for a final vote.

As much time as we've spent on this, as much good work as has been done by Cristina and Craig, this is a difficult subject, and it hasn't been easy to coalesce around recommendations. So we thought it was particularly important, I thought it was particularly important to make sure we had a full opportunity to air the issues.

With that preface, let me turn it over to Cristina. Are you going first?

MS. BOCCUTI: Yes. Okay, so in this final session this afternoon, Craig and I are going to present a culmination of many of your conversations over the last year and a half on this topic of medical education.

We are going to start with a discussion on the need to restructure financing in order to place higher emphasis on educational and workforce objectives. And then we are going to present a set of overarching principles for long-term restructuring. And considering that this set of principles may take a while to implement, we also present three specific recommendations that Medicare can take in the

interim. These are steps.

Next, please.

So, to start, in several ways, our nation's system of medical education and graduate training is excellent: It produces many superbly skilled clinicians while contributing to important advances in medical science.

Yet the overall output of our medical education system is not aligned with the fundamental improvements we need in our delivery system to increase value for patients and payers.

Delivery system reform cannot be accomplished without simultaneously ensuring that the mix of providers we need have the skills necessary to integrate care across settings, improve quality, and use resources efficiently.

Medicare's financing, which marks the single-largest GME payer, has created many of the problems. For example, payments based on hospital admission census and resident numbers are not an effective means for encouraging hospitals to foster ideal educational programs and environments.

Medicare spends over $9 billion with little accountability for educational standards or addressing

pipeline concerns. These could range from producing the right mix of professionals, assuring rural access, and increasing the racial, ethnic, and socioeconomic diversity of our doctors and nurses.

All this said, we must acknowledge that restructuring medical education financing is, of course, not likely to completely override the incentives embedded in the current fee-for-service system. The signals sent by those systems guide the career choices of both medical students and residents as well as the institutions that provide their training.

So on to a set of principles for restructuring medical education financing. The first is to transition to a general revenue financing model. If society benefits from the subsidization of medical education, then the costs should be borne out of general revenue funding rather than the Medicare payroll tax.

This broader approach recognizes that the current method is not an effective mechanism for meeting either education or workforce priorities across our country.

Pooling expenditures from Medicare, Medicaid, and other public sources offers the opportunity to implement

more integrated policies to produce the health care professionals we need for the 21st century.

We note three technical requirements that such a transition should take. It should be budget neutral. This transition -- or deficit neutral, excuse me. This transition should not cost the Federal Government any more than it is currently spending on medical education.

It should be phased in. Restructuring the funding priorities must be implemented in a way that minimizes the potential for unwanted disruption in medical education and training.

And it should assure funding stability across years. To meet educational and workforce goals, mandatory appropriations authorized for multiple years will be important in order to maintain a certain degree of funding stability.

The second principle we introduce is to enhance our capability to analyze health care workforce needs, develop coordinated pipeline strategies, and assess their impacts. It has become clear that market-based approaches to workforce policies are not sufficient to ensure that we have the right mix of health professionals in this country.

A general revenue financing model for medical education offers the opportunity to study and implement national workforce priorities. Through rigorous, unbiased analysis, we can better understand supply and demand factors across all health professions, inform a strategic plan for pipeline dollars, and conduct longitudinal program evaluation to assess pipeline incentive programs.

Multi-stakeholder input could play a role in informing the workforce center's research agenda and analysis.

Currently, the HRSA programs in place for addressing workforce priorities are through Title VII, which focuses more on physician training; and Title VIII, which focuses on nurse training; and the National Health Service Corps, which offers scholarship and loan forgiveness programs for primary care providers in underserved areas.

Together these programs are budgeted for about $600 million in 2010. These programs address disparities in patient access, and several are designed to attract students from minority, rural, and low-income communities into health professions.

I want to recognize Hannah Miller, who is in the

front row back there, who has become a resident expert on these HRSA programs, and we plan to discuss them in more detail in the June report. She can also help today with any questions on these programs that you might have. But for now, I'll just show her colorful chart, which is up here, which represents spending on Title VII. It divides Title VII funding by categories that are listed on the right hand side, including diversity, primary care supply, et cetera.

You can see that funding has fluctuated in recent years and that dollars for data collection and analysis have grown to zero. GAO has recommended in the past that greater efforts to measure impacts of these programs be a priority. Investing more in unbiased program evaluation will guide us to fund the programs that are most successful.

The third principle is to support accountability for high educational standards. To do this, payment formulas should reflect educational priorities. That is, they should be linked to achievements on set goals. Standards for these goals should be developed and assessed by educational and accrediting bodies, insurers -- that would be employers and health plans -- and patient organizations. Also, payment formulas should recognize the

need to support faculty teaching time and faculty development.

Teaching sites should also be accountable for the environment that they provide, in terms of both infrastructure and clinical care. It will be important to establish incentives to support delivery system reforms, such as team-based care, coordinated discharge planning, and understanding the relative costs of tests and treatments. The premise here is that residents and nurses who practice in these kinds of environments will learn skills that they need to incorporate into their lifelong practice styles.

So now we come to a draft recommendation on this overarching set of three principles. I have working glasses this time. The Congress should restructure medical education financing adopting the following set of principles: one, transition to stable general revenue financing in a phased-in, deficit-neutral manner; two, improve U.S. capabilities to analyze health care workforce needs, develop coordinated pipeline strategies, and assess their impacts; and, three, support teaching sites' accountability for high educational standards.

We also have implications here for spending.

Given that this is deficit neutral, we have no impacts here on spending on the federal level. And then for provider and beneficiary implications, we say that it would improve financing to address health care's educational and workforce needs for the 21st century.

Next we're going to talk about shorter-term steps that Medicare can implement in the interim. These steps would ultimately transfer to general revenue financing. But, for now, Medicare can take the lead by first redirecting its IME overpayments to high-priority areas that you have been discussing in several previous meetings.

MedPAC staff work led by Craig here has repeatedly found significant overpayments to hospitals for IME. For 2008, this totaled about $3.5 billion. These dollars could be deployed to the following five areas: pipeline goals, direct GME costs, supervision in offices and outpatient clinics, hospital quality incentive payment program, and Medicare solvency.

So, in a bit of a tag-team fashion, Craig and I are going to review each of these five items on the next five slides, the first one being on pipeline issues we discussed through Principle 2, so I'm not going to go too

much into the objective. But I do want to note that it's important for Medicare to lead the way in this area because Medicare's current financing has really no pipeline analysis component to it.

Subsidizing residents comes way too late to affect a person's career choice, and it overlooks other important health professions, like nurses and dentists.

MR. LISK: A second approach to redirecting IME funds is to use them to increase direct GME payments to support educational activities and faculty expertise. Redirecting some of Medicare's overpayments for IME to qualify for DGME would endorse the importance of teaching and recognize increases in direct GME costs that have occurred.

Remember, Medicare's direct GME payment rates were set based on hospital-specific rates from over a quarter century ago when the practice models for residency training were different and the emphasis on competency-based educational experience had not yet evolved.

Redirecting some IME funds to direct GME support would allow these payments to recognize increased costs due to more intensive accreditation requirements, particularly

with regard to the core competencies from ACGME, recognizing the importance of supporting supervisory costs during the training process, and faculty development needs for the faculty, in addition to increases in resident compensation that have occurred since these rates were set, particularly due to rises in benefit costs, for instance. Some of these funds could also be directed to providing direct support for clinical graduate medical education.

Now, there are a number of ways that these direct GME funds could be reallocated. We could just bump up the current per resident payment amounts. We could rebase the per resident payment amounts. We have not gotten into a discussion of that yet, but there are a number of different ways to consider how that could be done. And if we do that, that would also mean there would be some redistribution of how these funds would be distributed across teaching hospitals because it would be distributed in a different manner.

MS. BOCCUTI: The third source for redirected IME funds would be for Medicare to make payments to office-based settings and outpatient clinics that supervise residents and other health professionals.

As you have discussed, acute-care experience is essential for exposing students to a variety of serious illnesses, but equally important is adequate experience with ambulatory care, particularly for diagnosis and treatment of chronic illnesses.

Although physicians in community-based practices may enjoy mentoring residents and garner some prestige as "adjunct faculty," the productivity losses -- and thus the revenue losses -- that they face when supervising students, may deter them from this important activity.

So modest payments for community-based supervision could help offset the associated costs and may foster better experiences for residents in well-functioning offices and outpatient clinics. And better residency experiences may not only draw more physicians to community practice, but also train new physicians to practice in a high-quality environment.

MR. LISK: A fourth use of IME savings could go to funding a quality incentive payment program for hospitals. The Commission has recommended in the past that a quality incentive payment program be developed for hospitals. Such a program would provide a strong incentive for hospitals to

improve quality.

The Commission has previously recommended that Medicare fund a quality incentive payment program for hospitals through a combination of reductions in the base rates for PPS hospitals and from savings from a lower IME adjustment. The Commission, however, did not include the IME portion of the recommendation in this year's March report commending the Commission's broader discussion of GME financing.

In addition to the sustainability problems for Medicare trust funds, the country is experiencing soaring deficits. Teaching hospitals with relatively high margins have benefitted from an overly generous IME payment formula for over a quarter century. Reducing Medicare's liability for a portion of these overpayments could be a small but reasonable means for increasing the solvency of the Medicare trust fund.

MS. BOCCUTI: So here is the language for draft recommendation two summarizing these last slides. It reads: The Congress should deploy IME overpayments towards high-priority needs. These are: invest in workforce analysis, pipeline strategies and program evaluation; increase DGME

payments to support educational activities and faculty expertise; make payments to support supervision of residents and nurse practitioners and physician assistants in offices and outpatient clinics; fund a hospital quality incentive payment program; and improve Medicare solvency.

Spending implications. For this, savings would be equal to the unspent share of the IME overpayment for provider and beneficiary implications. First we note that it would reduce hospital payments to some teaching hospitals. It would improve pipeline analysis and program implementation, enhance medical education activities, improve hospital quality, increase community-based training experiences, and increase Medicare solvency for beneficiaries and providers.

MR. LISK: Okay. I'll transition to another set of recommendation topics, and this one is on increasing transparency.

As we should know by now, Medicare provides financial support to hospitals in two ways: one, through the direct GME payments, and the other is through indirect medical education payments, both of which go to hospitals.

Then hospitals provide financial support to the

residency programs. Sometimes this may be the medical school, too, but through the hospital. And they may pay the residents for stipends and benefits, supervising faculty, and program administrative expenses. Support for these expenses will come in part from Medicare, but also Medicaid and private payers potentially as well, to the extent -- through private payer revenues.

Residency programs, however, do not necessarily know how much support Medicare -- or Medicaid, for that instance -- provides to the hospital, and they may not feel as though they are getting their fair share of support from Medicare.

So how could Medicare foster greater transparency and help in this regard to IME and GME funding? CMS could produce an annual report on indirect and direct GME payments that individual hospitals and other entities that are eligible for these payments could receive. Such a report could be easily produced from Medicare cost reports and, in fact, CMS already creates a file that includes some of this information, but it is not necessarily in a user-friendly format or easy to find on their website. But that information is actually reported.

The New York Council on Graduate Medical Education also has a proposal on transparency that goes several steps further, which I describe in your mailing materials, and if you want, I can describe that more, if you want, in questioning.

So to help increase transparency, here is draft recommendation three, and it reads: The Secretary should annually publish a report that shows total Medicare DGME and IME payments received by each hospital. This report should be publicly accessible and clearly identify each hospital, the teaching payments received, and the number of residents and other health professions that Medicare supports.

The spending implications for this are none. It is already basically almost done within the current administration budget. We'd just be improving it. And what it would do for provider-beneficiary implications, it would provide greater understanding about Medicare's payments for graduate medical education and make them more publicly transparent.

Moving on, we want to next talk about reducing barriers to residents' educational experiences in community settings. Current rules and regulations create

disincentives for training in non-hospital settings. Time spent in didactic activities outside the hospital may not always be counted for Medicare payment purposes, for instance. In addition, rules governing requirements of hospitals to pay for all or substantial all training costs in non-hospital settings may discourage many training opportunities in many ambulatory settings.

There is also a paperwork burden placed upon programs in hospitals for tracking residents' hours in all the different sites that they attend to keep up with CMS' rules on this.

So those are some of the constraints on there. But even if we relieved these restraints, there are other financial disincentives for hospitals' experience, and those will continue. For one, residents provide a valuable service to hospitals, and they'd like to keep that if they can. In addition, paying non-residents if they want to take them out may end up being more expensive for the hospital. The other type of replacement staff may be more expensive.

Given the statutory and regulatory concerns that may provide barriers to training in many potential ambulatory settings, the chairman offers the following draft

recommendation for your consideration, and it reads as follows: The Congress should require the Secretary to count full-time residents as eligible for full DGME and IME payments. Residents' clinical, didactic, and other education-related time should count toward full-time equivalency regardless of the setting where the resident trains.

The spending implications for this is it would be a minimal increase. And the provider and beneficiary implications, it will help support community-based education and training and also reduce paperwork burden. This is essentially a recommendation that is also part of some of the health care reform bills, too.

MS. BOCCUTI: Okay. This is the slide. It is a summary slide, and it provides a summary of what we were talking about and the four recommendations up there.

The first was composed of a set of principles for restructuring medical education financing, namely, that it transition to a general revenue model, enhance pipeline analysis and strategies, and support accountability for educational standards.

But in the interim, under number two, Medicare

could redirect its IME overpayments to the five high-priority areas we discussed. I won't read them.

Then for three, increase IME -- let's see. I can't -- maybe you should read them.

MR. LISK: Three, increase IME and DGME transparency, payment transparency. And then four is modify the statutory and regulatory non-hospital provisions to encourage ambulatory training.

MS. BOCCUTI: So we'll just keep this slide -- this slide I think will be a good one to keep up on the screen. I think it will help people refer to what numbers we're talking about.

MR. HACKBARTH: Good. Let me just offer a couple additional comments. First of all, on this list under number 2, what I tried to do here was capture a list of ideas that have come up over the course of our discussion. These are the ways that we might apply the so-called IME extra differently to achieve different policy goals. I'm not sure that we would want to do all of these things, so don't infer from this list that this is a proposal that we divide up the $3.5 billion across all these purposes.

So one of my objectives for today is to see which,

if any, items on this list had the most interest and support among Commissioners. So that's something that I'll be looking for.

The other thing that occurs to me that might be a helpful reminder or clarifying for the Commissioners would be for you, Craig, to just briefly describe the process by which the DGME money is distributed, in particular the per resident amount, because we have proposals to shift money from IME to DGME, but that DGME may be a little bit murky to people, so if you could do that.

MR. LISK: I would be happy to. So direct GME payments were based on 1984 costs from a hospital, and it was calculated based on what they spent in 1984 inflated on a per resident basis. So each hospital has a per resident amount for each resident. So let's say it's $100,000 -- and it's actually close to an average of $100,000 today in terms of what the per resident amount is.

Now, there is a little bit higher amount for some residents who are primary care residents versus other residents.

In terms of Medicare payment, Medicare's payment is the per resident amount times the number of residents --

I'll actually say the weighted number of residents time Medicare patient share, which is determined based on the inpatient days to total patient days. That's how Medicare's share is done. It's based on inpatient share.

The weighting factor, this weighting factor counts -- residents who are subspecialty or who pass their initial board eligibility, it's half an FTE. So they're counted at 0.5 versus other residents are counted as 1. So we do have a differential for subspecialty residents here. So you make that formula in terms of what the weighting factors are.

There is a cap, though. We have the cap on residents, so hospitals that are over the cap, you know, are up to their cap.

The other important factor on the per resident amount to understand is back with the BBA and MMA legislation, there were changes to the per resident amounts for hospitals that had low per resident amounts, and they were brought up to an amount that's 85 percent of a geographically adjusted national average rate. So the low end was brought up. People who were at the high end had their rates capped -- the rate of increase, the CPI rate capped, so they would not be more. So if they're over 140

percent of the national average, their rates would not increase until they got to 140 percent of the national average.

So you have basically that -- here the basics are the per resident amount times the weighted count of residents, which may be capped, times the Medicare patient share gives you the total direct GME payments, which total about $3 billion in total today.

MR. HACKBARTH: So there are a couple points in particular that I wanted to make sure that people understood. One is that the idea behind DGME was, well, this is how we're going to pay for the stipends and faculty salaries and the direct expenses of the training programs. But because the amounts are fixed per resident amounts based on a 1984 base year, then with the series of adjustments that Craig has described, how much an institution spends today on those things doesn't influence their payment. It's sort of like a fixed, prospectively determined amount based on historical considerations. And I just wanted to make sure that that was clear to people.

Then the second thing that I wanted to make sure was understood was it's not a uniform amount. There's

substantial variation from the lowest per resident amount to the highest. Again, it's rooted in what was spent in this base year.

DR. CROSSON: I would just say the last point was the point I was going to make, because I wasn't quite sure in how Craig described it that that came across, that, in fact, when the baselines -- if I understand it right, when the baselines were set, they were set by institutions, not an across-the-board number that was then adjusted.

MR. LISK: That's correct.

MR. HACKBARTH: And Mark just reminded me to emphasize one other point. It was never intended to cover the full cost. It was all always linked to Medicare's share based on the admissions ratio.

Okay. So let's do round one clarifying questions, and we'll do a different pattern this time. We'll start with Bill and go down this way and around.

DR. SCANLON: To continue on this DGME line, do we have a sense of what share the current payments are of what would be the total Medicare share? In other words --

MR. LISK: Could you repeat that again? I'm not sure which share you're talking about.

DR. SCANLON: If we were to fully fund one of these resident -- a residency slot, what would that cost be today versus what we pay? And let's inflate the Medicare share up to 100 percent. Does that make sense? Because if Medicare is paying 40 percent, then -- what's 40 percent of the cost of a resident slot today?

MR. LISK: Right now, in terms of -- this is unaudited data, but between $130,000 and $140,000, is what we would say off of the cost reports, on average, in terms of the cost of what's reported.

DR. SCANLON: Okay. And then what would be the share that is Medicare on average? And what is the payment amount on average?

MR. LISK: Now, that's another good question because how Medicare's share is calculated, that gives you a different number, because Medicare's share over what resident services provide. So Medicare's share in terms of how the direct GME calculation is made is on inpatient share. Inpatient share is higher than what it is for the entire hospital, so that produces a bigger number. So, actually, if you look at Medicare's share for teaching hospitals in terms of Medicare's share of the cost and the

resident's cost in those units, if you allocate it that way, you're talking between 25 and 30 percent. If you talk about it the other way, you're talking probably between 35 and 40 percent if you talk about it based on inpatient share.

So if you talk about the total resident costs in one way, you can get different numbers here, depending upon how you look at it. And this is getting confusing. I'm sorry.

MR. BUTLER: I'll try to clarify from one person's perspective, and then you can tell me it's so, because I was involved -- I remember those base years. So in a very maybe, hopefully, clear, practical sense, we took the cost report, and you recorded all your direct costs of both the faculty as well as the residents' salaries and benefits as well as overhead that literally gets stepped down and allocated to the intern-resident cost center on the Medicare cost report. You divided by the number of residents, and that became your cost per resident, which had wide variation around the country, and still does today.

We have continued to report that every year on our cost report and continued to allocate those costs, and it bears no relationship to the payment, as was said, which has

been updated by the urban CPI, which, for example, this last year in a lot of metropolitan areas was actually negative. You use a different CPI update. Anyway, my understanding is if you compare -- this is at the heart of the issue -- the payment received today versus what the costs are showing on the cost report, the $3 billion becomes something like $4.3 billion. So there's about a $1.3 billion difference between the costs that are being reported today and Medicare's share of those costs versus the $3 billion. And that -- and let me finish, and I'll let you respond to this. That's one gap in the shortfall. The other is the ones that are over the cap. So there are about, what, 6,000 or so positions over the cap that have -- that would be in addition to this amount.

Now, the $1.3 billion that I have alleged, that I think is the AAMC's number, you can -- I mean, it's not a -- it's a number that can be verified, so it's not something that can politically be thrown out, but that's roughly the rationale in many ways why you would take some of the IME money and say these things have escalated in cost above the urban CPI, some for very good reasons because of the infrastructure accreditation, and some for maybe unknown

reasons, but the costs have increased more rapidly than the payment.

I hope that helps.

MR. LISK: And actually, what I would want to qualify, there are kind of two numbers. The 4.3 is based on calculating Medicare's share as it is done in the current direct GME payment formula based on the hospital. If you looked at it based on what share residents are in the departments where they serve, that number I estimate would be $3.6 billion. So it would be -- so you have a range here in terms of what you might think of Medicare's share.

MR. BUTLER: And if you threw in ones over the cap, you'd get another $600 million --

MR. LISK: And that would be a different number. That's --

MR. BUTLER: But, anyway, there's a difference between -- that is an opportunity to more appropriately align IME and DGME.

MR. HACKBARTH: Okay. Let's continue down the row here with clarifying questions.

MS. HANSEN: Right. This is a different topic, but what is also covered in GME, and I think I've spoken

with you, Craig and Cristina, about the question about the nursing money that right now is part of the GME. I believe the amount is about $100 million, ballpark or so?

MS. BOCCUTI: I think it's a little bit more than that, but it's between one and three hundred --

MS. HANSEN: But ballpark.

MS. BOCCUTI: Yeah.

MS. HANSEN: I guess the question, as we're going through this modernization process of looking at GME, given the fact that these are funds that go directly to hospitals rather than educational institutions, which is where professional nursing is being prepared, have there been some discussions -- and I know, of course, this is so sensitive just because there is a funding flow already. But relative to upgrading the professionalism and the kinds of things we're doing, any discussion or thoughts about that?

MS. BOCCUTI: Well, some of the things that we included in this presentation take into account perhaps some of the supervision payments, including supervising for nursing and physician assistants and residents, because we certainly have learned that nursing has much more application outside the hospital, so they may better benefit

from supervision help and payments in the community setting. So that is one way where we've brought that in.

Another would be from the pipeline issues, because I think that there are issues about integrating what the workforce needs are when you look across all the health professions, and so that would be another consideration there.

And then another one would be when we talked about the educational environment and teaching hospitals, I think that here is where team models could also be rewarded in an educational component, so a teaching hospital and residency programs that made sure that there was communication between nursing staff and physicians and residents and that in a professional way where even nurse practitioners could be teaching residents, you know, what they're doing. And in many regards, there is learning that can happen there.

So I think that there are many avenues to enhance the role of nursing in medical education. But I don't think that there's a specific one recommendation that we've discussed here that only applies to nursing and other professions. But we've tried to bring that in in many of these.

MS. HANSEN: I appreciate the options, and I wasn't asking really as much the question about nursing's role to medical residency education really. It was really the fact that right now under Medicare and under GME there's specific funding that is going directly to hospitals, bypassing really the intent of the educational system. So, again, it's whether or not we're preparing nurses in an academic manner rather than an apprenticeship manner.

MS. BOCCUTI: Yes, and that's why I think that outpatient setting -- and I think that's what you're saying -- is a better environment for that. And what's going to those hospitals you are talking about, it's a limited number of hospitals that are doing it, and it's for diploma programs, and that's sort of a vestige of an earlier model.

MS. HANSEN: And then to that point, the last thing I would say is if it's to be deployed differently, you know, there is a movement of even getting residencies for nursing. So if it was deployed definitely and using the similar graduate medical education model, you know, there is a movement for a graduate nurse education because oftentimes people -- hospitals themselves are finding that people graduating from schools are not prepared clinically, and as

a result, there's a turnover oftentimes easily of 20 to 25 percent in that first year.

So another thought of if we're going to efficiently use it for effective results, another concept.

MR. HACKBARTH: Clarifying questions.

DR. CHERNEW: I would like you to clarify what's meant by general revenue financing model. I didn't understand the description on page 1.

MS. BOCCUTI: Well, let's turn to page 1.

DR. CHERNEW: My specific question is: Is that just whether the money is raised from general taxes, like income taxes, or through the Medicare payroll tax? Or does that have something to do with the way the money is paid out as a part of the DRG fee schedule?

MS. BOCCUTI: More the former.

MR. HACKBARTH: And we'll come back and discuss this in more detail, but the short answer is it's the former. It's how the money is raised, whether it is through the payroll tax or through the progressive income tax. That's the short answer. But I know for a fact we will discuss this more.

DR. DEAN: I was curious, you didn't address the

issue of the cap at all in this. Why was that?

MS. BOCCUTI: Well, if you think about the workforce issue that did come up, the pipeline issues, I think that that may be an opportunity to look at that. But we weren't taking that on specifically. But, Glenn, you want to come in here.

MR. HACKBARTH: Yes, let me take a crack at that since it came from me. It seems to me that to address the cap, what we need to do is have a coherent assessment of what our workforce needs are, both the aggregate numbers and how they should be divided by specialty and the like and alternative non-physician clinicians, et cetera. And so it seemed to me that was part of a long-term effort as opposed to a short-term decision. That was my thinking on it.

Other clarifying questions?

DR. BORMAN: Could we just clarify a little bit about what we mean about make payments for office and clinic supervision? Is that increasing payment for the primary care clinic exception? Is that some new payment stream? Just help me understand what we might imply by making payments for office and clinic supervision.

MS. BOCCUTI: I hadn't thought about it being

related to the supervision requirements in the billing, like what you just said, but more related to whether it be a billable code for it or an add-on or an amount. I think sort of the technicalities of operationalizing this we haven't gotten to, but in some sense boosting payments to the outpatient clinic or to the physician office when they are actively supervising nurses and residents. So it wouldn't just be, you know, all the time, but for those kinds of activities.

MR. LISK: Recognizing the inefficiencies that may be associated with participating in the activity.

MS. BOCCUTI: You could bring up ways that you might think it would work well, and we can talk about that. But we haven't gone -- with many of these, we haven't gone down the steps of exactly how it could be implemented.

DR. BORMAN: But the intention, if I hear you correctly, was largely directed at places where there's not currently something going toward that. So, for example, if a resident went to an office of other than a faculty member for some specific exposure or curricular reason, and that physician wasn't billing as a teaching physician or getting something in some other way from the residency program or

the hospital, which presumably wouldn't give him anything either, that this then would be another mechanism to pay those physicians.

MS. BOCCUTI: That's right.

DR. BORMAN: That's sort of what you were thinking.

MS. BOCCUTI: Exactly.

DR. MARK MILLER: One thing on this to keep in mind, of course, if we do go down this road, we have to be conscious of the potential for increase in volume for billing for these things and think about some way of kind of building a bit of a house around it.

DR. CASTELLANOS: Just a continuation on Mike's question about general revenue. My question is stability. How stable is stable? And is it better or less stable than what we have now?

MR. HACKBARTH: And it's an important question, and we'll come back to that once we go through round one.

DR. MILSTEIN: I have three very narrow questions.

First, do we ever -- you know, we've actually made some great progress in the last, you know, few years on trying to think about Congress' idea of, you know, pay for

efficient delivery. Have we ever done that, that is, basically said, well, let's take the subset of residency programs that get an A-plus on their ACGME rating, and then actually ask what does it cost if the most efficient producer of -- if the teaching hospital is the most efficient producer of A ratings. So we begin to get a picture as to what IME ought to be if medical education is being -- if residents are being efficiently used in places that are getting great scores from ACGME. Have we ever attempted anything like that? Because I certainly -- my intuition is that we have scores from ACGME, we have a basis for -- ACGME has scores, and, you know, we have bases for doing cost studies. Have we ever pursued that, thought about that, so we could begin to sort of think about getting this onto the same platform, you know, that we've had other --

MR. HACKBARTH: Well, a critical premise there is graduated assessment programs by ACGME, and, you know, Karen knows way more about that than I do, and Craig and Cristina may also want to comment on it.

My impression has been that that's maybe an objective, but we don't have that infrastructure now.

Karen, do you want to address that?

DR. BORMAN: Yes, just briefly. The short answer I think would be that, yes, there are some things that could start toward a score. I think the plan is for it to get better and better through the Milestones Project, which Glenn is familiar with, but that there are some things now. For example, in each specialty there's a potentially longest cycle between accreditation visits, and so a program that gets the longest or near to longest, that's a reflection of a judgment that that program has commitments and processes and outcomes that suggest they don't need as much monitoring.

So there are a few things like that. It suffers the vagaries of they differ from specialty to specialty because there's different residency review committees. But there might be some things that would be a starter set on it, yes.

DR. MILSTEIN: That's good enough for me.

MR. HACKBARTH: So, Arnie, the way I thought about this -- and it may not be the right way -- was that our goal of having more rigorous graduated assessment of how well training programs do in producing the physicians we need is

a goal that people have repeatedly referred to in our conversation. I'm not sure we're quite there yet. So I had it on the longer-term part of the agenda. So the summary here, the third bullet, restructure our financing to support accountability for educational standards, and what I was thinking there was in the future be able to link payment to performance. But I'm not sure that's a short-term step.

DR. MILSTEIN: Thank you. A second very narrow question. This quality -- I guess this idea of taking some of the money and moving it into quality, we're referring -- that would be just for teaching hospitals. Is that right? Oh, the whole thing, okay.

MR. HACKBARTH: So that particular bullet is a basically a reiteration of what we've recommended for three or four years now about how to take 1 percent of the IME and put it into pay for performance.

DR. MILSTEIN: Then I think that leads to my third question, and I'm a little puzzled by this, because I think one of the examples in the quality-based payments said, well, let's start linking these quality-based payments to the content of what's being taught, team-based care, you know, et cetera. I guess what you're saying is that would

apply to teaching hospitals, but to the non-teaching hospital redirection of this into quality incentives that wouldn't be relevant because there'd be nobody -- nobody would be being taught.

But my question is more for you, Glenn, and that is, this is somewhat of -- this notion of linking it to educational content is a deviation from what I thought you'd said earlier, which I had grown to -- I'd migrated toward, which was this idea of, you know, look, what constitutes -- you know, great quality is going to change very quickly. So rather than, you know, link the quality payments to teaching hospitals based on certain curricular content, but you were saying instead let's begin to move it towards teaching hospitals that score fantastically on -- like Denver, you know, on quality, resource use, you know, the works. Why the change, or is it just an interim idea?

MR. HACKBARTH: Well, actually what I am trying to do is create a discussion here about how to do that. As I've listened to the discussion and I've had some follow-up conversations with individuals, I've heard sort of two schools of thought about how to increase accountability for performance.

One school, which I will characterize as the Arnie Milstein School, is sort of if we can get people trained in settings that are high-value settings, presumably that will influence the skills that they're taught, the culture that they're imbued with when they go out into practice, and we want to reward training in those high-performance environment, the Denver Healths, et cetera.

And, you know, one shorthand label for that is, you know, sort of think of teaching ACOs, we'll pay the extra only if the teaching is done in a certain type of high-performance setting.

Peter -- and jump in, Peter, if I'm not representing your views correctly -- is a little concerned that maybe that's too restrictive, that there are high-quality teaching venues that may not want to be accountable care organizations, not able to be accountable care organizations because, for example, like MD Anderson, they're very specialized. And so to say, oh, you're not eligible to get these performance dollars because you are, you know, a specialized institution as opposed to a more general purpose, that wouldn't be right.

And so Peter said, you know, let's see if we can

link our performance incentives to a rigorous assessment of how well they're carrying out the training mission, and perhaps ACGME can provide us the infrastructure to do that through graduated assessment.

Is that a fair characterization?

MR. BUTLER: Yeah. But I could see there might be some hybrid in the end. It's not black and white. But I favor more the latter. So if you look at Denver Health, for example, one thing that they take capitate -- you can kind of tell it's maybe the -- but if they didn't do LEAN training for any of their residents, they shouldn't automatically -- you know, it has to be part of the training program itself, not just an environment that is progressive in the delivery system; whereas, say Ron -- and he can't defend himself. I suspect his residents are being used in more of the traditional way in his system than maybe in -- I mean, it would be totally unfair, but I could see how that can happen. And so I would want to make sure the "curriculum," the program itself, would have attributes that, you know, earned them extra points.

MR. HACKBARTH: [off microphone] Okay. We're still on clarifying questions.

MR. GEORGE MILLER: You may have covered this, but my clarifying question that hasn't been asked is: Why the movement away from the payments from the general funds from what we currently have? Are you going to explain that later when we --

MR. HACKBARTH: [off microphone] George? Why --

MR. GEORGE MILLER: Why the movement to the general funds for funding?

MR. HACKBARTH: [off microphone] Why propose that?

MR. GEORGE MILLER: Yes.

MR. HACKBARTH: [off microphone] Okay --

THE COURT REPORTER: Your microphone, sir.

MR. HACKBARTH: I'm sorry. There are a couple issues here, and I know Bill wants to go into this as well. In fact, before we do that, why don't we let Nancy ask her clarifying question. Then we'll go to Bill, and we'll leap into this topic, I'm sure.

DR. KANE: Thanks. On Slide 11, you mentioned that we can put GME and IME towards workforce analysis and pipeline strategies, so that's not something Medicare has done historically, but others have. And I guess I'm

wondering, did you have some -- and also this notion that career choices -- I guess I'm trying to connect up what vehicle does Medicare use to change its role with health care workforce. There are parties that do that now, that do think about the workforce and that do think about career choices. So where would Medicare fit them? Would they just start funding these places or --

MS. BOCCUTI: Right. Some of these dollars with some of the savings could offset expenses that potentially other agencies incur from doing this work. So they could boost their resources for doing these services, or the dollars could come directly from other revenue sources and -- go ahead, Mark.

DR. MARK MILLER: I think one way to think about it is if you were just thinking of it in a unified budget, deficit-neutral way, you add money -- and I'm just going to say, because I know this has some sensitivity. You add money to Title VII and VIII programs, assuming they're functioning well and all of that, because I know that issue has been raised, and you offset it with a reduction in IME. Okay. That's why it says "with IME savings." That's kind of the thought there.

DR. KANE: Yeah, I caught that because Medicare is not [off microphone] -- Medicare wouldn't be playing a role other than paying for somebody else to do this job.

DR. MARK MILLER: Well, playing a unified budget role by lowering its expenditures and creating the room for some other expenditure to occur. Now, it's currently two different pots of money, just to keep that in mind, and I think when we get into the discussion that's going to be triggered by Bill's comment on, you know, Medicare's role and Medicare dollars, you know, you can raise the questions of whether Medicare dollars should directly go to this. But in this thought, this wasn't the statement that you made. Is this Medicare dollar traveling to a different program? Here it's being -- this is the interim one. This is just the thought of it would serve more as an offset in order to increase more of those activities.

DR. KANE: So do we have a sense then that those programs that might receive this money are able to change the way the workforce pipeline is? Have they had a history or how successful are they at achieving anything like this?

MS. BOCCUTI: Right. There is an issue here. GAO has studied this. We've been looking at it. Hannah has

been doing a lot of work on the articles. It's hard to point to very rigorous research on all of the Title VII, Title VIII National Health Service Corps work. The National Health Service Corps has been around the longest and does have more data on how many people they've produced. Like 80 percent stay longer than their service requires. You know, I think up to 50 percent of the people who participated stay at least five years past -- or, you know, I don't know these numbers directly, but they do keep some statistics on National Health Service Corps, and that goal is very clear, you know, to get primary care providers in underserved areas so it's easier to track.

But the goals for some of the other programs are more difficult to track. They change from year to year because the programs change, because sometimes the programs have to be new each time. There's also lack of funding for analyzing these programs. And I think we've tried to stress how important that's going to be. If you want to invest in pipeline concerns and issues, then you need to also invest in where you're getting the biggest bang for the buck and which programs are successful and which ones are not.

So it's very important, if you're going to put

money in, to see whether that money is working. And I completely hear your concern, and I have been hearing it before, that we don't know if they work and we're not comfortable endorsing something when we don't know how successful it is.

So we think that it's absolutely essential that we have program evaluation as a component of this kind of spending.

DR. MARK MILLER: And just so you think about the overall construct of the recommendations, this is clearly one where you could say because -- I've got two concerns. One if IME is reduced but the Congress doesn't choose to raise that funding, that's an issue. And, number two, if they do choose to raise that funding, but we're not sure those programs are functioning, this is also discussed more in the principles. And you could, as Commissioners, make a decision that this is the kind of thing that really needs to be handled more in where we're headed as opposed to the interim, and that's one of the things I think you have to think through on these interim steps.

MR. BUTLER: One more quick clarifying. I don't know if there's a substantive reason, but we keep calling

this, including the chapter heading, Medical Education Financing when it is graduate medical education financing. There is no money in Medicare for medical education, as it's known. Outside of this room, it gets probably -- you know, you say, well, all medical education is financed. That's not true. So I think that distinction is important.

MR. HACKBARTH: Just one last thought on this issue of the mix of people being produced. I don't think it can be overemphasized at least when I say I don't think we're getting the mix of specialties, for example, that we need, that is not an indictment of the institutions doing the training. In fact, I think Medicare bears a large share of responsibility for that, and probably the most important influence Medicare has on it is how we pay for services. And we shape the preferences of clinicians in training and doctors or students in medical school and how they think about their futures in medicine. And so I just want to be clear that it's not a criticism of the institutions. Medicare bears lots of responsibility for what's coming out of the pipeline. And so we're not assigning blame. We're trying to say is there a way that we can redeploy the resources to produce a mix that is more in keeping with

society's needs.

So if we are done with clarifying questions, let's go to round two, and Bill is first.

DR. SCANLON: Okay. Since the question of the financing has come up, let me give you my take on this. If you look at the summary slide and you take the second two bullets in one and the whole rest of that slide, to me, those are all about the issue of how do we invest in human capital that is going to improve the Medicare program for the future. Embedded in there are issues of what is it that we want in the way of human capital, sort of how are we going to sort of best accomplish that, how do we introduce accountability to make sure that we are accomplishing it. And a part of that is sort of greater latitude in terms of what we are doing now. And so I think those are all sort of very positive steps in terms of how we sort of make an investment that we think is going to have benefits to the Medicare program and to Medicare beneficiaries for the future.

Bullet number one -- the first bullet under number one is different. It's about financing. It's kind of where the money comes from and this notion of that we should

switch to general revenues can have sort of multiple motives. One could be that we are trying to save the Part A Trust Fund, but there's not enough money here to save the Part A Trust Fund, so I think we can take that sort of off the table.

The second one could be that what we're thinking about is the incidence of the taxes that are being used to support this activity. Part A is funded out of a payroll tax and general revenues are funded from different kinds of taxes. Thinking about it in those terms, though, I think is -- first of all, it's not the normal purview of the Commission, and secondly, to think about it in such a narrow focus is not the way one ordinarily would think about sort of tax incidence analysis because the issue in terms of tax incidence is what do I as an individual pay sort of in all forms of taxes and what do I get as an individual sort of in all forms of benefits. This is so isolated in terms of that that it is problematic to sort of think we would make a decision on the basis of that.

On top of that, a complicating factor is that the payroll tax here for Medicare is different than the payroll tax for Social Security. It has an unlimited base in terms

of earned income. It's also being discussed now to think about should we add unearned income to the base? Should we vary the rate? I mean, it would become a very different tax and so the whole sort of analysis would change.

The other thing, I think, to take into account here is the other implication of switching to general revenues which changes how this is dealt with sort of in the Congress. It puts it into the budgetary and appropriation process, and even if we -- in our paper, we have cited sort of the Children's Health Insurance Program as an example of something where there has been, I would call it, relatively stable funding. We had an initial sort of ten-year allotment or appropriation of funding, but when the ten years were up, we saw that it wasn't sort of necessarily easy to renew it, that when you go to renew it, you have to think about what are going to be the pay-fors, and the pay-fors can become a source of controversy. They can affect sort of whether or not you have disruptions in the continuation or whatever you have a change in level in the continuations. Those are not necessarily good things when you're thinking about making an investment for the long term.

When you're trying to build capital, and this is in some respects -- you know, we talk all the time about States having balanced budget requirements. Their capital budgets are often separate from that because there's a recognition that capital budgets are something that you're trying to build for the future and you want stability there. And so there's this question of thinking about how do we have sort of a stable sort of funding source for what is essentially a capital investment for the Medicare program.

So I actually think we shouldn't be sort of focused on this as one of our recommendations. We should be focused more on the question of how do we invest in the human capital that's going to improve Medicare, and what are going to -- there's a whole series of things we'd have to consider here. What's the target? How do we ensure that the target is being sort of met? What's the best mechanisms for doing sort of both of those kinds of things? Those are big challenges for us and those would be big changes to what we currently are doing now and sort of in a potentially positive direction.

MR. HACKBARTH: What I'm going to propose here is that we proceed by issue as opposed to just sort of going

around. So what I'd like to do is focus on the issue of general revenue financing for a second.

Before I turn to you, Bob, let me just react to what Bill has said. Bill at the outset said that there are different reasons why you might say general revenue financing versus payroll tax, and I agree with his list. All three were in my head. In Bill's list was save the trust fund. I don't disagree with his statement on that, however.

Second, the difference between financing social good using a payroll tax as opposed to progressive income tax. You know, I plead guilty to having made that point multiple times. But I accept Bill's point that that's really not something normally within our province, our expertise. Fair enough.

The one that is very much Medicare policy-related is this. I've been struggling with how we use Medicare-based financing and get to our goal of moving away from the Federal Government contributing to GME by add-ons to service payments. Instead, get to an alternative model where the Federal Government pools all of its resources for financing GME at a place and then deploys them based on a rational

model for planning our future workforce needs.

So I was sort of stuck on taking dollars from the HI Trust Fund to support activities that might be housed in PHS to develop a coherent workforce policy, and that was part of the reason that I was thinking it probably needs to come out of the Medicare funding stream. So of the three, that's the one that really seemed most important in my head.

DR. SCANLON: Okay. As I said, there is an alternative, which is the Congress creates the latitude for the Medicare funding stream to do some of the things that have been in the Public Health Service. But what we would probably say is do it with the assurance that you have accountability --

MR. HACKBARTH: Yes.

DR. SCANLON: -- for those dollars and that they are not on some kind of automatic pilot where they're not going to be stopped at some future point if they're not being used appropriately.

MR. HACKBARTH: Yes, and Bob may wish to address this in just a minute. If we can do that -- one of my concerns about taking it out of Medicare is the stability issue and assuring stability in financing. But we had

talked about sort of the CHIP model of the mandatory appropriation, but I recognize that is an imperfect solution.

Let me get Bob and then Mike.

DR. BERENSON: Yes. I do want to follow up on that, because I was going to make a similar point about the sort of theoretical niceness of using progressive taxes to fund the social good, but the reality of what happens in our budgetary process right now, which is to freeze discretionary spending and have no ability to do anything, really, with mandatory spending.

I found some data that was in a Macy Foundation report looking at Title VII, which we've talked about as one of the important pipeline programs, and it's currently funded at between $200 and $300 million a year. It got a one-time boost from ARRA. Apparently, in 1970s dollars, when it was originally funded, it would be funded now at $2.5 billion. It is basically being funded at about ten percent of what the original funding was. Now, it could be that somebody did an evaluation. My hunch is that that didn't happen, that it has just been subject to squeezing over the years.

So I'm reluctant to go down the road in which we would suggest to the Congress that they would support the pipeline aspects of what we are proposing by dedicating some of the IME funding over there. That wouldn't happen, in my view, and I think we then want to look at ways in which we can potentially target Medicare dollars for those programs with accountability, with evaluation. And again, the model that I think might be instructive is the apportionment to QIOs, which comes out of the trust fund. It's a specific apportionment for specific services. There's a scope of work. There's controversy over whether that's achieving its purpose. But I could imagine something comparable to support programs in the pipeline. So that was my point.

MR. HACKBARTH: Okay. So comments on this issue of general revenue financing? I have Mike, Mitra, Peter, and Herb.

DR. CHERNEW: So my original source of confusion was whether it's funded by a payroll tax through Medicare or general revenues is completely independent, as near as I can tell, as to whether or not it's paid by an add-on to the fee schedules. And it strikes me that the basic problem that we're worried about is we don't think -- and I agree with

this -- it doesn't seem to be a very effective way to finance education as an add-on to the fee schedule, because there's a whole series of distortions that occur when you manipulate the fee schedules for something that is not what you really want to pay for.

And that seems to me to be what the recommendation should focus on, removing the add-on payment and not how it's raised. You could even conceivably, for example, say, let's lower the payroll tax for the Medicare Trust Funds and have a payroll tax for the medical education part, if you wanted. That strikes me as a little crazy.

But in any case, I think there's a lot of ways to deal with the stability and the financing issues and the autonomy of who makes these decisions that are different than the basic problem, which I think is the crux of the discussion we've been having, which is we want to move away from a fee schedule payment system to paying for something about education.

MS. BEHROOZI: Yes. I think my comment is kind of related. This is a historical anomaly, kind of, that Medicare is the major player in financing graduate medical education because it's the only thing we've got close to

national health care policy or coverage or whatever. But it's not necessarily coherent that Medicare is looking at what Medicare beneficiaries need and that's what should inform how to enhance workforce analysis and pipeline strategies.

There's a whole medical profession out there that's not all geared toward servicing Medicare beneficiaries, and hospitals that depend on this money to support part of the training for physicians or as part of their general revenue stream or whatever it becomes, you know, I don't know that they're thinking so much about how am I educating these doctors to treat Medicare beneficiaries.

I think whether it's payroll tax or general revenue, it should be stable, and so I guess just regular old general old revenue. I get that it's not going to be a stable source, either, for the education or for the hospitals who have come to depend on it as general revenue, but I think, to me, as Mike was saying, detaching it from the status of being an add-on to payments.

Similarly, I think that it's sort of incoherent to have Medicare doing its thing and we do our examinations of

the physician workforce and all of that stuff, and then there are other sources of funding that we're not really talking to and coordinating with, and just an all-payer kind of strategy, the New York approach.

So I think you end up thinking about funding issues, but not so much first, but rather maybe as a consequence of trying to be more coherent about it.

MR. BUTLER: So just to distinguish one more time, the -- we keep talking about add-on payments. DGME is not an add-on payment, depending on volume, and is a lump-sum payment we get based on the percentage of Medicare business in the hospital. So the more you do, it doesn't mean you get paid more. It is a fixed amount. IME is the one that's the add-on.

Now, I think my perspective on the general revenues concept was that if I go back to last summer's retreat, we kind of went around the room on a base chapter that was pretty good and we kind of said, what do we want to do, and I think accountability was a theme, primary care was a theme, ambulatory-based training was a theme. Those are three themes I can remember, and I think we even had this on there but it kind of got lukewarm support for kind of -- we

kind of looked at all payer and think it is a good idea, but pretty difficult to do.

So I think now that it's suddenly kind of right at the beginning, it's overarching, is saying, have we really thought this thing through? There are a lot of logistics with it, including does it have both DGME and IME payments in there? I'm not clear. And then it says pooling the money from Medicaid and other payers. Is that what we mean? So I don't know if we have really a lot of answers to a pretty big principle if we roll it out as our overarching one. So I'm not real excited about this as a lead principle.

DR. CROSSON: Cristina or Craig, do you want to clarify the intent?

MS. BOCCUTI: I think -- thinking at the intent of the general revenue, as Glenn had talked with us, was more about the opportunities that are involved when you can coordinate all the public dollars. So that would be Medicaid, Medicare. There's more, even the HRSA dollars and VA, DOD may be separate. But the idea was that if, yes, if that were pooled, you'd have a better ability to think across all health professions, across all learning

environments, and have a more rational approach to answer the needs, the societal needs for the graduate medical education. So it was considering all the dollars, if that's the intent you're asking about.

DR. CROSSON: Right. So --

MR. BUTLER: Very complicated.

DR. CROSSON: In terms of IME and DGME, this recommendation, which is a long-term recommendation, as I understand it, is to move all the money out of --

MS. BOCCUTI: All of the dollars.

DR. CROSSON: -- the responsibility of the Medicare trust to general revenues. The short-term recommendations, which come later, which talk about moving the IME payment, is just limited to IME.

MR. BUTLER: But IME dollars are patient care dollars. They're not education -- they're a consequence of having an educational presence, perhaps, or correlated with, but they're not education. This is where it gets complicated, and beyond where I think we're at right now --

DR. KANE: The direct GME, part of that is that you're paying for residents to do a lot of work in the hospital. So it's not just education. I mean, I think

that's part of what -- well, I mean, it's not just education that you're doing DGME. At least, that's not how it's used, so --

DR. CROSSON: We have Herb next, and Bruce, then Ron.

MR. KUHN: Thanks. I want to pick up on a bit of a theme that Bill was talking about earlier, and that's the issue of stability here. He used the example of the Children's Medical Education Program and the ten-year reauthorization. But if you think about the need for stability here, you can get up to eight years in terms of training for a student in medical school or in their training program. And so again, I think, this augers for the need for real stability. So I would have difficulty thinking to move this out of the trust fund over into general appropriations.

Beyond that, just think about what that sends a signal, is it is a bit of a mandate, and to a degree an unfunded mandate, from an authorizing committee to an appropriations committee in Congress, and that sets up a dynamic that could, be problematic, as well, in terms of the stability that we're after here. So that would be my

concerns there.

DR. STUART: In listening to my colleagues, it seems that there's pretty clear almost unanimity that that first bullet be dropped, and it strikes me that that does not affect the next two bullets. So my recommendation would be -- now, this is awkward with Glenn not here -- that unless there's somebody that is really strongly in favor of that first bullet, that we really should probably strike it from the recommendation.

MR. HACKBARTH: I apologize for that. My son was repeatedly calling me, and he's 19 years old.

[Laughter.]

MR. HACKBARTH: The last thing a 19-year-old boy ever does is repeatedly call a parent unless there's real trouble, and so I just wanted to make sure what was going on.

DR. CASTELLANOS: [Off microphone.] Do you want us to help with the donations?

MR. HACKBARTH: Right. Right. That's all right.

[Laughter.]

MR. HACKBARTH: And I apologize, Mitra, for getting up while you were talking, but it doesn't happen

often and so I just needed to check it out. You can relate to that.

So, go ahead. Why don't you describe what I missed.

[Laughter.]

MR. HACKBARTH: Was it good?

DR. CROSSON: I'll be very summatious [phonetic]. Mitra talked about the fact that we need to move eventually to an all-payer approach, I think to summarize that. Herb expressed the fact that he sees a problem with this recommendation, at least the first bullet point, with the lack of stability and particularly that it would create an unfunded mandate to the appropriators. And Bruce was just commenting as you came in that he thinks he has not heard much support for the first bullet of the recommendation and recommended that we consider dropping it, but that we should wait for you to come back, and then you came back.

MR. HACKBARTH: Okay. And so what I'd suggest, I think we've had enough on this particular one and what I'd like to do is move on to additional issues.

Bill having gone first, let's go to Peter and see what he finds for us.

MR. BUTLER: Do you want me -- I can, in two or three minutes, just cover all of them. Or do you want to just do one at --

MR. HACKBARTH: I think it's better to do them one at a time. Then we can have sort of people chime in and organize the discussion that way.

MR. BUTLER: Okay. Well, then I will preface it with I don't like -- we have got kind of three categories we have in the paper. One was principles. Then we had interim, and then we had this transparency. I would rather just have, let's have five recommendations, whatever they are. There's some time differences between some of them, maybe, and we can put that in there. But it would be cleaner, because I can't in my mind -- is timing the only difference, principle versus --

MR. HACKBARTH: Yes, long-term, short-term, basically.

MR. BUTLER: So that wasn't clear to me. Okay. So I am -- of course, it's good to study pipeline. How can you -- I can't imagine there's a huge amount of money and it's something we should understand as we inform caps and things like that. So the logistics of using this money for

it, even if we do and can do it, it's not -- this isn't going to be a billion dollars to study pipeline, but we should understand it better than we do, so I can -- Bob was going --

DR. BERENSON: I didn't think it was to study pipeline. It was to support the pipeline.

MR. BUTLER: Well --

MR. HACKBARTH: Yes. Let me just leap in and then Cristina and Craig can help also. Bob is correct. So the basic ideas here --

MR. BUTLER: Okay. So the second one down below is the study which could result in pipeline strategies --

MR. HACKBARTH: So the basic idea is to say, as opposed to the current system where we put money into graduate medical education without regard to what's coming out the other end of the pipeline, we need to change from that and put out the Federal money in accordance with a strategy for producing the workforce that we need.

And the problem, or a problem that we've got is that we're not entirely confident that the existing programs that exist for influencing the pipeline are exactly the ones that we're going to need long-term. There are some

questions about their effectiveness and the like.

So what we're trying to do is make two points. We need to redeploy the resources to support a rational long-term workforce strategy, and as we do so, we need to carefully evaluate whether those interventions are working as intended. Is that a fair summary, Cristina?

MS. BOCCUTI: I think to clear up confusion about the second bullet under number one and the first bullet under number two, they're the same, and everything that Glenn just said applies to both of them. The reason they're repeated is because once there was a construct of being an overall principle, and if you had general revenue financing, you could do these pipeline and workforce priorities and the analysis that goes with them in the realm of the overall financing.

But to the extent that that wasn't going to happen tomorrow, Medicare could do some things, too, or with the IME savings, some things could be done, too, all for the exact same objective. So they're repetitive on purpose and they are the same. It's just where the dollars would come from.

MR. HACKBARTH: [Off microphone.] Is that

helping?

MR. BUTLER: Just a little bit. So I think I'll pass.

MR. HACKBARTH: Okay. So I'm not sure that we --

DR. KANE: [Off microphone.] The second bullet? Bullet number one or number two?

MR. HACKBARTH: Yes. I think the real focus here that Peter is raising is on the first bullet of number two. So we're talking about in the short term -- this is not long term, now -- pretty quickly saying we're going to take a piece of the resources currently devoted to IME and start reorienting them to support a pipeline strategy.

MR. BUTLER: So I wouldn't want to -- now that I've relinquished my time -- I wouldn't want to do that without studying the thing first and then say, but there is a potential recommendation that would come out of it, right? I guess.

DR. MARK MILLER: I think if you're talking about number two and there is a general consensus that people are not sure what effect -- which of those pipeline programs are currently effective -- that's an assumption if you reach that conclusion -- then I think the natural place you have

to get to is then you wouldn't do that right away.

MS. BOCCUTI: [Off microphone.]

DR. MARK MILLER: Say that again?

MS. BOCCUTI: What you're saying you wouldn't do is put the money right into a pipeline program --

DR. MARK MILLER: That's right, and --

MS. BOCCUTI: -- but that money originally could go towards the analysis component of how they're doing now and funding research to determine it.

DR. MARK MILLER: Okay. And I think if the conversation -- what I am going to say is this. If the conversation has shifted off the kind of Medicare general revenue, then I think the principle that the Commission has to keep in mind as you go through this is what is it -- how far are you going to extend the definition of Medicare funding, you know, from services to -- and I think that's what you have to keep in the back of your mind for this portion of the conversation, because now we're saying that Medicare dollars that were for service -- and remember this morning's conversation of beneficiary protections and how much we pay providers and all the rest of it. And now we're taking the Medicare dollar and saying we're actually going

to go further in defining what it's used for. That's what the decision we've made by moving off of the general revenue point. So keep that in mind as you go through it and talk about this.

DR. CROSSON: Let me just make one point, because I think what we decided, sort of, was to drop the first bullet --

DR. MARK MILLER: Dropping the general revenue --

DR. CROSSON: Right, but not to drop the general principle, right?

DR. MARK MILLER: Here is what I think is --

DR. CROSSON: That there should be a restructuring of overall financing --

DR. MARK MILLER: So here is --

DR. CROSSON: -- then Mitra made the case, I think, for --

DR. MARK MILLER: I've got it. So here's where I think this conversation stands. You're saying, I want to continue using Medicare dollars, and Bill, I fully understand Medicare is a trust fund and those are all accounting, you know, apparatus that can be easily dissembled. But for the moment, just let me go with I want

to use -- what you were saying is I want to use mandatory Medicare dollars to accomplish the principles or the objectives that we're going to talk through here.

So in a sense, just to give you one narrow illustration of this, what you're saying is a Medicare dollar could now be used for, say, a pipeline program, or even further, to study whether a pipeline program is effective. And that may be a fine point to come to, but I think it's just now the framework has shifted. You're using that dollar which was for IME or to pay the provider or whatever the case may be. That dollar will now be, if you think of what portions it's used for, some portion of that dollar would now go to studying Title VII and VIII, and I think you should be clear the precedent that you're starting to walk out here.

I'm not telling you not to do it, but I think the conversation shifts fundamentally when you say, okay, it's not a general revenue proposition. It's a Medicare proposition. Now you're talking about how are you going to use Medicare dollars. So I think you should keep that in mind as you go through and talk through the rest of your conversation.

MR. HACKBARTH: I have Mike and then Mitra, and let me see hands on this particular point is what I'm looking for. Karen, Ron, and George.

DR. CHERNEW: What I'm confused about in this discussion about moving away is I have lost track in number two, bullet point one, for example, who is making the decisions about how to do the workforce analysis and pipeline strategies. So as we move away from using IME dollars, tying them to service deliveries, and instead put them in some other -- I don't know what, that is my question -- there has to be some other organization -- it may be CMS, it could be out of CMS, I don't know -- but my question is, for that one, I don't know who's doing it.

And similarly, when it gets down to three under two, it says, make payments for office and clinic supervision, is that bullet point meant to increase the fee-for-service component that one would use that would be medical education going in those other settings, which I would have to probably oppose, or is there this other entity from bullet one that is now making maybe lump-sum payments?

And my only comment on that is, I think the right conceptual thing is to try and figure out where there's the

marginal and the fixed cost component because you don't want to run everything through the payment system so that the payment becomes really profitable for something that, for example, might be a fixed cost to an institution. Then you would want to pay it in a fixed cost way. But that requires some other institution to do bullet point one. I think also to do bullet point two, to do bullet point three, to do bullet point four, and I guess the last bullet point you could do just by paying less. But all the ones under two require one other organization that I don't fully grasp.

DR. MARK MILLER: [Off microphone.] Okay. The way I would parse through those five bullets are as follows. The last one, you're absolutely right. You pay out less IME, you've got some savings, some solvency.

The fourth one is the one that we've talked about many times here and we put it on hold during the update process and said, I'm going to reduce IME by, let's just say, a point, and that dollar is now going to become available to all hospitals if their quality performance is high. So that's that one. You remember during the update process we said, put it on hold because we're going to talk about GMEs. So, so forth, no entity --

DR. CHERNEW: [Off microphone.] -- fee-for-service.

DR. MARK MILLER: That's right. There's no super entity that says, I'm going to shift the dollar around.

The next one up, you could characterize as saying -- okay, and again, I think this is within a Medicare type of operation. You wouldn't need a super --

DR. CHERNEW: [Off microphone.]

DR. MARK MILLER: So anyway, the third one from the bottom, it says, okay, I'm going to make some adjustment to the fee schedule in order to reimburse the physician who's doing, say, didactic training outside of the hospital and it would be offset with a reduction in IME.

DR. CHERNEW: But you could do that not through the fee schedule.

DR. MARK MILLER: That's correct, but that was the thought there and I would leave it to you guys to answer to that.

The next one up, I think, is also potentially an inside Medicare type of arrangement, where you say -- I'm just going to take one of the possible options. The DGME base amount has now been increased and I'm offsetting that

increase by lowering IME. No super entity there. I think when you get to that first one, it starts to get a little bit hairier, which is why it was discussed as a matter of principle, because at principle it was, change the funding source. You probably would change who is making those allocation decisions if you were in a really different environment. And that's what number one was all about.

But here, I admit, on number two, the first bullet, kind of awkward.

MR. HACKBARTH: Yes, and I agree with that, Mark. So what I'd like to do, as opposed to spend a lot of time and say, yes, that's an important question, if the resources, if Medicare resources are going to be redeployed for bullet point one under number two, that raises some questions about, you know, who is allocating the dollars for what purpose, so that's flagged and we'll go back to it.

At the risk of being overly redundant, I do want to emphasize that I don't think we necessarily want to do all five of the bullets under number two, and so at some point in the not-too-distant future, I'm going to want to get input from people on which of those five people think are particularly important.

So on my list now I have Mitra, Karen, Ron, and George and Nancy. Mitra?

MS. BEHROOZI: Mark, the way you've laid it out is incredibly helpful because I think it jumps out that that first one is distinguishable because all the rest of those things, besides not paying, really fit within MedPAC's jurisdiction, and I think that's something we have kind of struggled with as we have delved into the very juicy, interesting area of GME and IME -- or graduate medical education, forget the financing part even, and how to create the workforce of the future that will care for Medicare beneficiaries and all that. And we always get a point where it's, like, but we're just MedPAC. Who are we to be making recommendations about what the curriculum should involve and all of that?

So I do feel like talking about all of those things has really pushed us to the point of saying it's got to be a bigger thing. There have got to be more payers involved and coordinated and all of that. So I think that really means that what we do in the interim should be limited to what our direct payment-related kind of items.

MR. HACKBARTH: Karen?

DR. BORMAN: Yes. I'm increasingly troubled by this what might be construed under number one and I share Peter's concern about the term medical education. I think, if I hear everyone correctly, we're really talking about health professional education in its broadest sense is really where collectively the group is talking about going.

I might make the suggestion that bullet number three under number one move down to number two and we perhaps back off on number one to say something to the -- that the topic here or the principle here is committing to getting to some sort of definition of what the workforce to meet the needs of the program are and the education that underlies all of that. Just keep the principle focused on that. Get out of the weeds with it. Move number three, or, like I say, bullet three into the second thing. Get rid of the top two bullets and just sort of move forward.

DR. CASTELLANOS: I guess I want to go back to round one just for clarification. I've heard so many things today that I'm not really sure where we are. Just for clarification, we're going to take off restructuring the medical education financing at this time? Or is that part of -- I heard so many things about that, I'm not sure where

we stand, not with two, but number one, just restructuring the overall medical education financing.

MR. HACKBARTH: Well, that's what Karen just proposed, is basically take out that first item except for the third bullet and move the third bullet into the second part.

DR. CASTELLANOS: Okay.

DR. BORMAN: Just to clarify, if we want to say it's a principle that this is a complex area, we need to reassess it in the context of overall health professional education financing for the appropriate workforce, great. Let's not go past that.

MR. HACKBARTH: Yes. And so, Ron, maybe a bit more responsive is based on the initial discussion about Bill's point on general revenue financing, we'll take that out.

DR. CASTELLANOS: Okay.

MR. HACKBARTH: Okay. And so that one is out. We can say that pretty definitively. And I'll think through Karen's point about the restructuring. It sounds right to me, I just want to think about it some more. Does that help? Is that responsive to you?

DR. CASTELLANOS: I think it helps. I just need to think about it. Thank you.

MR. HACKBARTH: Okay. I see some other quizzical looks.

MR. GEORGE MILLER: I may now not have a question because Karen really hit what I wanted to say, but in two, since you suggested that all of those are not -- we would choose one or two of all of those options, are we going to have some type of number -- maybe number is not the correct thing -- I guess analysis of if you do A, or if you do one versus two versus three or four, what's the number? And I keep using "number." I think you follow what I'm saying. What's the financial impact, or what would be the impact, because they're different.

MR. HACKBARTH: They are different.

MR. GEORGE MILLER: Yes.

MR. HACKBARTH: So in that category, number two, the IME extra is about $3.5 billion, I think Craig said in his presentation. So we're saying conceivably you could take up to $3.5 billion to redeploy for different purposes, and this is a list of sample purposes.

MR. GEORGE MILLER: You would have to have a

number --

MR. HACKBARTH: For each one.

MR. GEORGE MILLER: -- for each one of them to know --

MR. HACKBARTH: Well, you know, I'm not sure that, in fact, we need to get to the point where we'd say it would be 3.5 total and 1.65 would be for this purpose and 1.0 would be for that purpose. I think that's probably a level of granularity --

MR. GEORGE MILLER: Yes.

MR. HACKBARTH: -- beyond where we need to go. And I would urge us to think more in terms of a concept or recommendation to the Congress --

MR. GEORGE MILLER: Which is the higher priority of those?

MR. HACKBARTH: Yes.

MR. GEORGE MILLER: Okay.

MR. HACKBARTH: We think the priority areas among these are -- I think that's an ambitious enough task for us. Does that help?

MR. GEORGE MILLER: I think. But if I were to ask our panelists, if they were given this choice, they may both

differently make different decisions on this based on their needs. So we are trying to make a decision for the entire country? I'm just struggling with this, I guess. I'll think about it more.

MR. HACKBARTH: Well, let's come back. I want the next round to be about priorities among these items. So we'll come back to that in a minute. Nancy?

DR. KANE: Okay. Well, I don't know if I'm on topic or not, because I'm a little lost to what exact topic we are on, but I'm stuck a little bit on one, still, and so here's where I'm trying to go. A couple things have always bothered me about the way we pay for graduate medical education through Medicare. One is that a big chunk of it is going in DGME, which is resident salaries. A lot of what they do is service, not education. And in some ways -- and then a lot of other hospitals who don't have those residents are hiring people hospitalists or whatever, to charge for those same services.

And to me, we should really rethink DGME and perhaps say, oh, if a resident is doing a patient service, let's pay them a fee as though they were a hospitalist or something. We can move all the DGME that's there that we

say is for education, because it's actually for service to Medicare patients, and just say, now let's look at what programs do we want to train the kind of residents we need to take care of the Medicare population.

That would do a couple things. Then the dollars would go out on program rather than service, but it would do a couple things, one of which, which has always bothered me, is that if you don't have a lot of Medicare patients, even though you're training residents, you don't get any Medicare dollars. I've visited quite a few safety net hospitals this past year who are actively looking around to find some Medicare patients so they can get some DGME and IME in there.

So to me, we do need to reform, I don't know whether it's one or two -- I think it's one, a restructure. Rather than worrying about where the revenue is coming from, I would think we ought to think about is DGME appropriate to be paid out the way it is when right now it's being paid out as salary support for service to Medicare patients. And instead, let's just -- maybe we should say, let's start paying fee-for-service for that the way we do when a hospital doesn't have residents and then take all that money

and say, okay, we want to put that towards gerontology training or redesigning in family practice or training nursing home directors or -- so I just couldn't find in all those bullets where I was, if that helps some.

MR. HACKBARTH: A couple points in reaction. One, about the Medicare link, this has been one of our repeated themes. If this is how the Federal Government is going to contribute to graduate medical education, having this link to Medicare service delivery gets in the way. And so that's what a bunch of these things were about, was disconnecting the flow of dollars for graduate medical education from service delivery.

Having said that, you know, part of what, in fact, was proposed here was shift some IME dollars to DGME. Now, DGME is not based as a percentage add-on to service, but the Medicare share is an instrumental part of the formula.

DR. KANE: [Off microphone.] You have to have Medicare.

MR. HACKBARTH: Yes. And so, again, let's flag that, as opposed to trying to resolve it. I hear what you're saying. That is an important distortion in the system.

Now I'm blanking on the other thing that you raised that I wanted to react to.

DR. KANE: I'm just saying, none of these points really address these issues directly. And the other one was that we are really -- many hospitals have residents taking care of patients --

MR. HACKBARTH: Oh, yes.

DR. KANE: -- and when they don't have a resident, they have to pay them and they bill fee-for-service. So that gives -- sometimes it gives a disadvantage to the hospital who has to pay a full price to take care of patients.

MR. HACKBARTH: Yes. That's the one that I wanted to react to. So going back to our early discussions about this, the observation was made, and I think Peter substantiated this from his experience, some residency programs are more financially attractive than others because of the service that the residents provide, and if the residents are working in highly-profitable services, you know, those residency programs might exist without any government subsidization.

On the other hand, there might be other

specialties that aren't as lucrative to the sponsoring institutions and the number of those might be fewer in the absence of subsidies for the residents' salaries. And so we've got a continuum here of economic circumstances.

Ideally, what you'd want to do is dig into what the economics are of different types of specialty programs and vary the Federal subsidy depending on whether they're self-sustaining or not. That's an appealing concept. I don't know how readily operationalized it is. I know for certain that it's beyond the scope of anything that we can do in the reasonably near future.

So we could make the observation that the economics vary and a principle ought to be that we ought to, over time, strive to vary the subsidy based on the underlying economics of different types of programs. But I think that sort of would be a longer-term objective as opposed to something that can be done relatively quickly.

This second list that's in the interim list -- and forgive me if I'm being tedious here -- the idea there was to try to come up with some things that could be done relatively quickly, not long-term but relatively quickly. So it may be that we want to say that we would support some

shift from IME to DGME in the short-term, but in the long-term, what you want to do is gear the subsidy for DGME to the economics of the different types of training programs.

DR. KANE: Not just that, but to the programs that don't have Medicare beneficiaries but do have an important training function.

MR. HACKBARTH: Yes.

DR. KANE: And even IME could be shifted that way.

MR. HACKBARTH: Yes. So I think I understand what you're saying and let's think some more about how we might address that.

Did I miss anybody else on the list?

DR. MILSTEIN: [Off microphone.] Is this round two or round three?

MR. HACKBARTH: This is round two, but we are getting very close to the last round, which is why I want to focus on this list of five items. Again, this is sort of a catch-all list of things that have been mentioned in the course of our conversation. In fact, I'll even venture to add a sixth item, which would be --

MR. GEORGE MILLER: [Off microphone.]

MR. HACKBARTH: Let's not make the accounting any

more complicated than it needs to be.

So another potential item for this lower list under item two would be to put part of the extra IME back into the base rates for hospitals, which would, in effect, redistribute it to non-teaching institutions as opposed to sending it to the Treasury and taking it out of the system.

So this is a list of ideas that have been raised in our conversation. I don't think it would be coherent and best for us to say, oh, do a little bit of all these things. And so what I want to get in this round, a sense of who thinks particular items are important, and I would ask somebody to lead off, and then I am going to gear off of their statements. Peter?

MR. BUTLER: Okay. So I agree first with Karen's summary of what to do with number one, so I think we're beyond that.

So on number two, the ones that hit home are we overpay, clearly, for IME and it is directly tied to volume to service. We underpay for DGME. How much, we can calculate. And that if we shift money to DGME, I think there are several benefits, including you could look at the true costs -- you could reduce variation on what you're

actually paying out and get -- I think Arnie or somebody said, if you looked at the variation, you could eventually both get your arms around what is an efficient -- you know, what would the cost be, and you could also use it in a pipeline sense over time and you could leverage the dollars better in DGME and including addressing Nancy's issue, as well. You could eventually have formulas that weren't just driven by your Medicare share, and I think that's better done by taking the overpayment in IME and putting it in DGME as a principle, I think an important contribution that we could make.

I do feel strongly that a portion, sooner rather than later, should go for the accountability piece, because our real leveraging is the long-term behaviors of these physicians that are out in practice. And if we just say, well, that's not going to happen anytime soon, I'd rather kind of force us to kind of put it out there and as soon as possible use that as carrot to kind of earn up to X-number of dollars as a really important principle, because I think it can be an important catalyst in what we do.

MR. HACKBARTH: I think, too, this actually -- I'm going to constrain your list.

MR. BUTLER: Those are my two favorite.

MR. HACKBARTH: Okay.

MS. BOCCUTI: [Off microphone.] When you say accountability, is it all that we've talked about, both accountability for meeting standards for education and the environment?

MR. BUTLER: Well, I favor more of the latter than the former, but I confess there might be some kind of blending of the two.

MS. BOCCUTI: Okay. Thank you.

MR. HACKBARTH: As you know, Peter, I agree in terms of the accountability. This is a point that you've raised and Arnie has raised and others. I think that that's a critical long-term direction.

The question that I've raised is how quickly that can be accomplished, whether we have the infrastructure for that assessment of training program performance. That's a relative detail right now.

So Peter has identified his high priorities. I'd like to get other Commissioners to react to those, beginning with Karen and Bruce and Arnie.

DR. BORMAN: I'm going to support Peter's two

priority items, just for perhaps some slightly different reasons. One is that I am increasingly concerned about the 6,000 over-the-cap residents. And while we may all agree that perhaps they may be maldistributed, although I'm not sure we know enough about it to say that, they are, to some degree, getting funded out of this pool of money that we're now talking about moving around. I don't think any of us in this room are prepared to have 6,000 fewer graduates next academic year. I don't think our system is quite ready for that. So that's one concern I have.

A second concern I have is I want to talk a little bit about the issue that Nancy brought up about service. There is no doubt that there is some service going on. The line between service and experiential education at times is extraordinarily blurry and may relate to the incremental value of learning. So the 25th time you do something, maybe you learn a little less taking care of that particular patient than you did on the difference between number eight and number 15, but we don't exactly know how to say that, to measure that. We don't know what that is. I also think there's a lot of complexities to this.

For example, related to internal medicine, and

Glenn probably knows some things about this and certainly Bob, internal medicine has caps on resident workload so that lots of programs that -- or places that have internal medicine programs, for example, my own, regularly pay for coverage for the patients that aren't there similar to the situation that you described, Nancy, of a hospital that has no residents. So granted, there is still a difference there. It's not as big as it used to be. I just want to be very careful about thinking we really understand the service to education ratio and use it as a clear maneuvering point here.

So I think the Medicare solvency piece, I think, is minuscule, although I love the principle that sooner or later we have got to start to pay down on some things.

The office and clinic supervision, I found to be rather nebulous, and I also don't hear too many providers out there clamoring back that they aren't going to have residents because they're not getting paid and they don't want to buy into the GC modifier and all the other compliance pieces that go along with being a teaching physician. So I would take that one off the table, too.

So again, I think we're primarily left with

accountability, increased DGME, the enhanced workforce analysis, and some pipeline strategies. I just don't know. I guess I wouldn't oppose that being in there, but I personally have some concern about funding individuals who don't provide 24/7 coverage which physicians and residents do. And so I'm not sure that it's exactly the same to fund others, thinking we're doing something similar with those dollars that originally went to that. But the top two, I'm for.

DR. STUART: I generally support Peter's recommendations, as well. We haven't talked about that fund Hospital Quality Incentive Payment Program. That was a big piece when we got into this in the past, and the idea was that the IME overpayment wasn't really paying for education. And so the idea that somehow, something that wasn't paying for education is going to be then funneled back just for education, to me doesn't make much sense.

So I like to look at that fourth bullet point under the -- well, the bullet point, the Hospital Quality Incentive Payment Program is kind of a freebie that you get when you cut IME to its true cost, but also recognizing the fact that these IME overpayments currently go to medical

centers, and I would be -- that are involved in teaching, and I would be hesitant to say, okay, well, let's take this money that you had this year and next year we'll put it into the rates, which was one -- the base rate, which was one thing that Glenn suggested, because that would just take away that money and they'd have to fill that hole somehow. And even though maybe they were overpaid, it's not that that money isn't doing any good. Whereas funding Hospital Quality Incentive Payment Programs at least gives them a chance to keep it, or at least to compete for it.

So I'd like to keep that piece there. I think they make payments for office and clinic supervision, probably funds under -- that that would go through the current educational programs themselves. You indicate that this doesn't work very well. Maybe that's part of where you put a little bit on money on support accountability and educational standards. I'm not sure that it matters which of the bullet points you put that under, but that's my thought.

DR. CASTELLANOS: Yes. I'm still struggling with a lot of the conversation, but I'm still struggling with the stability of the financing.

DR. MILSTEIN: I'll start with Peter's basis. If we're overpaying, we're overpaying. If we're overpaying, I think we should take it back to the Treasury. That's what I think. And so I'd like to see, rather than increased DGME payments, it would be more like right-sized DGME payments. I take your point, Glenn, that that might take some analysis to figure out what is a -- of the programs that get whatever is the maximum high rating, an outside contractor could help us and the Congress figure out what is the most efficient provider of a high-quality graduate medical education program, and that's the amount I would like to pay.

I think your point about making it specific to the type of resident being trained is a really good one. But it's a reiteration of a point I made earlier, is that if we -- basically, I don't mean we, but the Medicare program can't move more quickly in relation to problems that have been obvious and around for a long time, then we're never going to -- we'll always be way too slow. We need to have more of a -- I know that this is not easy to do in a political environment, but more of a rapid cycle in a mentality for fixing these problems.

And so I would say right-sized DGME payments based

on an analysis that a contractor could probably do for us in six months to what an efficient high-quality program requires.

And then on the fourth, I support, but I do think, actually, I back Pete's idea, is only temporarily tie it to particular educational content. Otherwise, gear it to the value that that teaching hospital is providing using the same value definition that we've now introduced into the Medicare update program. It's the total use of resources, quality, and actual production cost.

I don't know whether -- it's funny. I'm a little -- so anyway, that's my recommendation. It's a variant of Pete's.

MR. GEORGE MILLER: I support Peter's recommendations. I'm not sure -- I support them. I'll save some time.

DR. KANE: Well, I support the whole idea of right-sizing the DGME and also workforce analysis in some way. But I wanted to put in a pitch for paying community-based supervision, and actually, I would change that to saying community-based, not office and clinic. I mean, I was on the board of a physician group that did a lot of

pretty innovative stuff with frail elders and we were constantly in demand to sort of train people and we really didn't have time and we couldn't afford it. And I think that's too bad. We are losing opportunities out there to expose residents and medical students to -- and, you know, nurse practitioners, as well, I might add. We actually stopped taking nurse practitioner students because we couldn't afford the time it took to oversee them.

So if we're really thinking about, you know, training physicians to take care of geriatric patients, I think we have to consider making payments for community-based supervision, and that includes house calls, nursing home, office, and clinic. So I still want to keep that one on.

The last two, I prefer to -- if we're talking about just IME, I prefer to redeploy it to improve the educational output of the program and not put it in the quality incentives, which I think in kind of a different way.

And Medicare solvency, there's too many things it needs besides this to solve the Medicare solvency.

DR. BERENSON: I think this is where I'm at right

now, sort of where Arnie is, perhaps with a modification. I mean, I see the potential of redistributing the IME dollars into DGME as a carrot, as an important carrot to get the accountability that we want. So I might do something like have a phase-out of the IME over an extended period of time, and if, in fact, the teaching hospitals and we and whomever else needs to be at the table can figure that out, we can transfer that money. I wouldn't just do it without getting something for it.

I still think in the long run, the best -- enhanced workforce analysis and pipeline strategies are going to be done by somebody and the question is whether we want to have any influence on it. In particular, from what I've seen about work to support Title VII, National Health Service Corps, those kinds of activities, they're sort of oblivious to the particular needs of Medicare beneficiaries and the Medicare program. I'd like to be able to play a little bit in that arena if there was a way of using what would be a tiny bit of Medicare money to be able to influence that process. I think that would be a valuable thing. But I understand there's this sort of precedent of are we going to just start picking at Medicare money to

support somebody's good idea.

So I'm not sure ultimately where I come out, but I do think in the long run, we want to be producing -- we have to get at before graduate medical education. We have to get into medical education and there might be a way of making a small investment in that area.

DR. CROSSON: I think I'm in the Kane camp because my number one is the support for broadening the payment to other sites of care, community-based sites of care, outpatient care. This is not a new issue. We have talked about it before. We have had this recommendation now to request regulatory changes in that arena. I think that correlates -- is likely to correlate with a better output. That would be my first one.

The second one is, in concert with that, is the support for accountability in general, because I think, again, we've talked of that. We're not sure exactly how to do that, but that would be my second one.

And then two-and-a-half would be --

MR. HACKBARTH: You're over budget.

DR. CROSSON: -- would be the IME to DGME. I have some question as to whether that's more than just doing it

for appearance sake, maybe a good appearance, but still not really changing the amount of money available except for the reallocation phenomenon. But I would support that as two-and-a-half.

MR. HACKBARTH: Others on this side? Bill?

DR. SCANLON: I guess until Arnie mentioned right-sizing, I was feeling very uncomfortable. I don't feel like I know enough to decide sort of what to do at this point and that actually -- I mean, it doesn't mean that it's going to take us forever to know enough. I mean, I think that if you redistribute money immediately, you create new constituencies that are going to be there to try to preserve that new status quo and I think that's potentially a problem that we'd like to avoid.

So I would say a very short-term but intensive investment in trying to understand more of the economics of training, and I'll go along with Nancy. Let's keep the money in training, this investment in human capital that we want to have, but let's figure out where to put it. Some of it may be community. Some of it may be DGME. But right now, I couldn't tell you how to do the allocation.

MS. HANSEN: Yes. I would echo the whole training

process in the community-based environments based on similar experience that Nancy has had with our PACE programs. That would be my number one.

And I think this concept of accountability, however we're going to build that in. There is just lots of interpretation onto that. But it would be probably components of that that I would probably want to lift up a little bit more, but I'll leave it at that in terms of going to Jay's one and two.

DR. CHERNEW: So I also believe in getting the payments right, and also I think, though, it's a question of getting them of the right form. So I think we have to be very careful. So it's not just, for example -- so my number one would have been make payments for office and clinic supervision, like was just said by Nancy and Jennie and some others. But that doesn't mean that I think we should bump up the fees for those particular services and I think we need to think clearly how that money works, because there are incentives associated with whether we distort the fees or otherwise send money there and I think that's a big issue there. That's my number one.

My number two, and I think I'm going to be in the

minority here, is extend Medicare solvency. Now let me just say, I don't think we should use any money to extend Medicare solvency, but I don't think we should spend it somewhere else just because we don't want to extend Medicare solvency. I think when we spend money, we should spend money that gets us some return. And if there's not another place to do that, and I think there probably is, but unless I'm convinced there's another place to do it, then we shouldn't spend the money, and that's where it would put me in the last bullet point.

DR. DEAN: Well, I would echo what Mike just said. I guess I was struck in looking at the -- obviously, no great surprise -- I think we need to support office and clinic education. But it seems to me that that is qualitatively different than the other issues, because to really support that requires a much more basic change in the whole formula. Then you have to get the residents there, and that's been a big problem, getting released from inpatient commitments, and there's a whole lot of other barriers.

So I certainly think once we can get them into an ambulatory setting, which I think we all agree is where we

need to shift the focus of the training, we've got to support them. But it seemed to me that this was a much bigger issue. These others were all places to use a little extra money if we had it. So that's grossly oversimplified.

MR. HACKBARTH: Yes. Well, remember, Tom, that it's basically a two-pronged approach. Number four is about taking out some of the existing barriers to residents leaving the hospital for training, and then the third bullet under number two is to say let's also make it more attractive for the people who would provide that training, that supervision on the ambulatory side. So it's doing --

DR. DEAN: Okay. And maybe I didn't completely have that all in context.

MR. HACKBARTH: Yes. Now, having said that, I think Cristina was absolutely right to emphasize earlier that even if there were no regulatory barriers, there are still pretty strong incentives for hospitals to want to keep their residents working there as opposed to having them out.

DR. DEAN: To me, that's a much bigger barrier than the lack of payment for the time, although what Nancy says is certainly true.

DR. CROSSON: Yes, but that could be dealt with in

this approach to what we were calling support for accountability.

MR. HACKBARTH: Yes, right, and that's a good point. One of the things that makes this such a confounding topic to talk about is the interrelatedness among so many different pieces.

So just to pick up on Jay's point, you could imagine three different pieces working in conjunction with one another. One is that the standards on what constitutes appropriate training increasingly emphasized that to be accredited, you have to get your residents into high-quality ambulatory environments. And then you want to take away some of the existing barriers that make it difficult for hospitals to do that and how the hours are counted and the documentation and all that. And then you also want to make it a reasonable economic proposition for the ambulatory sites that would provide the training. And so you want those three pieces to work in combination with one another if you're going to shift the locus of training.

I appreciate everybody's willingness to sort of plow through this. It is very difficult and what I ask is just a little time to sort of digest today's conversation

and try to figure out a recommended course for us.

I thought it was important to put up draft recommendations to try to focus the conversation, but clearly, we've got a significant ways to go here. And Cristina and Craig, as always, thank you for your excellent work on this.

So it is already 6:00 and what I want to do is have our public comment period. I suspect we've got some people out there. I would ask people to be sensitive to the hour. It's been a long day for us, and maybe for you, as well. So please keep your comments to no more than two minutes. Begin by identifying yourself and your organization.

I would remind everybody that this is not your only, or even your best, opportunity to provide input to the Commission. I urge people to use the website as a place to present comments. We also read our mail. And last, and most important, talk to the staff.

So when the red light comes back on, your two minutes is up and we'll move to the next speaker.

MS. BONE: I was going to say good afternoon, but I'll say good evening.

My name is Traci Bone and I'm here on behalf of the College of American Pathologists, CAP. The CAP represents 17,000 physicians who provide diagnosis and interpretation for physicians on cancer and other related diseases.

First of all, the CAP would like to thank MedPAC for its attention to the issue of the in-office ancillary services and its effect on increased self-referral of designated health services. We are encouraged that MedPAC will continue to study the impact of self-referral on utilization of physician services in Medicare, particularly pathology services.

The CAP supports the option to exclude certain services from the IOAS exception. However, we would encourage MedPAC to focus this exclusion on the time that the patient is in the office, not whether or not the lab tests or other service that can be provided on the same day.

Also, CAP has a bit of a concern that there's been no distinction between clinical laboratory services and anatomic pathology services. Anatomic pathology services, as you may know, are very different from the routine clinical lab tests that were initially contemplated from

Congress when they provided the in-office ancillary services exception.

Finally, anatomic pathology services afford no added convenience or quality of care to the patient because these tests are too complex and time-consuming to be performed and analyzed while the patient visits. Therefore, the time-based rationale for the IOAS exception should not apply to the anatomic pathology service.

We look forward to working with MedPAC on addressing these important issues.

Thank you.

DR. CZEISLER: Chairman Hackbarth, Vice Chairman Crosson, and members of the Commission, my name is Charles Czeisler, Professor of Medicine and Director of the Division of Sleep Medicine, Harvard Medical School, and a member of the Sleep Disorders Research Advisory Board of the National Center for Sleep Disorders Research at the NHLBI.

I have flown from Boston today to strongly urge the Medicare Payment Advisory Commission to address the issue of resident physician work hours as you contemplate restructuring overall graduate medical education financing.

In 2008, a blue ribbon Congressionally mandated

IOM Committee concluded that scheduling resident physicians to work for more than 16 consecutive hours without sleep is hazardous to hospital patients, many of whom are Medicare beneficiaries, and hazardous to the resident physicians themselves. Yet the ACGME has failed to implement the 2008 IOM recommendations to limit resident physician work hours and is currently sanctioning academic medical centers to schedule resident physicians to work 30 hours shifts twice a week.

Sleep loss impairs brain function, concentration, coordination, and increases the risk of error. After 24 hours without sleep, performance impairment is comparable to being legally drunk, clinical performance drops to the 7th percentile of its rested performance, and memory consolidation -- which occurs during sleep -- is, of course, impaired.

As with alcohol, those affected by sleep loss often do not recognize the impairment. One out of five interns have admitted to us that they have made a fatigue-related mistake that has injured patients. One out of 20 admits to making a fatigue-related mistake that has resulted in the death of a patient. These errors are costly just

with those numbers of admitted errors, costing more than $120 million a year.

Medicare has standing to implement safer resident work hours. It pays $10 billion a year to support IME and DGME. The Medicare program has the authority to require implementation of the 2008 IOM recommendations to limit resident physician work hours as a condition for Medicare participation in hospitals.

I certainly think that no increase in the cap of the number of residents supported by Medicare should be approved or recommended until the 2008 IOM recommendations on resident physician work hours are implemented.

Furthermore, Medicare beneficiaries -- three out of four whom say that they would want a different physician if they knew that the physician has been working for 24 hours and was going to care for them -- they should have the right to know whether or not a physician has been working for more than 24 hours without sleep before caring for them.

Thank you.

DR. MOHLER: I'm Jim Mohler. I was here today testifying at the House Committee on Oversight and Government Reform and thought I'd stop over here as well.

I am a urologist, the Chair of the Department of Urology at Roswell Park and the Chair of the NCCN Prostate Cancer Treatment Guideline Panel.

I just wanted to support the staff recommendation to exempt radiation therapy from the in-office ancillary services exception. We spent a lot of time talking today about how treatment and early detection for prostate cancer suffers when you over-diagnose and over-treat prostate cancer. The radiation therapy exception is contributing to this by removing freestanding radiation therapy centers from the CON process at the state level and then making it financially very attractive at the Federal level, and is resulting in over-diagnosis and over-treatment of men with prostate cancer.

Thank you.

MR. KETCH: My name is Todd Ketch. I'm with the American Health Quality Association. We're the organization that represents the national network of community-based quality improvement organizations that not only work with the Medicare program but Medicaid and other private payers and government entities.

I wanted to just say a couple of things about the

discussion today about the quality improvement organizations as it relates to the discussion of hospitals. It's important, I believe, for the Commission to fully understand that quality improvement organizations are not funded or tasked to work with every hospital in a state. So they have a very limited scope in terms of their ability to get out and work hand-in-hand with hospitals. So it represents a very small subset of the facilities in the state.

These exemplary organizations you had here today have great results but may not necessarily have been -- and I doubt were -- among the target set of hospitals that the QIOs were working with in either of those states because much of what they're doing is focused on those that are in the greatest need from a quality standpoint. And so these organizations are doing a great job and certainly we want to learn from them, but may not have been in the group that they targeted to work with. So I just point that out first.

For the Commission, just a couple of things that I would recommend is to take a look at how we can strengthen this really critical national quality improvement infrastructure that we've built. Part of that is making sure that the dollars that go to the program actually reach

the organizations that can do the work on the ground, these QIOs in every state.

A significant portion of those funds right now are diverted to national infrastructure development, which is critically important, has all the measures, all of the other things that go into that. We don't actually know where all of that funding goes, but that's the way it's labeled in the funding description for the scope of work. But it represents a pretty significant portion of the funding for the program.

So if we can find another way to fund those activities, those national activities, that's going to help to have more of those funds go toward the community-based quality improvement efforts on the ground.

I'll stop there. Thank you.

MS. FISHER: Hi, I'm Karen with the AAMC, and I hopefully will be brief.

I first applaud you for your endurance in dealing with these issues, but specifically at the end of the day.

I'd like to recognize Craig and Cristina, too, because in order to get your hands even somewhat around these issues and the myriad issues that you've dealt with

through the past year-and-a-half that range from general revenue financing and Title VII down to technical issues relating to how you count resident time in ambulatory sites. So it's a lot to take in.

I just want to focus in, though, on the disappointment we have that there hasn't been more discussion about the Medicare resident caps issue and the 6,000 residents that are not receiving any Medicare funding by teaching hospitals. As the comments pointed out, this may involve some long-term analysis and long-term thinking. But I think most people would agree that 6,000 -- we're going to need at least 6,000 additional physicians. And this educational safety net that is developing is getting frayed by teaching hospitals taking on these responsibilities without receiving any support at all.

And so I would like to hope that maybe between March and April you might reconsider your thinking about adjusting the Medicare cap issue.

Thank you.

MR. HACKBARTH: Okay, we are adjourned until 8:30 tomorrow morning.

[Whereupon, at 6:12 p.m., the meeting was

recessed, to reconvene at 8:30 a.m. on Friday, March 5, 2010.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, March 5, 2010
8:30 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, J.D., Chair
FRANCIS J. CROSSON, M.D., Vice Chair
MITRA BEHROOZI, J.D.
ROBERT A. BERENSON, M.D.
JOHN M. BERTKO, F.S.A., M.A.A.A.
KAREN R. BORMAN, M.D.
PETER W. BUTLER, M.H.S.A.
RONALD D. CASTELLANOS, M.D.
MICHAEL CHERNEW, Ph.D.
THOMAS M. DEAN, M.D.
JENNIE CHIN HANSEN, R.N., M.S.N., F.A.A.N
NANCY M. KANE, D.B.A.
HERB B. KUHN
GEORGE N. MILLER, JR., M.H.S.A.
ARNOLD MILSTEIN, M.D., M.P.H.
WILLIAM J. SCANLON, Ph.D.
BRUCE STUART, Ph.D.

AGENDA PAGE

P R O C E E D I N G S

MR. HACKBARTH: Okay, so first up this morning we have two guests [inaudible] [Technical difficulties].

MS. RAY: Good morning. This morning we're going to focus on giving Medicare flexibility to be a more innovative, value-based payer with two presentations. First, I'm going to look at the potential of three policies to improve the efficiency of the program. In the next session, John will discuss enhancing Medicare's research and demonstration capacity.

The pace of delivery system reform and improved efficiency in Medicare is slow, at best. The Commission has made the argument for delivery reform but the statute has not kept up. Medicare law affects the program's ability to adopt innovative strategies. In some instances, the statutory language does not clearly lay out Medicare's authority. In other instances, Medicare cannot implement these strategies because it does not have statutory authority. Some policy experts have recently noted that Medicare needs more flexibility in carrying out its mission.

This session focuses on giving Medicare flexibility to implement three strategies: reference

pricing, performance risk strategies, and coverage with evidence development. We have selected these three policies because their application could improve price accuracy and the efficiency of the Medicare program and decrease knowledge gaps.

Under reference pricing, also called least costly alternative, a single payment rate is set for clinically similar services. Medicare has implemented this policy most recently for durable medical equipment and also for some drugs but two recent court decisions have affected its future use.

Performance-based risk strategies link payment of a service to beneficiary outcomes through risk-sharing with product developers and providers. The basis of risk is the quality of the performance of the product or service and is measured by agreed upon outcomes. A change in law is necessary to implement this strategy.

Under coverage with evidence development, Medicare links payment to a requirement for prospective data collection for potentially beneficial services that lack clear evidence showing their clinical effectiveness among beneficiaries. This strategy provides an approach that

permits payers to move beyond the yes/no coverage decisions but the lack of clear legal foundation to implement this strategy has affected its use.

I want to remind you, that we have recently discussed these issues, the first two issues most recently in last year's June report and we discussed coverage with evidence development at the last November meeting.

We have brought two experts to discuss these three strategies, Peter Neumann and Sean Tunis. Peter is director of the Center for Evaluation of Value and Risk in Health, at the Tufts Medical Center. Sean is founder and director of the Center for Medical Technology Policy, an independent nonprofit research group. Prior to founding the Center in 2006, he was the director of the Office of Clinical Standards and Quality and Chief Medical Officer at CMS.

After Peter and Sean conclude their presentations, we look forward to Commission discussion on the pros and cons of increasing Medicare's flexibility to adopt these policies and ways to include safeguards to ensure accountability. We expect to include a discussion of these policies in the June report. This would be an informational chapter composed of this material and John's material on

enhancing Medicare's research and demonstration capacity.

Our goal today and at the April meeting is to capture you comments.

DR. NEUMANN: Thank you, Nancy, and members of the Commission. My name is Peter Neumann from Tufts Medical Center in Boston and I'd like to acknowledge my colleague, James Chambers, who's here with me today, and Lisa Meckley of Tufts Medical Center, who contributed to our report.

Health policy makers have advanced different ideas for value-based coverage and payment policies. These policies attempt to link payment to evidence of achieved outcomes and guide incentives to target resources towards patients most likely to receive appreciable benefits.

Rather than paying for services delivered regardless of results, the new approaches seek to reward performance. In theory, these arrangements can help better align systemwide incentives, reduce waste --

MR. HACKBARTH: We are having a microphone problem.

DR. NEUMANN: Okay. Is that better?

MR. HACKBARTH: Yes. Go ahead.

DR. NEUMANN: In theory, these arrangements can

better align systemwide incentives, reduce waste, and improve the overall value of the health system. These experiences could hold important lessons for Medicare.

Our specific objectives in our work from MedPAC were to describe various value-based policies for drugs, devices, other medical services adopted by payers in the U.S. other than Medicare and abroad, discuss the issues and challenges that U.S. and international payers have faced in adopting such approaches, and discuss implications for Medicare.

Here, we focus on three types of value-based policies, outcomes of performance-based arrangements or agreements, sometimes called risk-sharing agreements, value-based insurance design, and reference-based pricing strategies.

Under outcomes of performance-based agreements, coverage or payment for a product or service is dependent upon the collection of additional population-level evidence. We are tied by formula to a measure of clinical outcome in a real-world environment. An arrangement involves risk sharing, because both parties, typically the company and the payer, support the financial consequences of reducing

uncertainty.

Value-based insurance design refers to the idea of tailoring benefit design to encourage high-value services and discourage low-value care. For example, drugs with favorable evidence of value or cost effectiveness would receive preferential formulary status in terms of reduced cost sharing for patients.

Reference pricing refers to an arrangement in which health insurers pay a maximum allowable amount for drugs in a therapeutic class, and typically, patients pay the difference if they want higher-priced drugs in the same class.

In conjunction with MedPAC staff, we identified case studies of policies implemented for a range of technologies and services, though most of the cases focus on pharmaceuticals. Ultimately, we selected several cases: Beta-interferon for multiple sclerosis, MS; bortezomib, Velcade for multiple myeloma; the Oncotype Dx test implemented with United Health Care; sitagliptin, Januvia, an arrangement with Cigna; and risedronates odium, Actonel, an arrangement with Health Alliance.

We also looked at various value-based insurance

design and reference pricing arrangements. Our analysis is based on reviews of the literature reviews with senior officials working in different sectors of the health care system.

So let me go through the case studies in turn.

First, the beta-interferons for multiple sclerosis. This was an agreement in the U.K., and it's an example of a performance-based arrangement. Because of uncertainty about the drug's long-term benefits and concern about poor value, an agreement was established permitting prescribing of the new MS treatments conditional on development of a ten-year longitudinal cohort study in which the therapy's efficacy was monitored. The manufacturers discounted their products on condition that the prices would be adjusted based on study results. If any products failed to show benefits consistent with projections, the National Health Service in the U.K. would lower the price. A planned interim analysis in 2009 did not support the conclusion that the treatments offered good value.

Velcade multiple myeloma, also a case in the U.K., a protease inhibitor indicated for the treatment of multiple myeloma, is the subject of an ongoing outcomes-based payment

initiative. This arrangement involves adjustments to reimbursement after four months by the product manufacturer to the National Health Service conditional on the drug's effectiveness. If the drug does not shrink tumors by a certain amount, the NHS receives a refund. Two years following initiation, the arrangement seems to be viewed favorably by all parties.

Third, Oncotype Dx and United Health Care. Oncotype Dx is a molecular diagnostic test to predict the risk of breast cancer recurrence in patients with early-stage breast cancer. The test generates a recurrent score and thus helps target adjuvant chemotherapy to those at highest risk. Because of Oncotype's high cost -- over $3,600 -- and concerns about inappropriate use, United Health Care restricted coverage through a pre-authorization process that linked reimbursement to clinical criteria for testing. The contract specifies that if chemotherapy does not follow the test recommendation, United can renegotiate rates for Oncotype Dx. In the agreement's first year, 15 percent of patients were treated contrary to the Oncotype Dx results. In the second year, the rate decreased to six percent.

Diabetes medication and Cigna. In 2009, Merck and Cigna entered into an agreement involving sitagliptin, Januvia, sitagliptin plus metformin, Janumet. This agreement links rebates for the drugs to overall control of hemoglobin A1c levels and adherence to therapy. Under the agreement, Merck increases Cigna's discount for the drugs if there is an increase in the patients -- in the percentage of their diabetes patients reaching A1c goals -- under eight percent -- regardless of which oral diabetes medications the patients are taking.

Merck also increases the discount if the percentage of patients adherent to the drugs increases. In a sense, the better the drug works, the less it costs the payer. For Cigna, improved compliance rates would lower A1c levels, thus gaining them larger rebates and better managed care with fewer complications. The manufacturer gains by increasing drug utilization and perhaps market share for its products.

Risedronates odium, Actonel, the bisphosonate drug for osteoporosis, was the subject of a value-based agreement between Health Alliance, an insurer in Illinois and Iowa, and pharmaceutical companies who manufacture and market the

product. Under the arrangement, the manufacturers help pay for the cost of treating fractures for patients who suffer a fracture despite taking this drug. Health Alliance receives a rebate for each non-vertebral fracture suffered by its members. Notably, Health Alliance only receives reimbursement for fractures suffered by patients who have demonstrated adequate medication compliance. Thus, the agreement encourages higher compliance rates and in theory leads to improved medical outcomes. An analysis revealed the company's rebate to the insurer was lower than the maximum allowed in the agreement.

Policy makers have experimented with various value-based insurance design approaches in recent years. Some employers have waived copays for certain medications, for example. Programs have reduced drug copayments for patients with diabetes, asthma, high blood pressure, in an attempt to prevent high-cost complications.

Some programs have claimed the arrangements have improved health and saved money, though rigorous evaluations have generally been lacking. Some new evidence suggests some savings might be possible, at least from a societal perspective.

Finally, reference pricing. Under these arrangements, health plans pay the same amount for different drugs or other products judged to have identical or similar therapeutic effects. Health authorities around the world have used the strategy. Canada, Germany, Netherlands have policies. The government sets the maximum allowable rate for drugs in a therapeutic class and patients choosing the more expensive drug generally must pay the difference between that price and the reference price.

Medicare has implemented this policy most frequently as a least-costly alternative option, though there are questions about Medicare's statutory authority in this area.

So finally, let me just turn to some key challenges and lessons learned. Reference-based pricing models have gained a foothold in some countries. The strategy may lead to reduced spending, though questions remain about which products should be considered interchangeable, and on that basis be assigned the same price, as well as concerns about impacts on health and innovation.

Value-based insurance design options have shown

some promise, but experience and rigorous evaluations are generally limited. Moreover, the options to date have tended to focus on waiving copayments for high-value services rather than imposing them for low-value services.

Performance-based and risk-sharing agreements have attracted interest from many quarters. Their conceptual appeal is understandable. However, to date, they have had only limited testing. This may reflect the fact that they remain in an early adoption phase and experimentation is ongoing. The paucity of examples may also reflect the fact that to the extent they exist, agreements are not in the public domain. A third possibility is that it has proven difficult to find good candidates and difficult to find willing negotiating partners given the complexities involved.

A key challenge pertains to implementation costs. Developing data protocols, negotiating arrangements, assessing the performance of products, and designing procedures to adjudicate disputes can be costly and time consuming.

Ultimately, success will depend on how payers and manufactures view the risks and rewards. For success,

several factors seem needed: High intervention costs, substantial uncertainty about efficacy, concerns about inappropriate use, and willing negotiating partners. Ideally, the outcomes should be objective, clearly defined, reproducible, and difficult to manipulate. They must be valid measures of the desired treatment effect and should not be confounded by patient characteristics or other therapies.

Successful implementation will require high-quality information systems, databases, and operational and analytic expertise. Current systems typically do not capture the level of detail required.

Value-based policies would appear to present some unique opportunities for Medicare, given its leverage in the marketplace and consequence of non-coverage to product manufacturers and service providers. However, it also presents some unique challenges. To the best of our knowledge, Medicare has not implemented such a policy and a change in Medicare law would likely be needed.

Thank you very much.

MR. HACKBARTH: Sean Tunis?

DR. TUNIS: Well, thanks, Glenn and Mark and

Nancy, for inviting me to speak to folks today. I heard from all three of you that you don't care much what I say as long as I do it in ten minutes, so I will try to honor that.

[Laughter.]

DR. TUNIS: So I am going to give a quick overview of Medicare's experience with coverage with evidence development. A number of folks in the room have participated heavily in developing this program, including one of the MedPAC members, Herb Kuhn.

So what I'll do is give a quick definition of CED, what the purpose of the policy is, talk about the relationship to comparative effectiveness research, which I think in some ways is the most important thing about it, which is it's a potentially very important tool for promoting and supporting comparative effectiveness research particularly relevant to Medicare. I'll list some of the case studies that we examined to then extract some lessons learned about what has worked and what not worked so well and potentially how to fix CED in the Medicare program, focusing on the statutory authority, priority setting, how topics are selected for it, and also funding for it.

So first of all, the definition of coverage with

evidence development is kind of self-evident, but it's Medicare reimbursement that is contingent on participation of a patient in a clinical study, either a clinical trial or a registry. In other words, the service is not paid for unless the individual is enrolled in a systematic data gathering exercise. So that's all CED is.

In terms of the reason for it, the main reason for it is that there are not too many ways to reconcile the tension between a desire for good evidence about effectiveness and rapid adoption of new technology. By definition, when technologies are new, the evidence of their effectiveness and their comparative effectiveness is limited, but there's also a lot of pressure to adopt those technologies rapidly.

And one of the few ways you can actually reconcile those two recurring tensions is figure out ways to study things after they're being reimbursed, because if you impose too high a threshold for coverage or reimbursement, you may impose tremendous difficulties on actually generating the evidence that you want. So this is a sort of the quid pro quo of we'll pay for something in the context of getting the evidence we need to make a more informed decision later.

And as I pointed out there, traditionally, when evidence is limited, payers are in a pretty poor position to restrict access to technology, so while payers, including Medicare, talk a good game about evidence-based coverage policy, when there is public and clinical demand for a technology, the absence of good evidence of its effectiveness is not a very robust basis to deny reimbursement. Look at things like proton beam therapy or vertebralplasty or many things for which it's just not reasonable or plausible for a payer to actually say no, and so you end up saying yes, holding your nose, and living without any good evidence.

The approach here is to say, well, we might as well at least say yes and also have the potential to get some reasonable information to inform future decisions.

A key thing, I think, that is often missed about the importance and power of coverage with evidence development is it allows for Medicare's views on study design to be incorporated into the trial. So oftentimes you'll see studies that don't enroll Medicare patients or they measure outcomes that aren't particularly relevant to Medicare. With CED, because Medicare is approving the study

protocol before they approve a reimbursement, then they have a say in actually how the study is designed, and this is the key relationship.

Why CED is considered a tool for comparative effectiveness research is that comparative effectiveness research is really distinguished by the fact that it is studies designed to inform decision making. That's what distinguishes comparative effectiveness research from any other form of clinical research, and I'm going to illustrate that with my molecular basis of uncertainty, which is probably one of the few times that this Commission is going to be exposed to molecular biology, but I thought you'd appreciate it.

[Laughter.]

DR. TUNIS: So this is actually an explanation. You'll understand CER after I go through this slide quickly. So what you have here is you've got your decision makers inside the cell and you've got your research enterprise out here in the extracellular milieu. All of you will remember this from your education somewhere.

So most research is driven by intellectual curiosity that's published as evidence and then that is

forced into -- towards the decision maker inside the cell via KT1 or KT2. Those stand for knowledge transfer 1 and knowledge transfer 2, but they're just meant to sound scientific.

So the notion here is that you have this translation problem where there's published evidence that needs to get to the decision makers and a good amount of that is -- unfortunately, the decision makers are coated with those little low-affinity receptors for evidence, so that's one problem --

[Laughter.]

DR. TUNIS: But the real issue is that most health technology assessments identify major gaps in evidence. The questions that you really want to know haven't been answered, and the problem is that there's poor communication from those gaps in evidence out to the research enterprise. You have a defective transport here. So you don't get the most important questions from the decision-maker perspective acted upon by the research enterprise, and all comparative effectiveness research really is is targeted therapy for the defective transport so that the evidence needs of the decision makers are acted upon by the research enterprise,

because if you have poor transport at KT3, it leads to accumulation of ignorance inside the cell, which is toxic.

[Laughter.]

DR. TUNIS: So CED is really one mechanism by which the information needs of decision makers are communicated to the research enterprise, right, because if researchers aren't going to get their services funded unless they design a study that's meaningful to Medicare, then -- so by definition, CED is a tool for comparative effectiveness research.

So, hopefully, you will be convinced that CED is something that's important to figure out how to do well-

MR. HACKBARTH: What it makes me wonder, Sean, is how much accumulated ignorance is necessary to kill the cell.

[Laughter.]

DR. TUNIS: Yes. Well, that would need to be looked at in further research that should be funded.

[Laughter.]

MR. HACKBARTH: I fear we're close to the boundary.

DR. TUNIS: Yes. We could look into that for you.

[Laughter.]

DR. TUNIS: So the case studies that we looked at to sort of identify what's worked and what's not worked, a number. Lung volume reduction surgery, that was actually done in the mid-1990s before real CED. PET for dementia, off-label use of colorectal cancer drugs, use of FDG-PET in oncology diagnosis, several others, and one of the recent ones, genetic testing for warfarin. So this is just a list of examples of CED that we reviewed, and so here's the kind of lessons learned.

I'd say, and there are a number of folks from CMS here who may want to comment later, but I would say that CED remains a promising idea for which the implementation, though done with great valor, has been relatively unsuccessful for the most part, not uniformly unsuccessful. I think there are some examples -- the National Oncologic PET Registry, the ICD Registry-there's a few things that have really gone forward, but probably fallen well short of their real promise in terms of generating useful information for decision making.

And I would say the key problem is the statutory authority for coverage of evidence development is

controversial, which is probably a euphemism, but it's simply not sufficiently robust to allow the agency to use the policy when and how it needs to be used. And there's a good reason for that. Originally, CED was based on 1862(a)(1)(A), which is the reasonable and necessary coverage authority for Medicare. And when that was written in 1965, no one was imagining the idea of coverage contingent on participation in clinical research, so it's simply not -- it's not really conceptualized in the statute.

Currently, they're using 1862(a)(1)(E) as the statutory authority for CED, and that is an AHRQ authority which introduces a lot of collaborative complications and some timing issues. But fundamentally, what this leads to is that because the statutory authority is controversial and non-specific, not very robust, the agency has to be pretty conservative and minimalist in how they approach this and it's just not going to work if it's approached in a -- you know, without sort of going at it full steam.

Sort of related to that, the priority setting issue is CED has always been applied to technologies in a reactive way when someone comes in and requests a coverage decision. Therefore, each project is sort of created de

novo. It's a huge amount of staff time. It's very labor intensive. It's very kind of idiosyncratic, and so there's no kind of well-defined model by which it can be pursued. And the topics that are selected aren't necessarily the technologies for which you would most think that it would be appropriate to apply CED, because they have to come over the transom.

So some approach of horizon scanning, a careful priority setting process to intelligently select topics that would be good candidates for CED, i.e., technologies that have a high likelihood of disseminating without evidence, for which it would be a better idea to reimburse with the idea of getting evidence, is probably essential for this to work.

And then one other point here just to say is, you know, because these CED research protocols have to be developed in the time frame and the context of a coverage decision which is highly politicized with great financial stakes, it's not the best context to have a nuanced scientific discussion about what's the appropriate research protocol, and so a huge problem with most of the CED studies to date is that there are compromises on the science as a

result of the politics and the time constraints, as opposed to let's do the right study to really answer this question.

And then a final limitation, funding for research costs. There's been several CED efforts where they've come up with a study that would answer an important question about PET scanners, implantable defibrillators, and it's taken years to find the money to pay the costs of the research, even though Medicare is willing to pay the costs of the services. And in one case, for example, PET scanning for Alzheimer's disease, where Medicare agreed to pay for PET for suspected dementia in the context of a trial, it's, I don't know, six years later and there's one center enrolling patients and there's been several grant proposals to the NIH for funding of that study that have been turned down.

So if CED is going to work, you're going to have to come up with some solution of dedicated funds to support the research costs for doing these studies. If Medicare thinks there's a technology for which you need a CED study, there ought to be resources to pay the research costs for the study without having to go through a competitive scientific review process like any other NIH grant proposal.

So Medicare's experience with CED to date has fallen short of the original policy objectives, despite, I think, tremendous effort. My view is that the shortcomings of CED are not intrinsic to the CED concept, and in fact, I continue to believe that CED is not only possible, it's inevitable because, as I said at the beginning, there's a few other ideas that actually reconcile demand for access to technology with the need for evidence. The experience to date has highlighted ways that it could be improved.

There is growing interest among private payers in CED. We're doing a bunch of work with private payers on potentially implementing a CED approach, and CED that would align and coordinate Medicare with private payers around the same technologies would be incredibly powerful if we could figure out how to do it.

And so those are my comments. Thanks very much.

MR. HACKBARTH: Thank you. So we will, as usual, proceed with two rounds of questions and comments, the first round being strictly clarifying questions, and we'll start over on this side. Any clarifying questions? Tom?

DR. DEAN: Thank you. Those are very interesting. The CED process, is it more than just a registry? I guess I

wasn't clear about that. I mean, it would seem that as far as the costs are concerned, this would be relatively inexpensive compared to a lot of research, but maybe I'm offbase on that.

DR. TUNIS: So several of the CED initiatives have been registries, like implantable defibrillators. There's now, I think, somewhere between 300,000 and 400,000 patients enrolled in an ICD registry. And it is relatively low-cost and very limited data.

The original sort of CED before CED, the National Emphysema Treatment Trial of this lung surgery for emphysema was an 1,800-patient randomized trial. It took seven years, $50 million. But there are certain questions about, like that one particularly, the effectiveness of the surgery that actually require randomization. So while randomization imposes a lot more sort of technical and financial barriers, in some cases, it's probably the only way to actually accurately and legitimately answer questions about a certain technology, where for other things, registries are perfectly fine.

DR. DEAN: Okay.

MS. BEHROOZI: I had a question about the

performance-based agreements, and I wondered if the participants had looked at overall savings to the payer, for example, with respect to the Actonel, if they had done tiered copayments or excluded Actonel from their formulary as opposed to the rebates or payments that they got in relation to fractures. I mean, clearly, there's a health outcomes benefit, no question, but I just wonder if they did dollar savings in any of those cases.

DR. NEUMANN: Right. Certainly, the hope is that it will generate savings. I think, to date, we just haven't had rigorous studies. Some evaluations are ongoing, I think in that case, as well, but we just don't have peer-reviewed rigorous design studies that would allow us to say anything more, at least not yet.

MR. KUHN: Sean, good morning. It's good to see you. Great presentation. Two questions, just clarifying. One is the number of CEDs that have been launched by CMS thus far, if I remember right, it's about a dozen, and only one has come to maybe conclusion and that's PET for oncology. Is that correct? Do I have my numbers right on that?

DR. TUNIS: Yes. I think a dozen might be on the

high end, but that's the right range. It's between eight and 12 -- ten. So the PET registry probably has the most mature published results. There are -- there's been a lot of information generated and abstracts and I think some papers from the ICD registry. But for the most part, I think the general view is that there hasn't been a lot of published evidence that would rise to the usual level of decision making requirements of Medicare or any other payer.

MR. KUHN: And the second question is you did talk about the difficulty between (a)(1)(A) and (a)(1)(E), and those are difficult statutes to help make this work, but also to add to the complication of this, this is also tied to the NCD process, as well, if I remember correctly, which further complicates it and makes it difficult to process. Is that correct?

DR. TUNIS: Yes, I think for several reasons. One is just, as I said, sort of the political dynamics of the NCD process aren't a great setting to discuss kind of scientific issues and the best knowledge generation strategy, so how to do the best research. It also imposes kind of time constraints, because the NCD process is very fixed in terms of how long is allowed, you know, nine months

without a MEDCAC meeting, 12 months with it. You may or may not be able to work things out in that period of time. So I think, yes, a number of ways in which being tied to the NCE process is problematic.

Of course, when it was started, that was really the -- the reasonable and necessary authority was the mechanism by which you can actually link the requirement of reimbursement to data collection.

MR. KUHN: Right.

DR. TUNIS: So I suppose you could invent another authority to make that linkage, but, of course, that's the key thing, which is we don't pay unless the person is in a study.

MR. KUHN: Thanks.

DR. SCANLON: A quick question about the performance-based agreements, the Januvia example. Did I hear right that if the drug performed better, that the discount increased, which seems counterintuitive because shouldn't the manufacturer want a reward?

DR. NEUMANN: Right. So that's my understanding. It does sound a bit counterintuitive, that the better the drug works, the better the discount. So in a sense, the

plan has an incentive to make sure that the patients are adherent to the drug. And, in fact, they had a diabetes disease management program in place already and this is sort of an incentive to get them to adhere to that even more strictly.

DR. CROSSON: I just want to compliment you both on very clear presentations. Sean, I just had one suggestion for the diagram. You left out in the extracellular milieu the killer T cells that circulate and disrupt the entire process. Without suggesting what those might be, I just thought maybe you might want to add those.

[Laughter.]

DR. CROSSON: I actually have a question for Peter. With respect to the performance-based agreements, you listed three sorts of performance, actually, effectiveness, appropriateness, and then adherence. The appropriateness one struck my fancy a little bit, and the question is, you talked about it with respect to the diagnostic test Oncotype Dx. So in terms of determining the appropriateness for that, was that based on information that was contained within data already collected by Medicare, or did it require extra data collection?

DR. NEUMANN: Right. So it was contingent on data that had already been collected, but it was not Medicare data. But there had been considerable data that showed the test essentially gives a recurrent score and categorizes people into high, medium, or low recurrence and therefore adjutant chemotherapy is targeted based on that recurrent score. But certainly the arrangement sort of needed that pre-data collection effort to have preceded it.

DR. BERENSON: For Sean, I'm interested in sort of the operational logistics of registry data collection. I mean, two that you've mentioned, PET and ICDs, I think you've probably got a relatively limited universe of people who need to be reporting. Are there some kinds of technologies, I assume, where it would be all hospitals or a whole subset of doctors for which the issues around reliability and completeness of reporting would just be a real problem? And, in fact, in the current registries, is there an issue of incomplete or invalid reporting to the registry?

DR. TUNIS: Well, my sense is that the implantable defibrillator registry is least problematic because it was shifted over to the American College of Cardiology's

National Cardiovascular Data Registry, which is run by Duke University, and they have all kinds of very well-developed data quality and data collection strategies.

I think for the PET registry, it's been much more problematic, in part because the actual -- you know, you have the ordering physician and then you have the PET imaging facility. There's information that is required from both. It's not hospital-based, so you don't have the same kind of IT infrastructure. And the amount of quality assurance on the data reported was pretty limited. You know, that's quite expensive.

So one of the chief objections to the publications from the PET registry were the fact that the main outcome was the physician's self-reported change in diagnosis and management plan. Self-reported really can't be easily validated, and you've got a situation where everybody knew that the results of this study were going to influence future reimbursement for PET, so the incentive to be not fully accurate was fairly high.

DR. BERENSON: So, I mean, that's sort of inherent in this approach, right, those kinds of incentives?

DR. TUNIS: Right, the incentive that -- right.

If the results are known to be potentially influential of future coverage reimbursement, value-based or performance-based stuff, that is a problem and it means that the sort of data validation mechanisms exist by which, through auditing and sampling and auditing, you can validate data. So it's not as if the mechanisms don't exist. But you're correct to point out that you'd want to be, particularly in these studies, you'd want to be -- have pretty strong oversight because of those incentives.

DR. KANE: So I was sitting in on a doctoral research presentation a few months ago about reference pricing and one of the findings was that it was -- in the countries that have a lot of it, that their prices tend to stay a little higher over time because the manufacturers just don't want to bring in a lower-priced product and bring the whole group down. Have you seen anything like that, about reference pricing and sort of an anti-competitive effect over time on drug prices?

DR. NEUMANN: I have not, and I'd like to see that paper. It's an interesting finding. There have been some studies that have tried to sort of tease out the effects of reference pricing arrangements and impacts on everything

from health to spending to R&D and innovation. My sense is it's sort of mixed results and nothing really conclusive comes out of it we can point to as definitive.

The other thing I'll say is countries have implemented reference pricing in terms of where they set and how they set the maximum allowable price in different ways. So some countries are essentially pegging everything to the lowest-priced drug in the class. Some are using the average-priced drug in the class. And some are using sort of the third quartile, or not quartile, whatever the word is -- the bottom third price.

So the answer to the question of whether it raises or lowers price might depend also on actually how you do it.

MS. RAY: And just one other point. Internationally, in some countries, they do both internal reference pricing as well as external reference pricing, where they're linking the drug price to the drug prices in other countries. So that also is sort of a factor in thinking about it.

DR. MILSTEIN: I have one question for Sean and one for Peter. Sean, for better or for worse, our country is organized around a, to say the least, multi-payer system.

One of the challenges in generating public goods like the kind of information you're talking about in a multi-payer system is it's so easy for a subset to free ride, you know, off and on Medicare. So since we're going to have to change the law in order to make progress here, what are your thoughts on using our current, I'll call it common pathway, which is the FDA, by expanding their authority, versus giving CMS authority and then hoping somehow that CMS can persuade their payers not to free-ride on all the resources that CMS might be investing. That's my question for you, Sean. I'll hold off Peter until Sean has answered.

DR. TUNIS: So I'm not sure if it would look good for me to speculate on the idea of FDA increasing their authority, you know. I mean, so at an entirely conceptual level, I understand the problem it solves. But whether or not in some way the -- in some way, the general suggestion that the FDA demand more real world evidence or evidence of comparative effectiveness as part of their regulatory considerations, you know, is -- it would need a lot of thought to see if that actually is moving the bar in the right direction in terms of the balance between innovation and evidence-based policy making. So I honestly don't know

if it's a step forward in public health.

So to me, the free-rider problem with Medicare, I guess it doesn't seem impossible to me to envision that for certain technologies, there would be some, whether it's a government entity or a private sector entity, identifying promising emerging technologies, developing study protocols that would provide useful information on those, and then kind of allowing Medicare or any private payers to sort of decide to join the study and say, as part of our benefits, we'll reimburse for this promising procedure for any patient that's enrolled in one of these kind of approved studies that is developed with input from multiple payers and the clinical community, et cetera.

So I think you could find work-arounds to the free-rider problem.

DR. MILSTEIN: Peter, my question for you is there is a fair amount of evidence that within an average effectiveness of any particular therapy, there's massive variation for many therapies based on operator skill, clinician skill. I think this was highlighted in a recent New York Times article on robotic surgery, saying it can outperform some of the surgeons that are the aces, but

rarely. And it's a huge variable. How is it -- what are the challenges in bringing, I'll call it operator experience, operator performance into the calculation so we're not making judgments based on averages when, in fact, any given Medicare beneficiary is going to face a huge range in likely effectiveness depending on the operator skill.

DR. NEUMANN: Right. Well, I think there's been a real challenge in implementing these performance-based agreements for a whole series of reasons, but they tend to be very complicated for the reason you suggested and others. Most of them have been tied to pharmaceuticals as opposed to diagnostics or devices or procedures where perhaps there's less of a concern about operator skill. But I think the fact that we haven't seen them in these other areas is perhaps due to the reason you identified.

Even with pharmaceuticals, there are lots of challenges with heterogeneity in populations and effect sizes and so forth. The ones that seem to have succeeded better than others are ones where you have more objective measures. For example, the MS arrangement has proven difficult, in part because it's difficult to measure or more difficult to measure response. The Velcade example, where

you're looking at a biomarker that seems very predictive of tumor response, has proven more successful.

MR. BERTKO: This is for either of you guys. Is there a dollar threshold or a population cost threshold for which any of these mechanisms become really useful and below which they are probably not effective?

DR. TUNIS: I think the -- you know, in the case of kind of evidence development, there's actually a formal quantitative approach, value of information analysis that Peter can talk about, which is kind of how much resources would it be worth to generate certain evidence to reduce an uncertainty. So you can actually figure it out. And I think -- but I don't think there's a -- I don't kind of intuitively think that there are certain services for which the population is so small or the cost so low that it wouldn't necessarily be worth doing it. It all depends on what the uncertainty is and how much it would cost to reduce it in a way that would change decision making. So anyway, I just don't think that it's only for big-ticket items that affect lots and lots of people.

DR. NEUMANN: I'd agree with that. You are sort of asking when is it worth it to actually take the trouble

to implement this. And I'd agree with Sean, I think it's hard to sort of draw generalizations and make a blanket conclusion.

Obviously, you'd like the payoff to be worth the cost implementing it somehow, and that could be the case for different kinds of arrangements. I think it's going to depend a lot on the specifics at hand.

MR. BERTKO: So as Sean was, I think, suggesting, is that part of the study design process that happens on this?

DR. TUNIS: I think more in the priority-setting process of, you know, selecting -- in CED, anyway, selecting the technologies and services for which it would be a reasonable approach to look at the resources involved in, you know, designing and implementing the study, funding the study. And, again, I think you've probably worked on value-of-information analysis. And there are lots of people out there in the CER world thinking creatively about how to use value-of-information analysis in priority setting in CER, and probably with slight modifications you could say, well, a subset of those questions really ought to be approached using CED.

DR. CASTELLANOS: First of all, it was great presentation. I appreciate you both being here.

We've been watching the PET emerging technology, and this is really, I guess, a question for CMS more than anything else. When it was approved, it was approved for cancer. And we know that there are certain clinical applications where it has no value at all, and that information should be disseminated to the medical community; i.e., in prostate cancer it really has no value. It is not a hypermetabolic condition. Yet it is approved on a financial basis.

So how can we disseminate not just the value of the PET but the clinical applications?

DR. TUNIS: I know there are folks behind me who know these facts better than I do. I think actually that FTG PET in prostate cancer is specifically non-covered by Medicare.

DR. CASTELLANOS: I gave that as an example as it's not indicated, but there are other cancers where it is, it's approved but it's of minimal, if any, value.

DR. TUNIS: Right. And certainly that's not just true for PET scanning. There's lots of services that, you

know, Medicare and other payers pay for that are, you know, pretty generally believed or thought to be ineffective. And I think your question is really about educating physicians -- -

DR. CASTELLANOS: Absolutely.

DR. TUNIS: -- and sort of -- and I guess I would say there that, you know, while Medicare and other payers have a platform to educate physicians and perhaps a motivation to do it, you know, the physicians don't particularly look to Medicare as an educational resource. You know, it seems to me that the professional societies -- and many of them already do, as you know, like the American College of Cardiology, with their whole guideline program, you know, has been pretty active in identifying what's appropriate or inappropriate in trying to educate their membership.

I don't know if part of what you're wondering is whether Medicare should be sort of investing more energy in that as well, in reaching out to physicians?

DR. CASTELLANOS: I really am. I think that would be -- it's another service that we would like Medicare to do, but I think it's very, very important.

DR. STUART: I would like to add my thanks for coming. These were both very interesting presentations.

This is a question for Sean, and I've read the case studies, and I take away these little bits in terms of, well, there's a problem here, there's a problem here, and what I'm left with and what is our charge here at MedPAC is to say, well, how do we put that together and develop a road map. Let's just say that we think that this idea of CED has real potential that has been unrealized. Can you help us with that road map? Are there things that need to be done first? Is there an order of things? Is there some dollar amount, a magic amount that should be put toward this before we can say, all right, it's worth it, or it's not? Something that would help us move to reconcile some of these problems.

DR. TUNIS: So I think, you know -- and I agree with you that when you read the case studies, there are little insights here and there. I tried to pull those together into sort of the three domains of where I think sort of critical changes are essential in order for the approach to work: the statutory authority, priority setting, and the funding. So I would say of those three --

and I'm not sure exactly what order. I'd have to say that it seems to me that without some sort of recommendation on a more specific statutory authority to do this in Medicare, to somehow link reimbursement to a requirement for study participation, that it doesn't seem like any of the other problems can be solved until Medicare has a more stable platform to actually, you know, pursue this approach.

Then the second thing that is equally critical is there's got to be money available to sort of quickly and efficiently pay the research costs of the studies because it turns out it's not enough for just Medicare to agree to pay for the costs of the clinical services. It's just not -- you know, it's not a sweet enough deal. And, again, what we've seen in numerous cases is that it has taken a lot of time and a lot of energy to identify a poor of resources to answer the questions that are most important to Medicare.

One example of that which I didn't mention already is the original point of the defibrillator registry, the implantable defibrillator registry, was to see if we could better identify the 80 percent of people whose ICDs never fire. So of all the ICDs implanted, 80 percent never fire. So it would be really useful to be able to say these people

are at high likelihood of firing or low likelihood of firing, so a risk stratification study.

To do a risk stratification study, you need patient demographic characteristics and you need outcome information, like whose defibrillator fired? Well, it took five years to actually get funding arranged -- finally, you know, AHRQ came through with it -- to actually start to collect data on outcomes in the ICD registry. It started in January 2005. Sometime this year we will begin to have outcomes data in the registry. In the meantime, we've spent, Medicare has spent somewhere north of $15 billion on implantable defibrillators, 80 percent of which will never fire. How stupid is it -- let me correct that. It would seem to --

[Laughter.]

DR. TUNIS: It would seem to be more sensible to spend some portion of that money on, you know, collecting that information.

Are we allowed to correct the record?

[Laughter.]

DR. BORMAN: I recognize, for example, with drug-related coverage things that we no doubt get information

about adverse reactions or side effects or whatever we want to currently label them. But as we think about some of the other things here, procedures, imaging, so forth -- well, procedures is a little easier because presumably then we do collect complications. But, for example, things like the Oncologic Diagnosis Panel, do we typically set up a mechanism to identify the people in whom something turns out to be positive that turns out to be not clinically relevant and then gets pursued or is non-useful, which is a cost, an added cost to the system, potentially a bad thing for the patient, their physician, and so forth. And it seems to me that as we think about outcomes to collect, for example, on PET, do we -- as we think about the whole world of advanced imaging, we need to be thinking about ionizing radiation exposure and other things to our patients and the consequences of that.

So as we sort of step back and strategically look at these various ways to collect information in the context of Medicare service delivery, do we require any attempt to collect that sort of information, too? Or is that sort of dependent on the design of the trial? Do we pay any attention to that?

DR. TUNIS: I think mostly, you know, at least in the kinds of studies we've been talking about, registries or randomized trials, other prospective studies, you'll either have the information you decided to collect because, you know, people thought about it and determined it would be important to collect, like, you know, exposure to radiation might very well be information that's collected. In some cases, the hope would be that, you know, registries could be linked to administrative databases, claims databases, electronic medical records, that there would actually be ways to, you know, gather and analyze information that maybe wasn't conceptualized as part of the prospective study but is available if you could link to other sources of data.

DR. BORMAN: So do we or should we require that the set-up of some of these activities be sort of interoperable to other parts of data -- or other databases that CMS or other government entities may have? Should that be something that we're thinking about as if we say what is going to be the best way to utilize this mechanism in the context of the program? Are there some things we could specify up front that would potentially -- that we've learned would potentially broaden the impact of any given

investment because we could link it later to these other databases that we weren't smart enough to think about in advance? Is there that option?

DR. TUNIS: I think it's a great point to ponder. You know, my kind of off-the-cuff thought is that, say, the $400 million that Secretary Sebelius has available to spend on comparative effectiveness research, lots of which is going to be focused on building infrastructure for data collection, and including opportunities to link databases with registries and other -- you know, I'm not -- that probably will be useful in a service for CED studies as well as any other comparative effectiveness research study. And I'm not sure that there's something unique about infrastructure development to CED that isn't already somehow being thought about in the broader thinking related to expanding the CER infrastructure generally.

MR. HACKBARTH: So the two of you have described several different strategies that might be used for increasing the value that we get for investing in new developments, and each is appealing in its own way. But it seems to me that it all depends on there being a willingness, the political will, to limit the flow of new

stuff into the system until it has proven its value.

If you have that political willingness, then you have various strategies that you might deploy, and the strategy may be dependent on the nature of the technology. But absent the political willingness, it becomes very difficult to use any of these strategies. In a way, sort of the reference pricing concept to me seems sort of foundational in the sense that, look, you can come in, but we're not going to pay you more until you prove you are better. And the burden of proof is on the innovator to establish that value. Until you have the willingness to enforce that mentality, you're going to have a problem with any of these strategies, making them work.

So that makes me think that sort of the most important question is ultimately: Is there a way that we can create a decision-making process that's sufficiently insulated that you can create the necessary dynamic?

Let me stop there. Do you see the logic of what I'm saying? And I'd welcome your reaction to it.

DR. TUNIS: So one thought is, you know, you're sort of framing it as political will, and obviously political will is in some way, you know -- the more public

support you have, the less political will you need, right? So the question in part related to CED is: Is it a concept that is actually appealing to folks other than payers or policymakers? And, actually, I think that there is lots of potential support. I think the clinical community would not intrinsically be opposed to CED because they're as interested in having good evidence and using things, you know, thoughtfully and rationally and in an informed way.

I think even the patient/consumer universe, while there is often strong demand for access to new technologies, they also want to be informed about, you know, how they work relative to other options, particularly as they become more financially responsible for the impact of their health care decisions.

In the United Kingdom, their version of CED is called "only in research," so the National Institute of Clinical Excellence will sometimes approve services only in the context of research studies, and they did one of their Citizens Council meetings where, you know, all of -- just consumer representatives that advise NICE on the topic of only in research, and there was overwhelming support for that approach as one of the policy tools that could be used

at NICE.

I know the Brits are quite different from us in many ways, but, you know, it at least makes me hopeful that there would be some support.

MR. HACKBARTH: Let me ask you this, Sean. One of the issues that you laid out about CED was the murky statutory authority. Was there any effort made to go to the Congress and say give us unambiguous statutory authority for this? And what happened?

DR. TUNIS: None of my bosses at CMS suggested I do that. I don't know. Herb, maybe this is a question for you.

[Laughter.]

MR. HACKBARTH: You thought you got away from this, Herb.

MR. KUHN: I was afraid of that. It was talked about, it was discussed, but I think Sean said it right, there are certain components, there are certain people in the community that will support this and others that are less favorable to it. So there is some need for building more support for it.

DR. NEUMANN: My thought on your question is

certainly you need the political will, as you say, to implement these strategies. It does strike me that, to the extent the strategies are grounded in evidence, it might feed back into the political will; that is, you know, if we could agree on the process and on the sort of contours of the strategy and it's going to be grounded in evidence and people agree on the protocols to collect that evidence, it might have positive feedback on the political will. There are a lot of questions about it, how you collect the data and so forth. But I think, you know, the conceptual appeal of these strategies is such that, you know, it might help the political will.

MR. HACKBARTH: Okay, so we are now into round two. Let me see hands. Okay. We'll start down the row.

DR. DEAN: As a primary care doc, I find these things incredibly appealing because so often we are faced with decisions when we just simply don't have the evidence that we need, and so we make the best judgment we can. And so I guess I would -- and I've said before that some other -- it's relevant to what Ron and Arnie said. So often the pharmaceutical people will come with a new product, and they will say, "This is better than placebo." Well, I say, "So

what?" You know, that doesn't help me a bit. What I need to know is how does it relate to what I already have available. And almost never is that information easily available.

And, of course, you know, part of it relates to what we pay for, but even in terms of what we as clinicians decide, we really need this comparative information. And I realize I am -- you know, I'm sure there's no argument about that. But it just seems to me that these are mechanisms that are doable, even though there are obviously some barriers.

But it just seems to me that it is really crucial that we move forward with providing or trying to get the Congress to provide whatever authority and resources we need to move in this direction if we're ever going to get to really an evidence-based practice.

I urge you to push as much as you can, and certainly I'll be as supportive as I possibly can because I think this is terribly important stuff.

DR. TUNIS: Do you want us to in any way respond to this or not?

MR. HACKBARTH: If you want to. As we discussed

beforehand, I am eager to get a round for everybody in the second round. So you can just nod your head and say, "Right on," or --

DR. TUNIS: Yeah, yeah. Well, I'll say that, but the only thing, it actually raises a couple of important points, which is, as we were talking about before, related to your question of political will, it is really important, I think, to have the support of the clinical community, you know, behind us just in the ways that you stated, and also the folks delivering clinical care are actually going to be called upon to be willing to enroll patients, you know, and do the work. It's incremental work, actually. And, in fact, one of the -- we didn't put it as a suggestion here, but I actually think that there ought to be, you know, a billable service to enroll patients in clinical trials because, you know, it's important work to be done, and there's no reason to think that docs should necessarily do that without at least considering whether, you know, compensation -- if compensation for that would make it more likely that patients would be enrolled in the studies and that the data would be high quality, then that's something also important to think about.

MS. BEHROOZI: Yes, thanks. It's wonderful to feel like we're really pulling things together in terms of some of the things that we talk about were going on out there. And I would just bring back in what I was saying yesterday about the connection between this work and what we were talking about yesterday with respect to the potential benefit redesign.

I understand that, you know, the way it is posited today, it is about research, kind of, you know, and getting more evidence, but weaving it back into how we incent providers to reduce the variability of care provided to beneficiaries and for beneficiaries to have ways of making more informed choices, but also recognizing the political realities that you alluded to, Glenn, what you use the information for, what you do with it in terms of something like benefit design. Obviously, that is where the rubber meets the road, or whatever. And I think, Peter, you raised a really important point about the lack of focus on low-value services in value-based insurance design, and that kind of goes to some of what I was referring to and John, you know, proposed a tiered co-payment structure or whatever that would be just sort of flat dollar payments for seeing a

specialist or whatever. But, you know, I encourage the Commission staff to focus a little more on discouraging low-value services by going a little farther maybe than a flat $25 co-payment if a service is really unnecessary, which will obviously need certain other tools in order to implement that, whether it is some kind of prior authorization or that kind of thing.

But I feel like we are really developing a lot of information and our own sort of evidence base here for thinking about benefit redesign. So thank you.

DR. NEUMANN: I will just say quickly, if I may, it certainly seems to have proven easier to waive co-pays to do good things than to impose them to do bad things. And waiving co-pays to do good things is certainly admirable and attractive and appealing, but there are no losers in a sense if it works. And the hard part about the other side is you do create losers.

MS. BEHROOZI: I would just say that reference pricing is a way of penalizing the bad thing or whatever you want -- not necessarily the lower-value thing. So, you know, it's a little bit about how we articulate it.

DR. TUNIS: Since it hasn't been said explicitly,

but I think this point highlights it, it's worth realizing that CED kind of fits into the overall paradigm of value-based insurance design in that, you know, you can have different co-pays for high-value or low-value services, and then for services of uncertain benefit, you have a situation where the coverage is contingent on participation in a study. So, conceptually, actually it fits within the value-based framework.

DR. CHERNEW: I have a whole series of comments, and I'll try and say them all quickly.

The first one is it's interesting that so many of these things are related to drugs, because in the Part D system there's a whole separate set of rules that one would have to think about when one thinks about coverage or not coverage and how that works. And so I think that's some of the examples that were given for coverage, evidence development, of course, have been things that aren't drugs, but many of the ones for things are drugs, and I think how the Part D system fits in matters. That's my first comment.

The second comment is I just want to go on record -- and I'd love for everyone to stand up and say something about this collectively, including the audience -- which is

I think that the coverage for evidence development is central, but there's a broader issue of general access to the data that exists for the Medicare program that could be used in successful, completely independent of any coverage or non-coverage decision, and the ability to get that data to evaluate things that are clinical, to evaluate things that are systems, even when there's demonstrations for general researchers, I think is much harder than it need be if we wanted to have an ongoing management of the system for value.

And so until we have a data system that both protects privacy but allows researchers generally to access the data to evaluate things that we know Medicare has done, that we would like to evaluate but we can't for a number of reasons, I think it's going to be very hard to get the value, and I think the aspects of coverage of evidence development is just a part of it. And even figuring out exactly how we would implement the reference pricing or not is a little bit beside the point to the basic notion that we just can't get the general data to do a whole series of evaluations.

I think that's particularly important because in

many cases in these situations you face the argument that, well, the evaluation was done in a very rigorous design for the way we did the procedure three years ago, but now we're doing it differently; so the evidence that you have is no longer relevant, and we're not going to implement it.

So a continuing approach -- these are typically not one-time studies. It sort of needs this notion of this continuous approach, and in order to do that, I think we need a broader system of available data to do evaluations of clinical things and system-oriented things.

The last point I'll make is I think it's really important to think about how all of these things fit with the general fee-for-service payment system. Of course, if we move away from the fee-for-service payment system, some of these issues change how we think about it one way or another. And I think that matters.

I think it's also related important to think about some of these areas are patient-oriented type decisions where you could think about things like value-based insurance design, which you know I support. Others, I think really the incentives and the information have to go through the physician. And it just depends on the nature of the

service how you would adopt various aspects of things and how that would fit in with the broad payment system.

So my overall thematic comment is that we simply can't afford to manage a system that has the amount of inefficiency in it that our current system has, and the only solution to that seems to be to have a more clinically nuanced system in a whole range of ways. It is inevitable that in that system we will not be able to get it perfect, but we are not comparing the system of the future to the perfect system. We are comparing the system of the future to the current system, which, in my opinion, is sufficiently far away from the perfect that we can find areas of improvement that will be easier if we have better access to data and better support of broad types of research.

I am done.

DR. NEUMANN: So you raised many good points, and I'll try to address them briefly.

First, it certainly seems to be the case that most of these experiments are related to drugs and not to other types of services, at least value-based insurance design and some of the performance-based agreements.

We did, just to note, find the Oncotype DX is an

example of at least showing that it's possible to do such a thing with a diagnostic. And we even found an example that's just started of one pair that's experimenting with value-based insurance design for minimally invasive surgery, to waive co-pays if someone does that. So I think we'll see in the future -- why it's been the case that it's related to pharmaceuticals, you know, we can speculate that the data are better and, you know, perhaps some of Arnie's points about less variation related to operator and so forth.

Your point about access to Medicare data, I think that's the kind of question I would just say, "Right on," and I don't have to say anything else.

Then the final point I just want to say, I agree with you about the global -- the incentives, and just because we change the global incentive, if the actors implementing those incentives are not facing different incentives -- fee-for-service medicine, for example -- I agree, I think we need to think about how everything fits together, and we may not sufficiently address the problem.

DR. TUNIS: You know, I would just add I think this general notion of -- I was just thinking about your term, in order to get better value, we need a clinically

nuanced system and a clinically nuanced set of policies that are sensitive to kind of, you know, value from a clinical benefit point of view. And, you know, it totally agree with that because the only other alternative is a clinically insensitive system, which, by definition, seems less appealing.

The only caveat to that is, you know, clinically insensitive approaches to cost containment are, you know, politically relatively simpler. Like it's easier to just say we're cutting, you know, rehab stays by five visits, you know, five days, and you're not discriminating against anybody. You're just saying we're going to save that much money because we're not going to pay for five extra days. When you actually say we're going to ask you to pay more for your proton beam treatment for your prostate cancer because we think the evidence does not suggest that it's better, you know, you are picking on people with prostate cancer. And, you know, it raises a whole new set of --

MR. HACKBARTH: Identifiable lives versus statistical lives, sort of.

DR. TUNIS: But, you know, that being said, it's sort of yes, that's the path through the brier patch. But

avoiding the brier patch just means it's the clinically insensitive meat cutter approach.

MR. KUHN: Two questions or observations here to kind of help us think as we go forward on policy stuff here.

One, to revisit something that Arnie raised the issue on, and that was the FDA. And I think, Sean, you gave a good response there, but, you know, for more than a decade now, people have been opining on this issue of parallel review with CMS and FDA. And in a way, to kind of go back to the beginning when developers come to FDA but also have the payer there at the same time to start their discussion, and I think it is one way to deal with the issue that you raise, Sean, that is, reconcile the need for evidence with also advancing new technology out there.

So I would be curious of your thoughts on a parallel review process that we could think about be FDA and CMS, and then at the same time, Peter, it would be interesting to think about that in terms of pricing, because one of the things that payers see is -- we've been talking about drugs, but at least, say, on the device side, a lot of device manufacturers will come through the 510(k) process, which basically says the device is very similar to another

product in order to accelerate through the process, and then they get it approved, and they come to the payers and say, well, that's what I told FDA it was, but here's what it really is, and I want five times X what the reference was through the 510(k) process. And it gets a very difficult process. So I was wondering if a parallel review with CMS and FDA might help both on pricing as well as the evidence development.

The second issue I just wanted to ask about a little bit is that, you know, one model I saw back in 2008 that I thought was real interesting -- and, Sean, maybe you can opine on this as well -- whether this might be something -- there is some learnings for us here at MedPAC, and that was the compendia regulation process that CMS went through. Remember that within statute there were three compendias, and two of them basically went out of business, and so there was one left, and the community said, "We need more of those." And so CMS went through a process in about four or five months where they collected the evidence, approved some new compendias, and that worked very well. So it was a very short time frame. Obviously, other evidence is going to take much longer to gather. But I think there might be some

important learnings from that process that could inform us of how that worked, what didn't work in that, and came to a pretty successful conclusion. So any thoughts about that, if you have them, would be helpful.

DR. TUNIS: Well, the whole kind of better alignment of FDA and CMS I think is a hugely important and kind of migraine-inducing problem. And it's complicated enough that I only want to say kind of briefly a couple things.

One is you can try to better -- you know, the parallel review idea is a great idea, but that's only about aligning the process or sort of trying to make the process more efficient. What's the difficult part is the non-aligned evidentiary requirements or preferences of Medicare and FDA. And, you know, you're not going to sort of sort that out just by having a parallel review.

What I think is a real challenge facing industry, both the pharmaceutical and device industry, these days is that Medicare wants different stuff from the FDA, and in some cases what the FDA wants forces them to do studies that actually are by definition not as interesting or meaningful to Medicare. And so I actually think a huge challenge of

the whole kind of comparative effectiveness research enterprise, given that a lot of it is going to be funded by private industry, is being able to have a meaningful and genuine conversation between FDA and CMS about, you know, how those kind of requirements for evidence for regulatory approval and reimbursement can be better aligned.

One interesting place where this could actually play out, I think it's in Section 114 of FDAMA, but I might have the section wrong. But basically it's about the kinds of studies that industry would be allowed to share with payers and purchasers and not be in violation of marketing restrictions. So FDAMA actually asked the FDA to develop guidance about, you know, what sorts of studies would meet that. Well, that's kind of this perfect territory about where, you know, the payers, CMS and even the private payers, should be sort of involved in that conversation about deciding what kinds of studies should actually be meaningful or sort of identified as adequate in the FDAMA guidance. As far as I know, nothing is going on to develop that, and I think when it happens, it would be really important for CMS and FDA to both be in that conversation as well as private payers.

All that is my way of saying, you know, trying to develop a parallel process of review would be important mostly because it would force the conversation about the incompatibility of the evidence.

MR. HACKBARTH: Before you begin, Peter, I just wanted to do a time check here. We have about 35 minutes left in the scheduled time for this. Two hours seemed like a lot of time an hour and a half ago, and this is an incredibly rich discussion. But I do want to try to make sure we get all the way around again. So I'd ask everybody to keep their questions limited to one and please, Peter and Sean, try and be real concise in your responses.

In particular, as I go around, after we finish here, I'm going to ask for people who have not asked any questions at all and give George and Peter and some others a chance before we get anybody else in.

DR. NEUMANN: I just wanted to briefly address the point you raise about the disconnect between the 510(k) and the demand for higher reimbursement. I think it's a very interesting point, which I haven't thought a lot about, but it does strike me, on the one hand, it seems that there is a fundamental disconnect. How could it be that they're

substantially equivalent and yet there's a demand for a higher price?

But perhaps it could be the case that there really is from a narrow clinical sense substantial equivalence, but there is some difference that would warrant different payment, or at least patients might value a certain -- at one level, two drugs might be very equivalent, but one has a much more favorable dosing profile or convenience profile or side effect profile. And, you know, conceivably, there's a higher willingness to pay, and there could be a parallel to the device world. I think it gets to the different statutory missions of FDA and CMS.

MR. HACKBARTH: Who hasn't had any chance whatsoever to ask questions?

MS. HANSEN: First of all, I apologize for having missed your earlier part of this, and you may have covered it. Given how difficult doing this research is to begin with, you know, one of the areas we consistently try to cover is that of different populations, so whether we're talking about race, ethnicity, or lower-income individuals. Has there been any success in doing work that is designed in a way with an effective execution to cover these segments of

populations?

DR. TUNIS: I mean, I think that that continues to be a challenge, and I am trying to think of good examples in the past that have really focused on it. But for the sake of time, I would say that within the CER conversation, you know, vulnerable and underrepresented populations and minority populations have clearly been targeted as a historically underrepresented population and lots more needs to be done to get those folks into these studies.

One place where I think we need to be looking at the CED approach, you know, is with the Medicaid programs, which haven't to date been heavily involved in the idea. But certainly if you want to get lower-income individuals and some minority populations in these studies, it's going to be through payers other than Medicare and some of the other private payers.

So I just take your point, it's a problem that needs to be addressed.

DR. NEUMANN: And I would agree with that and only say that any discussion of these arrangements that we've been talking about sort of quickly begs the discussion of sub-groups defined in all kinds of ways. Typically, in the

value-based policies we've looked at, or the performance-based policies, it's sub-groups tied to clinical characteristics, so the Oncotype DX predicts recurring scores and certain types of patients based on their characteristics.

It certainly could be the case that these value-based policies should follow other characteristics related to demographics -- race, ethnicity, and so forth.

MR. BUTLER: So my question relates to kind of the size of the opportunity of what we might put under the CED umbrella. But first, you know, you kind of had me with the $15 billion -- $12 billion of which you said has never been used, in effect, because 80 percent is never fired. That's a big number for sure.

Then also I think about things like the drug-eluting stent, which is not on the list of the ten and had its own interesting messy process associated with it.

And then as I look at the ten that have been looked at, I think about eight of them -- two are drug and eight are technologies or so forth.

So what I'm trying to get my arms around is that if you were to have statutory authority, if you were to

prioritize, if you did have the funding, what might be the pipeline or the size or the number of things that we might be looking at if this were really humming along.

DR. TUNIS: That's a good question. You know, I think if you really had sort of the funding and an infrastructure to sort of quickly design and implement these studies, like, you know, that was all facilitated, I think there's probably -- you know, every year there's probably two or three technologies in any clinical field, you know, domain, that are important, promising, getting attention, and could really benefit from some accelerated, organized evaluation. So maybe, you know, if you looked across all services -- and obviously this is just wild guessing. You know, 40 or 50 a year, I mean, some reasonable number of things that would be -- you know, for which this approach would be applied.

Again, I think in some ways there are ways in which you can imagine that almost every new technology that is of, you know, any meaningful, potential importance that's approved by the FDA will benefit from additional collection to look at comparative effectiveness, effectiveness in new populations, et cetera. And a vast majority of those

studies never get done. So, you know, you could -- I could almost think of CED as becoming the rule rather than the exception for, you know, when decisions are made to reimburse meaningful new technologies.

MR. GEORGE MILLER: To follow along Peter's train of thought, should you have the statutory authority, I guess my question is: Does CMS have the infrastructure to implement all that we've discussed here today? I remember at another meeting that there were discussions concerning trials -- demonstration projects, I'm sorry, demonstration projects, and part of the problem with those demonstration projects is that CMS did not have the funding in place to help to evaluate them.

So my question really boils down to is there -- and this is probably a dangerous statement to make. But is there enough funding authority to implement these processes from your perspective? Or will part of this whole evaluation need to make sure there's enough authority for the infrastructure to make sure that this process could be implemented?

DR. TUNIS: Yeah, so, you know, in addition to needing to identify funds to support the research costs,

security would clearly need at CMS a larger number of people with the kind of scientific and clinical expertise to be able to really meaningfully, you know, address these things.

You know, the coverage staff currently I think has as many folks in it as the staff at the FDA looking at incontinence devices. You know, it's a tiny -- and the coverage staff at Medicare is supposed to do the entire universe of drugs and devices and procedures. So there isn't -- you would need more infrastructure capacity, you know, staffing and different kinds of technical expertise to be able to pull this off.

MR. GEORGE MILLER: I'm curious. What does that look like?

DR. TUNIS: You mean how many new people?

MR. GEORGE MILLER: No. Just dollar amount. Is there a ratio to the budget? Just trying to get a feel of what does it look like from a budget standpoint, not people. You all have to --

DR. TUNIS: Well, yeah, you know, you would clearly use a lot -- you would borrow a lot of resources and technical resources from NIH and AHRQ and FDA and CDC. So, you know, the incremental new staffing, you just need more -

- you know you probably need, to start off with, two or three times the number of people currently at CMS to even make kind of a meaningful run at doing this in a kind of noticeable, measurable way.

MR. HACKBARTH: Okay. Have I missed anybody else? Has everybody had a chance?

DR. SCANLON: To go back to the issue of capacity and so that we're not starting any of these things sort of at square one, sort of when we kind of get the bright idea that this is a particular application that we want to use, I'd ask you to think about the data that's required for this, both in terms of the types and the volume and what kind of a relationship there might be to take advantage of the meaningful use sort of requirements that we're going to have for this investment in IT that we're making.

The sense would be that we would want data in the systems that was retrievable and, you know, code-able so that it could be manipulated. But there's a question of sort of could we make real inroads there in terms of the kind of data that are needed if we do make those kinds of requirements for electronic health records that we're investing in. Or is that too pie in the sky? Are we always

going to be tailoring things for particular applications that are -- you know, you can't in some respects sort of build the general purpose, the Swiss army knife for these kinds of interventions?

DR. TUNIS: I think, you know, as many people have pointed out, there are so many comparative effectiveness questions all the time that it's just going to be impossible to design individual de novo studies and, you know, make a dent in the ocean, or whatever the metaphor should be. And so I think this idea of thinking of the meaningful use provisions in the context of what would support good comparative effectiveness research, including CED, you know, is important and it hasn't been a big part of the conversation, although it has not been entirely overlooked. I think there was a White House task force at OSTP that has been thinking about CER and meaningful use and some of those issues. But it's not pie in the sky at all. I think it's probably essential.

DR. NEUMANN: I would just add, for some of the performance-based agreements that I mentioned, it really requires a level of data that you may not have right now. The A1c levels, the biomarker for the Velcade example, the

multiple sclerosis score, which is sort of a function and cognition combination -- that's the kind of clinical detail that you might get out of an electronic medical record eventually or out of some other database but you probably don't have right now.

DR. CROSSON: I would like to return just for a minute to a topic I brought up earlier. A lot of this discussion has been focused in on, you know, what to do about technology or new technology where the effectiveness or the indications for the technology are not fully understood, and we spent a good amount of time and an appropriate amount of time on that.

One of the things that you talked about, Peter, still strikes me, and that's this question of using the performance-based agreements to look at the appropriate use of a technology when the appropriateness is known. You know, there are a couple of attractive things.

Number one, I could imagine that this sort of agreement would be much speedier than, for example, waiting for information about the ultimate outcomes of a therapy which could last over many years. You could imagine getting to appropriateness determinations within the course of a

year and then acting on that, and as in the case of the Oncotype DX, getting a change in behavior on the part of the sponsors of the technology in a relatively short period of time. So there's a certain attractiveness to it.

But as I said initially, to do this you sort of have to have a technology going in where you're pretty sure what the appropriateness is, and a lot of the things we've discussed, for example, lung volume reduction surgery, of course, you didn't know.

So the question is, you know, just roughly, are there enough things in this arena where the appropriateness is known going in and the problem is misapplication over time, promotion of uses beyond the envelope of appropriateness, to make that a viable policy direction?

DR. NEUMANN: Right. So a couple of things strike me. First, I certainly agree to the extent you have knowledge about appropriateness going in and you're looking is the right person or patient getting the right technology, it's a lot easier than trying to sort of adjudicate an outcome later on, and cheaper and more straightforward and presumably more effective. It does presume that you have that knowledge, and how often do we have that? I'm not sure

how to answer it. Certainly there are clinical guidelines in place sometimes that would allow us to say that. I think we could look at plans that are trying to tie drugs to on-label indications, which is, you might argue, a form of appropriateness, I suppose.

The Oncotype DX case, as I mentioned before, was an example where they actually had some data showing empirically recurrent scores as the measure of appropriateness. So there are probably other examples we could think of, and maybe that's a good way to separate the world into appropriateness, as you're saying, and what you might call outcomes agreements where we're really trying to understand appropriateness in a sense, or at least trying to learn about outcomes down the road.

DR. TUNIS: You know, I think there is a lot of data out there that could be used to sort of determine appropriateness and apply, you know, performance-based incentives, et cetera.

That being said, you know, and I think you were -- you know, both of these pieces of the puzzle need to be addressed. It is sort of, you know, doing what we can with the evidence we have today and making sure that we're not as

ignorant five years from now as we are now, because there are so many examples -- you know, looking at the appropriateness and rewarding how people use angioplasty or revascularization procedures, and we still don't have a definitive study that shows that revascularization is better than maximal medical management.

So you can apply all the financial incentives you want. You have no idea if you're doing the right thing. So at least, it seems to me, you need to be paying attention to both, which is, you know, generating better knowledge over time and also trying to apply as best you can what you know today.

DR. KANE: Yeah, I'm just trying to listen in to this. I'm not very familiar with a lot of the internal bureaucratic and legal issues surrounding this process, although I have sort of tracked it from afar. But it seems to me there are sort of two subjects we're on here at once, and I'm a little -- maybe it would help to get it clarified. One is sort of how do we figure out what constitutes value, what kind of research can we be doing, and to me that sort of all fell into this comparative effectiveness area. And when we talked about that in the old days, you know, a few

months ago, I thought we were talking about sort of an all-payer, multi-funding source approach to getting at this data and developing the evidence. The developing-the-evidence process I kind of thought would be no Medicare specific, but a much broader group of payers and funding sources.

So when I looked at the title of today's topic, I thought the next step would be, okay, so this evidence does get produced somehow, however the comparative effectiveness works. Then what's Medicare's ability to use the evidence? How do they get that implemented into practice using, you know, benefit design and, who knows, coverage decisions, et cetera? And to me those are two distinct things, yet somehow we're -- and I'm not sure which one we're really talking about here, and I think we've just of mushed them together. And certainly when you're starting to talk about financing the collection of data to figure out what is effective, that falls, I think, back up there in that whole topic of all the payers coming in to some broad agency.

And so I guess I'm a little lost as to exactly which topic we really mean when we say enhancing Medicare's flexibility to implement value-based policies. I'm just trying to help frame the discussion a little bit so that

it's a little more meaningful to me, but maybe I'm just completely missing the point.

DR. TUNIS: I think that's a good point. I think, you know, maybe the simple answer is that, you know, just by giving $1 billion to comparative effectiveness research, and even if you could get payers to put into a pool and have another couple billion, it isn't close to what's actually going to be needed to provide the resources to answer all the important questions. And some of what we're talking about is still other additional -- or the mechanisms that will be necessary in order to continue to generate the evidence, which can then be implemented through various approaches to -- you know, value-based approaches, et cetera.

CED, coverage with evidence development, I guess, you know, it sort of straddles the two issues because it's a tool for generating evidence and it's also a benefit design tool for promoting, you know, for kind of applying the use of evidence. So it does sort of straddle it. But maybe the confusion is that, you know, this all-payer pool of money to fund comparative effectiveness research is a great start and it's just not the whole solution to the problem.

DR. NEUMANN: I agree, you raise a good point, and I guess the way I've been thinking about it, at least in my section, we were focusing on strategies or structures or frameworks to change the way Medicare pays based on evidence and value and so forth. But it quickly begs the question about the quality of the evidence and who's producing the evidence and where it's coming from. So we sort of naturally get into that discussion.

MR. HACKBARTH: My thought, Nancy, was let's assume we have the comparative effectiveness enterprise fully funded and running. I don't think it's going to be feasible to say nothing's covered until it goes through that process and we develop adequate evidence. There's going to be this relentless pressure this needs to be covered now, and this is sort of a safety valve. Okay, what do we do in those circumstances? Are there ways that we can make the coverage conditional on evidence development or performance in the interim?

The world's not going to stop just because we have now funded comparative effectiveness research. CMS is going to face these pressures. Private insurers are going to face these pressures. So it's not all that clean, the separation

of the two.

DR. KANE: I understand, and I guess so then there's a third subject, maybe, which is actually what I think the title suggests, which is once you know what's appropriate, how do you implement it? And I thought that was kind of what -- so, you know, I can see that there is this -- there's a whole lot of stuff that we should be looking at that's already in place, not just new stuff. But once you know what's appropriate, how do you create policies that implement the value that you now know something about?

DR. MARK MILLER: A couple of other connections here. If the comparative effectiveness enterprise was running, which is a big giant "if," and a CED decision, coverage with evidence development decision, was made in CMS, some of the funding of the trial or, you know, studying the data that comes out of the CED could be running through the CE process, if you will, one. And two, at least one policy to implement what you -- now that I have some information, what can I do with it, I see as kind of the reference pricing point, which is it's one way to change the argument from yes-no coverage to yes, but based on this evidence, this is where the price -- that's at least one

thing.

And then, of course, there are the conversations that you guys have had on things like, you know, pay for performance, those types of things, which might indirectly inform on that kind of front.

DR. MILSTEIN: My comments really go back to Glenn's point. This discussion is a microcosm of every discussion we have. Our job is to try to improve the value of the Medicare program and, by derivative, you know, the value of the American health care system to the competitiveness of the economy and the workforce, et cetera. And this is such a beautiful microcosm of sort of the bigger picture.

You know, I think it completely makes sense that all of us have engaged in this question of, you know, do we have the mechanical tools, are they good enough, to do the evaluation; and then do we have the various tools to drive value and benefit design and pricing and coverage, you know, et cetera.

I think that's very important to do because if you can't come to a judgment that what we have is good enough for openers, you know, if you're playing poker, then all is

off.

But, you know, my view, at least in what I've heard this time and the last several times -- you know, Peter, you've been here to present, and I've heard you talk -- it isn't like -- I mean, I do think -- my personal judgment is the tools are good enough, certainly judged by any private industry standard, to make judgments, and we have a pretty good -- I think we have reasonable evidence on the tools one would use once one knew that a particular treatment provided higher value as to how you might encourage it relative to a lower-value treatment.

So for me -- and it's Glenn's point -- we need to assure ourselves that the mechanical part of this is ready to go. But, you know, the shortfall, the voltage drop, is typically not in that ascertainment. It's really in the political will. Okay, now who wants to go forward with it? And the fundamental problem is the ease with which anybody in opposition can demonize the rationalizer. You know, these are demonic bureaucrats who are going to, you know, deprive you of your life and quality of life and individual autonomy.

So, you know, realizing that neither one of you

are cultural anthropologists, but looking at what the other countries, the other wealthy democracies that have done a little bit better than we have in making sure that innovations coming into the health care system are of higher value rather than of lower value, can you share with us what you think might have been some of the characteristics of their system of doing this that you think may have interfered with the demonization and allowed the public to better trust efforts to improve value of health care delivery?

You know, you mentioned a Citizens Council. It sounds like, you know, about 10 percent of us on MedPAC would qualify for that, and I assume having no revenue in any way coming in from the health care system. What is it that in these other wealthy democracies appears to induce the level of public trust necessary to allow value-focused policies, information to drive value-focused policies to go forward?

DR. NEUMANN: Well, that's a big question, and I guess just some thoughts. I mean, certainly -- and I don't know that it's that helpful in terms of advice, but certainly as everybody knows, systems and history and

culture and everything is very different in other countries and allows solutions and policies that are difficult to implement here. And I think that is, you know, just the way it is.

I do think, though, having said that, there are some processes that have been put in place in some places -- the U.K., perhaps Canada -- around a citizens council, public input, transparency, posting things on the website, allowing for public comment, allowing stakeholder input, and on and on, that I think have helped the process. And those processes have not been without debate, of course, even in the countries that have done it. But I think it has allowed a kind of -- I don't know -- escape valve or, you know, some way to move the process forward.

But the fundamental political will that drives it I think is really more a reflection of those other things I mentioned at the outset.

DR. TUNIS: It's a great question, and I don't think I'm even a good amateur cultural anthropologist. But, you know, I would agree that it seems as though these issues of kind of transparency and participation of the end users, particularly the patients and consumers, is, you know,

critically important. But it's not as if that has escaped people's attention. I think folks are trying to do that. But I do think the Citizens Council at the National Institute of Clinical Excellence has been a huge asset to them in terms of the legitimacy of the process. They've tried to be very transparent, et cetera.

Another big difference is, you know -- and this in some ways begs the question -- somewhere at some point in the U.K. the NHS decided it was going to have a budget. And once you've kind of gotten to the point where you're working within a fixed budget or a budget that at least, you know, is in some way, you know, specifically increased over time, all of your conversations then become how are you going to allocate within this fixed pot for this entire system, and that really changes the nature of the conversation in terms of people's willingness to -- you know, then the whole notion of opportunity costs really makes sense. And, you know, NICE is always talking about opportunity costs. Well, if we pay for this, what is it that you'd like us not to pay for? Or, you know, if we pay for this very low value thing, you know, you have to think about the person who is not getting a higher-value service which we don't -- you know,

so it does seem like that changes the conversation.

There were some examples at Medicare where some programs were passed that had a fixed budget. I'm thinking specifically of Section 641 of the MMA, which I won't take the time to go into, but it was remarkable how having a fixed pot of money in a program in Medicare really changed the dynamics of the political will and the conversation. And I can tell you about that, Arnie, offline if you're interested.

MR. BERTKO: Okay. Ignoring the statutory limitations in terms of getting this done in Medicare, can you guys revisit the private sector and what lessons we could learn there? I'm thinking about the background readings and then the presentation from your today, it seems like most of the private sector stuff was in the nature of performance incentives types of stuff and not so much in turning things down. And I'm wondering how that relates to what I'm guessing is the private sector use of medical necessity to get there. Are lessons in the private sector much limited than what we've talked about for Medicare here today?

DR. NEUMANN: Well, I can address the performance-

based agreements, value-based insurance design, and the reference pricing. You know, I think one lesson is there's experimentation going on that's, you know, interesting to look at. It certainly raises challenges. I think conceptually all three are appealing, and in practice, they are harder to do than one might realize, particularly the performance-based agreements. The value-based insurance design, there have been some ongoing experiments with it, and Mike Chernew's very involved.

My sense until Mike's recent paper, we really don't know the impact. There are a lot of claims about its savings and health gains, but we really haven't had rigorous designed with control groups and, you know, sufficient data and evaluation periods and so forth. And I think the same probably goes for the performance-based agreements. I think, you know, we're in kind of an early experiment and churning phase. I think reference pricing we have more experience, certainly from countries overseas, and, you know, I think we could -- maybe some would argue with this, but I think there's more of a track record and more success with that strategy.

DR. TUNIS: I think lessons learned from the

private sector in terms of CED, you know, is kind of at the coarsest kind of level is, you know, kind of what I said at the beginning. You know, in the face of uncertainty, the default is often, you know, we pay as opposed to we don't pay. Uncertainty does not work -- you know, the fact that we don't know if proton bean is better is not a good basis to say we're not going to pay for it. That's just not the way it plays out.

So the idea of having a third option between yes and no, which is yes in the context of generating information we wish we had today, there's a lot of enthusiasm for that. And one of the major obstacles is, you know, contract language and sort of the state legislative oversight of reasonable -- and the implementation of reasonable and necessary. And I think private payers are equally faced with, you know, not an adequate contractual basis upon which to sort of link reimbursement with participation and studies.

DR. CASTELLANOS: I guess it's ironic because we're on a Payment Advisory Commission and, you know, we talk about value, we're talking about the value of the procedure and the appropriateness, but we kind of slip over

the cost of the procedure.

As an example, you brought up proton just right now, and there's a big difference between the cost of proton, which is $180,000, and a procedure called interstitial seeds, which is like $10,000. You know, we don't discuss the appropriateness of cost.

I personally think we need to get into that for the clinician to have a better understanding of making value-based decisions. Any comments on that?

DR. TUNIS: I'm just trying to think, I probably can't do myself any more damage today, so I might as well weigh in.

[Laughter.]

DR. MARK MILLER: I was just going to say, you're definitely there, so go ahead.

DR. TUNIS: But, yeah, I think sort of two things. One is, you know, for a lot of the work that I've done, I haven't been particularly focused on the cost issue primarily because it has been so obvious that the serious deficiencies in our knowledge about relative effectiveness, you know, unless you know something about comparative effectiveness, you can't say anything about cost

effectiveness without any reasonable confidence. So that is one point.

That being said, we oftentimes have some maybe uncertain but suggestive information about comparative effectiveness. In those cases, I think large cost differences ought to be known about and become part of the decision-making process, particularly in a context where patients and clinicians are going to be increasingly, you know, sort of exposed to the implications of those differences. So I would just say yes, I agree.

DR. STUART: This is a quickie. It's following up on the point that John made, and it's focused to Peter. I've read your three case studies of performance-based agreements, and I guess the question I have in looking at that: Is this a sample of three in a population of three? Or is it a sample of three in a population of hundreds? Do you have some sense of how big this enterprise is in the private sector?

DR. NEUMANN: One of the challenges, some of what goes on out there is not in the public domain, and companies are negotiating with health plans, and it's not entirely clear to those of us on the outside what's going on.

Having said that, my sense is there's not hundreds. Whenever we've asked -- and we've asked a lot of people about these agreements -- these are the three in the U.S. that come up, and the Oncotype DX come up. There are other agreements overseas that are going on, and we probably could have come up with some other examples. But my sense is there are not a lot of them yet, and we may see a lot more in the future, but I think we just don't have that many examples yet.

MR. HACKBARTH: I have sort of a related question. Again, I'm thinking at a high level of abstraction here, but my first question was about political will, and this is related to that. The question is whether we're likely to be more effective in dealing with these very difficult issues if we centralize decision-making or decentralize the decision-making. So, you know, one model is, you know, like the U.K., you have got sort of one-stop shopping. If it's going to be done in the U.K., it's going to be evaluated by NICE and a recommendation made. That focuses all of the pressure or all of the energy on a single source, and, you know, hopefully it's well funded and you have an open dialogue and that system works well.

Sort of another very different strategy is to say let's not concentrate the decision in one place. These are difficult questions. Let's allow, indeed encourage variation and have a very decentralized decision-making process. And, you know, if you use private health plans as the basis and people have a range of choices in private health plans, for example, through an exchange, that can be something that influences their judgment. They can choose to enroll in the plan with the very wide open coverage process, or they can choose one that's much more stringent.

As you look around the world, any evidence on which of those approaches works better or might work in the particular setting of the United States?

DR. NEUMANN: Well, what strikes me is we do have a Part D process where plans could experiment with value-based insurance design and other approaches, and maybe that's a very healthy thing that there could be decentralization and experiments going on by different plans. To me, the challenge is some of the data collection costs and research costs probably couldn't be borne by individual plans, and there might be a natural role for a centralized body of the government, Medicare --

MR. HACKBARTH: Well, you can have centralized research, you know, through the comparative effectiveness enterprise and, you know, large-scale public funding, but decision-making about the application of that research decentralized.

DR. NEUMANN: Right. And perhaps that's the model that would be workable. I think that would be interesting, you know, to study that further and see, and maybe there are some examples we could draw from.

It strikes me that even some of the strategies we talked about, performance-based agreements, might involve some intensive analytic work, additional data collection after Medicare would collect the original data, and whether or not that could be borne by the individual plans I think is still a question.

DR. TUNIS: I'm sure there's no right answer to this question. I've heard it debated all different ways, and clearly centralizing the evidence review process, centralizing the priority-setting process, you know, everything but the decision-making process. But, of course, when you decentralize the decision-making process, it becomes, you know, individual organizations that are much

less kind of politically strong, and they're, you know, subject to kind of legal pressures and, you know, et cetera. So, you know, there's a trade-off there, and at some point -- you know, I don't know if you've seen the movie "The Hurt Locker," but, you know, somebody has got to put on the suit and go out there where the bombs are. And, you know, there's no magic to -- you know, at some point there's a tough decision to make that is made in the setting of always some degree of uncertainty and great financial and political implications.

And so the question is, you know, you can't just toss hot potato around forever. Someone eventually ends up holding it. And, you know, I'm inclined to think that, all things considered, it's got to be, you know, something more centralized than disparate. But it's not obvious to me that, you know, the Medicare program -- you know, to me what's crazy about it is that if it's clinically nuanced decisions, you know, it probably would be better in the hands of physician organizations than government or payer organizations. But, Ron, you know, will know all the reasons why organized medicine isn't any more anxious to catch the hot potato than anybody else.

MR. HACKBARTH: Right. Well, maybe the image of "The Hurt Locker" is a fitting place to end this conversation. Thank you, Peter and Sean. That was very, very well done. We really appreciate your help.

Okay. Moving on to our final session on enhancing Medicare's research and demonstration capacity.

Okay. John, good morning.

MR. RICHARDSON: In the last session, you discussed three specific policy areas where Medicare may need greater administrative flexibility to become a more value-based and innovative healthcare purchaser.

This session continues on that theme and presents a series of issues and options to increase Medicare's flexibility with corresponding accountability to conduct research and demonstrations of potential innovations in plan policy and service delivery models, and to accelerate the dissemination of promising models into the entire Medicare Program.

We seek to engage you this morning in a discussion on these issues to guide further staff work in the area of reforming Medicare's administrative flexibility.

As Nancy mentioned at the outset of her session,

we plan to return at the Commission's April meeting for further discussions of our respective issues and will then combine that into a chapter in the upcoming June report.

Over the last several years, the Commission and other observers have noted that there is a growing disconnect between the constrained resources, flexibility, and resulting output of Medicare's research and demonstration activity, and the urgent need for Medicare to identify and test payment in service delivery innovations, and then to implement those innovations to reduce the unsustainable rate of growth in Medicare's overall costs and improve the quality of care for the program's beneficiaries or, ideally, both.

In thinking about options to increase the program's flexibility in this area, it is important to simultaneously consider how to include an appropriate degree of accountability and oversight of the program's activities. Before getting into some possible solutions or options for solutions, I think it will be helpful to spend a few minutes defining the problem we are trying to solve by orienting everyone to what the Medicare demonstrations currently are and how the demonstration process currently works.

Within the Medicare Program, research, strictly speaking, refers to data-driven analyses performed to suggest policy options for further exploration, whereas demonstrations are applied research. They change how Medicare operates in a limited geographic area or for a particular group of beneficiaries. A demonstration may be initiated by the Secretary under waiver authority that was granted shortly after Medicare was created, or by the Congress, typically through a provision inserted into a much larger authorization act.

Demonstrations usually are designed to test variations for Medicare's current policies governing payments to providers, beneficiary cost sharing, covered services, or service delivery models.

By design, demonstrations are time-limited and geographically limited, but the infrastructure at CMS and its contractors needed to implement these mini programs, such as claims processing and beneficiary enrollment processes, can be as complex as that used to operate the full program.

Part of this complexity is due to the need to generate and collect the date, in particular, service use

and quality data, that is essential to empirically evaluate the effects of the interventions being tested.

Finally, it should be noted that Medicare has used demonstrations to develop some of the most significant changes in the program, such as the inpatient perspective payment system, the skilled nursing facility and home health perspective payment systems, the Program for All-inclusive Care for the Elderly, or PACE, which integrates Medicare and Medicaid services to improve care for dually eligible beneficiaries and the hospice benefit.

The graphic on this slide presents a simplified picture of how the demonstration process currently works.

First, as I mentioned a minute ago, demonstrations are initiated by the Congress or by the Department. Once initiated, the key component within CMS that is responsible for the design, development, implementation, and evaluation of each demonstration is the CMS Office of Research, Development, and Information, or ORDI.

After initiation, ORDI will take the concept for a demonstration, bring to bear any supporting research, and develop a design proposal. The design will include plans both for how the demonstration would be implemented and how

it would be evaluated.

Next, CMS staff and policy officials will work with HHS and OMB staff and policy officials to refine and ultimately bet approval to move forward with the proposed design.

The OMB process includes a Paperwork Reduction Act review of all proposed information collection activities that will occur during the demonstration or as part of the evaluation, such as beneficiary and provider surveys and quality measures.

OMB also does a separate review of whether the demonstration is projected to be budget-neutral within its period of operation, and OMB will require changes in the demonstration's design until it is satisfied that the demonstration will, at a minimum not result in a net increase in Medicare spending.

Once the project is cleared internally within the Executive Branch, CMS begins the process of selecting and contracting with demonstration sites. In most cases, CMS must carry out this step in compliance with the Federal Acquisition Regulation, or FAR, which stringently governs the procurement of goods and services by almost every

federal agency and covers Medicare's contracting with demonstration sites.

Once contract awards have been made, the selected sites have been given lead time to prepare for implementation, including time to identify potential beneficiary participants for enrollment when the demonstration starts. Once it is operational, the demonstration typically runs between one and five years, depending on the terms of the final study design or the original mandate from the Congress, if there was one.

Sometimes, demonstrations are continued beyond their original planned time frame, with one or more extensions.

Looking at evaluations, interim evaluations may be conducted during the demonstration and often in forum the extension decisions I just mentioned, and a full evaluation will be conducted after the demonstration is completed. It is important to realize evaluations in their own right are significant efforts for CMS to administer, typically operating in a separate but parallel contracting process from the demonstration itself.

Then, the last step in the process is the decision

of whether the new policies that were tested in the demonstration should be expanded and will be expanded program-wide.

For a demonstration, in our lexicon, expansion requires an act of Congress. For a pilot, Congress gives the Secretary the advanced authority to expand the program after making a formal determination of whether the test program met any pre-specified costs and quality criteria, and I will come back to that distinction in a second.

I also wanted to present two recent examples to give you a sense of how long the process I just described can take.

This slide shows a time line for the Medicare Coordinated Care Demonstration, or MCCD. The MCCD was authorized by the Balanced Budget Act of 1997. The process of designing the demonstration, getting internal clearances, and preparing for site solicitation took over two years.

CMS solicited competitive proposals for programs to be MCCD sites in mid 2000 and completed the contracting process when it announced 15 program site awards in early 2002. The programs were initially authorized to operate for four years. And evaluation of the demonstration's

performance through the end of the original four-year period, that is, through mid 2006, was completed by CMS's evaluation contract in earlier 2008.

As shown in the last line of this graph, there have been two two-year extensions of the demonstration, one that was authorized in 2006, which continued 11 of the 15 original sites, and one in 2008, when 3 sites were extended for an additional 2 years. One of those sites subsequently withdrew, so, there are two sites still active.

A final evaluation report to the Congress is scheduled to be delivered in early 2011, or roughly 14 years after enactment of the law authorizing the demonstration.

The Medicare Health Support Pilot Program followed a somewhat more rapid course. It was authorized in the Medicare Prescription Drug Improvement and Modernization Act of 2003, or the MMA.

After a competitive solicitation process in 2004 and 2005, CMS awarded three-year contracts to eight program sites, and they began operations between mid 2005 and early 2006.

It is important to realize here, unlike most other Medicare demonstrations, the MMA explicitly gave the

Secretary authority to expand Medicare health support without further congressional action, if she found, based on an evaluation of phase one of the project, that the interventions were at least budget-neutral and increased quality.

CMS announced, in January 2008 that, on the basis of its evaluation contractor findings of significant net costs to the program and little quality improvement after the first 18 months of program operations, the agency was going to end the pilot as scheduled at the end of 2008, which is about five years after it was authorized in MMA.

It is important also to recognize here, though, the evaluation contractor is still conducting the program's final evaluation, which is scheduled to be completed in 2010 or 2011, and that will inform the Secretary's final, final decision about whether to extend the program.

So, now we are going to turn to the issues. In analyzing the issues and looking at the options to improve the current state of play in Medicare demonstrations, we have organized them into these three areas shown on the slide: funding, flexibility, and accountability.

The overall vision guiding the following

discussion is one of a research and demonstration exercise for Medicare that, compared to the current situation, could be more adequately and stably funded, could give the program's administrators more flexibility to more quickly design, test, evaluate, and disseminate promising innovations, and could maintain the program's accountability for results by increasing opportunities for input for multiple external stakeholders, and by requiring more reporting from the Secretary to the Congress on all of Medicare's research and demonstration activities.

First, funding. Looking over the last ten years, CMS's total appropriated budget for research and demonstrations was $138 million in 2001 and has decreased to about $36 million in the current fiscal year.

I want to point out the FY11 figure of $47 million shown in the far right is the President's budget request, and that may be increased or decreased depending on the appropriations process.

If we look over the same period, funding for research and demonstrations as a percent of the total amount appropriated for CMS program management activities, we seen basically the same pattern. The 2010 budget allocation for

research and demonstrations, which is $35.6 million, is about 1 percent of total program management funding for this fiscal year.

It is also important to realize that, within the current $35.6 million budget, only a portion of those funds are available for the actual design, implementation, and evaluation of demonstration projects.

This chart shows that, in FY10, about 57 percent of the $35.6 million budget is allocated to other research activities, most prominently to support ongoing implementation of the Medicare current beneficiary survey, which is a very important research tool both for CMS and external health services researchers.

Another 9 percent of this year's budget is allocated to congressionally-mandated research projects.

I just want to be clear about what this funding is. This category does not include the cost of performing demonstrations that are mandated by the Congress through the various authorization acts; rather, these are usually targeted funding allocations for specific research projects that are made through the annual appropriations acts.

The remaining funding about $15 million is what is

available for other Medicare research and demonstration activities, including projects initiated by the Congress or by the Secretary.

A potential alternative to funding Medicare's research and demonstrations through the annual appropriations process would be for the Congress to authorize funding for this activity directly from the Medicare trust funds, for example, following the current funding approaches used for healthcare fraud and abuse control activities, or the quality improvement organization program.

Multiyear funding allocations could be another way to build more stability into funding for research and demonstrations.

To increase the program's flexibility, one option would be to reduce some of the administrative requirements in the current demonstration process. Medicare demonstrations could be exempted from the Paperwork Reduction Act review during the approval process, and also exempted from federal acquisition regulations during the demonstration site contracting process. These steps alone could shave months, if not a year or more, off of the

typical demonstration time line.

On evaluations, most Medicare demonstration evaluations currently use a full or partial randomized controlled trial, or RCT, design. RCTs are considered the gold standard for evaluations in health services research, but some observers of this process have raised concerns about whether the RCT methodology is an appropriate approach for evaluating Medicare demonstrations particularly given the amount of time they take, and questions about whether they can produce the information policymakers need on a timely basis to explain why a given intervention succeeded or failed to produce the expected outcomes.

To accelerate the evaluation process, CMS could more broadly disseminate the quarterly monitoring reports it already prepares for sites in some demonstrations, and it could investigate if there are ways to use this information to produce ongoing reports of demonstration projects. It could also consider using alternative evaluation criteria instead of the RCT approach.

The challenge in any of these alternative evaluation approaches will always be to maintain the appropriate balance between scientific rigor, timeliness,

and usefulness of the information to policymakers.

The last area of flexibility shown in the slide is how to--is to revisit the concept of budget neutrality and how it is applied during the demonstration approval process.

The current application of budget neutrality has been criticized because it is typically calculated over the relatively short operational duration of a demonstration, and therefore does not take into account any potential for longer-term savings or costs. It also does not take into account the potential for an intervention to result in significant quality improvements with relatively small increases in net costs.

Then, to speed up the dissemination of effective innovations from these experiments into program-wide application, the Commission and others have observed that Medicare could substantially speed up this process if the Congress gave the Secretary the authority to implement pilot programs without further congressional action, if the Secretary determined that doing so would decrease, or at least not increases, costs, while also increasing or maintaining quality of care.

As I mentioned earlier, the Congress adopted this

approach in the MMA provision enacting Medicare health support pilot. A refinement of this idea is that the Medicare actuary could be specifically required to independently certify the estimates of costs and savings used in the Secretary's determination.

And the, with a positive determination by the Secretary, the agency would be able to expand the policy change program-wide without further action by Congress.

So, those are some of the flexibility options.

Now, looking at accountability. One option to increase the accountability and transparency of the process by which CMS at the beginning selects and initiates demonstrations would be to require the Secretary to engage in periodic consultation with public and private stakeholders on the agency's research agenda. This could involve the creation of a formal advisory board or body of external experts from other government agencies, such as the Agency for Healthcare Research and Quality, or the Institute of Medicine; it could include academic research institutions, representatives of providers and beneficiaries, and private payers and purchasers who are also working on innovations.

Then, to provide oversight in a more narrow sense of how Medicare is performing under the more flexible demonstration process I mentioned earlier, for example, the Paperwork Reduction Act waiver, or the Federal Acquisition Regulation waiver, a third-party entity, such as the HHS, Office of Inspector General, or the Government Accountability Office could periodically audit and report to the Congress on Medicare's activities under these process waivers.

And lastly, the Congress could assure more accountability by directing the Secretary to periodically report to Congress about Medicare's research and demonstration agenda, what is being learned from ongoing demonstrations, and what the potential effects could be if they were expanded.

These periodic reports also would give the Commission an opportunity to regularly review and communicate its views on both the substance and the process of Medicare's research and demonstration activity.

With that, I will conclude. I will put up the three areas of issues that we have organized these into and look forward to your questions and guidance.

Thank you.

MR. HACKBARTH: Thanks, John.

The heading under which I think of this topic is, how do we create a bias towards innovation in how we pay for care? I think the system right now is -- there is a bias towards the status quo, even though the status quo is problematic; it is very difficult to change it. So, as I think about this topic, I am thinking about it in terms of, how do we redesign the system so that there is a bias towards more innovation in it.

So, let's open the round one questions, beginning with Bruce.

DR. STUART: Thanks, John. I really appreciate the detail that you have gone into here, and I think this is an excellent framework for discussing demonstration projects and the activities that CMS -- how that can be improved.

This particular discussion, however, ignores the research part, and I have a number of issues that I would like to raise during the second phase about how the research side of ORDI and CMS in general could be enhanced to not only improve demonstrations, because these two are intricately associated, but also to provide another avenue

for obtaining information to help to guide CMS policy.

On the demonstrations themselves, I am going to give you a very brief alternative process that Congress has followed in terms of turning demonstrations into active public programs, or benefits under Medicare, and that was the Influenza Vaccination Cost Effectiveness demonstration that was promulgated in 1999 and concluded in, I believe, it was 2003. And this was established, ostensibly, to test the cost effectiveness of making influenza vaccination available as a Medicare benefit, but the way it was set up that the evaluation had to prove that adding the benefit would not be not cost effective to the Medicare program, and I was involved in a research team that spent four years looking at this process, and at the end of that four-year term we concluded that, in fact, we could not prove that adding the benefit was not not cost effective to Medicare. Obviously, you cannot prove a negative. And so, when that project report evaluation was CMS, Secretary Shalala, given her authority said, well, since it was not proved to be not not cost effectiveness, then it became a Medicare as of that moment, and I still have a letter from Secretary Shalala thanking me for helping add this important benefit to

Medicare.

So, there are other ways that Congress can do this. I am not suggesting that is a good model, but just for the sake of completeness.

MR. HACKBARTH: Where was the clarifying question in there?

DR. MILSTEIN: I have a real one.

Yesterday, in yesterday's presentations, we heard over and over again from these exemplary delivery systems that part of making progress is doing a lot better with the sick people. It makes sense: Healthcare tends to offer out more value to sick people than well people. And obviously, Medicare has a perfectly targeted demo that has been going on for many years called the High-Cost Beneficiary demo, and I think I have, every year, said, do we have any results? Because at this point, we are well beyond the end of the third year of the demo. And so, I have been doing my best to essentially understand why there is no evaluation information for us and for everybody else, and what I am told -- and here is my question: I do not really -- I would like to know if this is really possible. What I am told is that, for this particular demo, no funds are available for

any evaluation.

And so my question to you is, is that under the laws and regs possible, that CMS could -- ORDI could engage in a demo and actually not have been appropriated funds to do an evaluation that would enable people like us and Congress and CMS to actually know what came out of it?

MR. RICHARDSON: Specifically, on that demonstration, remember, we looked at this as one of the four things we looked at last year. We were doing a report, a chapter for the June report last year, on a practice research network and, in the course of doing that, looked at three demonstrations in the Medicare Health Support pilot, and I remember looking at an evaluation of the Care Management for High-Cost Beneficiaries demo that related to the quality -- and I think it was--it was an interim evaluation, so it was not a final evaluation. So, I am not sure -- and I could check with my colleagues at CMS to see what specifically they are referring to. I mean, I am not familiar with a demonstration where there was not an evaluation concept and plan built in from the beginning. What they may be referring to -- again, this is subject to verification with them -- is whether there was funding

available to share something either before the final report to Congress is available -- this is what I was referring to when I said, one possible option is with increased funding and flexibility an expectation that there would be more information available about the demonstrations on an ongoing basis, and that there would be explicitly some requirement and expectation that they produce reports like that that would allow us to see what is going on in a more open way.

DR. MILSTEIN: So, I guess, my question is, today, is it possible that a demo could be conducted -- what I understand has been developed are quarterly monitoring reports which are not suitable for public release or perhaps not even FOI discoverable, but is it possible under the law and regs for one of these things to run and literally for there not to be money available in a publicly releasable evaluation, because that is what I have been told.

MR. RICHARDSON: Okay. All of the congressionally mandated demonstrations that I am familiar with require there to be an evaluation. I do not specifically know -- I am thinking about the Secretaries authority under the law that was passed in 1967 to give him or her the authority to do these experiments. I do not think it refers specifically

to the need for an evaluation.

Let me do a little bit more digging and find out what the exact framework is there.

DR. MILSTEIN: We can check the fact point on that.

DR. BERENSON: If I could. I mean, this -- I am speculating, and there are people there who will be able to provide the answer, but as I remember, this is a demo that was a CMS demo and not a congressionally mandated demo, and if I were at CMS, I would be giving priority with limited resources to getting the congressionally mandated studies done first and then also do the CMS ones. And so, it may just be in the queue.

But I think, to me, the more basic question is, to what extent -- and I assume the answer is self-fulfilling which is, with a limited budget, the agency has to do congressionally-mandated studies as the priority and there are real opportunities being missed because of the Congress or the preempting what otherwise might be a more rational balanced research and evaluation agenda. And so, that would be an issue I would like to understand a little more about.

MR. RICHARDSON: My experience is that most

agencies will respond to the congressional mandates first and devote resources there, and do the rest, if they can.

MR. HACKBARTH: Clarifying questions.

MR. GEORGE MILLER: John, I have a similar question to Arnie. If a project is being pursued and there is clear evidence there is not going to be a financial benefit, does the Secretary have the authority to stop that demonstration or does it have to go through the entire process and then be evaluated? Or even with an interim report, it is shown there is no clear value for the beneficiaries --

MR. RICHARDSON: Well, for example, in the case of Medicare Health Support, that was an interim evaluation that the Secretary used to decide to suspend the pilot.

Often what happens, though, in the Medicare Coordinated Care demonstrations, and a good example of this, there is not good information one way or the other, again, because you have a small sample size or these other empirical reasons that that the evaluations that are coming back -- while it does not appear to be not to be working but it does not appear to be working, either. So, but there is some evidence that maybe some of the sites are, so, if we

will just extend them a little longer, maybe we will get some more information.

So, the Secretary does have the authority --

MR. GEORGE MILLER: That is the question. It does.

MR. RICHARDSON: -- to terminate them.

But, let me just -- and I discussed this a little bit in the paper, in the mailing materials, often, what will happen is if there is a congressional interest in a particular demonstration, Congress will step in and say, no, actually, we would like you to continue that.

The Municipal Health Services demonstration that I mentioned in the paper is a good example of that. It was created in 1978 and ended in 2006, and the interim evaluations -- at least the one that I was able to find some evidence of, suggested that it was not cost effective, but that ultimately Congress decided to keep extending it.

MR. GEORGE MILLER: She does have authority, but Congress can override. Okay.

MR. BUTLER: I feel that somebody should go to the LEAN Institute down at Denver Health on the cycle time thing, which was a major focus in the -- I am half serious.

My basic question is, how much of the cycle time on average you think we could really shrink if we adapted some of the recommendations.

And then, related to that, it might even be useful in a chapter show, here it is this way, and then, if we implemented the policies, this project would have gone this way and graphically map that out -- would make the point very visibly, but I do not have a sense of how much we could shrink if we adapted the kinds of recommendations you are suggesting.

MR. RICHARDSON: Right, right. And I was thinking about that when I was doing those timelines and, okay, if we had a counterfactual example of Medicare Coordinated Care demo, if some of these options were in place, how much shorter could it be?

I guess I would answer that in at least a few ways. One is, at the beginning, some of the flexibility we are talking about is to shorten some of that review time within that Executive Branch process.

During the operational part, I mean, by the nature of the things you are experimenting with often plan and policy changes, service delivery models, it takes a while

for those to have an effect. So, whether you could have shortened the four-year initial window of time that was set aside for the Coordinated Care demo to have an effect, I do not know. My experience is that often these interventions take time to have an effect.

If you have a small N in the sites, it takes a lot of observations to realize that. So, there is a certain amount of time that you really cannot compress too much. But at the other end, and this is a question about the evaluations -- and again, may I just remind you, the tradeoff, how rigorous those are versus whether they are giving you the information you need in a timely fashion to make decisions about, well, this just is not working. Let's just devote the resources to something else or, this part of it, these particular interventions seem to be promising. Maybe we should focus the demonstration more on those and stop doing some of the other things we are doing. Those could reduce the time, but you also increase the probability that you could make some decisions based on incomplete information.

But I think your suggestion -- I like that suggestion, thinking about, with these specific issues that

we are raising here, if you changed it like this, what would that do to the average time line, if I could come up with something like that. That is a good idea.

MS. HANSEN: Yes, on round two, I could probably give you a little frame, also, about the cycle time, since we moved it from demo to legislation. So, I could share that a little bit later.

The question I have is relative to demos and pilots and the shift that has occurred.

Proportionately, at this stage, what would you say some of the areas of demonstrations vis-à-vis pilots proportionate difference are going ahead, say, right now? Do you know? And when did that shift occur, because things always used to be in the demo mode much more?

MR. HACKBARTH: You are asking for -- what the proportion of demos versus pilots is currently?

MR. RICHARDSON: To answer the second question first, where I really noticed it was with the Medicare Health Support, and I think that was the first major occasion, anyway, although Bruce has also mentioned the flu vaccine case where -- a little bit smaller, I think. So, there may have been some other ones.

But so, let's see, there was the MMA of 2003, and there are not that many, to be honest with you. I think the pending legislation that is before Congress right now has a couple more of those, but -- one example, there are several demonstrations going on with value-based purchasing in the different Medicare provider types, and all of those would require congressional authorization to implement into the full program. So, there are definitely important things that the agency cannot do currently that they are experimenting with but they cannot do program-wide unless they have congressional authorization.

MR. HACKBARTH: But by definition a pilot has to be specifically authorized by Congress, because the Congress needs to say, okay, you can go ahead--

MR. RICHARDSON: When this is done and evaluated.

MR. HACKBARTH: --implemented without coming back. Everything done under the general demonstration authority requires you to go back through the congressional process for implementation.

MR. RICHARDSON: That's right, and that is a good--and even in the Secretary demonstration, the Secretary decides to do.

MR. HACKBARTH: Yes.

MR. KUHN: I would just say on that, I think it really was the Medicare Modernization Act with the Medicare Health Support that we really saw the efforts of Congress starting to extend pilot opportunities to the agency. So, I would agree with that assessment.

Going back to Glenn's introduction of the this, when he said, we really want to think about creating a bias towards innovation, one of the things, when we think about this, is really what is the ROI that we see as the result of the demonstrations. There have been the big ones out there that people talk about, the IPPS back in the '80s and maybe a $15 million investment produced, now, $25-30 billion; the number might be much higher.

The skilled nursing facility, PPS demonstration that cost maybe $10 million, that is probably well over $10 billion in terms of savings.

So, I guess, John, what are we seeing in terms of ROI overall, in terms of the demonstration work that CMS has done, and is that information that we can get to have as ultimately part of our reporting here? I think that would be useful to have.

MR. RICHARDSON: I have gotten some information, it did not get into the mailing materials, that I can -- from CMS that I can make sure gets into the chapter in June.

The demonstrations that I am more familiar with from the work last year, the Care Coordination and the Care Management demonstrations, I think part of the reason we are even discussing this issue is some frustration that there was an investment made in those and they did not see to yield the results. And I think, though, you have to think about not just whether -- consider only successful demonstrations to be the ones where there is a positive return on investment. I think CMS has learned a lot from implementing those demonstrations, and it does give you some empirical evidence to talk to people with certain perspectives who might be saying, well, this is definitely the sliver bullet or this is the way to go. That is a more intangible return but, I think, a valuable.

MR. KUHN: Yes, I agree. We have to take the good with the bad and, because not everyone is going to be successful, we will have a hypothesis for a lot of demonstrations that might not pan out, but I think we need to look at both sides so we really can see what they are or

why it really is out there, because these are useful efforts.

MR. HACKBARTH: It just occurred to me that there is an important exception to what I just said about pilots versus demos.

There are instances recently where the Demonstration Authority has been used to basically make program changes. The oncology issue several years ago, and then under Part D, and so, that is sort of a middle ground, a different type of case.

DR. SCANLON: True, but legally they were still characterized as demonstrations. They never were -- became the real program.

MR. HACKBARTH: Yes, except they affected the whole program. So, and, of course, we expressed reservations at the time in each case about that use of the demonstration authority, but there is that odd set of cases out there.

Mike.

DR. CHERNEW: I have a question that stems from something you wrote on slide 11, which is the particular bullet pint is, "Contracting for Demonstration Sites in

Evaluations." My question is, is there ever an example where there are multiple evaluations contracted for as evaluations--do you ever contract for more than one? And are there ever evaluations done that are paid for outside of CMS, say, NIA contracted with somebody to do an evaluation using data from CMS, which would be another to get this evaluation done outside of CMS, or is it really that CMS, as the bullet suggests, CMS contracts for all the evaluations?

MR. RICHARDSON: That is correct.

DR. CHERNEW: And that is often just one?

MR. RICHARDSON: That is right.

DR. MARK MILLER: I think there are examples where more than one contractor has looked into a given program.

MR. RICHARDSON: We can look into -- there is often a contractor that facilitates the implementation and a separate one that works on the evaluation, but I think for most demonstrations that I can think -- subject to validation with facts, but most of the ones that come to my mind right now, there was one evaluation contractor for --

DR. CHERNEW: Like CMS.

MR. RICHARDSON: Yes, it is a CMS contractor.

DR. MARK MILLER: I should not state my point so

strongly, but I feel like somewhere in my experience that there has been examples, but we should move on.

MR. RICHARDSON: Yes, we can find out.

DR. DEAN: My question has to do with the dissemination. When these things actually do get completed, is there -- are there plans within these programs for dissemination of the information? Obviously, the main consumers are CMS and Congress, probably, but on the other hand, those of us out in the community -- some of these things are very interesting and really do affect some of our decisions in the private sector as how to we structure programs and so forth.

And I wonder, is there any central databank or any central way to access the outcomes of these things, or is that part of the provision and plan at all?

MR. RICHARDSON: That is part of what we are suggesting here. I mean, CMS, every year, does publish an Active Projects Report, but it has very brief descriptions of what is going on with each of the projects. And I guess the short answer is no, there is no systematic way, and that is why we are talking about things like the Secretary having some requirement as part of the accountability piece of this

to have a formal report every year that says, this is what is going on, this is what we are planning to do -- this is what is going on and this is what we have found so far, and which would be much more publicly available than it is now.

DR. DEAN: Yes, or even a summary of the ones that have been completed and evaluated and what the outcomes were that would be fairly easily accessible, because I think it has come up in previous discussions that we put a lot of emphasis on gathering some of these data and then very, very little -- we shoot ourselves in the foot because we do all the work and then a lot of times the data does not get out to the people that could really make use of it.

MR. HACKBARTH: Okay. Let's turn to round two comments.

Bruce is going for a second bite of the apple here.

DR. STUART: Thank you very much, Glenn.

Well this refers -- my comments refer to the research infrastructure, and they go under four headings.

The first is enhanced research staff for intramural research and better preparation for demonstrations and CED projects and other activities. And

an important element of what CMS does and ORDI in particular in CMS is to prepare for demonstrations but also to make use of in-house datasets, including obviously Medicare claims and the Medicare Current Beneficiary survey, and at one time that was a significant activity that was undertaken by ORDI, and that has been severely constrained by the budget reductions in the previous year.

So, I think enhanced research staff for intramural research is really important, and what that really talks about is, well, what kind of intramural research should CMS be involved in.

And the other side of that is funds for extramural research on issues of interest to Medicare, and as you undoubtedly know that CMS has a project for contracts -- or has a mechanism for contracting with external researchers, in part through the demonstration process of evaluation contractors, but there are other ways that it can do it. It has something called IDIQ, master contracts. These are indefinite quantity, indefinite duration contracts that are essentially master agreements so that CMS can work with various research organizations to develop -- to respond to contract requests. Those have been cut back significantly

in the last four or five years from research contracts to technical assistance contracts. It has been a couple of years since I have seen anything that really has any research content at all in terms of what this extramural contracting has done.

And back in the old days, CMS had the -- I think it still has the authority but it does not have any money to issue RFAs for investigator-initiated research projects to help CMS develop areas of interest in which it is looking for the research community to bring in the ideas as opposed to saying, well, these are exactly what we want to do now, and in fact I really cut my teeth on Medicare research with one of these projects back in 1999, and one of the side benefits of having these external funds available for individual researchers is that, once you start working with Medicare data, then -- and you become interested in it, then you develop groups of people who have the capability of doing that, and I have been doing it ever since. So, regardless of the value of what I am doing, it at least kept me in the game.

Another element of that, which was an extraordinarily, I think, productive program that CMS ORDI

had until about, I would like to say 2004-2005 was the Dissertation Grant Program. Now, this is a really cheap way to develop new researchers in areas, again, interested in Medicare data. They paid $20,000 a year for research assistants. The graduate student would work with a faculty mentor on a project that was Medicare-focused, because otherwise you would not go to ORDI for that. So, I think that that is a really important element of CMS research activities that has been constricted and should be expanded.

The third element, and this was building on what Mike was talking about, is cheaper and easier access to existing data. And I will just give you one anecdote. I have a project funded by the Commonwealth Fund that was proposed to use CMS data, Part D data in particular. I filed a data use agreement in July of last year; it went through a very rigorous process of review, and was finally approved in October. We sent a check to CMS in early November after that approval for $67,000 for two years of data for a 5 percent file -- which gets to the point about how expensive this is -- for a one-project license. That money was for one project and one project only, and what is it? It is March 4, 5, I still do not have the data. So,

this has a real chilling effect on research, because I have a deadline in terms of when I am supposed to finish this and obviously I cannot without the data.

So, reduced acquisition cost is really important. Speed it up. Turnaround is important and expedited privacy review -- I mean, this is something that every researcher who works with these data is concerned about. It is not just the local IRBs that you have to go through; this is problematic enough, but having that same process non-expedited at the federal level makes it even slower.

And the last point, and maybe even the most important of all, is data development. You need funding for data development. And one of the things we talked about a year ago was a federal regulation that was promulgated by CMS to require that all MA plans submit claims and/or encounter to CMS for all of the activities that they were involved, and we had some discussion about the importance of having data from the Part C plan so that we could evaluate their performance relative to fee-for-service performance.

Now, I have no idea where that stands at this moment, but I can tell you it is going to costly, because those data -- first of all, all of the requirements for data

submission, I am assuming that has happened, but I do not know, those have to be promulgated. Once the data come in, they have to be checked, they have to be put together in a way that both internal and external users can use them for research. And I think at least from my perspective, that is probably the most important new data development that MedPAC should recommend is that funding -- help make sure we got those Part C data.

But there are some other things, and I am not going to take any more time, but just to suggest that there are data issues in terms of data linkages, data quality, missing data elements. Boy, if I could enforce a change in the uniform prescription drug claim from to require that there be a diagnostic code on drug claims so that I could figure out exactly what the doctor was prescribing for, it would really improve research activity.

So, without saying another thing, there, these four areas, I think, are really important additional areas where we should encourage Congress to provide additional research funding for CMS.

MR. BERTKO: So, John, if you could turn to slide 11, I am going to have a question that is narrow in scope

and possibly broad in implication, and that is the third sub bullet there, the alternative evaluation criteria.

You mentioned, I think appropriately, and I agree with this, that randomly controlled trials are the gold standard for evaluations, and I will agree with that completely and say that is impractical sometimes in terms of application. So, the broad arrangement of it here is, how do you role this out, particularly under any kind of payment reform?

Most of you remember Nick Walter who is part of the PGP, Physician Group Practice demo here, and his experience with that controlled trial stuff, at least in sidebar conversations, was problematic would be the most polite phrase that I would give.

So, the thing that we want to -- at least, I am suggesting that we be concerned about, and we have had some conversations with this Jeff Stensland from staff who, I think, sat through those -- and me, I have listened to part of the conversations -- is going to alternative methodologies. Randomly controlled trials has a technical problem: Once you get things big enough, you run out of control groups.

And then secondly, and this is more my opinion, maybe, than anything else at this point, when you are trying to get payers to shoot towards a goal, I think everybody -- all the physicians around here have said, physicians in particular are A students and high achievers, but they need a goal to achieve, and when you have a randomly controlled trial and you are looking at the results of the control group, you do not know what the answer or the goal is until a year or two down the road from when you have your results.

So, our Brookings-Dartmouth Group, at least under the ACO stuff, but I think it could apply equally to any bundling type of research to medical homes, to any other payment reforms, would be better set, in my opinion, with having a solid goal to aim at.

So, I guess what I am suggesting, John, is you and Jeff perhaps think about some more of those. I am certainly -- on my personal part -- open to revisions, new versions to do this, anything that gets us to having some kind of solid goal -- defined goal to work towards that is, at the same time, meaningful works maybe nearly as well as the randomly controlled trial type of group and is practical.

DR. MILSTEIN: A couple of thoughts in terms of

our next iteration of this.

Number one is, I think it would be nice to essentially have some of our recommendations put in context of all the money that the Federal Government is putting into a delivery system and payment method testing, because we have a lot happening now. We have all the ARRA -- competitive effectiveness research, and some of that may or may not be part of a bill that may or may not be passed. We have ORDI working on this, and I think it would be nice to essentially have something that began to essentially say, here is the pool. Now, the job is, how do we deploy these in a fashion that is, A, adequately funded, and, B, as much as Pete was saying, much-shortened cycle time.

What you would like is if someone from the lean institute came in to look at our CMS innovation testing funding, it would get an A. It obviously would not get an A either on adequacy of funding or on cycle time.

But I think it is hard -- it is very difficult, as the point was made earlier by Bob -- it is not fair to beat up someone for not running a four-minute mile if you have not fed them.

And you look at slide 9. Please put that up. It

is funny, yesterday, we all intuitively sensed that even though there might be a good statutory rationale for it, we should absolutely not put medical education funding at the mercy of general tax revenues. We said we had to have a secure funding base. Well, I feel the same way about innovation testing, whether it is within ORDI or it is the sum total of everything we are investing in evaluation research is that this suggests that leaving it to the mercies of general tax revenues is problematic.

I do not think that anyone from -- that anybody who can -- maybe from the Department of Commerce who can speak to what kind of investment in innovation testing it takes in any organization to get great results, that this likely qualifies.

MR. HACKBARTH: And if I am interpreting number 10 correctly, this overstates it by half, because basically half the budget is going to the survey.

DR. MILSTEIN: So, we are down to less than 1 percent. So, it would not pass any common sense test of level of innovation investment needed to drive a big socially and societally important system like Medicare let alone healthcare system.

DR. BERENSON: Well, I was going to -- my first point was going to pick up exactly on that.

One of the data points in your paper was that we are now spending .007 percent of outlays on R&D, and the rule of thumb I have heard -- not that I am an expert on the area -- is that most enterprises spend about 1 to 3 percent of revenues or something like that. So, even looking at it as a percentage of program management does not get us anywhere near where we would need to be for a real enterprise. So, that is point number one.

And so, I think, as yesterday's conversation where we talked about, is there a rationale for looking at mandatory side trust fund money to support outside organizations, the QIOs being the precedent, but we talked yesterday about perhaps limited medical education. Today, we are now talking about, can we do it to support program administration? I think we should be looking at that issue generically. What are the legal issues? What are the unknown side effects of going down that road? There will clearly be a lot of opposition to that. So, I think it is something to look at generically.

I want to pick up again on this financing thing on

the budget neutrality item. I agree with you completely, we need more flexibility on that one.

My understanding, and maybe this is just an urban legend, but I think I was even around at the time, unfortunately. About 30 years ago, a certain Secretary of HHS actually wanted to expand coverage by using demonstration authority and these things were not demonstrations. It was a way to get money to people to get healthcare services, and out of that came an OMB-based process for establishing budget neutrality. I am not sure anybody has looked at that since and whether -- and if the current way in which that is -- well, I would actually be interested to what extent we are captive of what might have been a perfectly reasonable decision made 30 years ago -- what kind of flexibility can we put into budget neutrality calculations, consistent with my view that sometimes you actually have to -- in an R&D enterprise, you cannot always be budget neutral in something as you are learning.

The second general point I wanted to make is around cycle time, and I am sympathetic with all those who want us to shorten it and get stuff out in the field much more practically, but I would remind people of an

alternative that I think happens a little bit too much in the private sector, let's say, health plan R&D in this area, and we hear terms like "nimble" and "flexible," et cetera. When I was doing practicing managed care work two decades ago, prior authorization was the way to go. There was not a lot of transparency about its effectiveness. There was not a lot of, well, basically, proof of concept, even though I think, if done right, there probably is. My experience was it was largely benefit consultants convinced purchasers that they had to have this in their contracts. It was not an evidence-based process. And more recently, I think, is the example of disease management, where every -- you keep hearing, oh, yes, this is very successful, very successful, but in many cases, using flawed methods of regression to the mean and it was only in the Medicare Health Support that we actually had a controlled trial, which proved at least in Medicare's hands it was not effective. Now, some of the disease management companies will say, well, you gave us patients who were too sick and you gave us patients who were too healthy, and if we could have used our techniques to pick them we would have done a better job, and maybe there is some truth to that. But again, we need some

transparency, we need some evidence around. So, if it is not going to be the gold standard, randomized clinical trial, we cannot go too far in the other direction of just asking an organization to say, this works, let's go with it. So, let's find a middle ground in this one.

DR. CROSSON: I will be quick because I was going to make the same point that Arnie made, and Bob.

It is probably unfair to compare CMS to a corporation, but if CMS were a corporation, the spending on innovation would be two to three orders of magnitude lower than what would be expected, and that flies in the face of the fact that, as John said, there are several examples, anyway, of where the return on investment to CMS has been in the thousands of percent. So, it is not like there is no justification for spending more money.

So, I think that the general thrust here would be one that we would support, more money, provided it is invested properly.

To Bob's point, I would probably say, rather than start with theory as the basis for innovation, start with things that have been proven to work, and then determine that broad applicability or not of those things.

So, if we could take Denver Health and just test the most important elements of that, we would probably get a better result than if we just started with some theory that somebody had come up with.

So, more money, less time, to the extent that that is possible, more focus, and then, more action orientation.

DR. SCANLON: I am also very supportive of increasing the investment, but I wanted just to note that I do not think that it is a total solution to move this into the trust funds, because there are -- my sense is there are two kinds of expenditures coming out of the trust funds: those where we say we are going to support a function, let's say immunizations, and we spend as much as it takes to cover the number of people who show up wanting immunizations.

For an activity like fraud and abuse and an activity like research, it very well may be specified as a dollar amount. We are going to spend this amount of money for the next, say, ten years or something like that. That means that that money then has to be renewed at some point in time. All we are doing by moving it in a trust fund is changing the group of, say, 15 people in each house that are going to say to the full house, please approve this

expenditure, because it is still going to go through a congressional process periodically.

What that implies, I guess, for me is -- that we need to think about is, is there any other alternative and, as well as, that there needs to be continuing attention, both make a point for the Congress to continue to focus on this as well as for future MedPACs to focus on this.

MR. BUTLER: Sorry for a brief but albeit vague filter that I would still like us to keep our eyes on. I would reinforce your innovation concept. I often think, are things moving faster inside your organization or outside your organization, as a test of whether you are contributing to the solution. And right now, you feel like it is moving slower inside rather than outside. And if we can somehow make things and use the Medicare leverage to move it faster inside, than I think we can contribute to both Medicare as well as a synchronization with the private side.

MS. HANSEN: Yes, I think I had three key comments here, and each one of them has been covered, but I just want to affirm them relative to the proportionality of investment that is evident that does not work.

The alternative evaluation criteria is one of the

things that, certainly on the ground, when we were demonstrating the original PACE Program On Lok in San Francisco, we found that some of the discussion and the argument about randomized control design for some issues did not work.

I will give you a specific example. I started out there as the research nurse, and I would do the -- I was doing the alternative comparison group. And I would go in and visit someone and that person ended up having a blood pressure reading of 220 over 140. So, what I did was I broke the trial, so to speak, I got on the phone, go the person to care. So, there are some things that just, ethically almost, do not work sometimes in these models. So, again, with people who have the rigor and the ability to take a look at this, how do you move a model of practice as well as financing at a time when sometimes some areas of these designs that would be gold standard would be something that would be in very controlled abilities, plus the volume of people. So, it is just something to think about for those of us who have done it on the ground.

I think the budget neutrality that was brought up as well, too, again, if we are going to use the business

metaphor -- and frankly, when we did this on LOCK and PACE, we had to meet the budget neutrality, so, and we did at that time, and I think we had that opportunity because the amount of inefficiency in the system allowed us to show the budget savings and so forth.

But today, I think a different model of when you are doing these much larger pilots or demos, the ability to think of the business model that things do not change on a dime without some investment. So, like, a regular business, it might take three to five years to finally find the ROI. So, again, I am not saying that is absolutely it, but whether it is the innovation, investment, the diffusion ability of the knowledge that I think that Tom was asking about. Can we get this out faster?

There are different models to take a look at. So, I think we need to move the research design side to the operational side to the franchising of knowledge and really getting that out there. And so, somehow, we get stuck with all knowledge whether it is structurally because the data on the high-cost beneficiary is not available. There is something that just does not flow real smoothly. So, the speed to market is perhaps another concept to really think

about when we have so much money going out on the front end with the services and the benefits, but we innovate and diffuse with such a tiny budget.

MR. KUHN: On the three issues for discussion you laid out there on funding, flexibility, accountability, let me at least talk to a couple of them.

On the funding issues, in terms of adequacy levels and stability, I do not think anybody can argue with that and I think there is unanimity here. My bias tends to be a little bit more towards trust fund and direct draws on that, but I heard what Bill had to say and if there are other innovative ways we can think about that, but the adequacy has to be there. I think the graphic that you showed us is pretty clear: We need to fund more aggressively in this area, and the stability needs to be there.

On the issue of flexibility, we do need to think about ways of speeding up these demonstrations, and a couple areas I can point to that are real road blocks that are out there. One is the whole PRA process, is very cumbersome, and I just do not know if it is that necessary and useful in terms of part of the process. I think we need to look pretty hard at that one.

Likewise, I think what Bob said in terms of the budget neutrality issue is something that ought to be looked at pretty hard as well, because as we start to look at more value-based purchasing opportunities, what it does is it creates a bias towards a tournament-type model in terms of demonstrations. And going into the kind of demonstrations -- could be problematic from the very beginning, and I would like us to see if we can avoid that.

At the same time, however, if you do not have the budget neutrality in there -- and CMS has to watch this very closely in terms of their stewardship role of the program is that they could get into a demonstration where it is going south real fast and they have to be in a position to cut it off, because you don't want to see money hemorrhaging out the door if you don't have that budget neutrality protection out there. So there is both sides to that.

And finally, the issue is really the level of scientific rigor that we have talked a little bit about here. Arnie, during the previous conversation, says, when are we good enough for openers, here? And they might be in a demonstration, and it might be a pilot, and they find out that, after a few years, they are 80 percent certain that

this going to work, and what we have seen is, if you really want the 100 percent certainty or 95 percent certainty it is a 10-year process, and I think we are going to have to pretty soon say, qualitatively, this is good enough and let's start moving forward. Now, that means that the continued scientific work needs to follow on behind that and we need to get there, and there are probably refinements as a result of that, but pretty soon we have to say, it is time to jump in and go and not wait for the whole process and then wait another decade before you can launch a new initiative.

So, I think helping us think about the scientific rigor, when it is good enough for openers, to move forward, would be helpful, as well.

DR. CHERNEW: I want to start by saying I think this is an extraordinarily important topic that deserves a lot of prominence in what we do, and I worry that sometimes this gets put at the very end and in the back chapter and it does not get heard particularly loudly, and I think it actually might be amongst the most important things long run for the program. So, figuring out a way to prominently feature and convey this, I think, is central.

The second substantive point that I want to make is that I think it is crucial to have multiple evaluations and many of them outside of CMS. I realize that the CMS evaluation process is important and I am completely on board with all the comments that were made. I want to point out that there is -- I am a member of an organization that looked at an evaluation of one program and felt that coding changes, perhaps upcoding changes, of an evaluation gave a result from the particular single evaluation that might not be the general conclusion one would take, suggesting that, in general, science progresses with multiple people doing multiple evaluations over a continuing period of time, and a system which is, CMS will do a demonstration, they will contract with one evaluator, they will do one report -- is not a system to get you to understand.

Things like Part D are being, for example, continually being evaluated by a whole bunch of people funded by places well outside of CMS where there is rigorous competition to get access to grants to do those evaluations.

So, I think, in general, the most important thing is to open up the data in CMS to a whole -- there are huge numbers of people around the country, and a lot of funders,

some of which inside the government, the government agencies AHRQ, NIH, others outside like RWJ, that would be really interested in funding if you could get the data per Bruce's story, and I think that is really fundamental to maintain not just the evaluation but in infrastructure of continued evaluation that does not have to be controlled from central CMS evaluation, because the scientific community will -- the health services will do a good job of evaluating this if the system is open enough to allow that to happen.

MR. HACKBARTH: Okay. I had a few thoughts. Five points and most of them echo things that have been said, but maybe with a little different twist on it.

One, I wanted to pick up on Mike's comment about the importance of this. I, too, worry about it being a back chapter labeled CMS R&D, and that is part of what I was trying to address with my opening comment about framing not as about CMS R&D but how we create a system that is more innovative. So, I think -- I am not a wordsmith, I do not know exactly what the right words are, but how we package this and frame it I think is an important part of the subject.

Second, I will just echo what people have said

about more investment in stability investment. I think that is critically important. And of course, I agree with the comments that Peter and others have made about streamlining the process. I think there is evident opportunities to do that and I agree with that.

The last two comments are a little bit more challenging, but I think also more fundamentally important. I would like to see us look at recommending that the Secretary be delegated broader authority to make changes on implementing innovations, in particular on payment policy, as opposed to the current process whereby that expanded delegation of the Secretary is done project-by-project, by Congress authorizing a pilot on disease management or whatever the issue of the day might be. I think there ought to be a generic delegation to the Secretary.

Now, as is true with all good delegation, it needs to be constrained. It needs to be delegation within some defined boundaries. And off the top of my head, I cannot tell you exactly what those boundaries should be, but they presumably would include things like, the Secretary would not be authorized to make fundamental changes in the Medicare benefit package or deny beneficiaries free choice

of provider, some things like that that are very political sensitive, for understandable reasons, could be constraints on the delegation, at least initially. But then, within that, there ought to be some opportunity for the Secretary to make decisions to improve management of the program.

The last topic that seems to me, as a non-researcher -- I cannot emphasize that too strongly -- I have no technical expertise to bring to bear. What seems to me a critical question is, what are we testing for? And I do not think you can answer that question generically. I think it needs to be specific to the intervention, the innovation that is being tested.

There are some things that CMS and the Secretary might be testing for with it is appropriate to say, we want to collect definitive evidence up to some reasonable standard of certainty about the effect of this intervention on long-term costs and quality of care. And perhaps, disease management is that project.

But it seems to me that there are other types of intervention where we may want to be simply testing for operational feasibility, and falling into that category, I will give two examples.

One, the group practice demo. So, here we have a system that is basically based on fee-for-service. Beneficiary choice is not impinged upon, and the idea is that we are going to share savings. The tricky part of that is how you set the benchmarks and how you operationalize the model and how you provide the feedback. I do not think the real issue is the long-term effect on cost and quality. And if we can work out a feasible operational model for establishing what the targets are and data flows and all of that, this is a low-risk enterprise for the Medicare Program. The Secretary ought to be able to work with groups on testing and developing a model and then go for it on a program-wide basis.

Similarly, I would say, bundling around a hospital admission. I do not think we need a ten-year process of evaluating the long-term effects of that on cost and quality. I think there are some very trick issues about operationalizing the model, but that is what the pilots ought to be focused on. And then, once the Secretary has some workable models, go for it and do not wait around for long-term evaluations.

So, those are just a couple of examples. I think

we need to carefully think about what we are testing for in each case.

Any other thoughts, comments, questions?

DR. MARK MILLER: Yes, just, I think you hit most of the things that I was going to say, but just a couple things to emphasize, and I will start with small and I think go to larger.

On the budget neutrality stuff, I think you guys in your exchanges hit well the two sides of those concerns, and why some of that came into play. And I think some of the things to think about beyond the methods that John has brought up, which I think we have some ideas on, are things like the time frame and also whether you limit the amount of money that goes out to some activity so that you understand that your overhead is limited in some degree.

I would focus a lot on the speed of innovation. And I think again we got out a good point here, which is there are certain parts of this infrastructure that you probably cannot collapse the time on. These things are hard to do. It is hard to get your participants in. It is hard to design these things -- and that we should focus our efforts on the places where we can speed things up. I think

some of it goes to what happens when all is said is done? Can you get it out into the field -- what Glenn just said.

But the other part of this conversation is the process, the internal processes that CMS has to go through to get these done, and I am just warning the Commissioners, there are going to be things that are going to be fairly arcane and sometimes can be unhappy to talk about just because they are so arcane, but just heads' up. These are probably the things that can make a difference, in terms of what you have to go through for contracting, what you have to go through to even pull a group of people together and ask them what their ideas are. I mean, they are not as free to do those things, and so, there may be some things there that are important to move, where you could get time, but will not be happy and fun to talk about, just on that.

I am also very happy that we got to the money conversation. I think it is very important, and everybody, I think, sees this point. We will have to think very hard to make it stable without being just a -- and have some checks on it that it is not just a bleed. And again, we have some ideas there.

And to your point, Mike, I think the whole point

of this session and the sessions that are going to follow is so that this is not the last thing in the chapter, that is, oh, by the way, CMS does not have enough resources.

You will notice a couple of things. In the March report, in addition to reaffirming that we wanted the encounter data and many other things, we said to the Congress, this is a lot of work for -- this is on the quality recommendations -- a lot of work for CMS. Do not do it unless you can give them the money to do it, and just being very clear that they need the resources to do it, and I think the point of starting this session is to very clearly make those statements to the Congress. So, I do not see this relegated, this is a front end -- and I know you got it, I want to make sure everyone else gets it.

And the very last thing I will say is there have been some factual points raised here, and if CMS is comfortable saying anything in the public session that follows, I would encourage them to address any of the factual points that we were searching around a bit for.

MR. HACKBARTH: Okay. Should we -- anything you want to say, John, in winding up?

MR. RICHARDSON: Thank you for all the advice.

MR. HACKBARTH: Okay, thanks.

So, let's turn to the public comment period.

Let me repeat the ground rules. Please begin by identifying yourself and your organization. Limit your comments to no more than two minutes. When this red light comes back on, that will signify the end of your two minutes. And as always, I would emphasize that people ought to use the other avenues to communicate with the Commission, including our website, where there's an opportunity to post comments and, of course, communicate with our staff.

With that, go ahead.

MR. LOVE: Thank you. Tim Love, CMS, Director of the Office of Research, Development, and Information, ORDI.

First, I wanted to thank the Commission for taking this topic up, and obviously, the interest and the appreciation of not only the complexity but certainly the resource implications, so I do appreciate that.

I also have to say that John Richardson did a great job of making some sense and explaining a very Byzantine process, so I just wanted to make note of that as well.

There was just one comment I wanted to make

regarding Commissioner Milstein's remarks about whether we do the evaluation at the same time as the demonstration. That's a very important point. And as John pointed out, we have -- within the law, we often are directed to do it, so that's the law, and we follow out. Within a discretionary demonstration, it is not the law, but it is certainly a policy that we try our best to abide by.

When we send a demonstration up the line -- and the folks who run the R&D shops respectively can attest to this -- I won't let it leave my office unless it's a soup-to-nuts budget, you know, from the beginning of what it costs to think about the demonstration concept to the end of the evaluation.

Where it gets a little complicated -- and I think this may be the situation with the high-cost demonstration -- is that demonstrations -- while the demonstration is in the here and now, the evaluation tends to be in next year or even out-years. And I don't have to tell this group about the austerity, the state of our budget. But when we get to having to steal from Peter to pay Paul, there is an opportunity cost that quite often has an impact on the evaluation budget.

The other unfortunate part -- I think it actually gets to a point that Herb Kuhn made -- is that ideally, or ideal current state, we have enough to do that sort of scientific rigor, 100-percent certainty demonstration. To do some of this turnaround work, quicker turnaround work, provisional analysis and how can we just get information to policymakers more quickly, that has some evaluation rigor to it as well which has resource implications.

So I don't want to say it's all about resources. Sometimes it's just juggling the balls. But we do appreciate that demonstrations and evaluations are really one unit, at least in the view of the folks that work in my office.

Thank you.

MR. GUTTERMAN: I am Stu Gutterman with the Commonwealth Fund, and I have a couple comments.

I wanted to echo Tim's remarks on the presentation and the discussion. I thought you had a terrific discussion. I think the dimensions along which you structured the discussion are the right ones. And I'd make more explicit that Congress, even when they mandate demonstrations, don't always -- in fact, I think relatively

rarely -- allocate money explicitly for the evaluation of those demonstrations, so that it ends up being a discretionary process inside CMS with limited resources, and that is what happens sometimes.

I'd like to make a couple of other points. I think, you know, the distinction between pilot and demonstration is one that's very vague because there have been demonstration projects that have been explicitly authorized by Congress where the Secretary has been explicitly authorized by Congress to continue a demonstration or to expand it.

I would suggest a different distinction between demonstration and pilot in the context of the Center for Medicare & Medicaid Innovation that's in the legislation that at least right now is still alive. And I think it suggests something that CMS I know is interested in and should be interested in in the future, and that is, distinguishing between -- and it is kind of along the lines that Glenn mentioned, distinguishing between projects that focus on specific aspects that you really want to test to see if they work to save money or improve quality, and projects that really are operational to be able to encourage

new approaches. You might even give that kind of project the title "Innovation with Evidence Development," because frequently we're asked -- when I was part of the process, frequently we'd get the question: Do you have proof that this is going to work? And my answer would be: That's why it's a demonstration. But that never seemed to hold very much water, that argument.

So I think we need to view the demonstrations, the broader innovation process in CMS, as an opportunity to try different approaches, not to test them but to try them; that is, to put some things into place, see if we can get them put into place, and then monitor their effect on the system and continue them if they are having a positive effect, either saving money or improving quality, or both.

And one last point on Mike's suggestion of multiple evaluations. Of course, anybody who has ever run ORDI kind of holds their head at the thought of having to fund multiple evaluations when we can't even afford to -- but I think the answer really is in the transparency that was on John's list. I think if you make things transparent and you have the data available for researchers, whoever wants to research any aspect of a particular project to be

able to do that kind of research, I think that would be a big step in the right direction and also open up the process and give CMS more flexibility to be able to work with the projects that they are developing and implementing.

Thanks.

MR. HACKBARTH: Okay. Thank you very much, and we are adjourned.

[Whereupon, at 12:02 p.m., the meeting was adjourned.]