PPAC Meeting Transcription – February 2004

CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

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Room 505A
Washington, DC

Monday, February 23-24, 2004
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Dr. Rapp: Good morning, I would like to call the meeting to order. This is the first meeting of the new year for the Practicing Physicians Advisory Council. I would like to thank all of the members that have come today. I appreciate their giving of their time for this work. Since our last meeting, obviously, there have been a number of changes in CMS. Tom Scully was here at our previous meeting and since then he has resigned. Tom Grissom from the Centers for Medicare Management has also resigned, and acting in his place is Tom Gustafson, who is on my right and he is carrying on the practice of Mr. Grissom and coming to the meetings. He's going to be here all morning. He tells me he has some other engagements this afternoon and he'll be here for a brief time this afternoon and tomorrow will be back again, so I think the Council is very appreciative of being able to talk and address directly the top echelons of the Medicare management. So I appreciate him being here. Diana Motsiopoulos is no longer handling things for us, but Cheryl Slay has taken her place, and I appreciate all the work that she has done in preparing for this meeting. David Clark is still with us, and Ken Simon is still our executive director, so we haven't had complete changes. It may seem like it's been a long time, but since our last meeting, also, the MMA, the Medicare Act has been passed and signed into law, and the last time we met, that was being discussed. So there are a lot of changes in a lot of our work. I think over the next couple of years is going to be involving making recommendations with regard to a lot of the implementation that CMS has to do on the Medicare Act.

Four members will be leaving the Council, effective with this meeting. Doug Wood, from Minnesota, Angela Moultrie, Joe Heyman, and Amilu Rothhammer. Joe and Angela and Amilu are not here right now at least. Angela will not make the meeting. But in any event, I do want to thank all of these individuals for their service on the Council. We're very grateful for the input that they've given and wish them luck in their many future endeavors. So thank you. [applause]

I was asked to announce what the schedule will be for the remainder of the year. And the PPAC meetings for the remainder of the year will be May 17, August 30 and 31, and November 22. Those meetings will be here in Washington as well. Are there any other announcements or questions before we get started? If not, I will now turn it over to Mr. Gustafson. Thank you again for being here. Any remarks you'd like to make?

Mr. Gustafson: Thank you, Dr. Rapp, and I appreciate the opportunity to be here and at least a key observer of the Council's work. We need to underline the importance of the Council to the agency. Tom Grissom has departed. I am normally, or was, Tom's deputy and am currently acting as the Director of the Center for Medicare

Management, so I come in with full faith and credit of that position. I am not expecting to be named permanently into that position and there will probably be a replacement in due course, who I'm sure in turn will be here with bells on to participate in the discussions. And I just wanted to note to you the work that the agency has been doing relating to implementation of the Medicare Modernization Act in the two months since that Act was enacted on December 8th. I had the privilege of being present when the President signed the bill. Even though I've been working in this agency for 20 years, that was the first experience I'd ever had of seeing the President take the pen and actually sign it, so that was a little bit of a thrill for me.

The amount of work in this bill is nothing short of staggering. We've been staggered before and are still upright, but we're being staggered again, and the work that is of most concern to our center, and I think many of elements could be of concern to this committee is actually the stuff that to some extent has flown beneath the radar screen, so that much of the attention in the press, as I'm sure you're all aware has focused on the prescription drug provisions, both the prescription drug card and the prescription drug benefit, which is supposed to sunrise in 2006 and in changes relative to the managed care program, which will change names from Medicare Plus Choice to Medicare Advantage. But hidden in the bill are six titles that are the province of our center, relating to the good old ordinary fee for service program, which as of today, still enrolls 89% of the Medicare caseload. Now that percentage may fall as the Medicare Advantage program is reinvigorated, but I don't think anybody expects it's going to wither on the vine, disappear, go away, any time soon. So we're still very much in business and have a immense amount of work to do over the next four or five years as a result of this bill. We started with an immense amount of work that had to be done on or about January 1st, and we're tracking the activities we need to conduct on a quarterly basis. The tracker, which is an Excel spreadsheet, giving details for the January 1st give or take implementation dates ran to thirteen pages. So we have already issued three regulations, and as of the last count I had 23 individual change requests. We're perhaps up to 25 by now. Those are sub regulatory documents that implement various parts of the bill. The most evident parts of these were the therapy cap moratorium was reimposed, that is to say the therapy caps were lifted on the date of enactment, and we scrambled around and got the system changes in place to make that happen with only a minor bobble in the production. We issued regulations to the end of December, that updated the Physician Fee Schedule rule. We had only just published November 1st, and that of course major change there related to the physician update, which went from negative to positive. I'm sure at least mildly gratifying to all

members of this committee. And also made some changes in how we pay for incident two drugs. We issued another rule which changed payment procedures under the out patient prospective payment system. Again, the major focus of concern there was payment for drugs. And we issued a notice for a one-time appeal for wage index reclassifications in the inpatient prospective payment system. My colleagues will be here a little later today to go into the changes of most interest to physicians in greater detail, so I won't dwell on those further.

The outlook here is there are going to be further changes. We've got a bunch more things coming April 1st. It's a smaller set of stuff, but it will affect some payment systems. Some changes coming in in July, and then we start hitting the big time again in October and January of next year, where we will have a lot of stuff that requires a little bit more maturing to put into place, and subsequent to that several more extensive payment system changes. For instance, moving to competitive bidding for durable medical equipment, which will sunrise in 2007 and which we're already scrambling to get the systems in place for.

So in many of the changes that have just happened, it is a matter of turning the dials on an existing system that's comparatively straight forward thing to do. In some of these later changes, we will be having to build whole new radios and introduce new elements of payment systems and we're not too far along on exactly what all of that will look like, so I'm sure many of you have questions about various elements of the systems that are going to be coming, most of which we can't yet answer. We're still in production. We hit the ground running when this bill was passed and we're not out of breath yet, but we haven't exactly had time to settle down, and we'll be continuing to detail things over the next year. So I'll stop there. The agenda supposedly gives me ten minutes to welcome you all and that's a quick and simple thing. So here's my welcome and I look forward to the day's events.

Dr. Rapp: Thank you very much. The next item on the agenda is Dr. Simon, our executive director, who will give us the status and update on the November recommendations and other old business.

Dr. Simon: I'll review the recommendations from the November meeting as well as provide answers to several specific questions which were sent to PPAC in regards to EMTALA. To begin with the old business from the November meeting, under agenda item D, relating to end-stage renal disease, PPAC recommended that reimbursement be increased for a creation of autogenous arteriovenus fistulas by surgeons who perform vascular access procedures for dialysis patients, as compared with the reimbursement for graft procedures in these patients. We are not able to adopt this, however, this recommendation positively addresses a key barrier to increasing fistula

use over grafts. Constrained as the agency is, by the need to adhere to the resource base relative value unit system, commonly known as the RBRBS system, this is unlikely to be feasible. Having said that, however, we do intend to pursue other sources of increasing reimbursement for physicians choosing to create fistulas, which will include reimbursement for procedures such as venous mapping, which currently are not routinely reimbursed when provided.

Under Item D2, the Council recommended CMS create a code for pre op to venous mapping. This is under active consideration within the agency, and we anticipate that this will be addressed in the Physician Fee Schedule Notice for Proposed Rule Making, early this summer. So we adopt this proposal.

Under D3, the Council recommended CMS develop a demonstration project, looking at physician incentives related to the treatment of ESRD and at this point, this request is under review. In light of the issues that the agency has to address in regards to implementation of a lot of the legislation by MMA, we're unsure when we can project a time frame when we would be able to address this recommendation by the Council.

Under agenda item F, out patient and Physician Fee Schedule, the Council recommended CMS do whatever possible to maximize the positive impact for physicians and patients of the potential 1.5% positive update to the Physician Fee Schedule. In order to notify physicians of the MMA changes to the 2004 fee schedule, CMS issued a special article that related the changes in the fee schedule and extended the enrollment period. This article was used by the carriers in their bulletins, web sites and list serves and this information was also disseminated through the CMS physician web site, and a special open door forum was held in November to make the medical community at large aware of the changes. Finally, through its carriers, CMS issued a letter to every physician and limited licensed practitioner.

Under agenda item H, for power operated vehicles, the Council recommended Medicare physicians receive from CMS an annual report of durable medical equipment purchases made under their UPIN numbers. We adopted this with modification. CMS will explore this idea with our statistical analysis demarks, commencement with benefit to the program. In other words, in light of the potential expense in anticipated value, we are examining an approach that would generate these reports to physicians who appear to be outliners based on data analysis.

The second proposal addressing power operating vehicles, the Council recommended that CMS develop a brochure and guidelines for Medicare physicians on prescription of power operated wheelchairs and that PPAC

review those materials. We adopted this proposal and we have developed a brochure and guidelines for Medicare physicians on prescription of power operated wheelchairs. It can be found on the Met Learn web site and the address is www.cms.hh.gov/metlearn/powerwheelchairs.pdf. And I would like to take an opportunity to thank the Practice Expense Advisory representatives from the AMA as well as the ACP representatives from the PEAC and the RUC representatives from the APC society that participated in working closely with program integrity to help develop guidelines that would be of use to physicians in the community. They played a large role in providing input to program integrity in this regard.

Under agenda item J, GAO report on Medicare communications with physicians. The Council recommended that CMS strengthen contractor evaluation by relying on expert teams to conduct contractor performance review, and assess the accuracy of physician communications. The agency adopted this proposal. Title 9, subtitle B of MMA, gave CMS new authority in the area of contractor reform. The law includes important changes around contractor performance evaluation and provider communications, as of October 1, 2004. For example, CMS will be developing a methodology to utilize claims error rates to give contractors an incentive to implement effective education to clinicians and suppliers. Through the MMA, Congress explicitly requires improvement in provider education and training, especially for small providers. And small providers, by definition within MMA, refers to physician groups or institutions that have less than 25 full time employees, and small suppliers are those that have less than 10 full time FTEs. The provider education group within the agency is currently reviewing the process of identifying implementation approaches. And once that information is available, it will be shared with the Council.

Under agenda item K2, Medicare and proper payment rate for 2003, the Council had recommended that CMS not use intimidation by the Office of the Inspector General as a method to improve the response rate for its evaluation of improper payment rates. We further recommend that the Office of the Inspector General not use findings from this program as the basis for decisions to perform audit. The Council supported and adopted this recommendation. In the Improper Payments Information Act of 2002, requires CMS to submit to Congress an estimate of the annual amount of improper payments made by the Medicare Fee for Service Program. While CMS does not dictate the OIG's work plan, the agency shall be explicit in expecting no intimidations of physicians by the OIG staff.

That concludes the recommendations from the November meeting. There were specific questions that would relate to the Council in regards to EMTALA, that I would like to address. The first question relates to what constitutes a specialized hospital? And the answer is a hospital that has specialized capabilities to stabilize an emergency medical condition. So, for example, a patient comes into the emergency department of hospital A with chest pain. The consulting cardiologist concludes that the patient doesn't have capability for stint insertion. They transfer the patient to hospital B, which has cath lab capability to provide the service. Hospital B is therefore a specialized hospital.

The second question that was raised: What is the criteria for defining stability? Stability means, under the statute, that no further deterioration in the patient's condition is likely to occur within reasonable medical probability to result from or occur during the transfer of the individual from a facility. If that definition sounds circular, it's because it is. It begs the question of what happens if the patient is not being transferred from the facility. The courts have wrestled with that vague language. Ultimately the reason that CMS chose to say EMTALA didn't apply to inpatients is because of this language and that's the basis that courts have used to hold true to the fact that EMTALA doesn't apply to inpatients. So under the CMS regulation, EMTALA ends when 1, the hospital concludes there is no emergency medical condition; 2, the hospital concludes there is an emergency medical condition but they can stabilize it, or 3, the patient is admitted as an inpatient.

The third question: EMTALA doesn't apply to inpatients. Are there any requirements however regarding inpatients and EMTALA? And the answer is no, once the patient is admitted as an inpatient, EMTALA ends.

And the last question: Does the Secretary plan to establish an EMTALA panel? The answer is yes, Section 945 of MMA directs the Secretary to establish an EMTALA technical advisory group. The agency is currently in the process of establishing such a group and once the charter is complete, and it's signed off by the Secretary, then nominations will be, that information will be published in the *Federal Register*, and nominations from the appropriate representative organizations will be taken. The technical advisory group will consist of 19 members. It shall consist of the CMS administrator, one member from the HHS Inspector General Group, there will be four hospital representatives, seven practicing physicians, two CMS regional personnel, and one person that deals with state surveys, and one other individual. But there will be a 19-member panel that will review EMTALA policies and provide advice and guidance to the Secretary in regards to EMTALA issues as they arise.

Dr. Rapp: Thank you, Dr. Simon. Does any member of the Council have any questions for Dr. Simon with reference to this. Dr. Wood?

Dr. Wood: Actually two things. Going backward on EMTALA. Does the advisory panel include somebody from pre hospital side? The technical panel, pre hospital care?

Dr. Rapp: I believe it's specified in the statute who's supposed to be on it.

Dr. Simon: It just says four hospital representatives. Two of whom would not have had prior EMTALA violations.

Dr. Wood: The only reason I was asking was that this also is an outgrowth of Secretary's Advisory Committee on Regulatory Reform and in our recommendation, relating to a technical advisory panel, we specifically recommended having at least one representative from the pre hospital care site. So if there's a way that could be done from a regular perspective, that might, a point of the panel within the confines of the statute, I think that would be an advantage if you can do it.

Dr. Simon: Two patient representatives?

Dr. Wood: No actually, it's pre hospital care, which would be ambulance service, EMS providers?

Dr. Simon: That's not indicated. The conferees indicated that the tag group would be comprised of one CMS administrator, the HHS Inspector General, four hospital representatives, and as I stated, two of whom have not experienced EMTALA violations, seven practicing physicians with specified experience, two patient representatives, two regional CMS staff involved in EMTALA investigations, one representative from a state survey organization, and one representative from a QIO. But your recommendation will be noted.

Dr. Wood: It may be possible in the context of the physicians to have somebody with pre hospital experience. The real reason for that was to make sure that in the organization of protocols within communities that there be an ability to recognize that EMTALA sometimes can get caught up in how you put together protocols for first response within the community.

Dr. Rapp: I guess on that, I know an emergency physician is one of the groups that has to be on there, and emergency physicians are typically the medical directors.

Dr. Wood: Right. I think that would give us our opportunity. The second question is regards to your suggestion of looking at outliners for prescription of durable medical equipment and wheelchairs, I would have two

concerns. One is how you proposed to look at outliners, because in reviewing the brochure that was on the web site there are only certain specialties that are likely to prescribe these sorts of things. So is the outliner analysis going to be looking only at those specialties?

Dr. Simon: It was my understanding that it would look at not the specialties, but the individuals that are actually prescribing and ordering the wheelchairs.

Dr. Wood: OK. Here's my concern about the way it's done. First is that that group obviously is the group that does a lot of prescribing and so by looking at outliners if you are not careful about that, you will probably catch a lot of legitimate people and create additional burden for them. While at the same time, then missing opportunities. Now, I'm a cardiologist, so I would not ordinarily prescribe these things, but there are a number of people who come to me with a piece of paper in hand saying I need a power wheelchair because I can't walk a couple hundred yards. But that's not a reason to have a powered device under regulation. And what's happening is these people are coming with everything actually filled in and now having watched many television ads where the companies are getting their getting the chair, then my concern is is somebody using my UPIN number to get that chair? And so I might not be an outliner, because I might only have, I mean my UPIN number may have been used by somebody only five or six times, but that's still five or six inappropriate times. If you spread that across enough providers, you may miss a substantial number of inappropriate prescribed devices or chairs. I think the intent of the Council was if we could have a report on an annual basis of what was prescribed against our UPIN numbers, we could help you in terms of program integrity, by sending back reports to you saying, "None of these were ordered," and then go after them. It was not the other way around, where you're looking at the physicians so much as being the offenders. It's that we're concerned that these companies are using UPIN numbers inappropriately and goal was to try to help. At least I think that was how I recall that discussion.

Dr. Rapp: Yes, actually, I'd like to underscore that. That that is exactly what we were interested in. It's the fact that the physician's number is used, and if it's just an outliner, then you find out, oh my goodness, I'm sort of—something's been going on, I'm an outliner. But actually I think the physicians would like to be involved or at least our idea was the physicians would like to be a check on the possible fraud. And another sort of similar aspect comes up in the Medicare Modernization Act. We're not talking about it today, but there's a change in the law, not having to do with durable medical equipment, but having to do with the physicians' fees themselves and now physicians are

going to be able to reassign their patients' benefits to an independent contractor. And there's language in the conference report that talks about it's desirable to have some program memorandum of where the physician can find out what is billed and collect it in their name, under the Medicare Program and currently there does not seem to be ready access to that information. So this is sort of parallel to that but the idea is that the physicians somehow have access to the data which will indicate to them to what extent their number and their ability to bill Medicare is being utilized by a third party. Just the structure of medical health care delivery these days is completely different than perhaps it was in 1965 when the Medicare Program was adopted and this wouldn't have been much of a problem. But now people, physicians work in the structures and so forth and are required to have these numbers. So anyway, I'd just like to underscore what Dr. Wood has said. Did you have anything else?

Dr. Wood: There's one a little bit later.

Dr. Simon: Just to add to what Dr. Rapp has said, in MMA, there is a section that again addresses contractor performance, where it does require the contractors to develop a methodology where physicians can, well, 1, there's an 800 number [break in tape] that physicians will have access to, to the contractors, and 2, where the information in regards to claims, billing, and any other data be available to physicians so that they would have access to that information. So to that extent, I think that I would follow up with program integrity to see what the legislation changes by MMA—how that impacts this particular recommendation and bring a follow up report to the Council at the next meeting.

Dr. Heyman: I was just going to make Doug Wood's point also about the UPIN number. I'm not quite clear on, by the way, in my entire experience on PPAC, I think this is the highest percentage of adoption of recommendations of the Council that I've ever seen. [laughter]

Dr. Rapp: Without even a grid!

Dr. Heyman: Well if you adopted most of the time, we wouldn't have need the grid. In any event, the fact of the matter is, I don't understand how we got from a recommendation that suggested that we use UPIN numbers so that physicians could figure out who was using their UPIN numbers to a situation where we're looking for physician outliners. I mean to me they were unrelated to each other. You've already made the point. I just hope we're not going to have a new series of outliner searches.

Dr. Powers: I agree with that point, and that was part of my point. My other comment is that if the OIG would just go after those handful of companies that advertise on television, in newspapers and other publications, they'd probably solve 90% of the problem. And why go after the physicians who happen to be signing these things unknowingly or semi-unknowingly without just going after the companies first.

Dr. McAneny: [off mike] The comment that we were looking at these for a way for physicians to learn whether they were doing proper billing and internal voluntary audit. I recently attended one of the Medicare billing updates. And they brought up the fact that you could go ahead and have one of these internal audits just so you could see whether you were doing it right. The questioner, the CMS employee, who was giving this course on billing and coding, asked how many people had done this. No one in this room of a couple hundred people raised their hand. And she asked why not. And pretty much the consensus from around the room was you'd have to be crazy if we did an internal audit, and we found we were doing things wrong, we would despite protestations to the contrary, that we would find the OIG knocking at our door. So in one sense you've got this program set up to try to teach us and let us test ourselves to see whether we are doing billing and coding correctly, but everybody is afraid to use it. So the, I think this is a very important recommendation and needs to be further worked on so that we can come up with a system by which we can do an internal confidential audit somehow, so that we can know that we're following the law. We basically all want to follow the law. But people are afraid to even find out.

Dr. Rapp: Any other questions for Dr. Simon with reference to his report? If not, the next item on the agenda—yes, Sir.

Dr. Simon: Since Dr. McAneny made the point, I'd like to just bring up two points that were incorporated and covered by the MMA. And one is it's under the section for regulatory relief. And CMS is prohibited from leaving penalties or interest on providers who have shown to have reasonably relied on erroneous written guidance from Medicare contractors. That's one piece. And then the second piece of information is that the Secretary is required to create a new Medicare ombudsman program for providers to furnish assistance on a confidential basis, concerning complaints, grievances, and resolution of unclear or conflicting guidance given by the Secretary and Medicare contractors. And there also be an ombudsman program created for Medicare beneficiaries, as well. So I think that there'll be a couple of avenues available where physicians will be able to gain further insight and access for information that pertains to their own particular practice.

Dr. Rapp: Is there a time table for implementation of those?

Dr. Simon: The conferees did not extend a date by which it has to be enacted, but all of these are part of several of the issues that CMS is presently reviewing and trying to prioritize implementation for.

Dr. Rapp: All right. Anything else on the report? If not, I would like to note for the record, at least, that we do have, before we get to the individual items on the agenda, we do have a number of written statements, and we have some other oral testimony and I would just ask the reporter to include in the minutes indication that the Council has received the written testimony of all the parties that have placed them before us and will have considered those as part of its information. The next item on the agenda is on the Physician Fee Schedule, Final Rule, Average Wholesale Price, Reform Sustained Growth Rate. We're quite a bit ahead of schedule, but I understand Marc Hartstein is here and Don Thompson is not here yet, and we will probably take Mr. Hartstein, and then we'll take a break at that point. Thank you for being flexible enough to start a little bit early.

Mr. Hartstein: I knew that Hatha Yoga would come in handy.

Dr. Rapp: Half a yoga or half a yogurt?

Mr. Hartstein: Hatha.

Dr. Rapp: Do some pushups now and you'll be ready to go.

Mr. Hartstein: I generally exercise in the morning, but I skipped my exercise this morning, so I could get down here timely, just because I would like the hear the deliberations of the Council. I will be here all day and tomorrow, Terry Kay will be here. I just want to introduce myself. I know I've talked to the Council before. My name is Marc Hartstein. Generally, I've spoken to you in my capacity as a senior technical advisor to the hospital and ambulatory policy group where I primarily worked on Physician Fee Schedule issues. Today I'm addressing you as the Acting Director of the Division of Practitioner Services, the group that does the Physician Fee Schedule, proposed and final rule, as well as all of the regulations that pertain to Physician Fee Schedule issues and a variety of ancillary policies. I'm going to be serving in this role for a short time longer. I've been serving in it since about the beginning of the year. I would like to introduce the permanent director to you because he will be taking over this position shortly, and his name is Steven Philips, and he's sitting back there. Steve is going to be taking over the position that was formerly occupied by Terry Kay, who you probably all know very well. I have to say I'm gratified to be turning over the reins of this division to Steve. I've known Steve for probably about 15 years. He's a good

friend of mine, and I know his wife, Katy as well, for a long time, and I think you're going to be in good hands. Steve's been the Deputy Director of the Division of Acute Care and various prior organizations of the hospital and ambulatory payment group. The group that does the prospective payment system. He was involved as a staff analyst in that area for a very long time and then he's been serving as the Deputy Director for quite some time and he's moving over to become the Director of Physician Services. Even though it's going to be a new area for him, I'm very confident that you'll be in good hands and he's going to learn this area well. And I look forward to assisting him in this role.

Continuing on with my presentation, Don Thompson, is probably on his way down. But because we're starting early, he's unavailable and I will do my best to address the portions of this presentation that are within his area of expertise. I have spoken with him on numerous occasions about these issues and we'll see how well I do through osmosis and listening to him speak. I actually did have some cross over with him during the regulatory cycle and did get familiar with some of the issues related to Medicare payments for drugs.

I'm going to talk mostly about the MMA provisions—

Dr. Rapp: What we could do is if you feel at some point that you've sort of exhausted where you should go, we can take a break at that point, and then maybe.

Mr. Hartstein: OK. I think I could probably represent his issues pretty well through the presentation period, but probably not through the Q&A to the extent that the questions get very sophisticated. But I'll do my best. I'm going to talk about the Medicare Modernization Provisions and how they affected the Physician Fee Schedule, and Don was intended to talk about Medicare Payment for Part B drugs, so I'm going to cover that as well. 2003 was a very eventful year as Tom Gustafson indicated, particularly in the Physician Fee Schedule area, we did a lot of work in the latter part of the year. I think you could take all of the work that we did in the months of October, November and December and say that we got a full year's work in just at that time. As Tom indicated, what we generally do, as you're well aware, in the Physician Fee Schedule, is we put out a notice of proposed rule making, generally in the early summer or the late spring. At least that's our hope. This year we didn't put it out until actually August 15th of 2003 and then a few days later, we published a subsequent rule, which would change Medicare payments for drugs and drug administration. And I think Don and I actually came to talk about that proposed rule to the Council sometime after the August 20th proposed rule was published. And then what our intent was, on or about November

1st to publish a final rule that would finalize the proposals in the Physician Fee Schedule proposed rule, as well as the proposed rule for drugs and drug administration. What we did was, on November 7th, we put into final all the proposed changes in the August 15th Physician Fee Schedule proposed rule, but we did not put into final all other provisions that were in the August 20th proposed rule. And the reason we didn't was because Congress was legislating in the area of drugs and drug administration, and we felt that it would be appropriate for the Congress to conclude its deliberations before we made a final resolution to the issue and a final rule. Because of the implications of what Congress was doing on that issue, we wanted to wait for that process to conclude. So the specific provisions that were in the January 7th 2004 final rule related to the Physician Fee Schedule conversion factor, geographic practice costindicess, as I just said, Part B drug payments and drug administration payment changes. And then of course we had also put into place a cap on Medicare payments for physical therapy, a per beneficiary cap. The statute put a 2-year moratorium on those changes that we implemented by carrier instruction.

First and foremost, I think this was the issue that was of probably the most importance to the physician community at large, relates to the Physician Fee Schedule conversion factor. The Medicare Modernization Act requires the conversion factor increase of not less than 1.5% for 2004 and 2005. It replaces a 4.5% reduction for 2004 that would have occurred under statutory formula. For those of you who are interested, that makes the new conversion factor for 2004, $37 and about 34 cents. The national average anesthesia conversion factor would be about $17.50. I do want to make a couple of comments here. On November 7th when we published a rule, this was prior to the enactment of the Medicare Modernization Act, at that time, we announced a 4.5% reduction in the Physician Fee Schedule under the statutory formula. The Secretary had no authority to change that result. It was done completely within a very specific prescriptive statute, although we did indicate that we would like to see that statute changed. There was concern on the part of the Administration about that 4.5% reduction. We published that on November 7th. The way our process generally works is we have to put that information into the payment files that go to the Medicare carriers shortly after that time. They also go into what's called a Dear Physician letter, where the carriers mail two physicians a letter, which announces what the rates are going to be for all the Physician Fee Schedule services for the following year, and then physicians make a decision as to whether they're going to participate or not in the Medicare Program for the following year—whether they are going to accept assignment on all claims. We did indicate in that Dear Physician letter that there was the possibility for a change to the rates and

that the 4.5% reduction would be replaced with a 1.5% increase. That is actually what occurred of course in the Medicare Modernization Act. I don't think we got that specific in the letter as to exactly what would occur in the statute, but that our thought was that there was potential for action to change the rates. The law was enacted on December 8th, and it required us to act very quickly because the provisions related to the fee schedule were effective on January 1st. So we had about three weeks between the enactment of the statute and the January 1st effective date to be able to review all the statutory provisions, determine what was required of us, develop and publish a regulation in the Federal Register. Of course get it through al the relevant clearances, make sure everybody who needed to know was well informed of what was included in it, and then make it available to the public on the Office of Federal Register web site, and then later in the Federal Register itself. It was actually published on January 7th but its provisions were effective on January 1st. The rule — we were really working very, very hard to try to make sure that it was available to the public before the January 1st effective date. We know that physicians are affected by those rates beginning January 1st. The soonest we could possibly get all of that work available to the public was on December 31st. And the vehicle that we used was the Office of the Federal Register web site, the public display copy. We also put on the CMS web site information that announced what the physicians fee schedule rates are, so physicians could go look up procedure codes that were of most interest to them, to find out what the rates were through a lookup application on the CMS web site and as Tom Gustafsen and Ken indicated earlier, we try to use other vehicles to try to publicize that there were new physician fee schedule rates. Unfortunately, we couldn't do another mailing because of resource constraints within CMS. So clearly the most significant provision was the ——

Dr. Rapp: Dr. McAneny.

Dr. McAneny: Yes one of my concerns, and I heard it voiced in many places around the country is that as we have this fee increase this year which we're very appreciative of, thank you very much, we'll have it this year, we'll have it next year. Yet that will be part of the calculation of the SGR target for 2006, and everybody's already apprehensive about the quote falling off the cliff. I'm wondering whether or not CMS is looking forward to 2006 to figure out whether there's going to be a major change in the SGR formula calculation or whether we're going to go by congressional fixes year by year, you know fight this battle one year at a time. Or are we going to try to have some sort of a forward looking plan so that we don't face disaster when this catches up with us.

Mr. Hartstein: well the first thing I want to say is I appreciate your kind words of thanks but I can say honestly that I was not responsible for it, in the most technical of senses, but, so I don't want to take credit or I hope you wont give me blame. I guess I don't want the blame either when there are problems. I can either answer that question now, or if you'd prefer I could try to leave that to the question and answer period.

Dr. Rapp: I'll let you answer however you want.

Mr. Hartstein: This is an issue that— certainly a question that I was expecting because I think it's a question that's come up in previous contexts. The way the sustainable growth rate system works is that it is a target system, and if physician expenditures are above the target, then the statute requires that the Secretary to reduce physician fee schedule rates. It's a little more complicated than that, but that's essentially the way it works. We start with the inflation rate and then we either increase it or decrease it based on how expenditures compare to this target. And the reason we were in the situation of having a 4-1/2% reduction for 2004 was that expenditures were well above the target, and so the statutory formula would have required us to reduce the inflation rate by —I don't recall if it was actually the maximum 7% reduction or if it was very close to that. So again, the Secretary had no authority on that, that was required by the statute. And what the Congress did was it came along and said for the next two years, increase physician fee schedule rates by 1.5%. But what it did not do was not say that the target should be adjusted to accommodate this increased expenditures. That means that expenditures are likely to be above the target again beginning — for setting the year 2006. And I think what this provision does is really give Congress and the administration another two years to try to figure out how to try to change the SGR system in a way that can lead to long term stability in physician fee schedules— equitable updates, controlled spending, and over the long term exactly how that's going to be achieved, I guess that's not for me to say, that's clearly a large issue that's for Congress and the administration to resolve together.

Dr. McAneny: A follow up question: Does that mean that CMS is interested in trying to restructure the SGR? Is that what I heard you just say?

Mr. Hartstein: Well again because I really don't have the authority to say yes or no to any particular changes as to the extent—I mean the SGR is a very complicated system. When I come to speak to you I really try to boil it down to its basic parameters, but they're very complex issues related to the SGR. To the extent that we're asked for technical advice and ideas for how to resolve these issues, we certainly provide them to the extent that we

have any particular opinions, and our opinions are welcome down those—we provide those as well, but these are certainly very large issues that get into how much do we want to spend on physician fee schedule services, they get discussed together with other government priorities, so certainly those are issues that require discussions between Congress and the administration, but again, we think about it a lot, we have a lot of technical expertise on the SGR, I work closely with the actuary, we're always thinking about ideas for trying to improve this system

Dr. Bergeron: WE in Louisiana really like our Mardi Gras, our crawfish, a few other things, and of course politics is one of our— Looking at this, taking together all the factors, all the mathematics, all the conversion factors, I still feel like the bombardment of the Congress and the Senate by the health care providers in this country, and the outcry was as instrumental in changing a 6% fee schedule arrangement if you will, meaning with my colleague from New Mexico, are we going to go through this year after year, are we going to get certain parameters that are fair, equitable, workable? Are we going to have to go through the political aspects, because, cross my desk, unbelievable number, call you congressman, call your senator, nothing about study up on the practice, study up on the conversions, what's the mathematics behind it? Get your congressman's ear, get your senator's ear, and well get these particular redresses that we are trying to get. So meaning this: when and if this is going to be a fixable entity, we'll have certain parameters, unarguably, everybody'll understand, and we'll know where we stand from year to year.

Mr. Gustafson: Let me just comment here. I think Mark has done what I think of as a somewhat masterful job of providing the bureaucrat's answer to the very real concern that you guys have.

Mr. Hartstein: Fifteen years of experience.

Mr. Gustafson: We know how to do this, we're good at it. And I'm just a bureaucrat too. You're not going to get any more out of me. (Laughter) I think we need to acknowledge that this is a big problem, and I can't speak in any detail for the administration on this. The administration obviously finds this a matter of concern. We're in a situation at present where we're between political leadership. Dr. McClellan of the FDA has been designated as our next administrator. We expect that he will be confirmed by the Senate speedily, but legislative people say that may mean the end of March, something of that sort. So I don't think we're in a position to give you any more than a bureaucrat's answer, but that is not to diminish the concern of the problem and we recognize that.

Dr. Rapp: On that though, one of the things that we recommended and I'm sure people are going to bring up again today, is the inclusion of drugs in the SGR with regard to — and the impact that has on the physician fees. Do you have some estimate or what would be impact if that were taken out?

Mr. Hartstein: I don't know right now but I've spoken to the council about that issue before and I know that it's of significant interest. For the members, just to recap what the issue is: The target is, for physicians services includes really three main categories of services. Physicians fee schedule services, clinical diagnostic laboratory services, and drugs that are paid for in physicians' offices, excludes other types of drugs that are administered through items of DME, durable medical equipment. At one of these meetings I was asked why are drugs and laboratory services included but only the physician fee schedule update is affected by this adjustment? And the reason for that is because the statute provides criteria to the Secretary. It says that the — it defines physicians services to include items or services that are either furnished by physicians or in physicians' offices. And this statutory language actually goes back to the predecessor of the SGR, back to 1989, to the Medicare Volume Performance Standard, and that language stayed in place when the Sustainable Growth Rate was enacted. And there was a feeling when the original target was developed that physicians order — that drugs and laboratory services, or the types of services that are either furnished by physicians themselves or ordered by physicians, and that they meet the criteria for being included in the target. The reason it's of interest is because drugs have been growing so rapidly and have contributed to spending being over the target. So now, when we covered this issue, I think there was a feeling that the potential for the system to result in more positive updates in the future was probably — there certainly was that potential, I can't say whether it was significant or insignificant, I just can't recall at the time I spoke what the prospects were. But certainly drugs have been growing more rapidly than other physicians' services and have contributed to spending being over the target. And I think that's probably still the case, although what the payment implications would be now under current law not that the balanced — the Medicare Modernization Act has been enacted, it's hard to say. I think that's probably an issue that CMS would probably need to go back and look at. Certainly if (?) all of the arguments are the same, it could be that some of the technical issues related to how it would affect the physician fee schedule update may be somewhat different, so it's certainly an issue we could look back at.

Dr. Rapp: So you're saying that the Medicare Modernization Act, you'd have to look at it because of some limitations placed on the drugs?

Mr. Hartstein: That's certainly an issue. As I said in response to Dr. McAneny's question, I think it seems very likely that without a change in law, the physician fee schedule update would probably go down after the two years, after 2004 and 2005 are gone. So I think both the issue you just raised, the changes in payments for drugs, as well as the prospects for the physician fee schedule update to be negative without an act of Congress, probably provide an opportunity to revisit the issue, or at least look at what its implications would be, even though probably the policy parameters, the arguments are probably the same.

Dr. Rapp: I guess my question is, do you have data that has attempted to quantify this, the impact of a change of policy, what that would be. Tom Scully, when he was at one of out meetings, he said, well, the drug issue really comes down to the impact, it would be too big an impact to make that policy change, not necessarily that it was a bad idea. And then the other thing is he — I sort of invited the council to figure out something short of that and I don't know what might be short of that, maybe dealing with the fact that the drugs are going up so fast in terms of growth, as opposed to the physicians' services. I don't know what that might be, but that was his comment at the time.

Mr. Hartstein: I think that's what I'm referring to. I don't know what the impact would be today. It would probably be somewhat different from the impacts that Tom Scully was talking about, or maybe not, I don't know. I guess we'd have to go back and re-look at that. Again, in the context of the other legislative changes.

Dr. Rapp: Would you like to go on with your thing and invite some more questions in a bit? Is that all right with the council?

Dr. McAneny: It seems like we ought to deal with the issue on the table.

Dr. Bergeron: I'm a dermatologist, and really we don't have much to do with dispensing drugs from our office, and there's a certain number of specialties that—oncologist, some (unintelligible) etc. Has anybody thought about going on and figuring out the fee schedule and carving out these specialties that utilize these drugs. In other words I feel, and I'm just being a devil's advocate her, that I'm being penalized. And when you figure out my fee schedule, and I do not dispense any drugs. Utilization of drugs in our office would be miniscule. So why couldn't you go on and focus on the specialties that utilize the drugs and use a certain parameter—you have all these other

conversion factors—I'm sure throwing another one into the gumbo would make that much difference for the ultimate product.

Mr. Hartstein: I guess I'd like to hear Dr. McAneny's answer to that question. (laughter) On that question, the target is a global target that applies to all physician fee schedule services. I know the Medicare Payment Advisory Commission, and perhaps the Agency for Healthcare Research and Quality, through a Rand study, I think they looked at expenditures over time under this SGR system. It's a global target. Certainly drugs are growing rapidly. I agree, you're probably correct that a small portion of the physician community dispenses drugs and receives those revenues while a large part of that physician community does not. However I'm sure that argument could be made for many other services. I think when these studies were done they'd show that in some cases diagnostic services and technical imaging services have been growing rapidly, and other physicians don't provide those. And I think they could make a similar argument. I think that when we looked at the large, large increase in spending in 2002, we saw a large growth in spending across a wide variety of types of service, including evaluation and management. So I think you're correct in what you're saying. I think the argument against that would be there are other categories of services that are growing rapidly as well that other physicians don't do. And then also there's the statutory argument. I think the Secretary right now would not have the flexibility to design a target that would apply just to individual groups of physicians. I think there's been interest over time in trying to do demonstration projects or look at sub national targets. I think one of the reasons there is that if you have a global target that applies to all 700,000 physicians in America, I think each individual physician will have trouble seeing their contribution to that target. So as an incentive system, incentives are so diffuse, I think it's difficult to see. So I think to the extent that kind of idea would be interesting or useful to be studied, we certainly couldn't do it under the current construct of the law, but I think the idea would be that you would want to have smaller groups of physicians subject to those targets to see that in that way they could more easily see how the incentive payment structure would work.

Dr: Rapp: Dr. McAneny and then we'll let you go on to your presentation.

Dr. McAneny: Actually you gave pretty much the answer I would have given. But two comments. One is I'm interested in whether or not the MMA allows the Secretary to look more favorably upon the idea of administratively removing drugs from the SGR. Before, the comments have always been that it would require an Act

of Congress, and we have now had one. So I'm wondering if they are going to look at back at that. And then the second question actually is more of a suggestion. As you look at data on the affect of this as more physicians are going to be stopping doing infusions in the office and transferring this to the Part B hospital out patient setting, where things are significantly more expensive, what we may find is that the drug component, which has been going up at this rate will take an exponential, well I don't know about exponential, but will increase as we start using the Part B hospital out patient setting. Yet they may be offset by the fact that they're going to be many particular rural and small town beneficiaries who are going to forego getting those drugs because it's just too inconvenient to go and do those kind of things. So, I'm suggesting that one of the data points that CMS might look at would be the cost per beneficiary of getting these Part B out patient drugs and then looking at the cumulative affect of that on the amount of drug contribution to the SGR.

Mr. Hartstein: Yeah. I mean I guess the thing—I'm not sure what the question was. But I guess you're getting into some issues that are going to be the subject of some of the next points. But I guess what you're asking us in the context of the legislation and the drug payment changes to evaluate the question, making some assumptions about what's going to happen with drug utilization over the course of time.

Dr. McAneny: Right, and the first part of the question was does the Secretary now feel that they can make more administrative changes to the SGR and remove the drug part, was this legislation sufficient?

Mr. Harstein: Well, I don't think our authority changed at all there. The statutory provision as to what's included in the SGR is the same. It's the, as I said before, items and services furnished in physicians' offices, or by physicians. So that does not change, although I would say that it does give the Secretary the authority to determine what those items and services are.

The next major provision in the statute relates to the geographic practice cost indices. This is, if the only provisions that we had to implement were the geographic practice cost index and the conversion factor changes, then I think the physician fee schedule would have been about as straight forward as anything could be. Because it really was quite prescriptive in telling us what to do. It was really the changes that I'm going to discuss after this that required more thought and more analysis and took more time. The geographic practice cost index, again, just to summarize what those are—those are adjustment to Physician Fee Schedule rates for area cost differences. There are three components to it. There's a physician work, a practice expense and malpractice. We only adjust for a quarter

of the difference in the physician work portion, and fully for the practice costs, for the differences in practice expense and malpractice. The physician work portion has been the portion that's probably been the subject of the most discussion. You're actually, has been a, there was a lot of news about this. There was some concern that by paying less in some areas of the country and more in other areas of the country, that somehow the GPCI was not treating some areas fairly. What the statute required us to do was to change the work geographic practice cost index to a floor of one. So any area of the country that had a work geographic practice cost index of less than one; it would be raised to one for the years 2004 through 2006. So that would benefit any area of the country which saw its geographic practice cost index rise. I do want to say that we put together very detailed impact tables in the January 7th, 2004 proposed rule. And if you look on page 1111 to 1115, it shows the impact of the geographic practice cost index alone on all of the Medicare payment localities and we've been told that people find that very useful. We showed the impact on the work GPCI alone, on how it affects payment for that one component of the Medicare payment rate, as well as what we call the geographic adjustment factor, or weighted average of the three. So for instance, you could see that in a state like Iowa, the adjustment was .909, which would mean that that was about a 9% reduction from national average rates in Iowa, for geographic practice cost changes. That's because costs in Iowa had been found by our data to be less than the national average. The provision in the statute in the Medicare Modernization Act, raised that index to .930, so that's about a 2.5% benefit to people who practice in Iowa, just from the GPCI changes alone. If you happen to be in Alaska, the changes were quite generous. It raised not just the work GPCI, but also the practice expense and malpractice GPCI to 1.67. That's about a 50% increase in Physician Fee Schedule payments in the state of Alaska.

Dr. Castellanos: Can I ask a question about GPCIs? As you know, I live in Florida, and we've had a tremendous variability in malpractice issue in Florida. I went up 380% last year. For some reason, you started a modulating factor of .5 to adjust the difference between the new and the previous malpractice GPCIs by 50%. I wonder why you did that?

Dr. Rapp: Is Terry Kay going to discuss this tomorrow?

Mr. Hartstein: Oh yeah, I was going to ask that you maybe you could hold off that question until tomorrow. I think what we did was we wanted to use more recent data on malpractice to the best of our ability, but there was some concern that some of that data was estimated and there was a lot of volatility in that data. So we wanted to

diminish some of that volatility by only taking into account half when more data comes in. But I'm somewhat unsteady in my expertise in this question, and Rick Ensor, who is my malpractice expert, will be speaking with Terry Kay tomorrow on this subject. So I would encourage you to ask the question again.

Dr. Castellanos: Fine, thank you.

Mr. Hartstein: I do want to also add that that provision was part of the November 7th rule, the original fee schedule final rule, not the January 7th rule that was published after the Medicare Modernization Act. Part B drug payments. This is actually the area that Don Thompson was going to discuss. I will just cover these briefly to the best of my ability as these bullet points are stated. There are three sections of the rule that revise Medicare's current payment methodology for Part B drugs. Sections 303, 304, and 305 of Medicare Modernization Act. Section 303 applies to drugs and drug administration, services furnished by oncologists. Section 304 is actually an identical provision and applies to drugs and drug administration services provided by other physicians. And section 305 is specific to inhalation drugs.

The kinds of drugs that are affected. Drugs furnished incident two a physician's service. These would be the types of drugs that are provided in physicians' offices. Generally they're going to be injectable drugs, most commonly they're going to be cancer drugs furnished by oncologists to cancer patients, but they will also include other drugs, for instance rheumatologists infuse a drug called Remicaid that would be affected by these provisions. There are some other drugs that are also paid under this provision that are furnished by other physicians and those would all be affected. Drugs furnished under the durable medical equipment benefit. This would generally be inhalation drugs that are furnished through an item of DME. Most common drug would be albuterol sulphate and ipratropium bromide. I'm trying to pronounce that now for the last seven months and I think that's the best I've ever done.

Dr. Rapp: You can't be that.

Mr. Hartstein: Oral anti-cancer drugs. Those would be different from injectable drugs that are furnished and incident to a physician service. These actually have their own statutory benefit. And they would also be affected by the section 303 through 305 changes. Immuno-suppressive drugs and drugs furnished by Dow Facilities that are not included in the ESRD composite payment rate. Each of these represent different categories, different benefit categories that are specified in the statute that give authority to the Secretary to provide payment for drugs. There

are definitely exceptions for some of these categories of drugs. I'm going to try to talk about the general payment provisions. Effective January 1st, 2004, most drugs are paid at 85% of average wholesale price. The average wholesale price as of April 1st, 2003. If you recall from prior meetings, drugs have generally been paid at 95% of average wholesale price. So what the statute does with some exceptions is make the payment 85% for the year 2004. This would affect new drugs, those drugs that are new, since April 1st 2003. It would affect separately billable ESRD drugs; those drugs that are not included in the composite rate. Vaccines, blood clotting factors, and infusion drugs that are furnished through a covered item of durable medical equipment.

It says other exceptions. It did mention what the first exceptions were. The exceptions are specific percentage for certain high volume drugs. The history on this is that the Office of the Inspector General, and the General Accounting Office studied Medicare payment for drugs in prior years. I think the GOA study was in 2001. And what they found was that some drugs had, they found what the specific mark up on particular drugs were. For those drugs, the statute requires that you use the average percentage of AWP that physicians obtain the drugs for. As identified in the GAO and OIG studies. So for most of these drugs, the percentages could be somewhat different than 85%. Generally, a little bit more or a little bit less with a few exceptions where they were under 80% of average wholesale price. And in those cases, the statute limited the reduction that could occur in one year to I believe it was 15%. So there are no reductions larger than 15% to the price that Medicare pays in any single year. The percentages of the April 1st, 2003 AWP are based on data submitted by drug manufacturers before 10/16, before October 16, 2003, and or between October 16, 2003 and January 1st. This has to do with some exceptions. There was a process put in place where manufacturers could argue or provide data which showed that the price that Medicare was going to pay is different than the price that was found in either 85% of AWP or the percentage found in the drug tables of the August 20th rule of the statute referred us to the August 20th rule, which reflected the average of the OIG and GAO percentages. So there was an exceptions opportunity put into the statute, which allowed us to change the price that we pay. So those manufacturers had an opportunity to submit data. Before October 16th, 2003 under our August 20th proposed rule, and then a second period to provide data between October 16th and January 1st, 2004, by the Medicare Modernization Act.

Dr. Rapp: Yes, Dr. McAneny?

Dr. McAneny: I'm sure you're surprised to see my hand in the air. Just a little feedback about what's going on with these changes from the real world in terms of practicing oncologists, in that with the numbers of drugs that we're going to be reimbursed, just for the drug costs, not the true acquisition costs, but the purchase of the drug itself, people who have a volume were able to go to the drug companies and say, "This is what Medicare is paying, so if you want me to prescribe your drug, you will sell it to me at this price or less." And so that's happened for larger practices. For smaller practices they're saying, "You can't get it for that amount. Those patients are going to the hospitals." The other thing that's happening because of an oncology, the folks who have no Medigap insurances are currently being sent to the hospital. In talking to practices, through ASTRO's clinical practice committee and other groups across the country, I know of hardly anyone who is in the office setting who is treating those patients who do not have a Medigap, which, in my practice, is 20%. Those folks off the top are going to the hospital. We're continuing interestingly to be able to treat those people who have no insurance whatsoever, because I can get free drugs from the drug companies and not lose money. But if we have a Medicare patient with no Medigap, those people are already being sent to the hospital.

Mr. Hartstein: OK. Thank you. So that information…

Dr. Rapp: So, can I ask you a question for someone who's not involved in this. The average wholesale price sounds like a certain figure that that's what you'd get that for, but that's not really the case.

Mr. Hartstein: Yeah, this is an excellent question because having worked for the Medicare program for a long time and not knowing what average wholesale price means, is to a layperson, you say average wholesale price, this is the price that it sold for and now Medicare's paying 95%, and we must be paying less. I think the concern about average wholesale price has been that Medicare has used these pricing catalogs to get average wholesale price, but it's not a true reflection of the price that a physician acquires the drug for. And what the Office of the Inspector General and General Accounting Office found was that physicians frequently are able to obtain the drug for far less than the average wholesale price that are listed in these pricing catalogs, and that this methodology led to significant overpayments for the drugs. That has been the long standing concern about this pricing methodology and what the statute is now doing is trying to come up with a different concept to try to avoid referring to catalog prices which may or may not reflect the actual prices that physicians purchase the drugs for. And really focus on average sales price, the price that physicians obtain the drugs for. And I don't remember if my presentation talks about what's

going to happen after 2004, 2005 and beyond. In 2005 and beyond, the Secretary is required to establish a new methodology to pay for drugs. Beginning January 1st, 2005, we're supposed to pay average sales price plus 6%, so we're going to pay 6% above the average price that the physicians purchase the drugs for. So this is a, the feeling is that this is going to be a better methodology because we're going to look at the prices that the physicians actually pay and pay 6% greater than that amount.

Dr. Rapp: That would seem like logically, instead of driving down the price, that would drive it up. I mean from an economic standpoint, I would think, if you paid the average sales price, then we're dealing with a cost plus thing, and that always drives up prices, doesn't it? Especially you get the 6% on the average sales—bring it on, whatever you—

Mr. Hartstein: That's certainly a relevant argument, and that argument has been raised. I would add at this point that there's a third component to the drug payment reform. And that is related to competitive bidding. Beginning January 1st, 2006, the Secretary is required to develop in selected areas a competitive bid model. What this would mean would be that drug manufacturers could compete for Medicare's business. They would bid a particular price for drugs. And then a physician would have the opportunity to either select the competitive bid, so the physician would be out of the model altogether, they would just acquire their drugs directly from the competitive bid supplier instead of from the manufacturer directly, and submit a claim to Medicare. So they would just get the drugs from the competitive bid supplier. The competitive bid supplier would then bill Medicare. So the physician would have a choice, beginning January 1st, 2006 between the competitive bid supplier and the average sales price plus 6%.

Dr. Rapp: That would be a demonstration project, is that what you're saying?

Mr. Hartstein: It's not actually a demonstration project. It is in law that we're required to do this. Although I have to say, from listening to Don speak it does sound like it's an ambitious task to be able to do competitive bid. We have had some experience with it before, and have found that it is a difficult task to do. He's already in process starting that, that's why there needs to be such a long lead time, but it is in law. It's not a demonstration project.

Dr. McAneny: Two comments. The question is average sales prices started this moving target that don't really know how you're going to calculate and we'd very much like to know when we're going to know how we're going to calculate that. Plus, if you take the bell shaped curve of sales prices that physicians actually purchase

something at, and you select your average sales price, by definition, 50% of physicians in the country are going to be paying more than the Medicare allowable for that drug. And then Medicare of course pays 80% of that. So one of our concerns with average sales price is that you immediately chop off the top half of that bell-shaped curve, those physicians stop providing the service in their office, go out of business, send people to the hospital, whatever, but they can't continue to purchase the apple for five cents and get four cents for it. And then that lowers the average selling price. So I think it may actually lower prices. But it may also destroy a lot of the infrastructure of our oncology cares being given.

The other concern I have with the competitive bidding process is in areas, the overhead costs of that at a time when physicians' offices are going to be pressed to be more and more and more efficient is astounding. It would be a little bit like asking your grocery store to stock each family's foods separately and not let them all mix. You have a freezer for you and a freezer for him and all these kind of things but not be able to combine any of those things to be able to get any benefits of scale. So the competitive bidding model is viewed in the oncology community as something that really makes it impossible to treat patients. You can't switch inventories. The idea of tracking something if you borrow a drug from this person's inventory to use it for a change in treatment for that person, or the competitive group decides that they're going to not give it to the patient because they don't have their 20% co-pay ready up front is just a nightmare. So that's something that strikes terror into our hearts and I suspect into urology and rheumatology, neurology, everybody else who uses these drugs, that the overhead is horrendous.

Mr. Hartstein: I keep looking at the door, thinking when is Don going to get here! [laughter]

Dr. Rapp: He's supposed to be here in ten minutes.

Dr. Castellanos: Just emphasize part of his point about letting physicians know ahead of time. We're not the federal government. I can't run a deficit and still stay alive. I can't have deficit spending. I need to know my budget ahead of time, I need to know my expenses ahead of time. I'm a small business man. And I'm sorry. I can't run—I'm saying this out of heart, that CMS sometimes waits 'til the very last minute to let us know things. And we need to know upfront about average sale price now before it becomes January, 2005.

Mr. Hartstein: Absolutely. And this is an excellent point, and I want to emphasize this as I have several times in a variety of different meetings where I've been. 2005 will not be like 2004. You've heard me say before that 2004, we published the rates for the following year on December 31st—we actually didn't publish them until

January 7th. But that's because Congress is legislating in this area late in the year. There was a lot of debate going on throughout the year on the Medicare Modernization Act, and it just wasn't within our—we did our best to get out a rule on November 7th, with the knowledge and understanding that Congress was going to be legislating in that area. And I know it was not the ideal situation for physicians. They had no idea what the rates were going to be in November and December, because Congress was legislating and then Congress acted. And then CMS needed some time to be able to announce what the new rates were. And I received tons and tons of calls in the month of December from physician groups and from physicians themselves, very concerned about what the rates would be for the following year. Not just for drugs, but for Physician Fee Schedule services as well and we understand that physicians need to have advance planning in time to do that. And that's why we try to publish these regulations at least 60 days before they go into effect.

This is what our plan is for 2004, to announce 2005 rates, to try to not be in that situation. And of course we, at this point, don't expect it to be complicated by the legislative process, because we're not anticipating today that there's going to be legislation later in the year that's going to change rates for 2005 and Congress established provisions that affect physicians for several years to come. So we're planning on implementing those provisions. Later this year, right now we're hoping for sometime in June, we plan to publish the Physician Fee Schedule proposed rule. The Physician Fee Schedule proposed rule will include all of the proposed changes to Physician Fee Schedule rates for 2005 and will obviously include the 1.5% increase in the Physician Fee Schedule conversion factor. It will also include the average sales price payment changes. We're planning to show you how we are going to calculate those rates. It will be a 60-day public comment period on that proposed rule. So that would be hopefully over the summer period, where we would expect comments like those that were just made by Dr. McAneny to the extent that the physician community wants to weigh in on average sales price. It would be very helpful for us to get those comments if they think that we've done something wrong or we've not calculated in a way that's consistent with the statute, or somehow doesn't recognize what physicians think is an appropriate sales price. That's what the proposed rule process is for, is to get input from the public on what we're doing, make sure that we get it right, and we frequently do change our policies after we propose them in response to public comments from physicians and others. Anybody in the community. We can't anticipate every scenario that's out there and that's why we rely on the physician community to provide us with assistance. So again, I would urge anybody who has an interest in our

payment rates for 2005 to use the public comment process to let us know where they think we need to make changes. Then, of course, what we have a statutory obligation to do is to read everyone of those comments, and we do, I can tell you that. I've been working on the Physician Fee Schedule rule since 1999. I worked on the original fee schedule in 1991 through 1993. We spent a lot of time in the autumn reading those comments, drafting up responses, trying to figure out to change our policies. I have not watched a baseball game, post season baseball game on TV for several years because of this. Because I'm always at the office, reading the comments. But it is a responsibility that we take very seriously and we do act on those comments. And then of course on or about November 1st, we will publish the new Physician Fee Schedule rule, which will announce the Physician Fee Schedule rates, as well as the payments for drugs for the year 2005, at least 60 days in advance of their effective date. So it provides a lot time for physicians to know what we're planning on doing before those rates go into effect. I was very concerned in December when I was getting calls from folks who were telling me that they were going to start referring patients away from their offices to the hospital based on speculation as to what would occur with the payment rates for drugs and drug administration in 2004. I was concerned about that because there were provisions in the statute that substantially raise payments for drug administration. The provisions were designed, as I will say in a few minutes, were designed so that their payment impact would be that the drug payment reductions would be offset by drug administration payment increases in the year 2004. So I think physicians would be well served to follow what's going to happen through our rule making, to be well informed as to how rates are going to change and not to make precipitous decisions, based on speculation. Again I was concerned about that in December, but it turned out that much of that concern and speculation we were able to address by implementing the statutory provisions because the payment reductions and the payment increase virtually offset—

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: Yes, this is for information purposes only. Specifically, how binding is your competitive bidding? Number 2, for what duration of time? Basically, is it like we have so many used cars on the car lot and you have five days to come purchase it, otherwise it'll be a thousand dollars more? In other words, basically when you get your competitive bid, how binding is that particular bid, so you can predicate what you're going to be charging for this, and for what length of time—is it a year's duration?

Mr. Gustafson: Mark's looking puzzled, and I can give you just some quick answers. First of all, this doesn't start happening until 2006. And it is completely voluntary on the part of the individual physician, as to whether they choose to participate or not, as I understand it. I don't think either of us or Steve knows—I'm getting a nod back there—some of the details that you're asking about, about how binding it is, how long you're locked in for, when you have to make choices and so forth. My suspicion is, since I don't recall of this from the statute, my suspicion is there are matters that may be up to us, but I can assure you if that's so, we haven't gotten very far in terms of working them out. But we'll take your concern at heart.

Mr. Hartstein: And clearly in our rule making, we would provide that kind of information.

Dr. Rapp: When you publish these drug, this, the proposed rule that you're talking about, do you list each drug and what the price is, is that what you do?

Mr. Hartstein: We didn't last year in the August 20th rule. I don't know what we'll be doing in this proposed rule. That's really a question that you're going to have to ask Don. Of course, the issue of drugs was not considered by the Congress in isolation, nor was it considered by CMS in isolation when we developed any of our rule making documents. Clearly an important aspect of drugs is drugs have to be administered. So, injectable drugs that are provided in physicians' offices also have a code for administration. The statute had very specific provisions on this as well. I don't want to get into all of the details of the practice expense methodology because it's fairly complex, but we do have a model to crunch different data sources down to develop a practice expense relative value units. This applies to all physician fee schedule services. The general argument when the issue of drugs was being raised both to CMS and on Capital Hill was that there was a pretty well acknowledged acceptance that Medicare overpays for drugs, but there was a concern that Medicare underpaid for the administration of those drugs. So what CMS proposed and the statute required us to address this issue. The statute in some fairly prescriptive ways, but it did require us to look at the statutory provisions, and try to understand exactly how we would go about doing this. In general, one of the important data sources that we use in the practice expense methodology, or practice expense surveys, most of the surveys come from something called the American Medical Association Socio Economic Monitoring Survey. This was a survey that was done for many many years and we were using data from the late '90s to develop the practice expense relative values. We use this in combination with estimates of practice expense inputs for individual codes, like how much nurse time, how much medical supplies, medical equipment are involved in

individual procedures. The American Society of Clinical Oncology did one of these surveys in 2002. We established a process where people could supplement or substitute for the American Medical Association's SMS, the Socio Economic Monitoring Survey. We originally had some concerns about the use of the ASCO survey and did not propose using it until we had some further meetings with ASCO to try to explain some of its results. We did have those meetings in 2003. And we actually did propose using it in the August 20th proposed rule. We didn't finalize that proposed rule, but the statute required us to use the ASCO survey data. That had a substantial, that alone, would have a substantial result—the result would be a substantial increase in the practice expense relative value units for several drug administration services. The statute also required us to adjust the wage rate for the oncology certified nurse that is used to determine the practice expense RVU. Again, we use one of the data source we have, our estimates of how much nurse time is involved in doing all of the different procedures on the fee schedule. We recognize a staff type that's different than a registered nurse for the drug administration services. It's called an oncology certified nurse. A specialized nurse that's used in oncology practice. We used some information from the ASCO survey to determine a different wage rate than we do for other nursing personnel in the practice expense methodology.

Another provision was the statute required us to establish work relative value unit of 0.17 for specific drug administration services. It actually required us to link the work RVU for the drug administration services to the same level of work that's involved in a level one office visit. On my right is Don Thompson [laughter]

Dr. Rapp: Now that he's here, why don't we take a brief break, since we've been going for quite a while, and then you can have a chance to update him on where we are, and we got a little ahead of the game. He's been sweating and you know biting his fingernails and everything [laughter].

Dr. Bergeron: He's got a crick in his neck, he's always looking toward the door. Hey Joe, give him an adjustment this morning.

??: I bet you've been out there for about an hour, just listening.

Mr. Hartstein: I've known Don for a long time, and he's been my good friend. He's testing that.

Dr. Rapp: OK, let's take a 10-minute break.

[BREAK 10:12 am]

[RESUME 10:29:40 am]

Dr. Rapp: I would like to call the meeting back to order. And we have at the table Donald Thompson, who's the Director of the Division of Ambulatory Services. On time, don't want to imply that he's not on time. He's actually early, but we got ahead of the game. So he's going to take over, I think. I believe, I don't know. Marc, are you at your transition point?

Mr. Hartstein: Actually, we were a little past it. [laughter] I don't know if Don wants to make any remarks or if there are any questions that specifically about the drug provisions that anybody will want to ask.

Dr. Rapp: Why don't we let you finish your formal thing, and then we're going to grill him a little bit.

Mr. Hartstein: OK. Drug administration, as I had said before, clearly drugs are only half the story. Drug administration is another part of the story and there are significant concerns about potential underpayments for drug administration and the statute required that we addressed that issue as well. I think where I started was I went through the first three bullet points on this table, this overhead, and was at the point where we established work relative value units of 0.17 for specific drug administration services. With the way the statute, it said use the same level of physician work for a level one office visit, and it put that level of work in specific drug administration codes, particularly the chemotherapy, drug infusions, as well as the non chemotherapy drug codes. And we described all of this in the January 7 *Federal Register* and we provided payment impacts for specific codes as well in that *Federal Register*. Oncologists provide both the chemotherapy and non-chemotherapy drug administration services. Other physicians generally provide the non-chemotherapy infusions. Payments for those codes went up substantially and I'm going to talk about that in a minute, refer to some of the detail and information that you can get out of our *Federal Register* on that topic. In addition to all of these changes, which did substantially increase payments for drug administration, the statute required that we increase them further by an additional 32% for 2004 only. You'd have to look at the statute and try to read all of its provisions to try to figure out what all of this was attempting to do, but I think it's fairly obvious that what the statute was attempting to do was to try to make a transition to a new drug payment system in 2004 by reducing payments for drugs, increasing payments for drug administration, and then adopting a new drug payment system beginning in 2005 based on average sales price. As I said before, the impact of these provisions is that payments for drugs and drug administration changed in such a way as to, drugs went down, administration went up to offset each other.

Dr. McAneny: I want to make a comment on one of the points on that last slide. The slide before this, before he goes on. First of all, it would be absolutely fine to have a rational mechanism of paying for drug administration rather than the traditional one of cost shifting from the drugs, but the key is there on rational. And I was just curious whether or not CMS, when in their looking at the law's determination that we're going to get this practice expense increase for 2004, which I've calculated my office and puts me pretty close to the break even mark for treating Medicare patients, not quite, but pretty close, for those who do have a medi-gap. But what do you expect to happen to our practice expense in 2005 and 2006? When you get rid of this 32% increase, that puts us almost to the break even line in 2004, how am I supposed to pay the nurses, run the inventory, pay the rent in 2005 and 2006? Is CMS planning on doing anything to look at that?

Mr. Hartstein: I'm going to talk about one of the provisions that gives some flexibility to the Secretary in about a minute or two. But I do want to talk again about this methodology that I referred to you before. It really has three components to it. Two components, but it's an objective methodology, where data goes in and then at the end of it, a relative value unit comes out. Now one of the important data sources that I mentioned was the practice expense survey information. A second important piece of the model is the estimates of practice expense inputs for individual codes. With respect to the survey, if a specialty—any specialty—feels that the survey data is not representative of its cost, then that specialty can do a survey. And this is exactly what the American Society of Clinical Oncology did, so to the extent that the survey has got it right, got the costs for oncologists correct, then that's one element of the model that we think is working well. I would point out that the ASCO practice expense survey is I believe it's about $189 per hour. So that statistic, that $189 per hour is an important statistic that goes into determining the practice expense relative value unit. I don't recall what the second highest specialty is, but I can tell you that that is well above the practice expense per hour for any other specialty currently.

Dr. Rapp: That was incorporated by statute into…

Mr. Hartstein: It was incorporated by statute into the methodology, but we did propose using that data as well. So we had intended to use that even without the statutory provision. So the statute required us to do at least one thing that we were already planning to do, and then it required us to do several other things in addition to what we had proposed.

The second major element that I discussed is the estimates of practice expense input for individual codes. This is where you get down to the medical supplies, the medical equipment, and the clinical staff, and for those of you who are familiar with how this process works, there's a multi-specialty panel, known as the Practice Expense Advisory Committee, also known as the PEAC. There are rules of procedure. Many different specialties are represented on that panel. Each specialty has an opportunity to come and make a presentation to the PEAC and the codes are what is called refined. The codes for drug administration were last refined in 2002. So the oncology community had an opportunity to go and make a presentation to the Practice Expense Advisory Committee. The Practice Expense Advisory Committee has been around for several years, and has been making recommendations to us on thousands and thousands of codes. We've generally accepted all of those recommendations without modification, which is what I think we did for the drug administration codes. So again, this is an opportunity that the oncology community, the physician community participates in, makes recommendations to us. If there's some problem or fault with the inputs, they certainly should bring them to the attention of either the Practice Expense Advisory Committee or to CMS, but those codes were last reviewed in 2002 so we feel that the estimates of practice expenses for those codes is probably correct. We're using the American Society of Clinical Oncology's own survey data in this methodology to determine the practice expense relative value unit. So we have two data sources that we think represent oncology practice expenses very well. The only other question would be does the model work, and we've had that model out for notice and comment rule making for many years and we think the methodology's been generally accepted by the medical community. This system is design to establish appropriate relative value units. It is not designed to pay physicians' cost. The statute overall addresses the absolute payment rate for Medicare on Physician Fee Schedule services.

Our goal, what is the goal of the Secretary of Health and Human Services, and us at CMS is to make sure we're establishing the appropriate relative value units; that we have relative resource costs appropriately valued within the fee schedule, relative to each other. We have worked very hard to try to do that and as I said I think with these drug administration codes, I hope we got it right because we've had several changes to those codes just recently, based on data that comes from the physician community itself and the cancer community itself.

Dr. Rapp: You mentioned oncology specifically. Are the codes limited to oncologists?

Mr. Hartstein: No, they're not. There are essentially two sets of codes. There, for those of you who administer drugs. 90780 through 90781. Those are non chemotherapy infusion codes. Those are used generally by oncologists and other physicians for non oncology drugs. Payments for those drugs went up substantially. The first hour of an infusion in 2003 we were paying $42.67. The permanent increase in payment in 2004 would be up to $89.23. So that's about a 109% increase in payment for the first hour of a non chemotherapy infusion. All physicians that provide that service, oncologists and non-oncologists, will receive payment at that rate. And again, I want to emphasize, that's the long-term payment increase for that particular code. There was an additional 32% payment increase for the year 2004 on top of that, which will raise the payment to a national average of $117.79. So a total increase in payment of 176% from 2003 to 2004. I picked that code because that's a code that's very high volume drug administration code that's performed by oncologists and non-oncologists. I also want to talk about the first hour of a chemotherapy infusion, which is procedure code 96410. That's a very very high volume code, predominantly used by oncologists. Can by used by other physicians, but I think its primary use is by oncologists to administer chemotherapy. Payment for that code was $59.22 on average nationally in 2003. The permanent increase, without the 32% transition in 2004 would be $164.66. So about 178% increase from 2003 to 2004, then on top of that, in 2004, alone, there's another 32% increase, which would bring the payment to $217.35. A 267% increase. So what's going to happen for 2005, without further changes, and I don't know whether there are going to be further changes or not, but without further changes, that drug administration service, that 96410, the chemotherapy administration, will pay about $164.66 for the first hour of an infusion. So I want to emphasize that there were large increases in payments, permanent large increases in payments for some of the drug administration codes, as a result of the Medicare Modernization Act provisions. So even though the 32% amount is going to be going away, relative to where these codes were in 2003, they're still some very very large payment increases.

While I'm on the topic, I want to say that what we do in our physician rule, and we've gotten some comments about what we've done. People have found the impact statements to be illuminating and helpful. What we do is we model all of the payment changes that we are undertaking, and we try to show what the impact on payment is on specific codes that are familiar to physicians, as well as on the different specialties that provide physician fee schedule services. We did this through a series of tables, some of which show just the payment impacts for physician fee schedule services alone. And one of which combines the payment for physician fee schedule services with other

revenues for other Medicare services. So, in particular, we combined the payment impacts for drugs and drug administration into a single unified table for six different specialties that receive significant revenues from drugs. This table can be found on page 1109 of the January 7th *Federal Register*. I want to bring this to your attention. I wish I had given it to you as a hand out. I'll make sure that you get that subsequent to this meeting because I think it is helpful, so just for point of illustration, oncologists receive about 77% of their Medicare revenues from drugs. They received about a 12% reduction on 77% of their revenues in 2004 for drugs. They received about a 47% in payment on 20% of their revenues for drugs. So the combined impact of those two changes, together, the drugs and drug administration changes would be about no change in net revenues. We estimate payments in 2004 will go about 500 million on the drug administration side and that they would be reduced in the aggregate about 500 million on the drug side.

We've actually had some talks with one of the groups that represents oncologists on this and they said they did their own work, and they felt that our analysis was valid and consistent with what they would have expected. Although I would say somewhat different from what they would have expected in December, when they were speculating on what some of the payment changes would be. Again, making me urge that before anybody takes any changes for 2005, I think it would probably be helpful to wait and see what we put in our proposed rule and what the payment changes will be.

Other drug administration provisions. There was a provision, currently Medicare only allows, prior to January 1, 2004, only paid for what was called "one push" per day. That's a type of drug administration chemotherapy by the push technique. We only paid for one administration per day, prior to January 1, 2004. The statute requires us to review that policy and effective January 1, 2004, we're paying one push for each drug administered. So if a physician administers more than one drug by the push technique, they can be paid for multiple pushes. A provision that's actually of interest more to other physicians and not the oncology community as much is the next one, which exempts payment changes for drug administration for budget neutrality. Generally, when we make changes to relative value, and it's the Secretary that has the obligation to make sure that the aggregate change in payments doesn't increase or decrease by more than $20 million. That's a very tight limit in a system where we pay probably close to $50 billion. So usually when we increase payments for one group of services by law, we're required to offset those increases in payments by general reductions in all other services. The statute exempted the

changes in drug administration from those budget neutrality requirements. So the increases in payments for drug administration really had almost no impact on any other physician fee schedule services. And then there was a provision in the statute that allowed other specialties to submit practice expense surveys to the Secretary under the same authority that the oncologists had. The oncology survey was exempt from budget neutrality. Other specialties can submit practice expense surveys to us, they're just not exempt from budget neutrality. The statute included a provision that allowed certain specialties to submit a survey, which they already had the ability to do that. It's just that if we receive that survey by March 1st, of this year, March 1st by next year, and there's a further increase in payments for drug administration, those payments would be exempt from budget neutrality. The statute specifies that the specialties that are eligible to submit survey under that exemption from budget neutrality, they have to have 40% or more of their revenues coming from drugs. And the two specialties that would be subject to those provisions would be urology and rheumatology.

One other provision on drug administration. There's a provision again, which exempts from budget neutrality. It says the Secretary must promptly evaluate existing drug administration codes to ensure accurate reporting and billing, taking into account, levels of complexity in resource administration. The statute says we should use our existing processes to consider coding changes and we should consult with physicians affected by drug payment changes. We've taken a look at this provision. It provides, I think, fairly broad authority on the Secretary, with the sort of the limiting authority being that we should do it promptly and we should do it using existing processes. It's not specific as to what exactly that means, but we do believe that existing processes probably suggests that we consult with the CPT editorial panel while we're considering changes. We've also had some discussion internally among the CMS medical officers and with the PRIT, some preliminary discussions as well as some preliminary consultations with the CPT panel.

And then, finally, I mentioned at the beginning of my talk, the statute put a two-year moratorium on the physical therapy caps. For those of you who may recall this, there was a $1500 cap per beneficiary established on physical therapy beginning in 1997. It should be updated for inflation. The statute has put a moratorium on implementation of that cap. Several times the cap was due to expire. The moratorium on implementation of the cap was due to expire. We started enforcing that cap late in 2003. The statute put a moratorium for an additional years. We implemented that provision through instructions to the Medicare contractors.

And I would be happy to take any additional questions that you have.

Dr. Rapp: OK, so what we'll do now is take any additional questions for Mr. Hartstein or Mr. Thompson. And then I would like to have the testimony of the organizations that desire to present testimony. And then after that, I would like to at that point, invite the Council to propose any recommendations that they might. So, questions? Dr. Urata?

Dr. Urata: How does hospital infusion center being affected by all this?

Mr. Thompson: It's a different payment system, with the exception of certain new drugs that are called pass through drugs, for the most part, it's an entirely different payment system. So they're paying under the hospital out patient prospective payment system and both for the drugs and the administration. So it's not really affected by what we've been talking about. There were changes in the law that impacted how the hospital out patient prospective payment system pays for drugs, but what we've been speaking about today does not affect for the most part the out patient hospital provision these services.

Dr. Urata: Do you not take that into consideration, though, when you look at this?

Mr. Thompson: It's an interesting point, and to a certain extent the Siloh Effect, created by the statute. The statute doesn't give us the flexibility to say OK, you have one payment amount that goes across both systems. Not to say we don't look at that. We definitely use that information. We look at the results of their statutory system, and they look at the results of ours, but in terms of the law itself, we're not allowed to pay under the hospital outpatient what we pay and they can't pay what—

Dr. Urata: What's the impact to the patient then, the Medicare patient?

Mr. Thompson: It'll be to be seen in terms of access issues, because you can see in terms of site of service shifts, the potential there, given that there could be different payment amounts between the two systems. One could also argue that there could be different cost structures in the two settings so it may or may not be appropriate for the cost to be exactly the same.

Dr. Urata: So if the patient cannot go to Dr. McAneny and is forced to go to the hospital infusion center, what's the impact? Negative, positive?

Mr. Thompson: In terms of quality cost?

Dr. Urata: What's the cost to the patient? I mean that's the bottom line. If the patient can't see Dr. McAneny, then go to her infusion center, it has to go to the hospital to get the chemotherapy, how does that financially impact the patient in the long run?

Mr. Hartstein: I just want to make two points on this question. First, the statute was not designed to move office space services into the hospital. So the system was designed to pay 6% above average sales price for the drugs, so the physicians should be able to acquire those drugs. That's the way the system was designed. I know you could argue as to whether or not that's going to occur, but that's certainly what the intent of the statute was to do. And then on the administration side, to make sure that we had an appropriate practice expense relative value for the drug administration service. So the intent of the law is to make sure that both drugs and drug administration services are paid correctly, fairly, equitably, and that physicians are to provide those services in their office. That said, we put out a proposed rule to allow physicians to make comments on these things to let us know if they think it's not working. On the drug side, I'll defer to Don on those questions, but again, if we're paying 6% above average sales price, it could be that the market response in some way, that either allows physicians to acquire at those prices, if they can't already, with that methodology. We had heard some anecdotes that actually the variation around the average may not be that great. That many physicians use purchasing groups, although obviously there may be physicians who don't where it could be a problem. But again, what we really want to know, and that's why we put this out for comment. The January 7th rule is out for comment now to the extent that physicians feel that we don't have it right on the drug administration side. They really should tell us when we're using the ASCO survey, we are recognizing higher costs for oncology certified nurses, we're using data from the medical community on the estimates of practice expense inputs. So to the extent that people think that we're not paying much for the administration, we're really like to know why and then how we can change that and then of course on the drug side, the same would be true.

Mr. Thompson: And as Marc points out, we don't even want the premise to occur. To the extent we're paying appropriately for the drug and appropriately for the administration, then the cost shift will not occur. And if we're not paying appropriately for the drug administration, let's try to find out why. We're looking for input. Essentially here's what we've done. We think we've taken all the data that we had that should result in appropriate

payment for the administration. We're paying ASP plus 6% should allow you to get the drug, so we don't expect a cost shift.

Dr. Urata: Well, in my community, it is a small rural community, 30,000 people, and I used to give chemotherapy in the office, but then it came about that part of the chemotherapy I was administering is dangerous, and so we had to get hoods and things of that sort, and that became prohibitive for my small clinic to do that, so we moved to the hospital. And the rest of the of practitioners in our small community ended up sending everything to the hospital, to the infusion center. So my question was more does any of this affect my patients. Because I'm still sending them to the hospital infusion center. They have their hoods and all that sort of stuff and so far we've been able to do it this way. And I'm wondering if any of this would affect my patients being able to get their chemotherapy through the hospital, or is the hospitals going to start complaining about not being able to recover their costs of all this. And it turns out that, seems to me, in the economically it may be more beneficial for many patients to continue to do it that way, through economy of scale, but I don't know. I imagine in the bigger centers, it would be better for patients to go to their doctor's office, like to Dr. McAneny and continue to get their infusions through a program like that. But you don't look at that, or you're not supposed to look at that, is that what you're saying?

Mr. Thompson: It's not that we don't look at it.

Dr. Urata: Because you're taking away business from one person and giving it to another in a sense.

Mr. Thompson: Again, if the goal was that if we want to pay appropriately in the hospital out patient setting and pay in the physician office setting so that the care is provided in the most appropriate setting for the patient, what we want to do is focus on to the extent if we have problems in the payment amounts in the physician setting, we're seeking input. Here's what we've done. We think based on the data that we have, we've got the administration, the data we have correct, we've got the drug administration at AFP plus 6, and somewhere on the hospital side, try to get an appropriate payment there, so not to provide incentives to do site service shifts.

Dr. Rapp: On that, the hospital out patient, the DRG, do you break it down by drug cost, or it lumped thing. Infusion plus the drug costs? In other words what you pay for the drug for the hospital, is that separately identified or is that just, and if so, how does that relate to this average wholesale price plus 6% or whatever?

Mr. Thompson: On the average sales price plus 6%, we don't have the data in yet, we'll be able to have a much more informed discussion after April 30th, when we get that data in house, but as to date, there is no data that we can look at that would say what the 2005 payments would look like. So it's a little premature to speculate what the impact of that might be until we have the data. But once that data is housed, sure, then we would be able to, depending on the drug, and how it's bundled or…

[START SIDE THREE 11:03:10 am]

[cont. Dr. McAneny]: …have a co-pay to pay their 20%. So we have a system which is taking, very much is looking at how can we specialize in giving these specific, dangerous, medications in a safe and effective manner to patients, and we're going to have some shifting. So one of the questions I would really like to hear you guys address is what data points will CMS be using to determine whether or not we're truly affecting the access of care, given that a lot of folks in rural areas who don't have a system set up now for administration in the hospital are going to say, "It's too much of a bother, I'm not going to drive four hours to Albuquerque, forget it." And then, will that determination of access be timely enough to prevent the loss of the oncology infrastructure that currently exists to provide these services? In particular, I'm worried about oncology nurses, because if we're in a situation where I let oncology nurses go, they're not going to go sit on a shelf until we fix the issue, they're going to go become dialysis nurses, or ICU nurses or something else and get paying jobs elsewhere. They won't be there when we try to reestablish the system.

Mr. Hartstein: Again, I don't want to sound like a broken record, but just reiterate the point that I made before, and the provisions of the statute were intended to pay 6% above the acquisition costs for the drugs and then substantially increase the payments for the administration to get the payments rights. So I think the statute was designed to try and prevent an access problem, to pay appropriately on both sides. The statute does include an obligation for the Medicare Payment Advisory Committee to study access to care, section 303, A5 requires MedPAC to conduct a review on the payment changes that I described and Don described for items and services furnished by oncologists and for drug administration services furnished by other specialists. And the report is due, actually there are two deadlines: January 1, 2006, and January 1, 2007. So I think the idea behind the statute was that it would establish a payment system that was equitable on both the drugs and drug administration side, however, it did want MedPAC to look at the issue of access in the events that, to make sure that it in fact did that.

Dr. McAneny: So the answer is you're just going to let MedPAC do it?

Mr. Thompson: I think in addition to what Marc mentioned, we do our own kind of environmental scanning activities with respect to access. One vehicle that we use is the 1800 number, to the extent patients start calling 1800 number saying that's shifting here. So I mean there's certain mechanisms that we use and ORDI uses to monitor access. This is just one example of where we monitor access, but we've always been concerned about access in the history of the program. So those activities that ORDI conducts with respect to access would be just as applicable here as well.

Dr. Heyman: I'm just going to ask the same question Dr. Urata asked, but I'll just ask it differently, and that is the patient has a 20% co pay. Is that 20% bigger when the patient goes to the hospital, or is the 20% bigger when the patient goes to the doctor's office. That's basically the question that we were asking. In other words, is it tougher on the patient financially when they go to the hospital rather than the office?

Mr. Thompson: I think for 2005, it's an open question because we don't have the data yet for the ASP. So you don't know on the drug side, how that's going to play out in terms of the co-insurance.

Dr. Heyman: On the drug administration side, it's not an easy question to answer because there are different procedure codes for drug administration provided in physician's office and drug administration provided in hospital outpatient departments. And the codes are not quite comparable. It's a counter payment in the hospital out patient department. It's a per hour payment for the most commonly provided drug administration services in the office. But I would say that with these payment changes, taking a look at it, it's not clear that we would necessarily pay more in the hospital out patient department for the administration. It's not quite comparable, but it's not clear that we would necessarily pay more. On the beneficiary question, I think actually that was the motivation behind the statutory provisions, that we were overpaying for drugs, and that beneficiaries paid 20% co insurance on the drug overpayment, so it certainly was a concern about beneficiary access because of the co insurance provisions on the old AWP provisions.

Dr. Castellanos: I'm a urologist and we have some unique applications of chemotherapeutic agents into vessels specifically through a catheter. Out patient, there's pretty good data that shows that if you administer this drug right after a surgical procedure where you removed these tumors that you can decrease their recurrence. Now because that is a bundled charge, we can't afford to give chemotherapeutic gauges at that time. Some of the patients

don't have access in our office, we send them, because we're outlying communities, we send them to the hospitals. And the hospitals just don't have the facility or ability or capability of administering these drugs. Have you looked at whether hospitals are going to be able to take are of this load that we expect that we're going to see?

Mr. Thompson: Again, in terms of expect that we're going to see, I think the question goes back to we want to pay appropriately so that those types of reimbursement issues don't drive site of service decision. So again, we're trying to get it right on the physician administration and trying to get it right on the payment for the drug on the physician side and trying to get it right on the out patient side so that's not a driver. So I think the recurring premise is, well, when this happens, what are you going to do about it? And I think some of our response is well, we don't want it to happen, so we want to make sure, and that's why we're seeking input on where it is in our payment system? What part of the data that we've gathered, in terms of the drug administration and what part of the data that we're going to be collecting in terms of the ASP plus 6 might drive that, almost try to prevent the premise before it occurs.

Dr. Castellanos: Could you answer the question about the bundled charges for out patient surgery? Do we add on top of that an intravesicle agent?

Mr. Thompson: So this is when it's provided in out patient hospital?

Dr. Castellanos: Well, these procedures are done in the out patient facility, yes.

Dr. Rapp: No, this is under the physician office out patient.

Dr. Castellanos: Where there's a bundled charge.

Mr. Thompson: The drug administration is bundled?

Dr. Castellanos: The whole charge for the procedure is bundled.

Mr. Thompson: Bundled into—

Dr. Rapp: What's the procedure that you're getting paid for, and what's the one you're not getting paid for?

Dr. Castellanos: You get paid for a TUR [inaudible], and if we administer a drug on top of that, we're not getting reimbursed for that.

Mr. Thompson: I'm not familiar with the specific code, but to the extent it would be bundled, it would mean, I'm delving into an area that's not my expertise, but it would mean that essentially the resource inputs for that procedure are in fact reflected in the procedure you're getting paid for. I mean that usually the rationale for the

bundling. So to the extent that procedure is considered to be bundled, the resources required, if they were typical, would be bundled into the primary payment. But again, I don't know the exact input into that code.

Dr. Castellanos: Maybe I'll sit down and give you the [inaudible] code.

Dr. Simon: Yeah, I think that information will be helpful, because if you're referring to CPT code 52647 and 648, which are the TUR codes, installation of chemicals into the bladder, is not part of that service. That's reported by those CPT codes. So you would not expect to be compensated for that service if you're using those CPT codes. Are you using a CPT code that would specifically refer to installation of drugs into the bladder at the time of the TUR?

Dr. Castellanos: That's correct.

Dr. Simon: What codes are you using?

Dr. Castellanos: Let me give you that data.

Dr. Simon: OK, we can discuss it off line but I think that it be clear to know whether we're talking about distinct services or whether you're performing separate services and anticipating being billed under the service code, which is not generally being caught.

[off topic chat]

Dr. Rapp: Now what I'd like to do, if you gentlemen would—I want to thank you for your extensive testimony and information. I would like now to invite—but I would ask you to kind of move from this table, but hang around in case we have some more questions, and invite a representative from the American Medical Association to make their comments.

Dr. Hill: Mr. Chairman and members of the council, my name is Edward Hill. I'm an immediate past chair of the board of trustees of the American Medical Association and a family physician in Tupelo, Mississippi. I want you to know that the AMA is very grateful to CMS Administration for their support of the Medicare Prescription Drug Improvement and Modernization Act, or MMA. This bill, of course, as we've heard several times today, includes replaces the expected 4.5% cut in 2004, with a 1.5% update in 2004-5, as well as increased payments for geographic disparities in physician scarcity areas, which I think are defined in the statute. I hope they're defined they're defined in the statute, the scarcity areas. The AMA would also like to acknowledge the work and service of Dr. Heyman, Wood, Rothhammer and Moultrie for their service on PPAC, and want you to know that in addition to

his significant contributions as a member of PPAC, Dr. Heyman served on what we call the original CMS, which was the AMA's council on medical services. And now serves on the AMA Board of Trustees. Dr. Wood, who's also an AMA member, who has made significant contributions as Chair and Secretary of the HHS Advisory Committee on Regulatory Reform, as well as through his chairmanship of the Evaluation and Management Task Force. So we want to thank all of you for your leadership and your strong voice in medicine for patients and physicians. AMA has the following comments about the Physician Fee Schedule for 2004.

First, we've previously discussed with PPAC, CMS includes the cost of Medicare coverage physician administered drugs in calculating sustainable growth rates. You've heard that many times today. Some CMS officials believe that including drugs in the sustainable growth rate counter balances incentives for over utilization of drugs. Now the AMA does not agree with this premise and surely such alleged incentives were eliminated by the substantial payment reductions for these drugs mandated by MMA. Therefore, we believe it will be appropriate for PPAC to again ask CMS to reconsider its current policy of including drugs in the sustainable growth rate formula.

Second, a number of MMA provisions will impact the utilization of physician services, including first a Medicare prescription drug discount card, available in June of 2004, the new Medicare benefits for a long list of preventive services, and the new Medicare prescription drug benefit that will become effective in January of 2006. It would not be appropriate therefore, for CMS to include the cost of the newly covered prescriptions drugs in SGR and we recommend that PPAC urge CMS to provide assurances that the agency does not intend to do so. Further all of these new MMA benefits are going to significantly expand expenditures for physician services. Example: More patients are going to be going to physicians to get prescription drugs and one of the new preventive benefit tests that these patients will have to be monitored by their physicians much more thoroughly and closely for the impact of these drugs and for follow up tests, and will probably also, there will be uncovered other conditions for these patients that are going to require a good deal more care. Even more important to that is one of the concerns that we have is if we think the error problems and the problems with adverse drug effects are of significance in the hospital, that pales in comparison to those adverse drug events that occur in the out patient setting. So what we're doing here is opening up a whole new potential adverse drug event and errors and a significant safety problem in the out patient area, which is going to increase costs tremendously. So we urge PPAC to recommend that CMS include in the SGR

the direct and the indirect increases in spending that'll be resulting from the MMA benefits, including the additional services that are going to be triggered by these benefits.

Third, we urge PPAC to recommend that CMS establish work values for vaccine administration codes. Now vaccine administration is a unique service involving distinct physician work. Especially with an earlier and sicker flu season such as the one we have currently, or had this year. It triggers a vaccine shortage. Physicians keep a considerable amount of time keeping up with just the changes in public health policies about administration of the vaccine on a priority basis. A work value is needed to insure that vaccines are administered to as many Medicare patients as possible. I find it fascinating that we spend so much time worrying about things like SARS and West Nile Virus that kill a few people, but we lose 30,000 people a year to flu. To me that's just unbelievable. Our sense of values there seems to be somewhat on the wrong track.

Fourth, I'd like to address the MMA mandate of a new payment system for Medicare covered prescription drugs and this is the average sales price issue that you heard so much about already today. We urge PPAC to recommend that CMS ensure that the physician community is provided early notification and an opportunity to comment. And from what I've heard today, that opportunity is certainly going to be available. I hope that's what I heard. Without such knowledge, physicians may not be able to maintain enough inventory, even worse, they may not be able to afford to purchase a drug at the average sale price, and patients may thus suffer serious access problems. We've also heard that today.

Now we have specific ASP related recommendations in our written statement relating to a system from monitoring access to drugs and we urge PPAC to recommend that CMS adopt these recommendations. In addition, as part of the new average sale price payment structure, the MMA mandates the Secretary to evaluate existing drug administration codes as we've just heard and use existing processes for consideration of coding changes and establishment of related relative values. We urge PPAC to recommend that CMS again ensure that the process for achieving this mandate is as broad as possible to maximize effective input by the impacted parties. We further urge PPAC to recommend that CMS provide the Council with a timely report concerning the agency's process for achieving that mandate. The report should focus on a number of factors that are listed in our written statement.

Fifth, with regarding to the upcoming Physician Fee Schedule rule for 2005, we urge PPAC to recommend that CMS ensure that this proposed rule is not delayed to certain initiatives, such as data collection for Medical

liability gypsies, and in the event a delay is necessary, we urge CMS to issue two separate proposed rules. This will give physicians timely notice of certain information that's critical for their financial planning and the maintenance of patient access.

And finally, while HIPPA is not on PPAC's agenda today, we want to alert PPAC to some related problems with enrollment backlogs and barriers to HIPPA compliance as are discussed in our written statement. And we urge PPAC to request that CMS adopt the related recommendations that are listed. On the February 23 front page of *AM News* is an excellent article in the real world about the significant problem with this enrollment backlog issues.

I want to thank you for the opportunity to be here today and we'd be happy to try to answer any questions. Thank you.

Dr. Rapp: Any questions for Dr. Hill? If not, thank you, Sir, for coming today. The next group that was interested in providing testimony was the American College of Surgeons, but I under there's maybe a time confusion on that point, and American College of Radiology has a representative.

Dr. Thorwarth: Good morning and thank you for having us. I'm Bill Thorwarth and a practicing diagnostic radiologist in Hickory, North Carolina.

[chat]

And I hope that you all have received a copy of our comments. I currently serve as president of the American College of Radiology as well as chairing the Commission on Economics for the college. We appreciate PPAC's role of providing invaluable advice to HHS and to CMS leadership on how CMS's rules and regulation affect the practicing physicians today, and specifically in our case, practicing radiologists and radius oncologists. I'd like to focus my comments on two issues that we have with regard to the current Physician Fee Schedule. And changes that have been made with the last iteration. First, the consequences of the adjustments to the physician work and practice expense relative value units to accomplish the much needed increase in malpractice RVU and then secondly, and I will comment to a lesser extent because most of it's already been said by other commenters on our concerns with regard to the sustainable growth rate formula.

There's certain consequences with regards to the shift of RVUs from physician work and practice expense to increase the malpractice component of physician reimbursement that affects hospital based physicians and radiologists and radiation oncologists feel particularly that these need to be addressed. In essence, what's been done,

in order to increase the percentage of RVUs in the malpractice component of physician reimbursement, in essence it's a rob Peter to pay Paul that the physician work component and the practice expense component have been reduced in order to increase the malpractice RVUs. We have a couple of concerns with that. First of all, we think that it certainly does not help physicians pay their malpractice premiums if in essence the RVUs are simply being shifted from one physician reimbursement component to another. But more specifically, with regards to services that have both professional component and technical component services, radiology services being very common in that group, there's a problem in that there are three practice settings in with radiation oncologists and radiologists practice. One is an office-based practice, where the physician owns the office, they are providing both professional component and technical component. The modification have been made in the fee schedule, in essence shift those RVUs from one portion of reimbursement to another. And in essence, it's a net of zero. However, if you go into a hospital-based setting, or into an outpatient imaging facility setting, where the facility is owned by someone other than the physician, what happens is there is a net shift from professional physician reimbursement to facility reimbursement. The reason is, is because of the malpractice component of reimbursement for those codes is in our opinion disproportionately assigned to the technical component. As an example, right now, if I read a mammogram, the facility that produces the films is paid twice as much malpractice RVUs as I'm paid for interpreting the mammogram. The variation is anywhere from two to twenty-six times more reimbursement to the facility than to the physician who provides the service. Now, if you take away from the physician work, and you take away from the physician's practice expense, in order to bolster the malpractice, clearly there is a net shift from the professional component to the technical component reimbursement.

On another sphere, when you're practicing in a hospital setting, that's reimbursed under, say DRG's or HOPPS, whether it be in patients under DRG or whether it be facility-based and hospital owned facilities, who charge for the technical component of these services. Again, what happens is, the physician professional component, the work portion of that professional component and the practice expense portion of that professional component have been reduced to accommodate this shift in malpractice. But in a hospital setting, they're reimbursed under DRGs, or they're reimbursed under HOPPS, so there is no concombinate increase, even to the facility for the malpractice. So in essence what happens, there's even a potential net savings to Medicare, based on that reduction of physician work and a physician practice expense in order to cover the rising malpractice component. And this was

not addressed in the impacts in the federal rule and our recommendation is that PPAC as listed in your handout, the ACR respectfully requests that PPAC recommend CMS investigate all effects of our RVU adjustments, by examining the impact of such adjustments, acknowledge if there has been in fact a net savings to Medicare, and if so, provide information on where such savings are being realized and what redistribution impact between specialties results. If you take this out a year, again with a reduction in the professional component for these services, if in fact next year's conversion factor update is calculated based on these shifts, and it's deemed because of this reduction in physician work and practice expense reimbursement, it has not targets and therefore the conversion factor is readjusted based on that, that ends up being redistributed over all medical specialties and not those specialties that have been negatively impacted because their professional component has been disproportionately reduced.

So I think these are impacts of this methodology. It's, in essence, a systematic methodologic problem that could result in long standing reductions in reimbursement to any physician doing hospital-based or facility-based procedures.

As I say, the second portion of our comments that you have in hand are with regard to the sustainable growth rate. And most of those issues have been covered by other commenters. But again, the ACR recommends that PPAC recommend to CMS that they accept the public comments and initiate discussion on revising the update formula to bring about a more sensible methodology for more accurate physician reimbursement. Recognizing that the annual update and SGR formulas are Congressionally mandated, we believe that CMS and HHS can advise Congress, and have the opportunity to advise Congress on appropriate methodology to correct this program.

Again I think you very much for the opportunity to present and would be happy to answer any questions with regards to those issues.

Dr. Rapp: Does anyone have questions for Dr. Thorwarth?

Dr. Heyman: Could we get some sort of a CMS response to the first recommendation that he made so that we understand whether they agree with him that there is some cost shifting?

Dr. Rapp: Would that be appropriate for you, or tomorrow?

Mr. Gustafson: That would be fine.

Dr. Rapp: Thank you very much, sir.

Dr. Thorwarth: Thank you.

Mr. Hartstein: The issue that he's referring to is a fairly technical one. We have three pools of relative value units. Physician work practice expense, and malpractice, and then of course we have an inflation index, the Medicare Economic Index, that measures cost increases separately for each of those three components. And what the actuary does periodically, is they try to estimate what proportion of physician costs can be attributable to which is essentially the work component, which isn't really a cost per se. The practice expense component, and the malpractice expense component, and then what we want to do is we want to adjust the relative value units so that way they reflect those proportions because we want Medicare's payment system to reflect those types of resource costs in the way that physicians incur them. And overtime, the proportions attributable to those three components are going to change. We've heard in this panel quite a lot about concerns about malpractice. And when the actuary went and revised the index, the Medicare Economic Index, the inflation index, what they found was that malpractice, instead of being at about 3%, or 3.2%, is really closer to 3.9% of physician cost. So that's about 20% greater than what it had been in the index before it was what we call rebased. So what we did in the policy shop was we wanted to adjust the relative value units to make our payments reflect those proportions. So we increased the malpractice portion of our payment. We took the aggregate pool of RVUs for malpractice relative value units, and we increased them 20%. Except the statute requires us to do this in a budget neutral way. So we had to reduce practice expense and work to accomplish this change. And we adjusted them as well in proportion so they matched up to the weights in the MEI. Of course, is a larger portion of your payment is attributable to malpractice RVUs, this change would have benefited you in our view for perfectly appropriate policy reasons, because as a proportion of your total revenues, as a portion of your total costs, your malpractice costs have gone up and that Medicare payments through the relative value unit system should reflect that. Similarly, physician work is now and practice expense would now be a smaller proportion of your total cost and we would adjust the relative value units to reflect that. I'd call your attention to page 1100 of the January 7th rule, because we provided the impact of this provision alone on Physician Fee Schedule payments to specialties to about 51 different categories of specialties. In large part, the impacts of these provisions were almost nothing. These were very very small adjustments. They did have a result in a minor increase in payments for some of the specialties that are heavily oriented towards surgical procedures that have higher malpractice RVUs. For instance, neurosurgery, emergency medicine, and a few other specialties that receive a larger portion of their revenues from malpractice RVUs are estimated to see an increase in payments of about 1%.

I don't think there were any impacts that rounded to minus 1%. There could be some small impacts, less than a half a percent that would show up on this impact table, but the idea was that it would be budget neutral and it would be a policy improvement by directing our payments towards those services in proportion to the way they incur costs.

Dr. Rapp: So if I get this right, the malpractice goes up. Certain specialties more than others. Then the RVUs are reduced across the board to make it budget neutral.

Mr. Hartstein: Correct.

Dr. Rapp: Now, the Council previously recommended not doing it that way and to change traversion factor instead to make the adjustment that way, so as not to basically distort the work units and…

Mr. Hartstein: Yeah, this comment came up twice. It came up on the Physician Fee Schedule proposed rule. Our feeling was since it's a uniform proportional reduction, that it wouldn't distort the work relative value units. Nevertheless, that point became moot, because Congress required us to increase the conversion factor by 1.5% and we had to both increase the conversion factor by 1.5% and meet the budget neutrality requirements to do these adjustments. And we felt there was no way we could do it on a conversion factor and beat the budget neutrality requirements in the statute.

Mr. Gustafson: Can I just intervene here for just a second. I think a point might have slipped by us here that was sort of in what you were saying and I think we can get distracted a lot in the relatives, not that those are not important, but was it not the case that the MEI went up last year went up significantly because of an increase in malpractice expenses?

Mr. Hartstein: Yes. Correct. We incorporated somewhere, I think, a 20% increase in malpractice insurance premiums into the index itself, and then we gave that increase a bigger weight in the overall index.

Mr. Gustafson: So there's both an absolute and a relative effect in another words, that all physician payments went up as a result of the MEI increase, or would have gone up had the MEI been permitted to act.

Mr. Hartstein: Correct.

Mr. Gustafson: And another point I was going to make here connects to what the speaker mentioned about the possible shift—

Dr. Rapp: Thorwarth.

Mr. Gustafson: --of payments to hospitals. That's pretty difficult to disentangle. And Steve Philips might have something to add on this, but the payment rates, the way we pay hospitals doesn't distinguish malpractice as a particular element of the payments. And so to know what affect a shift of the sort that was described might have on Medicare bottom line, Medicare savings, you'd have to be able to make some assumption about how Congress would have changed the update for hospitals one way or another to reflect that effect. It's probably beneath the radar screen and it does seem to me there is a question lingering in here somewhere about the relationship of the technical versus professional components of the radiology services, and whether that might be something we should be looking at further. [inaudible]

Mr. Hartstein: I guess I would think of that as a relative value unit question, the specific points about how much we pay from malpractice to the technical component versus the professional component, and Rick Ensor's going to here to talk more about malpractice RVUs tomorrow.

Dr. Rapp: OK.

Mr. Philips: Steve Philips, former Deputy Director Division of Acute Care. Just a quick point to kind of elaborate a little bit further on what Tom was saying. On the inpatient side, the market basket update to the DRG rates includes a specific professional liability component as well. So any increase on the hospital side would be picked up in that part of the market basket, which corresponds roughly to the MEI on the physician side, so it would increase the overall payments to reflect that.

Dr. Thorwarth: I guess the point and maybe I didn't make it as well as I'd hoped, is that if malpractice as it's currently the case in the Medicare Fee Schedule, and we have commented year after year about what we feel is an inappropriate apportionment of malpractice RVUs professional component versus technical component, but with—

Dr. Rapp: You think what should be done?

Dr. Thorwarth: We think that the professional component bears the majority of the malpractice risk and we think particularly with the increasing liability premiums malpractice costs, and yet if I read an MRI, the tempera men did their joints tomorrow [??], the hospital is paid 26 times more or the facility, not in a hospital setting, but say in an office facility, if I'm at an out patient imaging center. That facility's paid 26 times more malpractice RVUs than I'm paid for reading the study. And that's just the apportionment. The malpractice RVUs were assigned

proportionate to, in essence, the sum values, so if you get into expensive technology, it sucks up more of the malpractice RVUs. But in any case, across the board, regardless of whether I'm reading a chest X-ray or any other study, the distribution of malpractice RVUs is heavier on the technical component side than on the professional. And with the new methodology, what then happens is as you drop back inventory, as you drop physician work, and practice expense, and particularly the practice expense then on the professional component side, you're doing that to pay more to malpractice, most of which is going toward the technical component. So in essence, what I'm talking about is a physician to facility shift. In the facility based setting, as was mentioned, because these are reimbursed under other methodologies that don't have a specific malpractice component, what's happening is the physician work value and the physician professional component practice expense value are going down and yet the malpractice is in this other reimbursement process that doesn't specifically identify malpractice. So I'm sorry, I just wanted to make sure that I got my point across as far as that differential.

Dr. Rapp: OK, I think we got that.

Dr. Heyman: Did we get an answer to that?

Dr. Rapp: Well we have a recommendation that that be changed, or be looked at further.

Dr. Heyman: Does CMS agree that that situation exists?

Dr. Rapp: Do you agree that he's correctly describing the paradox?

Mr. Hartstein: I guess maybe I misunderstood the first time. Maybe I'm understanding his point a little bit better, but I think the point is not really so much about the adjustments that we made in the fee schedule as it is a comparison between what gets paid on the hospital, what's included for malpractice in the hospital payment system versus what's included for malpractice in the physician payment system. And they each have two independent mechanisms for establishing payment. As Don described—

Dr. McAneny: It's tech fee versus pro fee.

Dr. Rapp: No this is, I'm not an expert on this, but like if a radiologist has their own facility, they can charge for doing the X-ray and they can charge for reading the X-ray. And when they're in their own facility, their out patient radiology office, they don't care because they're getting both fees. When they show up in the hospital, however, they don't get the technical component because the hospital does the X-ray. They just get, they now read it, but they feel that the way that the reimbursement for the malpractice component is distributed between the doing

the X-ray versus reading the X-ray is weighted way more on the technical component and then they get under-reimbursed for reading. And yet they're doing what leads to the risk. The hospital's not going to sued because the X-ray wasn't, was crooked or something.

Mr. Hartstein: Yeah, I think this gets into, I think that what Dr. Thorwarth is saying that we already pay in his view, we already pay too much in malpractice side to the hospital, and that this problem is going to be magnified by the adjustments we made because we're further reducing the technical component practice expense RVUs, so I think it's still a comparison. If all radiologists, or all people who provided services between the hospital, if they provided the exact same mix of services between the hospital and non hospital site, I'm not so sure that it would be an issue. I think the issue he's raising here is because hospital-based radiologists are only seeing reductions. They're not seeing increases, as opposed to an office-based radiologist would see both, maybe not as much as you would like, but I do think it's a pretty technical issue.

Dr. Heyman: Even if all the radiologists saw exactly the same amount of patients in the hospital as well as in their clinic, there would still be an issue over the fact that when they saw a patient in the hospital, they were taking the risk, but the hospital was getting the reimbursement.

Mr. Hartstein: Which gets back to the point of the—is the malpractice RVU correct on the physician side, or is the relationship between what we pay correct to the hospital versus the physician.

Dr. Heyman: Well, I think the entire morning has been devoted to the fact that the entire system of payment is so incredibly complex and unfair that we need a new system of payment. This is just an incredible mess. And we're going to continue for the next five years, or two years, or whatever it is talking about the unfairness of this system and how to fix it, when the truth of the matter is, we got to dump it and find something that's better.

Dr. McAneny: What we'd actually done last time was pended a motion to this one and I didn't see it on the agenda, so one of the questions is how we're technically going to do that, but the gist of the motion made at the last PPAC meeting was that it is inappropriate to rearrange the work unit and practice expense RVUs for budget neutrality reasons because those should be relatively objective things created by the RUC and the PEAC. And so we pended that motion for the same reason that CMS did not want to pursue that avenue, because they did not want to see the conversion factor look even worse than the minus 4.5% we were facing. So I think what we need to do with this meeting is to bring back the inappropriateness of adjustments to the work and practice expense RVUs in order to

achieve budget neutrality for the malpractice unit that anything like that shouldn't have gone into the conversion factor, and leave the work units the same. Plus we need to address I think this issue of the improper disposition of them between the tech fees and the pro fees.

Dr. Rapp: Didn't you say, though, that you couldn't see how one could do that with a prescribed 1.5% adjustment?

Mr. Hartstein: Correct.

Dr. McAneny: What did happen to those after the 1.5%? Did there still, was there still a decrease to the work unit RVUs, or…

Mr. Hartstein: Yes. We revised them from what was in the November 7th rule because the policy was to make the weights match up to what was in the index. And because there were new work RVUs and changes to practice expense RVUs, the adjustments change. So the adjustment to work became much smaller than it was before so a lot fewer services were affected. Malpractice was about the same and practice expense was a little bit larger. But we made the adjustments, they were just different from they were when described earlier.

Dr. Rapp: Thank you. At this point, I would invite if there are recommendations that members of the Council would propose we make?

Dr. McAneny: We need to wordsmith some more.

Dr. Rapp: You want to wordsmith? Or do you want to break for lunch and then…

Dr. McAneny: Let's break for lunch and then come back with recommendations.

Dr. Rapp: We'll break for lunch. We will come back in one hour, ten minutes to one to allow the time we're going to have.

[BREAK FOR LUNCH]

[RESUME]

Dr. Rapp: …back to order. So I would entertain if there are any recommendations that the Council would like to propose at this point? If not, then we'll move on to Dr. Wood's presentation. Hearing none, Dr. Wood's on.

Dr. Wood: OK, well ladies and gentlemen, this will be an update of the work that we have done on evaluation of management codes and to go through the presentation for today, we'll start with a little history lesson, then we'll talk about the work process that we are currently engaged in. The concept of total physician work, which

is the basis of a new E&M structure, and how clinical example serve to support that. And then we'll talk about the process we're using for example, development, and what potential next steps might be. In 1992, new E&M codes were adopted at the same time that the fee schedule was implemented. And at that time, there was no definition in CPT about key turns, like single system examinations, multi-system examination, comprehensive detail problem limiter, none of those were defined. A set of guidelines was actually developed on the basis of the work of an ad hoc group that met in 1993 and as long as historical lessons are in play here, I actually ended up chairing that ad hoc work group and we met here in Washington for three days trying to decide on some of these critical issues. That was the work that was the basis for the first set of guidelines, the 1995 guidelines and those guidelines were criticized for several reasons, including their now famous bullets, their tendency to clutter the medical record with unnecessary verbiage and the concern that they disadvantaged some specialties, and in particular, I will share the end of that three-day meeting, there were four specialties for which the work group concluded that there was no way they could ever bill anything above a level three service. Because they wouldn't meet the definition of a comprehensive single system examination in their specialty. And many specialties, actually, in that meeting withdrew offerings that they had for single system examination because there was literally no way that you could define a single system, and if you look at those single system examinations that are now recognized, they all look at more than one system. And the reason is they had to meet the work equivalents of a multi-system examination. The RVUs that were related to multi-system examination had to be matched by a single specialty or a single system examination.

Well a few years later, there was another effort, and this was in '97. At this time, however, there was a grace period, that HCFA used to try to implement these. And after the grace period, there were some very significant problems identified, so these guidelines were never officially implemented. They were delayed indefinitely and physicians were given the chance to use one or the other and then a couple of years later, another effort was undertaken and this one was then referred to as the new framework. In 2000, after review of the '97 guidelines and the new framework as proposed by the editorial panel, then HCFA decided that both the 1997 and '99 framework had serious flaws and that they should go back to 1995 and try some alternate approaches. Now, there are two important things to remember about what HCFA was interested in at the time. And Paul Rudolf, who was formerly the executive director of PPAC, was leading the project at the time. And his concern was that we ought to be able to find a way to simplify documentation and eliminate bullets if we could. And we ought to be able to make code

selection easier and the idea was perhaps medical decision making would be the primary criterion for service selection. And so that was the basis of at least two pilot projects. Now at the same time, there was a feeling that perhaps we could make this better by collapsing the number of codes in five-level families down to three. And that was also evaluated. And that was one of the concerns that led to decisions to postpone that project. PPAC was the group that was reviewing the work in that project, and in 2001, when the preliminary results were back, this body actually recommended delay, and in a sign-on letter, a number of specialty societies also recommended delay and so the project was abandoned. And at that point, CMS decided it should think about having its own task force to address the problem on E&M services. The editorial panel was also concerned about the process, and after a period of discussion, both CMS and the editorial panel decided that they would appoint a joint task force to address these particular problems. The membership included representatives of specialty societies and editorial panel members, and RUC committee members, one Medicare Care and Medical director, and commercial care and medical director, and we had active participation from CMS policy staff as well as CMS program integrity stuff, and they were very helpful in the early parts of our work in figuring out why we needed to go certain directions. So I'll highlight that for you a little bit later.

Dr. Heyman was the PPAC representative on this group and there also was a representative from the AMA House of Delegates Ad Hoc Task Force. It was a separate task force on E&M appointed by the House of Delegates that had been meeting for about three years before we actually started our work. Now, we started in January of 2002, and had six meetings, lots of conference calls. We had public testimony from specialty societies. We looked at public and private sector E&M frequency data, examining trends and patterns and specialty and aggregate utilization. We looked at actuarial analysis of E&M utilization. We surveyed practicing physicians over their use and understanding of E&M codes, and used that to help us decide how to proceed. Now, we identified a number of problems with the current system. The structure itself is relatively complicated and so is the rule system for using the codes. And the documentation guidelines have always been problematic. The adversarial environment between providers and carriers I think cannot be over emphasized and I'll share with you a couple of observations about that in a moment, and it's also important to recognize that there have been some substantial changes to medical practice. In fact, if you look at the results from the NAMC survey, the National Ambulatory Medical Care Survey that CDC does, the 2001 data have just been published, and they're very revealing. Because what they show is that in the year

since 1992, when the fee schedule was put in place, and the current set of E&M codes had been put in place, medical practice has in fact changed. Patients are older, they have more complex diagnoses per visit, they have more medications managed per visit and there are more and more visits that involve therapeutic decisions either for imaging of other diagnostic procedures, or actual treatment. So the complexity of medical practice is increasing in the last ten years, but if you look at the patterns of code utilization, they have been relatively stable. And the reimbursement has also been relatively stable. So there is a significant disconnect between what is actually happening and complexity of office practice and how office practice is being reimbursed. The current system also tends to emphasize clerical skills rather than physician skill, physician intellectual skills, and leads to a number of problems with the medical record, including the fact that you end up doing things that you don't need to just to be able to bill what you think is a reasonable level of work for the service that you had done. There is some additional work that comes into audit, particularly because the added verbiage of the record may sometimes make it a little hard to determine what was medically necessary or appropriate. To review some of the limitations, you have five service levels, but four levels of history exam and decision making and for code selection for some services you need three out of three key criterion. For others, you just need two out of three, and in other circumstances, you can use time as a secondary criterion. We've talked about this particular problem, and many of the people who worked on the task force, the first task force I should say, recognize that increasing, especially in subspecialty practice, it is not necessary to require examinations. Just to give you an example, I do cardiac electro physiology. And so if I'm asked whether a patient needs a cardiac defibrillator or not, the only thing I need to see is a piece of paper that has ventricular fibrillation on it. I don't need to examine them to know that they need the defibrillator. However, the service requires if I'm going to bill for a consultation, the service requires that I do an examination and if I want to bill at a four or five level in key components, it will have to be a comprehensive single system examination in that regard.

There are a couple of other pieces here. The error rate has been a problem for a number of years. The error rate is calculated on the basis of dollars. And so it's important to remember that on that basis, overpayment will always exceed underpayment, even if the actual transaction rate is the same. That is, if the over coding rate balancing the under coding rate, the error rate will still be a positive number. And Care and Medical Directors often

misconstrue medical necessity for medical decision making when we're looking at the documentation. And they will often deny on one basis when they mean something else.

The other difficulty is how this system actually works. There have been published studies in the literature in family medicine practices, internal medicine practices and emergency room practices, where specific services were handed to coding experts and they were asked to then code the service. And the concordance of their findings has always been very low. They get capa scores of point three, which means that they agree only 30% of the time. So 70% of the time, experts in coding who disagree about the assignment of the code, however in those circumstances, the code level is never more than one off. So there is a natural distribution then, of codes that actually exists. And when you look at the coding patterns and when we were looking at the patterns of specialties over ten years, we found that there was in fact a relatively natural distribution of codes by physicians over about three levels. And it was somewhat specialty specific. Some specialties would use one, two, and three. Others would use three, four, and five. Others would use two, three, and four. But there was fairly consistent over the years and that was an important piece for us as we were deciding what we wanted then to do in the long term. We've talked already about the important change in medical practice. And the impact here is that as you take care of patients who have more and more chronic conditions, you may have to spend more time in things that are not well recognized by the key components of the service. And in particular, we heard from many specialties who take care of patients with chronic conditions that the 1992 framework doesn't really help them in recognizing the value of the work that they do in caring for patients with chronic conditions. And the testimony I think you'll hear later today from the Academy of Family Physicians, this is an ongoing problem for them as well as when we heard in our own testimony from the geriatricians.

Our research findings were illuminating. 60% of respondents told us that they found a clinical example very useful and that they used them. They also told us that they more often used medical decision making in examination than they did in history and that about 40% of the time, physicians did use time as a basis of selecting a code. Very disturbingly though, only one of five users thought that the instructions for code selection were clear and a third of the people who've used their own criteria. We didn't ask them what their criteria were, but they had their own criteria. Not the ones that are published in CPT and not the ones that are published as part of the documentation

guidelines, but something innate and the Heyman description for this, by the way, was "gut coding." But that's the way that it was.

So we set about our work with a mission statement of working to develop a coding system that physicians can use to report their service while practicing medicine according to the needs of the patient. We adopted several principles to follow. The system has to be easy to understand and use, in contra-distinction to the current system; that codes should be clinically meaningful and the services have to be described in a way that allows you to differentiate one service from another. There should be some code consistency. There's consistency between families. The choice of a code ought to be easy. You should have to try to think more about what code to select than you actually did in the service, and sometimes with the documentation guidelines, it takes you longer to think about did I have all of these bullets in place than it did to do the service. And there ought to be maximum flexibility in demonstrating level of work. If you think about it, the current guidelines would say, OK, for a dollar of work, I have to for a certain level, I have to have 35 cents worth of history, 35 cents worth of examination and 30 cents worth of medical decision making. But for the same level of work, if I wanted to report more medical decision making, and less examination, I can't do that. I can only report it one way. That's how prescriptive the actual code descriptors happen to be. So that was a particular problem for us as we went forward. And we also did not want physicians to have a reduction reimbursement of implementation of an improved or simplified coding system. There were some, by the way, who thought that the easiest way around this was to just to go to a three-level coding system for all of the codes, and if you want any proof of why that will not work, if you examine carefully the overpayment reports you will notice that one code in particular, that is of a three-level family, has a high error rate in it. That's subsequent hospital care. So intuitively the idea that the three-level code is going to be less complicated and have fewer errors than a five-level code is in fact not true. And then last, the coding system has to reflect contemporary practice. Now this just reminds you of the components of physician work and it is also a reminder that in any particular service, there might be a different mix of each of these components. In looking at how we wanted to proceed, we recognized that this different mix was a reflection of the evolution of medical care over the last decade, and that there will often be circumstances where varying amounts of history and examination will be necessary. There are not all the same every time. So there had to be some flexibility for physicians in how they would determine total physician work. Now we actually thought about lots of solutions. One was to maintain the status

quo, but just try to change the documentation guidelines. We didn't like that too much. It had already been tried twice, and nothing had come out of that, so that one was put aside fairly quickly. We did consider the idea that we would just base everything on time, but that would not be terribly helpful, especially in some of the more complicated specialty situations. It was also suggested we think about a three-tiered approach to code selection, simple intermediate and complex kinds of patients. A single E&M code was suggested and it was suggested that we revise the new and established codes and create a modifier for consultations, so eliminate consultations as a primary code. We also thought about creating a mechanism of demonstrating the complexity of a patient regardless of the code type by using ICD9 codes to try to develop for you some measure of disease severity that you could use as a proxy for the complexity of the care of the patient and then weight the work that you did in the service that way. We did consider the proposal that came especially from California in terms of looking at out-lyer analysis as a basis for audits. And that was actually one that program integrity told us about early. And they said, look, as long as the codes are set up in a way that say that you have a very prescriptive amount of work for every code, we're going to go after every code that way. So one of the things you have to consider is how you're code descriptors are currently written. If you want to get away from some of the concerns about our audit. We also considered using two out of three key criteria for all code selection. But again, that would not solve the underlying problem that program integrity staff had mentioned to us. That is the codes are indeed quite prescriptive. We contemplated reducing the number of levels of service to three or maybe four. We thought about creating global period for E and Op services. Part of the problem with this is in essence they have a global period of their own now because there is infra service work and then pre and post service work. And so there is a global period. It's not very well defined, but it in fact it exists. The only part that's been valued for the service is the infra service work. All the specialties that have provided testimony to us told us that the infra service work over the decade of implementation of the new codes has been shortening. But the post service work especially has been lengthening and increasing in its intensity. And the difficulty then was how do you balance that shortening of the infra service work while you can still recognize the post service work you've done on the back end and then the other conundrum is where does post service work from a visit stop, and pre service work for the next visit begin? So we never were able to get past that particular discussion. And the last was to maintain the current levels but revise the descriptors and rules for code selection to allow maximum flexibility and the reason we opted for this last point was that if you look at again coding patterns, physicians coding

patterns are relatively stable. Where they get into trouble is then on the back end where you come into audits. Now total physician work. This concept represents a combination of the key components; decision making and a clinically appropriate history and examination, not one that's defined by the code, but indeed a clinically appropriate level of history and examination and the time that necessary to evaluate and care for a patient. And so we created new structure that would be based on the concept of total physician work. And in this particular circumstance, rather than have the codes be very prescriptive, what we would do is have a set of codes that would be based on reference levels, and examples would be used to guide code selection for reference levels. So for a five-level code family, you would have a reference code at three, right in the middle, and then a reference code at five. On the top. And the idea was that you would then develop examples that physicians could use in selecting a code and that ideally if someone picked up a record, and looked at a progress note, they could look at that note and they'd say, that is a level three, that's a level five, that's a level four. They would be able to recognize it intuitively without having to sit down and go through counting of bullets. So that was the original goal.

Now we did a few other things in the structure. These included eliminating confirmatory consultation codes, eliminating inpatient follow up consultation codes, crafting a new set of concurrent care codes to use in the inpatient setting and there were some revisions that were necessary to the nursing home codes that we incorporated. Now this system would run on clinical example, so why are the clinical examples important? They are important because they have to accurately represent physician work. And if you look at the examples that are currently in CPT, they're all usually relatively short and some of them describe some really unusual pitches that you don't just see every day. And so what we really need are a set of examples that describe real life medical practice. Common patients, common conditions, and which would describe the total physician work. At the same time, they have to reflect differences in work for new and established patients at the same level of service and you have to also be able to show the difference between say a level three and a level five service. They have to also be used carefully. They should not describe a standard of care, but instead, what is common and usual for a specialty. We thought that in particular, it there were groups of physicians who were seeing really complex patients who have lots of chronic conditions, that this would be a good opportunity to write a series of clinical examples that would describe the patient coming with four problems, seven drugs, or ten drugs or whatever, and make it very easy to them look at what work had been done, in the service that had been described.

Now we set out a process for development and review of clinical examples. You may remember some of us have been with this group long enough that when we were talking with CMS about the original project that was done with Aspen, when it came time to do the pilot projects, program integrity insisted on the fact that there could be no grace period and there could be sort of hold timeless clause for physician who participate in a trial. So that if you did this real time, you would expose yourself to pretty significant risks. That didn't soften any in the discussions. And so we set about to look at a different set of approaches. And what we settled on was a process where we would go back to the specialty societies and ask them to develop examples and then before implementation, we would actually do a process where we would survey physicians and have them do the coding to see if we could do a reasonable job of achieving our goals and to reiterate, there were three very critical issues that were in the back of our minds when we started this. First, code level accuracy, meaning that you got the right code chosen; work equivalence, so the level three work that I do as a cardiologist would be equivalent to the level three work that Dr. Urata might do as a family physician; and then last would be the utility for Care and Medical Director review and physician audit protections. So many physicians told us that as much as they dislike the bullets, at least when it came down to the time of having a fair hearing, or if they would go far enough to go to a AOJ for an appeal, they could at least look at bullets, and count bullets in terms of defending their documentation. So that was an important piece for us to consider.

We set at this by asking eleven specialties to develop examples for some common conditions and specialty conditions. And we assigned conditions to specialties. And we took things like back pain, chest pain, abdominal pain, sore throat, and we assigned them to different specialties and the reason for that was to give us a sense of work equivalence. So we could see how an ENT approached a patient with a sore throat and how a family physician would do that. Or how an internist and a family physician would approach a patient with abdominal or chest pain as opposed to a gastroenterologist or cardiologist doing the same. In the circumstance then we asked each of the specialty societies to take usually their coding committees, a group of physicians who of the specialties will tend to have the most expertise in these kinds of issues and have that group develop the examples. And then on the basis of the work done by those committees, we would send it out for survey, and we would have physicians in practice then code those examples. This is a more extensive piece of work than was done for the 1992 implementation. Because in the 1992 implementation, after Shall and his colleagues did some work on a few basic codes, they actually just went

to internists and family physicians offices. They did not look at work equivalents across specialties and they did not survey specialties. So our approach here has been a bit more extensive, and as a result, it's actually taken us a little longer than we thought, and the survey actually was a little bit longer than we thought it would be for physicians who were responding as well. But our goal here was to test code level accuracy, and then begin to also look at work equivalents. After that point, we're currently at that point. The results of that first phase are not being collated at AMA and they will be presented to a meeting of the Task Force on March 12th. But if it looks like we can achieve code level accuracy, then the next step for us would be to go to Care and Medical Directors and see then if this would work in actual practices. Can they use it to make their jobs easier? And would physicians then have audit protection? So if you lined up an actual progress note with an example that it makes sense, and could a physician then sit down with a Care and Medical Director, and easily make the Care and Medical Director understand what service the physician in fact had provided? After that, if necessary, we might go through the process of conducting more intensive cross specialty surveys for work equivalents, although this is a very difficult subject and it was one that again, if you go back to 1993, when we started trying to talk about work equivalents, between a multi-system examination and a single system examination, there are going to be some significant problems in that assessment, and so I don't think that it is possible to say that you will always be able to show in the current coding system and in any example, absolute equivalence of work across specialties for every level of coding. So if we can do it on a general basis, I think that would be sufficient.

Now, Phase I again is confined only to eleven specialties and not all codes and so in Phase II, what we would need to do is expand to additional specialty societies and additional codes. We did not want to do a huge effort for all specialties and all codes if it was apparent we were going to have some difficulties. It would be better from our perspective to do this on a smaller survey of physicians. And so that's why we've broken it up into phases. And if at any point in Phase I, we find any concerns about how we're going to be able to make this work, then we have the ability to stop or pause and reconsider the position without having to force everybody into a solution that not everybody would like. So we are now at this decision point. As I mentioned, we will have a meeting on the 12th of March here and here in Washington that is, and as we see that, we'll have to make a decision about it and go forward. I have not seen the final data so I can't tell you exactly what we're going to be able to do.

Philosophically, my only concern is that physicians have been down-coding for so long that I'll be very interested to see what coding experts, that is the coding committees of the specialties have figured should be a level five service. If their colleagues in practice code those as level fours, that's going to be a really interesting conundrum for us to deal with. And I do worry that that might in effect be the case.

Now a few other thoughts. The Medicare and Proper Payment report has some very interesting reading. The high level summary that was presented at the last PPAC meeting, but as you look into the detail, let me share a couple of thoughts with you. When we're talking about coding errors, we're really talking about only a very small part of total Medicare improper payments. In the improper fee for service payment report of 2003, coding errors accounted for only 12% of all improper payment error types. So E&M coding is not in terms of percentage piece, is not a big piece. Another important consideration is that no documentation was a problem in 2003. There was much speculation about why this in fact occurred, but in order to complete the report, methodologic adjustments were made and one piece to remember here is that if the adjustment had not been made, the portion of the paid claims error rate due to provider non-response would have been 55% and the coding error rate would have actually been only 6.7%. So whenever there are corrections that are made to data sets, you always have to kind of wonder well what does this mean, and how does it skew the data?

There are a couple of other points. This actually shows the percent claims error rate. And what you see here is that from about 1998 on, the error rate is relatively stable. This actually also tends to match the coding patterns that we saw when we look at coding patterns as part of our work. After the '95 guidelines were established, the coding patterns of specialties settled down about two years after those guidelines went into place and after the specialty societies had had the opportunity to go forward and do the education of their members. So about a two-year lead in. Now if you put that together with this slide, what it begins to suggest to you is that in fact for the last six years, the coding patterns have been stable and the error rate is stable. And when you consider the inherent complexity of the coding system, another interpretation of this slide is that what we are seeing is what could be called natural error. Or an expression of the fact that you have a complex coding system with new providers that are entering the system every year that have to constantly learn. And the question is how far can you drive this rate down? Again methodologically, it would never be zero because of the calculations that have been made. Could you achieve a 4% error rate, as has been suggested? Maybe. But it may be that we can't do very much better. This is the

same slide, but just in terms of dollars. Now what we didn't do here is if you actually consider how many millions of E&M services there are, and you broke this down to a dollar per claim, it might be a pretty small number. And you might then see why physicians don't really bother too much to send things in when the amount in question is so small, it costs you more to send the documentation in than it does to ever do anything else with it. So that's another particular problem in terms of looking at how much you can make this get better. There is a point of diminishing returns. And indeed and I think it's important for CMS and contractors to ask what that point of diminishing returns might be. And that gets to the point of this slide. If there is a natural error rate, and in particular, if individual providers and practices show a relatively low error rate, then perhaps we should leave those areas alone and concentrate our efforts in other areas. It's also important to think about what we want to look for in terms of the error rate. Is it the sensitivity analysis, which is dollars paid? Or is it the actual transaction rate? For CMS purposes, the sensitivity analysis is important because those are dollars that can be used for something else. So you can't ignore that important piece. Now there have been some concerns raised about CMS direction by some of the specialties. We actually have been told that folks are worried that unless we can get some guarantees from CMS before we move forward, they're not interested in the new system. That is one of the reasons that we have had CMS involved in this project from the beginning, and why it's very important that program integrity in particular needs to get back at the table. There have been turnovers of staff at CMS, both from payment policy and program integrity. We've had recently good continuity on the payment policy side, but the turnover in program integrity has been really complete and so at the moment, we have a little bit of a gap and are hopeful in our discussions with program integrity folks we can get them re-energized, and re-engaged in the process.

As you think about what opportunities there might be for additional collaborative efforts, here are some. We know from the improper payments report that there are certain specialties that tend to have a higher error rate than others. And what would be very interesting, is to look at the codes and the error rate report that are high in terms of errors, and then if we see a similar pattern developing in the work that we are doing, that might offer us a very substantial opportunity to concentrate our education and example development. And in that circumstance, we might actually want to do a lot more example development for those specific specialties so we can do a better job of helping them and choosing codes, and then helping medical directors in their audit activities. And in that

circumstance, what we might want to do is to look at the specialties that have a higher error rate and see if we can engage them in more aggressive and more detailed example development than we have so far.

There may be some opportunities also, in a pilot project with Care and Medical Directors. We haven't discussed that yet. We're not at that point, but as we get to that opportunity, then we might have some additional chances to do some work that could help both CMS and physicians. And I do remind you that the Medicare Modernization Act, or MMA does require pilot projects before any new documentation guidelines are put in place. And I think that again if we can get everybody back at the table, especially as we're getting the data together, we might have an opportunity to redirect our efforts in a direction that could be helpful for everybody. So we're at a decision point soon. It reflects about two years of work. It's been a little slower than we thought at the beginning. Only because we wanted to do more work to make sure that we had this right before we moved into wide scale implementation. I can't prejudge what the results are going to be, so we just have to wait and see, but we appreciate the opportunity to share with you our progress to date and at Dr. Rapp's discretion, I'll be happy to entertain questions or hear comments.

Dr. Rapp: Questions? Comments of Dr. Wood?

Dr. McAneny: With this whole process of the E&M guidelines and doing away with bullets, so that no one can count them, currently, a lot of the coding for example with hospital stuff and physician Dopplers is done by coders who go through the, and fill out this humongous form that says how many bullet points. Are they going to be able to do that? And if somebody comes back later and challenges it, how would you defend it if you, I'm not defending counting the points, which is an irritating thing. I'm just asking how you would do it in terms of protecting yourself when you get audited and they say well you may have said that you spent a lot of time agonizing over this decision with the patient and the family, but we don't buy it.

Dr. Wood: That's exactly the concern about audit protection. So what the examples have to reflect is they've got to reflect the work that the physician in fact accomplished during the service. So what we're hoping for is the examples will be written in a way that is pretty clear that there was a fair amount of work done in thinking about differential diagnosis, test order, therapeutic interventions with some risk, medications to prescribe, medications to coordinate, multiple chronic conditions. If we can do that well, then it ought to be easier to show at the time of an audit or a concern raised by a Care and Medical Director that in fact that was the service. And that's

one of the reasons that we identify that as a significant issue or piece that needs to be addressed before we would go forward. So we have to solve that problem.

Dr. McAneny: Does it mean that the current bullets of saying: I have [something in Chinese?] system be replaced by: I considered the following 27 drugs to use for this and eliminated them for such and such a reason. I considered the 27 but possible diagnoses for this. I mean will we end up having to chart that kind of macro instead of the other kind of macro?

Dr. Wood: The goal was to spend your time documenting what was clinically appropriate and relevant. Not having to do any additional work.

Dr. McAneny: I sort of appreciate the goal of getting the chart back to something that's a useful tool to convey what one physician things to the next one. But I do worry about conveying what I think to someone from the OIG.

Dr. Wood: Right. That was a concern and we had that as one of our significant issues and that's why the goal is to have the Care and Medical Director do this real practice and see if it would work.

Dr. Urata: Just give me a little background in understanding this. Did this whole issue come up back in the '90s because for the purpose of making it easier for somebody to audit us? For CMS to audit?

Dr. Wood: Did the documentation guidelines [inaudible]?

Dr. Urata: Yeah.

Dr. Wood: No, actually, remember that in 1992, when the codes were adopted, there were a number of new terms and rules for use and no one understood what they were, and no one understood really what the basis of determining the appropriateness of payment would be. So the Care and Medical Directors obviously have to look at a service and say, well I understand that that was a level four service billed. It was a level four service that was delivered and then was it a level four service that was appropriate. So in order to get to the idea that it was a level four service delivered, that's where the documentation guidelines came in. And that, they hoped would, I think, help them a little more in making that last decision; that was the medical necessity of the piece. So that's where those original guidelines came in.

Dr. Urata: So in a sense, it was for auditing?

Dr. Wood: Well, it was for making sure that you were paying an appropriate—that you got what you paid for. Still an important piece.

Dr. Heyman: I wanted to address Barbara's concern. I think the idea here is that if you can establish what's a normal level three, people don't get audited because they do too many level twos and level ones. They get audited because they do too many level fives. So if you establish a level three and level five, and you look at what that general level three is supposed to be, if you do something that's more than the level three, but less than a level four, then it's going to be a four. And if you have an audit, the most you're going to argue about is one level. And frankly, my own personal feeling about arguing about one level is that it's ridiculous because no two coders can agree on a single level. But I think that it makes it easier for us to code if we know what a level three is and a level five and we just code either a level three, four or five, or a level two if it's less than a level three. And I think it makes it easier for those who might want to audit us if it's pretty plain what a level three is and what a level five is. And I just think it takes all of that, what I consider to be harassment, and you're right about the gut thing. I mean, you know, I do most of coding on the basis of time now, because as far as I'm concerned, the rest of the coding is ridiculous. So and I actually had an OIG guy come up and introduce himself to me at lunch one day, when I showed how I actually, when I actually told him my whole practice was coding, which was basically the type of exam we were doing. So I just think this is a much more reasonable way of doing this and we don't have to find ourselves documenting a bunch of stuff that we don't really need to do just for the sake of getting paid. So I think this is a vast improvement.

Dr. Powers: I am by nature obsessive compulsive, and then I was also raised in the Hearst rate system where we had to have 172 points with review systems, but I was very nervous about this at first. About not having my bullets to document with. The more I sit here and listen and think, I'm actually very glad, because in the old system, the bean counters are going to come in. I see an ALS patient for the first time and I know that's what it is and we have a lot to talk about. And I need to spend that time talking and if I miss one vital sign, all of the sudden I'm dinged from a five to a four or three, and yet you miss the point completely. And with this new system, just looking at the diagnosis, you're going to assume that this is—just because I missed one point in the sensory exam, it should be that important. So I'm actually happy. I hope it works. I don't know if it'll work, but I hope it works. It should work.

Dr. Wood: We don't either. We'll have to find out.

Dr. Bergeron: Yeah, I want to commend you and your committee for the excellent work you've done. I did just exactly what Joe said and I did everything with my 99213 and I was still audited. And I still went over an inordinate amount of time. So you know what I do now? A 99212 because I don't want to be bothered again, and I just work two extra patients in in the afternoon, and it washes out. So basically, I don't know what the answer it. It has to be better than that. Because as a dermatologist, I know we definitely under code most of the time because we don't want the—I mean, hey, everything documents. And this is the fifth time I've been audited because we have big volume. We see a lot of Medicare patients because their insatiable demands. I go into the room: "How about my toenail, Dr.? My hair's falling out. I'm on forty different drugs. Got a skin cancer. Got actinic keratosis. My hemorrhoids are hurting." Basically, come on, you know? So right now I said I don't want to be audited again. I've had five audits and you know I'm through with them. Give me a 99212 and I'll just work two patients in at the end of the day and wash it out.

Dr. Wood: I don't think you're unusual in that regard. Especially many people that have to deal with chronic patients. Lots of problems to deal with. They often end up, just because it takes them too long to document what they would otherwise, they often end up down coding.

Dr. Bergeron: But I want to commend you.

Dr. Rapp: Could I ask a couple questions here? First of all, I'm not sure even after that I understand exactly what the new system is. Is it a system of you just have five levels and then you have some examples and this case is like that case and that's it?

Dr. Wood: I didn't bring the code descriptors to show you, but briefly what a level three reference code would be: An out patient E&M service for new patient involving the level of work described in the referenced example for this code. And then you go to a table of examples and you look at the examples to help guide you on the code selection. And the examples would be, will have some specificity to them, but you could use any other example that you want to. What the codes would not say was that you have to have a detailed history with a comprehensive single system examination or detailed decision making. So they give you considerably more latitude in terms of choosing the service. And the example is intended to help you pick the service. So if you took you practice, your group might develop a series of examples at a level five that would be an acute MI patient with the cardiogenic shock. That would be an easy level five. And a level three would be something like chest pain in a

young person who wouldn't have any significant risk factors for heart disease or something like that. I mean we would depend on each of the specialties to set their own examples of what they thought was appropriate.

Dr. Rapp: There was a time that there were examples. What happened to them?

Dr. Wood: They are still in the

[START SIDE FIVE]

[Dr. Wood cont.] book. And many people use them. In fact, our research indicated that 60% of the people use them to help them choose a code. Many of them are relatively short. Only a sentence at most and they often actually include a reference to a diagnosis, or a diagnosis is fairly easy to figure out. Like aortic stenosis, heart failure, hypertension on two drugs with side affects, that sort of thing.

Dr. Rapp: Right. Why is this system better than the CMS was doing this with ASPEN, doing a consultation. They were developing vignettes, right? Why is this better than that?

Dr. Wood: Well, they wanted to look at the concept again of trying to use some sort of example. There were a couple of concerns I think that were raised about the ASPEN project. The first of them was that there would be a move to try to consolidate to three codes in the five level families in particular.

Dr. Rapp: And what's wrong with that?

Dr. Wood: Well there may be several things wrong with that. First thing wrong is that it forces a significant redistribution of payment among specialties. So there are some specialties that would be huge winners, and some that would be significant losers. It was also, and again if you look at the payment error report, there's some very important in it. If you conceptually think about three-level code family as being inherently easier and prone to less error, and that was the argument that was presented to us by proponents of going to three level codes, I would ask you to go back and re read the error report very carefully because it identifies one of the codes that has the highest error rate as being a three-level code as subsequent hospital care. So that's pretty persuasive evidence in my mind anyway, my own interpretation that the idea that you simply go to three levels will eliminate the discussion. There are always going to be problems about what is the change from one level to another. And the fact that you condense a five-level series to a three may not necessarily reduce the number of errors or disputes about whether you're in the middle level or a high level or middle level or low level.

Dr. Rapp: Other questions?

Dr. Heyman: The other problem with the ASPEN proposal was they were going to give you clinical examples for all five codes. And then there was going to be less flexibility for you to be able to figure out if something was between one code and another code.

Dr. Wood: And they wouldn't have been developing any specialty societies to represent.

Dr. Heyman: And the first initial group of them were so absurd when we saw them that that was a problem as well.

Dr. Rapp: OK. Dr. Urata, then Dr. McAneny?

Dr. Urata: Do you need a recommendation from PPAC regarding the energy level of CMS or the concerns about CMS's direction?

Dr. Wood: We obviously are anxious to reengage Program Integrity so that I think would be helpful from our perspective. I think we will. We've had some discussions from Program Integrity folks, so I'm optimistic that we can get them back into the loop.

Dr. McAneny: I had a recommendation I wanted to do, but I also have one question first. And that is, how much of the soft time concerns in terms of some patients it just takes longer to get to a decision point than others. You know if I'm explaining acute leukemia to a member of the Navaho nation it takes a little longer than to someone who's world view includes cells. How do you—or there's just some families where every decision is painstakingly dissected and it just take a lot longer.

Dr. Wood: Two ways to do that. One is we left time in the codes, so you could use that as a guide. And then we left prolonged services in so you can do that, too.

Dr. McAneny: Then my recommendation was that CMS request that, or that PPAC requests CMS and Program Integrity work with the E&M work group to facilitate a pilot project for the new E&M coda exista by providing some degree of hold harmless policies and grace periods so that the new system can be evaluated for accuracy and for ability of physicians to avoid audits or successfully defend themselves.

Dr. Rapp: Is there a second to that?

[Seconds]

Dr. Rapp: Is there discussion?

Dr. Heyman: Would that meet your needs?

Dr. Wood: I think all we really need is just to get CMS Program Integrity kind of back engaged in the discussion. We've gone round and round with them before about the concept of immunity and there are some very—I'm not a lawyer, but I do understand the lawyers concerns about what those terms and words mean. So you've got to remember that the CMS folks were really contributing heavily to this. They were in fact writing examples. They were engaged as part of the work group. So I think if we got them back in the work group, really at the same level of energy and contribution we would have a much better long term product, regardless of where we end up actually. And the reason I say that is because this is a very complex issue. Coding for cognitive services has changed over the years. I think all of us are struggling with how we need to make it more applicable to modern practice and for the future. And having that dialog would be very positive for going forward.

Dr. Rapp: Just a note. I happen to have the conference agreement on E&M for the Medicare Act, and the recent changes and it's rather complicated as to what has to be done on pilot projects. For example, it says that pilot projects have to be done to test any new guidelines and it has no other stipulations, and then says that pilot projects are required to be conducted on a voluntary basis in consultation with practicing physicians, be of sufficient length, no longer than a year, to educate them on the guidelines and a range of different projects would be established include at least one project that uses physician peer review method, that evaluates medical record information and alternative method based on face to face encounter time is conducted and services furnished in a rural area in one outside a rural area, in a teaching setting, in a non-teaching setting and so on and so forth. It's rather, very specific.

Dr. Wood: Right, and those actually are I would suggest somewhat independent from what we are doing, and even if we did nothing, if CMS wanted to go forward with new documentation guidelines, they would have to meet the requirements of the statute. As we would go forward, I mean if we get to the point of offering a larger projects, then we would have to fit into that framework.

Dr. Rapp: So basically it's going to come down to, what is this hold harmless? I'm not sure I understand that. Why is that necessary?

Dr. McAneny: I think a lot of folks as they talk about this, they say if I try out this new system and you decide that I'm up coding, I don't want you to be able to come in, do trouble damages, and extrapolate it to my whole practice if I'm one of the volunteers who say you can use my practice to do that. So what I was trying to

convey to that is not to play lawyer as much as to say, "I'm concerned about trying out a new system and then having somebody say 'you tried it, thank you very much, now we'll nail you.'"

Dr. Rapp: But the trying out the system doesn't have anything—your trying out is going to be something that—

Dr. Wood: Well, see the reason that we've done it this way is to get around that particular problem. We're not going alive with the system where then you're filing the claim, and you would be then potentially held responsible for an erroneous claim.

Dr. Rapp: You'll just test it as a test without actually billing under that basis and then in so far as CMS decides to use that, they're going to have to have pilot projects that have four or five stipulations here as to what they're going to be. Before they're ever adopted. This is, so you're like, after they do their work, after CMS does this and has more pilot projects and they finally implement it, then for a period of time after that, they're not supposed to be able to use them for enforcement.

Dr. Wood: I think the concern here is exactly what Barbara was saying. That is, in the pilot projects, if you were participating in the pilot project, and you made a coding error, then the Program Integrity folks have told us that they need to go after that as aggressively as they in the current system, because it's an overpayment and their responsibility is to protect the trust fund by recouping over payments. The point of the pilot project actually is if in the pilot project, you're trying it out to see if it's going to work, nobody's agreed about what the right answer is, so how can you hold a physician in error when nobody has agreed what the right answer is.

Dr. Castellanos: Nobody would volunteer.

Dr. Wood: Right, nobody would volunteer.

Dr. Rapp: And then they're supposed to make a report to Congress no later than October 1, 2005. OK, could you read the recommendation back?

Dr. Heyman: Could we discuss the recommendation a little more?

Dr. Rapp: Sure. I'm just trying to make sure I got it straight. But go ahead and discuss it while.

Dr. Heyman: Well, first of all, PPAC is already on record on any number of occasions, at least two that I can think of. Of course we don't have the grid, so you can't see it. We are on record on at least two occasions of opposing pilot studies where anybody would take more back than just the actual error that was made for that one patient. We made those recommendations several times when Barbara Paul was, in the beginning of her projects. So

if you want to make that recommendation again, it's fine, but we're already on record about it. And I think that we need to divide the question between the issue of how pilot studies should be conducted and the engagement of program integrity with this group. Because I think we want to emphasize the fact that they haven't been there and we want them to be there again. And by putting this other issue in the same resolution and voting the whole thing at once, it makes it look as if we're more concerned about the pilot program conduction than we are about engaging the folks back in there. So if you can divide the question into the two parts, they would both probably get affirmative votes, but I think that we would be emphasizing our need for program integrity to become involved again in this process.

Dr. Rapp: OK. We'll have to read the resolution back to see if it can be divided.

Dana: I'm sorry, I'm not sure I got the entire thing, but I do have: PPAC recommends CMS and the Program Integrity group work with the CPT Evaluation and Management work group to facilitate a pilot project with some degree, a pilot project that includes some degree of grace period and hold harmless to ensure physician participation.

Dr. Rapp: You want to withdraw that and let, or restate it, or have Dr. Heyman try two things?

Dr. Heyman: My suggestion would be—let's do first one. And then do the second one. My first one would be that we recommend to CMS that Program Integrity be again engaged in the process of establishing these CPT guidelines with Dr. Wood's committee.

Dr. Rapp: Are you satisfied withdrawing your motion, Dr. McAneny? Without objection that's done, so read this first one back here.

Dana: PPAC recommends that CMS's Program Integrity group again become engaged in the process of establishing CPT guidelines with the CPT Evaluation and Management work group.

Dr. Heyman: Thank you.

Dr. Rapp: Is there a second to that?

[Seconds]

Dr. Rapp: Is there more discussion on that? If not, all in favor?

[Ayes]

Dr. Rapp: Is anybody opposed to that? The motion carries. Next.

Dr. Heyman: In the conduction of pilot studies, PPAC recommends that voluntary participants be held harmless for disagreements about coding.

Dr. Rapp: Is that clear enough? What you said before was that any error not be extrapolated—

Dr. Heyman: Well I figured it was more complicated to say all of that, but you can say it any way you want, the point being that nobody's going to go into your office and extrapolate on the basis of your entire practice because you had a disagreement about one thing in a pilot study.

Dr. Hamilton: What you really mean is that deviations that are detected during this pilot project not be used as the basis for further investigation of other [inaudible]

Dr. Heyman: And also not be use in a formula which looks at your entire practice and then—

Dr. Hamilton: Being strictly limited to those—

Dr. Heyman: I don't know how to, I'd be happy for somebody else to make the recommendation and—

Dr. Hamilton: I think you just made it.

Dr. Rapp: Well, wait a minute. That's the way we work and we have to have the precise words and we can read back.

Dr. Hamilton: Read off what you have.

Dana: Do you want me to incorporate what Dr. Hamilton just said?

Dr. Rapp: Yeah, Dr. Hamilton's got the floor right now for this. Why don't you say it—

Dr. Hamilton: That pilot projects be designed to hold volunteers harmless for deviations in coding during the course of the project so that these variations will not be the basis for investigation of other medical records.

Dr. Rapp: Is there a second to that?

[Seconds]

Dr. Rapp: OK. Would you read that back?

Dana: PPAC recommends that CMS design pilot projects such that voluntary participants are held harmless during the course of the project so variations are not used as a basis for further investigation.

Dr. Rapp: So that, OK? Got it? I think there was a second. Any further discussion. All in favor?

[Ayes]

Dr. Rapp: Anybody opposed to that? That motion carries. Any other item on this subject? If not, thank you very much Dr. Wood. Yes sir, Dr. Johnson?

Dr. Johnson: I wanted to thank Dr. Wood for his testimony. This also not only sheds a light within this area, but also some of the information that he gave, particularly dealing with the adjusted accounting for the non response rate and the coding errors will help us back on the state level and helping to properly and more accurately address some of the issues that we deal with legislatively about perceived coding error problems and helping, particularly the state of Florida, we engaged this last year and it'll be back with us this year. Some of the testimony that was provided will be very useful in dealing with some of those issues to help to get the facts out. Thank you.

Dr. Rapp: Thank you, Dr. Johnson. All right the next item on the agenda is the Medicare Prescription Drug Improvement and Modernization Act. Tim Trysla. Well we're three minutes early.

[chat]

Dr. Heyman: I would ask that we recommend that CMS report back to us at the next meeting about the discrepancy between technical and professional liability costs. The business of, I don't know how to say it—

Dr. Rapp: Do you want to ask—

??: [Off mike]

Dr. Heyman: Right and about what the actual effect is. If you've got a better recommendation on that, that would be great.

Dr. McAneny: PPAC asks CMS to evaluate the distribution of changes in the malpractice RVUs between professional and technical fees, so that the increase in malpractice RVUs results in an increase to the party bearing the risk and expense?

Dr. Hamilton: Second.

Dr. Rapp: What was the second part of that?

Dr. McAneny: So that the increase in the malpractice RVU results in an increase to the party bearing the risk and expense.

Dr. Rapp: I'm not sure I understand that last part.

Dr. McAneny: Well, one of the concerns was that when the malpractice RVU was increased, that the increase in money went to the technical side, but the risk and the increase in expense goes to the professional side.

So the benefit from the malpractice RVU being increased did not follow, the money didn't go where we wanted it to go to, which was the person, the party bearing the increased risk and the increased malpractice expense. PLI expense, excuse me.

Dr. Hamilton: She worded it in such a politically correct way that should the opposite be the ace, if indeed that should ever occur, it could be included in that recommendation.

Dr. McAneny: Right. Exactly so.

Dr. Rapp: OK. Is there a second to that?

[Seconds]

Dr. Rapp: Can you read that back?

Dana: PPAC recommends that CMS evaluate the distribution of changes in malpractice RVUs so that the increase in malpractice RVUs results in an increase to the party bearing the risk and expense.

Dr. McAneny: You left out the clause that says between professional and technical fees.

Dana: Professional and technical fees?

Dr. McAneny: RVUs between the professional fees and the technical fees.

Dr. Heyman: Could you read it back again because it doesn't sound like grammatically it makes sense.

Dr. Rapp: Could you put that in just regular language so—

Dr. Simon: Barbara, this is what I had that you had is CMS report at the next meeting between the distribution in changes in malpractice RVUs, between professional and technical fees, so that the increase in the malpractice RVUs go to the party who bears the increased risk and malpractice expense.

Dr. McAneny: Right.

Dr. Rapp: That's exactly right.

Dr. Heyman: But what do you mean by they should report so that? Are they going to report on what's happening or are they going to report on what should happen?

Dr. McAneny: I said evaluate originally, the distribution. Because we can't—I mean ideally we'd like to have them fix it.

Dr. Heyman: "So that" seems superfluous to me.

Dr. Rapp: Wasn't the—is this is reference to what Dr. Thornwarth had to say? They have a very specific recommendation.

Dr. Heyman: That's what I was looking at.

Dr. Rapp: Why don't we do what they, what he recommended understandable?

Dr. Urata: It doesn't say anything about professional fees or technical fees, and I think that specifically is what we need to get a handle on.

Dr. Hamilton: His recommendation does not include that, but his entire talk focused around that.

Dr. Urata: Right, his whole talk focused on it, yet he left it out of his recommendation.

Dr. Hamilton: Right, that's why we're trying to fix his recommendation.

Dr. Urata: No, I understand that.

Dr. Simon: What I have is that MCR recommends that PPAC recommend to CMS to investigate all physician work adjustments and practice expense adjustments in relation to the professional and technical fees.

Dr. McAneny: That's more broad than the malpractice thing and I think that would be fine.

Dr. Urata: I'm always afraid if you make a broad recommendation, you won't get very much, where as if you make a specific one then you can focus on that one problem and then maybe we can fix it.

Dr. Wood: I think the concern was that the adjustments were out of line with who bears the risk? And so the specific recommendation might be, if you want to be more specific, that would be, CMS should investigate shifting all of the impact of the change in professional liability back to the physician work component and not to the technical component.

Dr. Rapp: That's really what he wanted.

Dr. Hamilton: That's what he wants.

Dr. Rapp: Why don't you read that again?

Dana: I'm sorry.

Dr. Rapp: He's going to say it again. We always are at great risk if we have to say twice the same thing.

Dr. Wood: CMS should, I think the intent was that CMS should report back to us an analysis of shifting to the physician work all of impact of the adjustment and professional liability expense.

Dr. Rapp: You did better the first time.

Dr. Wood: I thought that was exactly what I said the first time.

Dr. Rapp: Not quite.

Dr. Heyman: It was really good the first time.

Dr. Simon: You said that CMS should investigate the first time.

Dr. Wood: Well let's try it again. That CMS should investigate the impact of shifting the entire correction of professional liability and insurance back to the physician work component of the fee schedule. Is that OK?

Dr. Rapp: Well, I think it's RVU adjustments, I think.

Dr. Wood: Should investigate the…fundamentally the problem was in order to maintain budget neutrality, the staff had to make an assumption and they had to decide who they were going to reallocate the RVUs on the physician work side and on the technical side. And as they did that, they over corrected on the technical side. So what the concern, I think, of the ACR was that we need to go back and correct that so that the professional side is not unfairly penalized in that regard. That more of the RVUs should remain in the physician work and all of the negative adjustments should be on the technical side.

Dr. McAneny: Which is what I said, only I left it open just in case it was the other way around.

Dr. Urata: Is it possible to also include something like, as referred in the ACR report?

Dr. Rapp: How about something like this? PPAC recommends that CMS evaluate the effects of RVU adjustment for the malpractice component where its service includes both a professional and a technical component?

Dr. Castellanos: I think they've done that. What you want them to do is shift from the technical to the professional where the liability really lies.

Dr. Urata: We want them to correct it. We can't tell them to correct. They have to look at it and then decide.

Dr. Castellanos: So they have to look from the technical viewpoint.

Dr. Urata: Because they're looking at two reimbursement programs, two different.

Dr. Simon: And I guess one question is, he made reference to one particular service, which was mammography, so—

Dr. McAneny: There's a lot of things where the tech [inaudible]

Dr. Rapp: Somebody should write this down, then see if you can get it right. Somebody between now and tomorrow put it actually down on paper so that when we read it back twice it'll come back the same way.

Dr. Hamilton: We got to have a recommendation related to the AMA

Dr. Rapp: I'll come back for it. Let's just go. This was—so somebody work on that. In the meantime, we're going to now move on to the next item on the agenda. We're going to listen to more recommendations later. But Tim Trysla is here from the Office of the Administrator, a policy advisor. He's going to tell us about the Medicare Prescription Drug Improvement and Modernization Act of 2003.

Mr. Trysla: Thank you. I'm glad I was on time, or at least I'm late. I've got a presentation in your book and what I thought I'd do is give you a cursory overview and probably get to the most important part of this presentation and that is your questions. Obviously the Medicare Modernization Act is going to be a huge first step for the Medicare program and a huge implementation challenge for CMS. Let me move to the first slide. Just a reminder of why we passed this bill. Try to make this as educational as possible. You know Medicare today covers 41 million beneficiaries, $284 billion worth of expenditures. The real policy arguments was really that we were slow to adopt for new technologies and make for new and innovative ways of providing medicines. Obviously the prescription drug and the way prescription drugs have impacted all of our lives is an important component. Let me go to the next slide, and the next one, actually. Medicare today, if you look at what we're trying to mirror in the under 65 market and over 70% of folks under 65 are in the, choose a PPO model, or point of service model, 25% are in HMOs and 5% are still in fee for service. Medicare's kind of slow to adopt in the sense that 90% of our beneficiaries are still in a kind of check the box fee for service system without any real quality controls, utilizations oversight, and real focus on quality or providers. 10% of our seniors who are currently receiving benefits through an M+C or an HMO model, and that is really a model that's past its time in the sense that it's, by definition is a closed network HMO. We wanted to provide more flexibility and more expanded coverage to the system.

Obviously it was pretty clear what seniors wanted. Right now, Medicare, while it's been a wonderful financing system and a social safety net that we think and a social contract that we think needs to be continued, was slow, and provide a needed assistance to Medicare seniors and people with disabilities. Right now, it is only covering about 47% of all health care costs, with the majority of those costs being covered in prescription drugs, so the fundamental here is that while Medicare has been a wonderful program, it's been a poor financing system for

coverage of prescription drugs as well as the needed benefits that seniors need today. Seniors wanted a prescription drug coverage, more choices, better benefits, and a health care delivery system that reflects the 21st Century. We believe that the Medicare Modernization Act is also a great way to focus more on quality and actually focus on improving access. We were very concerned, especially access and the uptake of physicians that were either not seeing more Medicare beneficiaries or just freezing their enrollment. One of the best first steps was obviously to eliminate any negative reductions in the fee for service for our physicians.

First thing out of the box, and one thing I do on a day to day job is focus on the implementation of the Medicare discount card. We believe this is a great first step to starting with a dialog with seniors about the prescription drug options. Really this option is really focused on the ten million Medicare beneficiaries who don't have current coverage for prescription drugs. One of the things that we think is most beneficial is the sense that low income seniors will have access to a $600 credit. This ten to twenty-five percent estimate really is a average of the drugs that we're currently going to be providing under these prescription drugs. These cards are going to have, and we put out 209 classes of drugs, classes, subclasses of drugs that formularies can be built on. So this will be an expanded list of drugs, and those groups and subgroups of drugs really reflect the overall most commonly used drugs that our seniors use, and more importantly the people with disabilities. We vetted those groups and subgroups. So this is going to be an improvement on what's currently in place today and any cash cards that's going to be available. And more importantly on average, seniors are spending about $1,038 on out of pocket costs for prescription drugs. We think that the $600 which is an annual basis, really this is going to $1200 over an 18-month period will go a long way of focusing needed relief for low income seniors.

The new prescription drug benefit obviously is focused on a $250 beneficiary deductible. Medicare will pay 75% of the drug costs up to $2,250. The beneficiaries will be paying about 25% of these costs, and about 100% of these costs for catastrophic coverage up to $3600 for out of pocket costs. Really, this is going to be a very generous benefit. For people who are quimbies (?) and slimbies (?) and QI-1s and for low income seniors below 150% of poverty, there's going to be limited or no cost sharing. People with about 135% of poverty will not have a $250 deductible, will not have any of these out of pocket costs, will not have a doughnut hole and really will be incurring about $2 for generics and $5 for branded drugs. This will be an opportunity for us to focus most of the dollars at a low income benefit, as well as protecting seniors from catastrophic out of pocket costs. We think this is

going to be an added improvement. And one thing I want to highlight about this new prescription drug benefit, is it is 100% voluntary. Seniors can opt out of this and certainly can join to continue to have their employer provide health care coverage in this bill today. This prescription drug benefit also encourages and mitigates any drop offs from employers in the sense that we'll be paying $.28 on the dollar for every dollar an employer contributes toward encouraging employers to stay in the game.

I want to highlight that probably the most attractive aspect of this is what I've already kind of focused on. All people who are entitled to Medicare and full Medicaid benefit coverage will have no premiums, no deductibles, and only minimum co-pays. Those in nursing homes will have no co-pays and people with incomes below 135% of federal poverty level will have very limited cost sharings.

The Medicare Modernization Act really is also about reforming and improving the current Medicare benefits. Starting January 1, 2005, we'll have the welcome to Medicare physical exam. This is newly enrolled seniors. And seniors will have six months upon enrolling into the Medicare Program of getting a new physical exam. We think this can go a long way of identifying people with hypertension, diabetes, as many of our seniors have practiced good wellness and have seen their doctors and gotten their physical exams. But many of our low income seniors have never had a physical exam or haven't had one for years. And we think this is a good way of identifying folks current problems, maybe getting them on a cholesterol controlling drug, as opposed to seeing them five or six years later in the hospitals. The other new screenings will be blood tests and heart disease, and for diabetes, as well as some targeted preventive services: bone mass measurements, vaccinations, and cancer screenings.

The new Medicare Advantage Program will have options much like the old Medicare plus choice plans. This is where you'll see PPO options and other expanded health care options. Seniors will have three choices. They'll be able to choose to do nothing, and stay with their current coverage, stay in their current Medicare program, fee for service if they like, number two they'd be able to choose a free standing prescription drug benefit that goes on top of their current Medicare benefits, or the third option will be the Medicare Advantage Program, in the sense that there'll be more integrated delivery system in the forms of PPO and M+C options.

We believe that this will be the first new option that seniors will be seeing. We've just announced in April that a 10.6% increase in current plans are currently providing Medicare expanded options and health plan options to seniors. So right along in April or May, seniors will be seeing new expanded benefits, lower co-payments, expanded

drug benefits due to this enhanced measurement. So this will actually be the first step of the impact Medicare beneficiaries will see through expanded Medicare Advantage Programs.

In 2006, the Medicare Advantage Program will have additional resources targeted toward a prescription drug benefit. This is when an important option, especially for rural providers. One out of four of our Medicare beneficiaries are currently reside in rural areas. We think a PPO option will be an added advantage to bringing new and expanded health plan options to seniors. Again, this is the most common and popular plan for working Americans. While we believe that this may have a minimum impact on the current beneficiaries are in today, we believe that over time, people who change, especially the Baby Boom generation, from 64 to 65, as they enjoy their current options in the employer market, they'll be able to keep those options and look for those options in the Medicare Program. These options aren't currently available to them today.

Another added advantage of this Medicare Modernization Act is extra help for rural America. We believe that the added resources will improve access to quality doctors, hospitals, ambulance, home health care services, and there's nearly $25 billion of increases in reimbursements to rural providers. Also regarding the sense of competition, there will be more choices in the regional markets. There will be added resources for these plans to stabilize Medicare Advantage plans if they have an inability to negotiate and set up networks in rural areas. Additional resources—and the MMA also ensures that the options will be available to rural areas in the sense that they will maintain at least two Medicare Advantage plans in a regional area. The Secretary will have to promulgate regulations on determining how many of these designed areas for Medicare Advantage plans will be in place. I believe the current statute limits the Secretary's choice to between ten and fifty of those regional areas.

The next slide is the helping rural states through equality. We believe that this is going to be a huge improvement in addressing some of the access issues. Hospital payment for wage index will be increased by 62%. There will also be increased fundings for Medicare DSH payments.

An added advantage of the Medicare Modernization Act is the health savings account. This is largely an option for people below 65. This will be an improvement on the current Archer medical savings accounts, in the sense that you'll be able to make tax free contributions to these accounts. And the buildup will be tax free as well as the expenditures, as long as they are accredited for health expenditures. The pay out for health expenditures also will be tax free. The first dollar of coverage has to go toward a catastrophic plan, and I believe the limitations are $2,000

of catastrophic and $5,000 for a family has to, for high deductible plans. This is a real opportunity for us to change and reform the health care system, I believe and will have long term effects on the current employer market in the sense that health savings accounts are portable and they are not limited to an employer setting, much like your 401 K plans, your health savings account will travel with you across employers. There's not revisions for part B drug payments, chronic improvement programs, contract reform, quality provisions and consumer information.

As I mentioned the health savings account, tax advantage for savings account available for everyone in 2004. The IRS has promulgated guidelines on these provisions. HSA are designed to combine with high deductible catastrophic insurance policies. HSA's contributions by employers are not included in taxable income to the employer or the individual and in the sense that employers will be able to offer this as an option to their newly retirees, employers will be able to offer this as an option for a future benefit for retiree populations. Again, the most popular provision, I think, is the fact that HSAs are portable and not tied to your current employer.

Part B payment. I know this has been of considerable concern to this Advisory Council. Congress has put in place a reduction from the current AWP system for injectable and infused drugs. Drugs infused through durable medical equipment will also have some reforms as well as coverage for oral cancer drugs, and anemic drugs, hemophilia drugs, and clotting factors also. There's approximately $1 billion worth of savings in this.

CMS has already promulgated regulations for 2004 in the sense that we've reduced the cost of these drugs from 95% of AWP in 2003 to 85% of AWP in 2004. We also will be putting out regulations instructing manufacturers on how to report, because in 2005, we will be moving to a new system—the average sales price, plus 6%. One thing that is not highlighted in this slide is the added discretion in the statute that allows CMS to go in and look at OIG, GAO reports, was well as other market resources and making adjustments beyond ASP plus 6%. So there's an added discretion by the Administrator and the Secretary of HHS to make more appropriate payments for these drugs. I'm sure I will get some questions on that. Let's go to the next one.

Chronic care. There is a couple demonstrations. A demonstration 721 in the MMA that actually allows us to target more treatment of chronic disease. And what this slide highlights, and many physicians at the table certainly know this, is that the highest health care expenditures are going to the last days or months of care. We believe that if you do a better job of managing disease upfront, that we actually can have improved quality and better outcomes both for patients and providers, as well as provide a more integrated benefit. This is one thing that we've

focused on throughout our demonstration. Basically, the provision makes permanent what we've been working for in CMS through disease management demonstrations.

The chronic care improvement program is one I referenced. It's the voluntary program in the traditional

[START SIDE SIX]

[Mr. Trysla cont.] Medicare fee for service program. In other words, it won't be limited to demonstration. It provides chronically ill beneficiaries with useful tools and support services. CMS will hold chronic care improvement organizations accountable for improvements in quality satisfaction and cost efficiency. Programs will begin as a large pilot in 2005. This is largely building off our population disease demonstration that we currently have underway at CMS. And literally, this will be a way to better not only identify patients with these kinds of conditions, but also provide multi-disciplinary approaches to those patients. For instance, giving the diabetic access not only to their physicians and nurses for services, but dieticians, pharmacists, and others in a more integrated approach.

Another improvement we believe that we've been working on at CMS for quite a while, is the contractor reform provisions. This requires that all of our contracts by 2011 be competitive contracts. We believe this will create greater efficiency from the Medicare Program. Many providers for years have had problems with the accountability and responsiveness of our contractors. Medicare is administered, I think, by over 80,000 contract employees. This is literally moving to a common sense approach that we're actually going to be paying our contractors, based on their accountability and the fact is, they give an answer, and have a sense of responsiveness and customer service that many people are currently accustomed to in the private sector.

One of things also we've been very excited about is the quality provisions in the MMA in the sense that hospital market basket update now will be tied to submissions of quality data. Quality improvement organizations will be expanding their responsibilities to cover not only Part A, but Part B, but also will include Parts C and D. And one issue that I think is going to have an overwhelming amount of attention in the future years is electronic prescribing. There's a voluntary program in 2006, in the sense that the Secretary will be promulgating standards I think by 2005, undergoing a pilot in between 2006 and then making those standards final in 2008.

Consumer information empowers beneficiaries with information to make more knowledgeable decision. This statute requires PBM to publish purchase prices in the Drug Discount Card. Public nursing home quality

comparisons is another thing that we want to codify and public home health agency quality comparisons. This is something that CMS is continuing to do as well as in the form of hospital satisfaction surveys that also will be something that we'll be moving forward with.

Just to highlight some of the fundamental changes the MMA currently encompasses: It modernizes the benefit package, protects those most in need, expands accountability for our contractors and empowers beneficiaries with better information. One thing I want to focus my additional comments on are really the implementation dates. I think it will be important for people to understand. In 2004, we've already promulgated payments for rural hospitals, we've eliminated a therapy cap, we've increased payments to physicians and also will be promulgated regulations on specialty hospitals. We've already, in March 2004, issued Medicare Advantage payment rate increase, and these will be in the form of refilings of ACRs for Medicare Advantage plans. And as a reference, this will be the expanded benefits that health plans will currently be able to offer Medicare beneficiaries. June 10, 2004, we'll be out there with a Medicare discount card. In April of this year, the Social Security will be targeting a letter toward the low income populations in May, the Secretary will have a letter out there announcing the drug discount card. Seniors will be able to enroll in these discount cards in May and cash and discounts will be in place by June, 2004. In January, 2005, the preventive benefits, the welcome to Medicare physical, the physician scarcity payments that are referenced in the rural payment provisions will be in place in January 2005. Then January 2006, the drug benefit in the regional Medicare Advantage plans will be in place. Just to highlight this time table, literally to meet these guidelines governed by the statute, we will be out there with a proposed regulation, sometime this early spring or summer with a title 1 regulation, which is the free standing prescription drug benefit regulation, and a title 2 regulation, which is the Medicare Advantage. This truly will be a proposed rule and we will be having I'm sure thousands and thousands worth of comments. We'll have to finalize these comments by January 1, 2005 in order to get bids out there, have plans, file ACRs and other bids in place, and literally seniors will be able to enroll and select a Medicare Advantage plan or free standing prescription drug benefit plan by November 2005, in order to make those choices for January 1, 2006.

So it's a very ambitious implementation plan and it certainly something I'm sure this advisory council will be focused on. And we concluded this slide to highlight all this plan, the discount card, the prescription drug and others is all going to be a huge challenge for the Medicare program to educate beneficiaries. If I can just talk a little

about the discount card program, this is an opportunity to start a dialog now with seniors about their drug options. What's a prescription, what's a branded drug, what's a generic drug, what's a formulary, what's off formulary? How to talk to their physician, how to talk to their pharmacist about their prescription drug needs. You've already seen ads go up in place, announcing that there will be no change to the Medicare program, but only additional benefits. That's caused some controversies with some advertisers, but really, we believe that we have not only a statutory obligation, but we have a moral obligation to educated beneficiaries about these new options that are available to their program.

And with that, I appreciate this opportunity to come talk, and I'll be happy to answer any questions you might have.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: In talking to some of the family practice primary care folks in my area about what this new physical examination, the welcome to Medicare physical, will do, it cross walks pretty well to that initial preventative care medical examination, which takes about an hour to do. And given that most family practice overheads are about 55%, what they estimated was that for this to be worth their time in doing it, the fees would have to be about 250 per Medicare exam. So about a million new Medicare beneficiaries per year, 250 per exam, that's $250 million. So that's well over the regulatory impact analysis statement. And I'm very concerned about where that money is going to come from. Is that going to be added into the SGR? And help us hit our target that much further? Or are we finding some new money to put into this exam?

Mr. Trysla: Actually that is a great question that'll be something that will be, is currently in discussion today. And I think that we'll be out there with regulations and certainly be focused on that. We will be, we have to meet that deadline, and it certainly is an ambitious one, but that's something I can't comment on because it'll be something subject to regulation. But I appreciate and I'll take your comments back.

Dr. Rapp: Dr. Heyman, Dr. Urata…

Dr. Heyman: I actually have five different things, so let me combine three of them and that would be the discount card. I don't understand, first of all, when the card first comes out in the beginning, and there's this 10 to 25% discount, I'm not sure who's providing that discount. Is that the government who's subsidizing it, or is that somebody who's just offering the drug for less, or what is that? Let me give you all three. Because maybe he can do

all three at the same time. The second question I have is when the supplement comes in and whatever the thousands of dollars was that the government pays and then there's that little empty space, and then there's another part where the government pays again, do people still use the discount card at that time and still get the discounts at the same time that they get the subsidy from the government? And the third question I had was you mentioned that people could opt out of the prescription program, and if they do opt out, do they get compensated by a lower premium on something that? Those are my three questions about the prescription card.

Mr. Trysla: And they're easy ones. Let me just go through them quickly. On the discount cards, first of all you can't receive the Medicare endorsement unless you've shown that you negotiate rebates from manufactures and agree to pass those rebates through in the form of lower price concessions. And Medicare beneficiaries largely will be able to call 1800 Medicare, give them their zip code, and their regional area. And I always give my parents as an example. But they'll be able to choose cards based on the lowest, on these negotiated prices and depending on their individual drug use, that 10 to 25% is really an average. We believe that there'll be, especially in the cholesterol controlling where there's a lot of me too drugs and a lot of competition, certain cards will have better deals cut on Lipitor, or Methicor, or whatever the particular drug is that they'll be offering. And seniors will be able to make those selections based on their individual drug uses, but the bottom line is you can't become a Medicare approved card, unless you've shown that you negotiate with manufacturers and passed those rebate dollars on. So it is a combination of both the manufacture rebates, and also price concessions from the pharmacists.

Dr. Rapp: But the beneficiary has to pay something for the card?

Mr. Trysla: For the low income seniors, the cards are free. So it's 600, we're actually putting 600, and the statute says you can charge up to 30 dollars on an annual basis. We actually think there will be a lot of competition around that enrollment fee. We had over 104 applications with a very generous response by the private sector, by wanting to participate in this plan, and I think there will be some competitions around that enrollment fee. But seniors can't be charged no more than $30 if your just in the discount world, and it largely will be billing off whatever best negotiations that we have. And we've seen the National Association for Chain Drug Stores announced that they're going to do a card with express grips, where they'll have a pharmacy alliance so you have participation with pharmacies. I think some of the manufacturer cards will come in place. I think Merck has announced that for example that they are offering free drugs to wrap around the $600. So there's a lot of response to the fact, and I think

there's a good business sense in the sense that these are seniors largely who don't have coverage today and there will be a certain amount of branding also in the sense that if you like United Discount Card, you'll be looking for United drug benefit. That's just an example for United in 2006. Having said that, let me segue into your second question.

The discount card only lasts for about 18 months. And so it goes away. If you still have cash on your cards, and you haven't made that selection, that cash carries over in 2006, but only until you choose a prescription drug benefit. When I mentioned that it's voluntary, it's that if you have current prescription drug coverage through Medigap Plans or through an employer, you certainly do not have to choose this benefit. And you'll be able, for instance, if your employer stops providing coverage, or doesn't provide credible coverage in order to receive our subsidies, you can choose a Medicare prescription drug benefit or Medicare Advantage plan penalty free.

Dr. Rapp: It's something additional, you sign up for.

Mr. Trysla: Right. Completely voluntary, completely additional. As far as the so-called doughnut hole, which doesn't exist for the low income seniors, but will exist for higher income seniors, that's why we will have on behalf of our—this is a competitively bid process—so we will be having the same people who are negotiating prescription drugs for IBM, pharmacy benefit managers, or insurers, out there negotiating on behalf of Medicare, and they'll have to come in and show us, and that's why these negotiated prices will be awfully effective in mitigating some of those higher costs of people who have that kind of gap in coverage. The theory behind the plan was the fact that we're focusing most of our low income seniors who need it the most, and focusing also additional dollars to providing that catastrophic coverage for people who would incur, and people who have $300 worth of drug spend, which is very common for this population, will actually hit that cap and will have 95% of that cost sharing the catastrophic coverage will be covered by the federal government. So we think that it will make sense in the sense that these will be additional resources and having the ability for seniors to get the advantage of negotiated prices.

Dr. Rapp: But back to that point, that hole that gap there, when I read about the law, the interesting this is if you have an HMO now, and something's not covered, you don't get the benefit of the HMO negotiated rate. You go to a hospital. It's a $6,000 bill, the HMO would have paid $1000 had you been covered, you pay the $6000. Under this deal, is what I read, is for that hole, period, you get the advantage of the negotiated prescription drug benefit rate

so your paying those low prices for the drugs rather than now all the sudden you're not covered for that $3500 or $3000. You're still paying a much better rate.

Dr. Heyman: The other thing I wanted to point out to you and this'll be the end of my part, is in Massachusetts, the duel eligibles, you had a slide up there about the dual eligibles. In Massachusetts, the co-pay, the 20% is paid by the physician. I just want to point that out.

Mr. Trysla: I'm not sure if that would continue. Those dual eligibles will be federalized, and we will have uniform rules for those cost sharing.

Dr. Heyman: That would be a wonderful thing.

Mr. Trysla: Well, we'll be buying out money, these costs for states. We'll have to uniform rules for those particular folks. And for states, I don't know if this is a Massachusetts issue, but for states whose definition of dual eligibles is beyond 135% of poverty, they also get lumped into the lower cost sharing, so it really is, we think in the long run is a better, more integrated way of providing these services.

Dr. Urata: I was just making a joke. About co-pay, I mean about down paying.

Dr. Rapp: Dr. Bergeron is the only one allowed to make jokes.

Dr. Bergeron: Would you educate the Council on what parameters are going to be used and what documentation are going to be used and high and low income, low income, and lower low income in order for these particular categories to be satisfied. In other words, patient comes in, this is my income, you're going to have to have the income tax form, you're going to have to have it notarized, you're going to have your lawyer—in other words, who's going to screen all these 80 million people, and therefore I see another agency stepping in, because I don't, what's 130% lower low income, would you edify me on that?

Mr. Trysla: It's about $12,132 last year.

Dr. Bergeron: And who's going to determine that?

Mr. Trysla: Social Security Administration or the states.

Dr. Bergeron: And is that going to be a specific agency?

Mr. Trysla: Yeah, the Social Security—

Dr. Bergeron: And that will be power to the patient?

Mr. Trysla: By statute, this is largely an SSI kind of—

Dr. Bergeron: You're not creating another bureaucratic mountain.

Mr. Trysla: No. And I'm frankly, depending on how today's meetings go, I think Social Security Administration may be the ones to do it. The states are very concerned about being able to do this and getting their folks trained, but the statutes pretty clear that both states and Social Security offices will be doing this. So if you choose a plan and you think that you qualify for additional subsidies, you can choose a plan much like you've enrolled in Medicare today—

Dr. Bergeron: You go back to your local Social—

Mr. Trysla: And then you can go back to the your local Social Security Agency and undergo—

Dr. Bergeron: Now, will data be sent to the private physicians' offices? In other words, patients come in, and they expect us to take care of their medical problems, their insurance problems, their marital problems, any other problems that they may have, will we have any documents in the office when patients come in and say, Dr. Bergeron, how do I qualify, where do I go? Or will they receive that from Social Security?

Mr. Trysla: Actually you'll get it both places. I know for a fact, for the discount card, we'll be providing that information to physicians, and I know it's underway for the prescription drug benefit. If nothing else, to call 1800 Medicare is one way to do that. But yes, we are going to be working with providers or stakeholders. We think that the real test for this will be the reaction not only of patients, but more importantly of physicians and pharmacists to make sure that this plan is easily understandable. And it will be an education issue for pharmacists and physicians, and we plan to conduct that. That's why I focused on my last slide by saying one of the greatest things we have to do is really educate providers and more importantly beneficiaries about the intricacies of these plans and these new options.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: Under the welcome to Medicare physical exams, you talked about the financial needs. I can tell you in our community, it's going to be a manpower issue. Physicians just don't have the openings in their practices to do something like that. I'm sure in rural communities you're going to find the same problem. It's going to be a manpower problem and there is not going to be enough physician time available to provide that service.

Mr. Trysla: Again, I will certainly take that underway. The one thing we wanted to highlight about the new preventive benefits is this took an Act of Congress in order to put these preventive benefits. Something as common

sense as doing screenings for cholesterol and other things. One of the advantages of joining these health plans, as science and medical care kind of evolves, health plan will adopt those new screenings and new capabilities without going back to a statutory change or issuing a regulation, or having to have an Act of Congress to do that, so while these are something that we think makes a lot of sense, and we push for in the traditional Medicare Advantage plans, these will also be widely available, we expect, under the health plans and there'll be more flexibility to address the timing, what's incurred as far as the benefits. So it won't be as, I don't think it will be as prescriptive as people anticipate, especially in the health plans.

Dr. Powers: How, this business of contractors and competitively bid contracts. How close a control do you have over those contracts? It scares me that the sharks are gathering out there and that these private companies that don't have the same ethics as other health care people have are out there wanting to skim off the type and not buy the services. Of course what we found in Tennessee with a different situation, but with NCOs is that these people poured money into their own pockets and then took off with it and never paid anything in return. And it was because no one had any power to do anything to those people. Can you get rid of those contractors? I mean how soon can they be turned over? Or is this going to just go on and on and on?

Mr. Trysla: Well, many of our contractors have been with us since the inception of the program, and these have been cost contracts and so the idea is that you would competitively bid these and put this more of a performance measure as opposed to just paying for the services that they get. And obviously we've seen, especially from the providers side, a fair amount of criticism about how responsive or how consistent the actual answers—we do open doors at CMS on a weekly basis. And I can tell you 99% of our questions are related to, you know, I called the contractor and got this answer and called an hour later and got the next answer. And so really what we want to do is now measure folks and say, if you want this book of business, there's going to be strings attached, as opposed to just paying for what you get. So I think that oversight will be enhanced, I think our oversight will be something that people will scrutinize. But we're welcome to the challenge and think that this is a good step in order to make the Medicare program work better, not only for providers, but more importantly for patients.

Dr. Iglar: Two questions. First of all, Medicare providers have a Medicare formulary like many of us have with this insurance program, this or that.

Mr. Trysla: Well let me speak to that on two programs. The discount card, we encourage the formularies to be used in the sense that that's how you get better negotiated prices. For the $600, the formularies doesn't apply. The $600 can be applied to any drug as long as it comes within the definition of covered drug. For the—the statute does put some strings on about if you're going to develop formularies. We expect plans will have open formularies and closed formularies, and there will be fairly prescriptive appeals process in place if a physician feels that a patient needs a particular drug. But much like you've seen in the over 65 market, and retirement benefits, or under 65 market, many of the competitive that PBMs and assurers use will be available to the Medicare program now. And so I anticipate that there will be formularies and there will be that type of needed integration.

Dr. Iglar: Second question is what is the big hurry other than political?

Mr. Trysla: Well, again, that's above my pay grade [laughter]. We have an, I think we've done a historic under leadership of Secretary Thompson, an historic regulatory action in the sense that we promulgated a final reg two days, on the drug card, two days after the statute was signed. This is a huge challenge for this agency. It'll take quite a bit of resources to do and quite a bit of manpower. I can't really speak to Congress's intent, but any plan, Democrat or Republican, had a implementation time of two to three years. And that's the extent that I can probably comment on that.

Dr. Rapp: Dr. McAneny?

Dr. McAneny: I was pleased to hear that there was an option for the Secretary to adjust the ASP plus 6. I'd like to have a reference on that on where that might be. But also I was concerned under your quality provision options, when you're talking about the quality improvement that the disease management companies have provided. And it seems to me that we actually have a pretty good disease management situation in place all the way across the country, called primary physicians and that if we took them off the treadmill of having to see X patients per hour and bill 27 review systems, etc. etc., that we might, and we looked at some novel ways of paying for email or telephone consultation or non face to face encounters, or management fee for taking care of the chronic diseases that we might get a lot more bang for the buck, keep the money in the local arena, instead of sending it off to a disease management company headed in what, Cayman Islands or someplace, and have that money recalculate there. It seems to me in my experience with disease management companies, what I've had is they call up patients and tell them that they should call a nurse who lives somewhere else, who then for her back up, tells the patient to go to the

emergency room. Which is exactly what you don't want to have happen. You're much better off if you have a local physician who knows that person managing that chronic disease. So I'm hoping that as you look at the pilot project for this, that one of the pilot projects you will look at is setting up the primary care physician with a disease management fee, with some innovative payments, for them to do the things that you want done, and compare the outcomes of that with a telephone company with somebody on the end of a line.

Mr. Trysla: Yeah I think that that evaluation will be taking place. And again, really this is a demonstration, so it's really who comes in and what models we look, and we think that that community-based model is certainly something we're very interested in. In fact, we've got, we've been a leader in that. I know in Missouri for example, we've got 45,000 Missiourians identify they're on more than 9 prescriptions a month in a disease management model under the Medicaid program, and it is a community based focus. So I think it really will be on what kind those bids, but those evaluations on what format—is this a data intensive or education intensive approach? I think this is something that we all are trying to get our hands around and certainly is worth the debate. I think your points are very valid and something that Medicare needs to get smart on quickly.

Dr. Rapp: Dr. Urata?

Dr. Urata: Just a quick question on that entry physical. Was there a time limit in which you had to get that done by? Was that 6 months?

Mr. Trysla: Yeah.

Dr. Urata: That could be extended though, by you, in case patient can fit into a doctor's office in a timely fashion.

Mr. Trysla: That's statutory, but we can go back and check.

??: Statutory that you have six months?

Mr. Trysla: No, no. That if you want it, I think you have, from the inception of getting eligible for Medicare, I think you have six months to raise your hand. And it's not for current beneficiaries. It's not like current beneficiaries who are already in the Medicare program can access it. It's actually new people.

Dr. Urata: Yeah, that might be where the problem develops in terms of lack of providers. But time line can be expanded a little bit.

Mr. Trysla: I'm not quite sure. And I'll have my staff check it.

Dr. Urata: That seems like obvious solution.

Dr. Rapp: I had a couple questions. The first page, the $270, $84 billion dollars, I read the other day is $5—

Mr. Trysla: That's Medicaid. Add in Medicaid.

Dr. Rapp: You added Medicaid?

Mr. Trysla: No, you need to add in Medicaid to get that number.

Dr. Rapp: No, I'm talking about the prescription drug benefit is expected to cost a lot more, more like $500 billion.

Mr. Trysla: Oh yes, the CBO and OMB estimates are really discrepancy on not only the data, but the participation in the Medicare Advantage as well as the pick up or uptake of the HSAs. And they both use different assumptions. There would be a certain amount of cost savings, and actually expenditures, additional expenditures if you choose HSAs because people won't be paying taxes on that money, so you actually loose money if you get an uptake of the HSAs, but by law, the Senate and House and the Congress is linked toward the Congress Budget Office estimates and obviously those—you know, $1.7 trillion dollar estimate, I believe that's about a 2.1% discrepancy. And those numbers get awfully big, awfully quick when we're talking about those dollars.

Dr. Rapp: That's what I see. The way the prior medical savings accounts work, you could have some deductible, and then there was a gap till you had a high deductible thing.

Mr. Trysla: That's correct.

Dr. Rapp: Is there a gap in this anymore?

Mr. Trysla: Not a gap in the sense that you have to have a $2,000 deductible and I think $5,000 deductible for family. So the point is that you want to encourage people to have a catastrophic plan that looks like a catastrophic plan, but we think that there'll be added advantages. I mean the MSAs in the past I think were limited to small businesses and others. And you also see probably changes in the, I believe, in the market place in the sense that you've got more people out there offering—

Dr. Rapp: You said the individual you could put up to $2,000, family $5,000? Your catastrophic policy can start there, too?

Mr. Trysla: That's correct.

Dr. Rapp: $2,000 and $5,000 will be totally covered then.

Mr. Trysla: And what's an advantage for employers I think over time will be an advantage, is that they can put that first dollar money in place and say, and it's, and they're not on the hook for paying any monies until people have a certain—

Dr. Rapp: Is there any change in terms of the deductibility of the catastrophic policy for an individual that is something not provided by your employer? Or is that…

Mr. Trysla: You know, I'd have to go back and look at the IRS guidelines. I mean right now you can't deduct anything over 7.5% of your gross income. And obviously those rules don't apply to these vehicles.

Dr. Rapp: It says, something in here about the PBM is supposed to publish the drug purchase prices?

Mr. Trysla: We believe especially on the discount card, and this is still open policy issue for the actual drug benefit, that giving beneficiaries information about discounts on average or for certain percentage of AWP, I've asked physicians, Senate lobbyists, manufacturers what an average wholesale price is. I don't think anybody's given me a straight answer just yet. So what we thought would make sense was give seniors actual prices to choose. And so I mentioned, in the enrollment of the discount card, we're actually going to have price comparisons so you can shop in that illustrated phone call that my parents would make in Nebraska, the five cards are cost cards, and if they're all Lipotor, one card would do $70, the next one would be $40, the next one would be $65, and they'd choose based on those prices. And it would be down to the pharmacy. So they'll know in their community what kind of negotiate prices. And they certainly know what prices they're paying today. Especially if they don't have any drug coverage.

Dr. Rapp: And lastly, on the implementation schedule, there are a lot of administrative changes above and beyond the benefit and so forth that are in the Act, and I guess it would be helpful from the Council's standpoint, to have more details on that so that we can sort of anticipate our…

Mr. Trysla: I apologize. We had a little snafu with our staff, but what I was planning to give, and I will do to the Council, is what we provide at the Hill, giving you a section by section brief note as well as the statutory dates. It's a not a voluminous document, but it's quite extensive and I'll be able to provide that to you this afternoon.

Dr. Rapp: Great. That would be helpful. Anything else on this?

Dr. McAneny: One of the questions that we have is that we can get free chemotherapy for people who have no insurance through patient assistance programs. What we've heard from many of the folks in the industry is that

those patient assistance programs will basically go away and we won't be able to handle that. I recognize that CMS's concern is not the uninsured, but as the uninsured get bigger, it's an increasing concern for all of the rest of us. Have you heard anything about whether the patient assistance programs will indeed be going away?

Mr. Trysla: Yeah, let me just speak to that. This is not, this is just my personal opinion in the sense that that's counter to what I've heard from manufacturer programs and their pharmacy assisted programs, that they would continue this their programs. Another thing I want to highlight in the MMA, we also in Section 641, we actually provide a bridge benefit till December 31st, 2005, of particularly Part B drugs that deal with replacement therapies. Tomoxifin, Remicade versus Embrol, kind of debate in the sense that Medicaid would only pay for a certain approach to an injectable but wouldn't pay for a new advancement. This bridge benefit—it was done in our demonstration authority, but actually it's more of a bridge benefit in the sense that it allows for $500 million to be spent on these drugs, and enrollment of 50,000 patients, and that's basically how the statute was written and applies Part D type of cost sharing to these folks. So there is immediate relief. This 641, the Medicare discount card, is all a way of mitigating or expanding immediately coverage to needed patients and we believe that we had planned to try to implement that as quickly as possible. But my information, based on what I've dealt with from limited knowledge is that those pharmacy assistance programs would continue. And other thing I want to highlight—a state pharmacy assistance program, you mentioned the doughnut hole in your question earlier. State pharmacy assisted programs can actually target their money and for certain populations or for all of their populations, can fill the doughnut hole. There's no, and that payment that the states would make would count toward a true out of pocket cost, so it would count toward reaching that catastrophic $3600 limit. So if a state chose to expand to 200% of poverty and pay in the doughnut hole for those folks, that's another option for state pharmacy assistance programs. And so we believe that we will be offering new opportunities for new assistance and obviously that's not targeted toward your uninsured population, but it goes a long way of meeting some of those goals for the Medicare population.

Dr. Simon: Section 611

Mr. Trysla: What is this, friendly fire? [laughter]

Dr. Simon: Section 611 of the MMA addressing the coverage of an individual initial preventive physical examination it states that covering an initial preventive physical examination is performed no later than six months

after the individual's initial coverage date under Part B. The provision applies to services furnished on or after January 1, 2005. But only for those individuals whose coverage begins on or after such date.

Mr. Trysla: And we have to look at, I mean, my own, I should even raise this issue, but I think you can enroll in Medicare three months prior to your 65th birthday and I'm wondering if you could actually get that physical prior—we'll have to straighten that out.

Dr. Rapp: But I think the point is—

Mr. Trysla: You may have more than six months is my point.

Dr. Rapp: OK, anything else? If not, thank you very much for coming and explaining this. And appreciate the offer to give us more detail. Now we have a few more minutes, and I understand there are more recommendations. Are you on the docket here, Dr. Heyman?

Dr. Heyman: OK, well, I was going to go through the AMA recommendations and the first one is that we request CMS to give us a time frame at the next meeting for the various regulatory relief provisions included in the MMA. And I think that's what he was discussing. Was that going to cover all of those or was it just the prescription part?

Dr. Rapp: It had to do with the administrative. I think he, that's one he's going to do, but I'd go ahead and make the recommendation.

Dr. Heyman: Well that's great. All right, well I'll make the recommendation in case he's not going to, but it sound like he was going to.

Dr. McAneny: Why don't you wait and make that resolution tomorrow if he doesn't?

Dr. Heyman: OK, fine.

Dr. Rapp: Can you repeat that for us—it's the AMA, it's the first recommendation that CMS update PPAC at its next meeting concerning CMS's time frame for implementing the various regulatory relief provisions, including the MMA.

Dr. Heyman: So they haven't changed.

Dr. Rapp: There's a second?

Dr. Heyman: I mean I don't think it will hurt.

Dr. Rapp: Do you have that Dana?

Dana: Changed from this?

Dr. Rapp: It's basically that, we just made it more abbreviated.

Dana: PPAC recommends that CMS update the Council at its next meeting concerning CMS's time frame for implementing the various regulatory relief provisions including the Medicare prescription drug improvement and modernization act, 2003.

Dr. Rapp: That's it. Any discussion? All in favor?

[Ays]

Dr. Rapp: Any opposed? That motion carries. Next.

Dr. Heyman: That PPAC recommend that CMS use its discretionary authority to remove drugs from the SGR.

[Seconds]

Dr. Rapp: That motion's been made and seconded.

Dr. Hamilton: Could I suggest that in keeping with this that we expand that just a little bit to include that CMS report on the affects of the current policy, which includes physician administered drugs for the calculation of the SGR and to use CMS's discretionary authority to remove the cost of these drugs from the SGR?

Dr. Rapp: Why don't we just vote on his and then you can do yours, but stop when you get to and. Dana, can you reread Dr. Heyman's?

Dana: PPAC recommends that CMS use its discretionary authority to remove drugs from the SGR calculation.

Dr. Rapp: OK, that's been seconded. Is there discussion? All in favor?

[Ays]

Dr. Rapp: Anybody opposed? That carries. We previously recommended that as well. Dr. Hamilton?

Dr. Hamilton: In light of the fact that they're probably not going to do as was just suggested, I would make the following recommendation [laughter], and that is that PPAC request that CMS report on the effects of the current policy, including physician administered drugs for the calculation of the SGR.

??: Second.

Dana: PPAC requests that CMS report on the effects of its current policy of including physician administered drugs into the calculation of the SGR.

Dr. Rapp: And you mean by that what we were talking about before, what would be the impact on the SGR itself versus what would be the impact of a target, if physician administered drugs were excluded.

Dr. Hamilton: That's right.

Dr. Rapp: You mean say it the way I said it?

Dr. Simon: In other words, how would the SGR be affected if drugs were removed from the SGR?

Dr. Hamilton: That's correct.

Dr. Urata: Physician administered drugs.

Dr. Rapp: Physician. OK can you read it back so we make sure that we—

Dana: PPAC requests that CMS report on the affect of its current policy of including physician administered drugs into the calculation of the SGR that is, how would the SGR be affected if these specific drugs were omitted from the calculation.

Dr. Rapp: OK, does that work? That's been seconded. Any discussion? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? Motion carries. Dr. Heyman?

Dr. Heyman: I would like to ask that PPAC recommend that CMS not include the cost of prescription drugs under the new MMA Medicare drug benefit in the SGR.

[Seconds]

Dr. Rapp: Is that—I guess we didn't ask him that. That's, is the prescription drug benefit part of the SGR? I don't think it is, is it?

Dr. Hamilton: I like the wording that the AMA suggested. Says provide PPAC with assurances that the CMS does not intend to include in the SGR the cost of prescription drugs included in the new MMA Medicare drug benefit.

Dr. Heyman: That'd be fine.

Dr. McAneny: We had discussed that with Mr. Scully before who assured this that it was Part D Medicare and it never would be. I'm not speaking against the motion. But I think it's an important point to make sure that now that we're going to have new administration that we're concerned about it.

Dr. Rapp: So that's been seconded. Other wording? Dr. Hamilton's wording?

Dr. Hamilton: You want me to read that back, or you…

Dana: I didn't get that, I'm sorry. I saw the AMA wording and Dr. Heyman's wording.

Dr. Rapp: That's all right. We're going to modify it slightly. Wait a minute, we're going to take the AMA…

Dr. Hamilton: Well, I wanted to change it just a little. Let me just read it to you and you can wordsmith it some. It says: move that PPAC request that CMS provide PPAC with assurances that CMS does not intend to include in the SGR the costs of the prescription drugs included in the new MMA Medicare drug benefit.

Dr. Rapp: Do you like that?

Dr. Heyman: Sure.

Dr. Rapp: OK, is there a second to that?

Dr. Heyman: I'll second it.

Dr. Rapp: And discussion? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed?

Dr. Heyman: And then I recommend, well PPAC recommends that for purposes of calculated the SGR target, CMS consider and account for all direct and indirect costs of all provisions in the MMA that would increase physician spending.

Dr. Rapp: Physician spending or…

Dr. Hamilton: Why don't you say will increase health care costs? Physician spending sounds…that's not very good.

Dr. Rapp: It's really will, will increase the amount of services provided by physicians. Because that's what the SGR.

Dr. Heyman: Right.

Dr. Hamilton: So it's just health care costs.

Dr. Rapp: Well, no, it's not health care costs. It's the—

Dr. Heyman: Services provided by physicians is the terminology.

Dr. Rapp: The SGR target tracks the services provided, versus the target—

Dr. Heyman: So now it would say

[START SIDE SEVEN]

[MISSING MINUTES]

Dr. Urata: Information where the most recent data available.

Dr. Simon: I guess one question would be what that—what I have is that CMS include in MEI all factors that will more accurately capture the cost of practicing medicine.

Dr. Heyman: That's perfect.

Dr. Simon: But what elements do you want to have—

Dr. McAneny: Including but not limited to—

Dr. Simon: Sure, but what elements because we have such a large universe.

Dr. Rapp: Such as?

??: Malpractice?

Dr. Rapp: That's already in there.

Dr. McAneny: The quality improvement requirements?

Dr. Rapp: Joe, what do you want to put in here? You're the motion maker.

Dr. Heyman: Well, you know what, I will come back to you with a better worded motion.

Dr. Rapp: We'll come back with a better worded motion. That's temporarily withdrawn. Anything else?

Dr. Heyman: The last one is to establish work values for the vaccine administration codes 90471, 90472 and G0008, 0009, and 0010.

Dr. Rapp: PPAC recommends at the bottom of page two, there.

[Second]

Dr. Rapp: Discussion? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? That motion carries. Dr. McAneny?

Dr. McAneny: I'd like to make a motion that CMS—PPAC recommends that CMS develop a contingency plan in case in case their assumption that no point of service shift will occur is incorrect to ensure that patients continue to have access to infusion and chemotherapy services in physicians' offices.

Dr. Rapp: Is there a second to that?

Dr. Castellanos: Could you read that again please?

Dr. Rapp: Was there a second to that or not?

[Second]

Dr. McAneny: PPAC recommends that CMS develop a contingency plan in case the assumption that they're making that no point of service shift will occur from office to hospital, in case that should occur—

Dr. Rapp: Did they make that assumption?

Dr. McAneny: Multiple times. That was their assumption on why they wouldn't talk about what would happen if because it isn't going to happen. But if it going to happen is not correct, then we maybe need to have a plan B.

Dr. Rapp: Where do they make that assumption?

Dr. Hamilton: They made it very clear that the purpose of the regulation was not to shift the site of care, whereas in fact it probably will shift the site of care.

Dr. Rapp: I think they're going to make—I think there was a lot of discussion about it wasn't their purpose, but in any event, what contingency plan did you have in mind?

Dr. McAneny: I would like to have them make a contingency plan to ensure that patients continue to have access to infusion and chemotherapy services in physicians' offices and the plan should include comparison of hospital out patient department costs with physician offices' costs, safety, and patient satisfaction.

Dr. Rapp: OK, there's a second to that. Is there discussion on that? Dr. Wood, and then Dr. Urata.

Dr. Wood: That one to me sounds like we're asking for a study, not a contingency plan.

Dr. McAneny: What I'm wanting them to do on that with the plan is to say, to look at Medicare as a whole and take it out of the various silos so that they don't just look at the out patient physician office, out patient hospital office and figure out how they're going to shift that back. First I think they are going to have to do some sort of a

study, but they're planning on not doing it until first MedPAC will have reported January of 2006, which will have given us a year with the 2005 cuts. So I think they need to have some sort of a plan in place to rebuild things if that shift occurs, which we think will and they think won't.

Dr. Hamilton: You're right. It does ask for a study.

Dr. Urata: I just want to make sure that we allow for flexibility because in the area where I come from, we can't do it in the office anymore and we still believe that we can do in an out patient hospital setting with high quality. Granted we don't have all the specialists in our community to provide this service. We still think that we get enough advice from our consultants in Seattle to provide great service. So I don't want that this would push the money to go exactly one direction. We still need to have the money available in multiple areas to accommodate the variations in how medicine is practiced in this country. So we have to be careful how we word this. Now I understand your position.

Dr. Simon: I was going to ask in the absence of data, is this a request that the Council is seeking from CMS before the next meeting? Because it's very unlikely that any data will be available between now and May. So I'd like to get a time line if that's what the Council is requesting.

Dr. Rapp: Dana can you read it back please?

Dana: PPAC requests that CMS develop a contingency plan in case the assumption that no point of service shift will occur from offices to hospital out patient facilities is incorrect, that beneficiaries will continue to have access to infusion and chemotherapy services in physician offices. The plan should include a comparison of costs, safety, and patient satisfaction, between hospital out patient facilities and physician offices.

Dr. Rapp: I'm going to take off my hat as chairman for a second and state that I'm going to vote against this. I think it's entirely too specific and I didn't hear that in the testimony. I heard that they were trying to appropriately pay for both types of services and that they were interested and concerned with access in general. So I'm going to vote against that particular motion. Any further discussion?

Dr. Simon: I would have questions in terms of the way the question is posed. I'm not sure of all the venues where we would get information to determine if access is actually denied by patients and how we would be able to validate that. So we would need clarification on what venues you would like us to use to find out that patients are being denied access in a way so that we could validate it.

Dr. Wood: I actually have some of the same concerns that Dr. Urata does. In rural Minnesota, we provide these services in smaller communities in the hospital because it's the only place where you can do it reasonably safely. And I'm concerned that what we're asking about at the moment is an impossibility. What you're really asking about is what is the relative cost difference if any between delivery in the physician's office versus the hospital. The access is—so supposed, for example that patients leave physicians offices but they get the same treatment in the hospital. So they're still going to have access. What I heard actually was the concern about what is the out of pocket expense for the patient. Is the policy implication for the patient that they'll have a higher out of pocket expense for their care by shifting it one way. And if that's the case, then it seems to me that what we would want to ask CMS to do is to work to minimize the financial impact of the patient, regardless of where they get what would be medically necessary and appropriate care. And that's a totally different policy issue that you have to consider fairly carefully I would think.

Dr. Castellanos: To add to that, it's not just to the patient, but to the physician also. The cost to the physician.

Dr. Wood: What's the cost to the physician?

Dr. Castellanos: Acquisition price.

Dr. Wood: Not if they leave the physician's practice.

Dr. Castellanos: If we administer it in the hospital, it comes out of the hospital. If we administer it in the office, the acquisition costs the—

Dr. Wood: Right, but we're talking about the patients leaving the office, so they're going to the hospital.

Dr. McAneny: I'm very aware that 20% of all cancer patients receive their chemotherapy very safely and very well and very happily in hospital-based out patient infusion departments. That's not the issue of this. The issue is capacity. If the assumption that they're making, and I heard them say several times because I asked them several times, and the answer I got if what would happen if this occurred, if physicians are sending their patients to the hospital, was well that won't happen because that was not the intent of our regulation, our law. So they never got past the "that will not happen," so they to me are making the assumption that this shift in point of service is not going to occur. However, if that shift in point of service occurs, and you ask a system that is currently doing 20% of the work to suddenly step it up to some significant fraction larger than that, perhaps the Medicare part of that, which

is generally about an extra 40 to 50% in most venues, to whether or not the hospital out patient departments can do it, will it cost more to the Medicare system as a whole, will it cost more to the Medicare beneficiary on an individual basis in terms of their co pays and will we be, because there are limited numbers of oncology nurses, pharmacists familiar with chemotherapy, etc., etc., will we be adversely impacting patient safety and I know Medicare doesn't promise that patients will not have long waits, etc., but I think that there's a possibility that if you overload a system, you may adversely impact patient satisfaction. I think that it would be reasonable to ask CMS to consider that possibility, and whether they want to call it a study or a contingency plan or whatever, I think it's reasonable for us to look past our immediate assumptions into another set of assumptions and figure out what are we going to do if.

Dr. Simon: I fully understand the question and accept the concern. I guess the question is, in light of the way the system is designed, we would not if we were to embark upon this question today, we wouldn't have the information from the out patient data until well into next year. So again, I pose to the Council, in the absence of data, if it's the pleasure of the Council, then the question needs to be posed in a manner where we can either provide a response for May, or define the time line that you would like for us to work with that.

Dr. Rapp: Any further discussion on this?

Dr. McAneny: On the time line issue, I think that's a very valid point, and I think that at least having an update perhaps at the next meeting of how CMS would propose to monitor patients' access for all the reasons I just went through would be reasonable and then have ongoing access evaluations, recognizing that there probably won't be any real data until probably spring of 2005.

Dr. Rapp: Let's read the motion back and then vote on it.

Dana: The motion hasn't changed?

Dr. Rapp: No.

Dr. McAneny: Unless you want to change contingency plan to study.

Dr. Rapp: Just read the motion.

Dana: PPAC recommends that CMS develop a contingency plan in case the assumption that no point of service shift will occur from offices to hospitals is incorrect. The contingency plan should ensure that beneficiaries will continue to have access to infusion and chemotherapy services in physician offices. The plan should include a comparison of costs, safety and patient satisfaction between out patient facilities and physician offices.

Dr. Rapp: OK, all in favor, raise your hands. All opposed? Motion fails. Any other items.

Dr Bergeron: Can we resurrect the motion? And amend it?

Dr. Rapp: Dr. Wood's got the floor.

Dr. Wood: PPAC recommends that CMS evaluate the impact of shifting the professional liability adjustment to more fairly recognize the physician burden of increased risk at psychologic stress in the physician work component of a service. This requires that no negative adjustment be done to the physician work component and that the entire adjustment should be on the practice expense component of the fee schedule.

Dr. Rapp: Is there a second to that?

[Seconds]

Dr. Rapp: Is your writing legible?

Dr. Wood: Now that's a really good question.

Dr. Heyman: We're going to find out.

Dana: PPAC recommends that CMS evaluate the impact of shifting the professional liability adjustment to more fairly recognize the physician burden of increased risk and psychological stress in the physician work component of a service. This requires that no negative adjustment be done to the physician's work component and that the entire adjustment should be on the practice expense component of the fee schedule.

Dr. Rapp: Is that it, Doug?

Dr. Wood: Yeah.

Dr. Rapp: OK, there's a second that. Is there discussion? If not, all in favor?

[Ayes]

Dr. Rapp: Anybody opposed to that? The motion carries. It is now time for our, let's see, we have another item on in three minutes, so why don't we take a brief break and then we'll also consider more motions that may be made at the end. So 7.5 minutes. [laughter]

[BREAK]

[RESUME]

Dr. Rapp: And I'd like to welcome Brady Augustine, who's the senior advisor to the acting director of Center for Medicare Management. And he's here to speak about ESRD quality initiative demonstration projects.

Mr. Augustine: Mr. Chairman, Council, it's a pleasure to be here today and for the record, my title just changed today. CMS people tend to move around a lot. I'm unofficially the ESRD Senior Executive, for the ESRD program and the chair of the ESRD Steering Committee. But my official working title is Acting Director of the Division of Continuing Care Providers in the Center for Medicaid and State Operations. So it's a mouthful.

Dr. Rapp: What's that mean?

Mr. Augustine: What does the title mean? It's a survey and certification group. I'm assisting down there temporarily to help fill out their management team. But I still, as I stated lead the ESRD program and chair the ESRD Steering Committee. It's my pleasure to speak with you today about quality in the ESRD program. I'm going to read a little bit and I'm going to fill in some blanks, and then I'll open myself up for any questions. There's a lot going on in the ESRD program presently. The Centers for Medicare and Medicaid Services quality initiatives are an integral part of the Department of Health and Human Services commitment to assure quality health care for all Americans through accountability and public disclosure. These initiatives aim to number one, empower consumers with quality of care information to make more informed decisions about their care, and number two, stimulate and support providers and clinicians in order to improve the quality of health care at large. The initiatives use one or more strategies in order to obtain their goals. One is supporting shared methods or standard methods. Second is to promote and create collaborations in partnerships, third is to give plans, clinicians, providers technical assistance. The fourth is to reward desirable performance. The fifth is to structure coverage and payments in order to improve care, and the sixth and last is to establish and enforce standards. The ESRD quality initiative, which fits into the department's quality initiative, has not been publicly announced. But quality has been at the center of the program since it was conceived in 1972. For example, the ESRD networks were created in 1978, which was significantly earlier than the PROS or the QIOs today. And CMS initiate the ESRD health care quality improvement project in 1994 to focus the ESRD networks on improving care. The activities have led, as well as other activities the agency has undertaken, have led to demonstrable improvements in patient care. But being a quality person by trade, we always realize there's more we can do and there's always more performance we can squeeze out.

Now I do have for the record, I can leave this today. This is a Peer Review Journal article for Health Care Finance and Review. The title of it is, "Improving the Care of ESRD patients, a Success Story." It talks about the health care quality improvement program and the improvement in outcomes since the initiation of that program.

Now the individual strategies that CMS uses to improve care and associate activities, and this is where I'm kind of going to go down and do a little more ad libing about what's currently underway in the program. As far as supporting standard methods, we have the clinical performance measures project, which is an annual report that CMS issues right here. In the ESRD program, we were measuring quality even before HEDIS and some of these other measurement systems came out. This was initiated in 1994, under a different name and expanded in 1999 or 2000 to become the clinical performance measures project. It is based on an expert council and clinical practice guidelines in the community which are very well, very scientific base and very well thought of throughout the community. So it makes it a lot easier to use these guidelines to develop measures to improve care. And this is a 5% sample of all of the ESRD patients throughout the country. And it's showing sustained improvements which are documented in this Peer Review paper of improvements over time. As well, we have whereas the clinical performance measures, or summary measures, we're also presently working with the renal community to develop what's called a core data set. One good thing about ESRD is it's very numerically oriented because it's based a lot of lab mice, PTA's test, hemoglobin tests, things of that nature. So what we were doing right now is we were working with the Lawrence Alice's Corporations as many of you may know, about 70% of ESRD patients are covered by five for profit dialysis corporations. We're working with them to get raw data feeds, so that not only do we have 5% of our outcomes, but 100% of our outcomes for all of their patients. This will help us target activities and provide feedback to providers and maybe potentially develop incentive programs in the future which I'll discuss in just a little bit.

The next item that falls under standard methods is dialysis facility compare, which web site that we have, where we provide information to consumers, to patients, in order to make better decisions. Information about the individual facility structural type characteristics, and there are some patient characteristics in there as well, some measures like hemoglobins and adequacy rate. As well, we have the Fistula First project, which some of you may be familiar with. What we did during this last scope of work for the ESRD networks, we teamed up with Don Berwick's shop, the Institute for Health Care Improvement to develop a nationwide quality improvement program, which we have since named, the Fistula First project or initiative. And this is a comprehensive view, not only looking at the networks going out there and trying to educate and share knowledge with individual facilities and with surgeons and with hospitals, but CMS is also based I believe, is supported by the recommendations by this

Council, I believe at your last meeting were looking at how we can incentivize proper AB fistula usage in this community. It would lead to significant improvements in care, and also reduce burden on the trust. We believe that so many of these patients receive hospitalizations that could be prevented with proper access utilization, we think that's something that we really need to focus on. And we've made a concerted effort to do so. We started rolling out the Fistula First project at the beginning of this year. And we're excited about what we're going to be able to find out from it.

And the last on the support center methods is the ESRD CAHPS, patient experience with care survey. It's like the surveys for hospitals and this is CAHPS surveys for managed care. Basically, right now, our beneficiaries do not have a lot of opportunity to give input directly to Medicare, so that we can act on it. A lot of information goes through the networks so we have very little information about how patients feel and if they're receiving appropriate care. So we're teaming up with the CAHPS team within CMS, Ryan Westatt and some of the contractors who develop a patient experience with care survey that we will determine how we're going to administer that in the future. Whether it be voluntary or whether or not we will pay for it to happen, we don't know. But it is an exciting development and we are glad that we're going to have more opportunity to listen to our beneficiaries. And the next strategies, I'll list, but some of these things just run over and over again, so I won't go through them.

The second is promote and create collaborative relationships and partnerships. In one of those, it was a major change by the previous administrator, was ESRD Open Door Forum, which I am the chair of. That has made a big difference in the community because people feel like they can come to CMS, ask questions and there's someone, a name and a face, that will respond to their inquiries. The next is ESRD Stakeholder Meetings. We're presently having a stakeholder meeting next month where we will talk about all the initiatives. Primarily the ESRD CAHPS initiative and our dialysis facility compare with the ESRD community. We already have over 200 people that are going to be showing up in Baltimore to attend that meeting. As well on every major activity we have underway, we have technical expert panels, which include expert nephralogists, patients, providers, all different types of stakeholders in the community, to ensure that what we do is appropriate to meet our goals of improving care and protecting trust.

As well, we also participate in all types of community efforts. Like the dialysis patient provider conflict initiative. The ESRD formed networks joined together and bought experts like clinical ethicists and lawyers and

CMS and patients, social workers, to look at how we can deal with conflicts that occur in the dialysis facility, because a lot of these patients are getting discharged for being difficult or asking tough questions and have no where else to dialysize, and in essence, it's a death sentence. So we're trying to see how we can better structure our conditions for coverage, to ensure that that happens only when absolutely necessary.

Dr. Rapp: What did you just say there?

Mr. Augustine: Sir?

Dr. Rapp: What did you, would you repeat what you just said?

Mr. Augustine: The entire portion, or just the last part?

Dr. Rapp: That death sentence part.

Mr. Augustine: These patients need dialysis in order to survive.

Dr. Rapp: And what happens?

Mr. Augustine: They die.

Dr. Rapp: No, I understand that, but why is that?

Mr. Augustine: Well, we can't force any provider or any physician to take on the care of a patient. So if a patient is disruptive or creates an antagonistic environment within the clinic, they can ask that patient to leave. And then if there's no where else for them to dialize, then, in essence, they could die. Or move, yes. So we're quite concerned that the proper due process is in place and ensure that this is minimized as much as possible.

As well, we are also collaborating with the National Institutes of Health on a study on altered modalities, specifically nocturnal dialysis and more frequent or daily dialysis. That collaboration will continue until—I believe they're not going to initiate the study until mid this year, and it's a one-year study, and we'll use the information gathered from that study to determine whether we need to change payment policy to allow these new modalities.

Then last on the collaboration section, we're trying to get state surveyors in ESRD networks to work and speak more frequently so that they work together better.

The third strategy is giving technical assistance as primarily ESRD networks, but also CMS and myself spend a lot of time on the phone with renal physicians associations, the American Society of Nephrology, American Association of Kidney Patients, helping them understand the program and providing technical assistance. So it's a major part of my job—one of my major roles is outreach and I take that seriously.

And the fourth one is reward desired performance. Now on that we have the ESRD disease management demonstration. And in that demonstration, we have a 5% hold back that's paid out for quality. And there's five indicators. One indicator for each 1% and let's take bone disease for instance. Bone disease is one percent. You get a half of that percent for bone disease whether or not you meet the national average, or you're at least as good as the national average. You'll get another half a percent if you increase your performance by 10% or reduce your deficit by 10% over the last year. And so it not only focuses on meeting targets, but also improvement percentages. And that would be paid to these facilities based on the outcomes of their data. And we'll be getting data from them on a quarterly basis. As well, dialysis facility compare is a way of rewarding performance, but it's not financial. It's more in terms of recognition. As well in MMA, there's section 238, which directs the Institute of Medicine, the Secretary, to contract with the Institute of Medicine or to evaluate performance measures and options to implement policies that align performance with payment. And that's something we'll be assisting or liaison with IOM on that particular study. As well, the fifth strategy is structured coverage and payments to improve care. The first is we have a report in Congress that was issued last year on expanded bundle and market basket. We believe that if we pay for an appropriate bundle of services and providers have to worry less and less about trying to maximum separately billable drugs, which in the ESRD program is where the margins reside, and if people can focus more on appropriate utilization, and potentially even better patient care, as opposed to trying to increase margins. Of course any expanded bundle would really to go into place to be truly effective would need to have some type of quality underpinnings which is the QA portion, and also to be wholly effective, having a nice incentive on the top end would be ideal. We do not have the ability presently to undertake all of these activities at one time. And we see the payment system maturing as our data systems mature as well. As well we changed the drug payment through MMA, Section 623, to pay more appropriately for these separately billable drugs, to reduce the incentive to over utilize. We have the Fistula First project, as I spoke earlier. We also changed the way nephrologists get paid for managing the care of ESRD beneficiaries. We changed it to be more in line with their own professional recommendations, ESRD recommendation, Renal Physicians Association, and American Society of Nephrology's practice guidelines. And then also we were currently reviewing our anemia management coverage and payment policy.

And the last strategy is to establish and enforce standards. And the most important lynch pin of that is ESRD conditions for coverage. That is currently under review in the department and we hope to have it published by

the summer. That's a major change. Most of the aspects of this program have not been revised in 25 years. For instance, these conditions for coverage that all facilities have to operate under are 25 years old. The physician payment system was 20 years old. So a lot of changes are underway. We realize we can do a better job in providing and incentivizing appropriate care.

As well, increases surveyors and surveyor training has gone underway, and we're also, as I said earlier, we're working to increase the collaboration between the state surveyors and the ESRD networks.

I want to thank you for the opportunity for giving me a chance to speak with you today and talk about quality in the program. It's really near and dear to my heart, because I've, these patients really deserve the best care possible and we can all work together to attain it. Thank you.

Dr. Rapp: Dr. Urata, Dr. Wood, Dr. Hamilton.

Dr. Urata: I have two questions. Do you have any comments on periteneal dialysis? That's part of your program, too?

Mr. Augustine: Yes, sir. It's both in the statute, but also in our regulations. We're quite clear that home training and home therapy should be available to patients and because of not only the fact that there are more and more studies, in fact there was a major, I don't know if it was the same or not, study that came out the other day, talking about how it's better modality. We were quite in favor of that and are looking at ways in the future to kind of turn the ship around because PD used to be about 12% of the total population, now it's gone down to 8%.

Dr. Urata: The second question I have is, our small community has gotten a, is going to become a satellite clinic of a nephrology clinic in Anchorage, Alaska. I live in Juneau. And so they're starting to have programs. And how do you look on that? I guess they're developing more satellite clinics, they're trying to do that in Fairbanks, out of this one clinic, and so apparently reimbursement to the nephrologist has improved to allow that to happen. I guess we had to get a waiver though, in our community to allow for it to become Medicare licensed. Do you know anything about outreach to rural areas for your dialysis? Because in the past our patients would have to move out of town in order to say alive, and a community group of people got together to get this thing going. They figured that they need 16 patients to stay in the black, to break even.

Mr. Augustine: That's one of the best things about home therapies is it helps out in rural situations. We are quite attuned to what is going on there and as I said, I spend about an hour or two a day speaking with patient

groups, speaking with the networks, trying to learn what we can do. That, they're still going to have to be certified. I don't believe there'd be a waiver. I mean they would have to go through the certification process, through our regional office, and the state would have to come in and survey them as well, but

Dr. Urata: This is an actual dialysis center that we're going to have. We have home people now, but we also will have a dialysis center.

Mr. Augustine: Well, they would still have to be certified. And by the state and recognized by the regional office. So really, satellite clinics are good in many regards, because they do assist patients because they're close to their home. Patients lives are disrupted less and it helps out with the rehabilitation issue, which is one of the reasons why the program was instituted in the first place, was to get patients to continue to work.

Dr. Wood: On the dialysis compare program, since, by your description most dialysis is provided by one of a few companies and it sounds like there's not a lot of choice for patients, are you going to be moving that program more toward quality improvement than was currently the circumstance I think that is, you're just putting the numbers out there for people to look at? You can't really choose which provider you're going to if there's only one provider in a hundred miles.

Mr. Augustine: One of the things that we're really trying to focus on is to make dialysis facility compare as easy to understand as possible. And so we're coming out with a major revision to it, I believe in March, maybe April. We've had it cognitively tested with our beneficiaries to see what matters to them, can they understand the way this is phrased, trying to take as much jargon out as possible, so there will be a significant improvement in that regard. We think we need to have it to be understandable before we can move it forward in other directions. As well, since the DFC is primarily out there for the education of patients to get them better information to make decisions, it's not really a QI tool, even though it can be used in such a fashion. The other thing is it's based on claims data and what we'd like to do is now that we're working on a core data set, we'll actually get real clinical parameters from the medical record, we'll be able to develop QI activities around those parameters that will be much more consistent and accurate as far as the providers and physicians are concerned. And so the DFC is primarily for patients, even though I know facilities and providers look at it, we are evaluating whether or not to put survey and certification information on there, whether or not it would be appropriate or biased. We are looking at what we can do to expand

that web site to make the most value of it to our beneficiaries as possible, and we're going to continue to work on the back end and get the data that we need to enhance and enforce our QI perspective as well through the networks.

Dr. Hamilton: When you compare quality among these five providers, you'll be comparing specific dialysis facilities of these providers, not just the overall results, because there's a huge variation, depending on the administrator and the docs and the nurses and the people in each individual facility. Is that correct?

Mr. Augustine: Yes, sir. Thank you for pointing that out. Just like Dr. Winberg has shown his Darbirth Atlas, the same thing happens in dialysis. And one of the things that makes quality so important is that dialysis is very process oriented. It's much more homogeneous as opposed to other treatments that you may provide. And so one of the things I did when I was in the private sector was did some sig sigma analysis on reducing variation in the process and improving outcomes. And it's quite amenable to that. That said, even though there are practice guidelines that have been out there, seven, eight years, by very reputable source, very scientifically based, very well respected in the community, there is still a huge amount of variability. Even within the same dialysis chains. So we are working right now through our quality improvement efforts to reduce that amount of variation. Not only to squeeze the curve, but also to shift it to the right. And that's a major undertaking when you have 4500 facilities, but we're working with the networks, we're working with payment policy, we're trying to squeeze, you know the old saying, you squeeze the balloon on one side, it just pops out on the other? Well what we have to do to improve care is to squeeze it from all sides at once and just hope it doesn't pop.

Dr. Hamilton: My other question was what are your parameters to evaluate bone disease management among these centers?

Mr. Augustine: Well, the National Kidney Foundation just came out with practice guidelines for bone metabolism. And we do not have those as clinical performance measures yet, but it's been sited by numerous clinicians that bone disease is the most important aspect of the ESD program that is yet to be addressed because these patients are primarily dying from heart disease. Not only in the ESRD stage, but also in the pre ESRD or chronic kidney disease stage, and so one of the things I, and others in the H have been pushing for is to get these adopted as CPMs. The only real hesitancy that we have are number one, we have to pull together our expert panel from outside to make sure that it has valid input from the community and also I understand the National Kidney Foundation, their lit review only went to 2001, for those guidelines that went out in October of last year, and since

so much happened when that lit review and the release of the guidelines, that they're going to come back with a revision early this year, and so we're kind of waiting for that occur before we put things in stone.

Dr. Hamilton: So you haven't really adopted any specific parameters that you're going to monitor, because there's lots of them, including bone density, to blood calcium, to alcaline phosphate, all sorts of parameters that you can follow. I was just curious how you were going to compare them.

Mr. Augustine: The ones that are pretty much adopted now for ESRD, but the relationship between them are cal phos and PTH, but we're going to continue to work on those. Those are very important to our patients and to us.

Dr. McAneny: It was my understanding that a lot of the dialysis companies already have a whole series of monitor that they have to meet and I'm wondering if you're incorporating those or developing a new one. Plus my other concern is the satellite clinics. I was interested to hear that they're starting some in Alaska, because we're worried about whether or not in some of the small communities in New Mexico, we'll be able to keep ours. A lot of those work very much as sort of break even propositions and with the new dialysis codes requiring a certain number of visits and payment level per visits, if you're a physician who's flying to Juneau and you have to see that patient and that patient happens to be on vacation, getting their dialysis in Albuquerque that week, you miss seeing them, you don't get that billing in, you don't get that code in, your dialysis level drops, and if those people are in the hospital, or you don't go on the day when they're there, it just makes it a lot harder for the limited number of nephrologist around to actually get out to provide that. I'm wondering if CMS is looking at relaxing any of those criteria or adding some other type of incentive for people who are setting up dialysis programs in smaller communities. Health care being local, I mean these people either have to move or die of it.

Mr. Augustine: That was addressed in the comment period, what I call the geographic exception issue. And we try to alleviate that as much as possible by allowing mid level practitioners to provide some of the visits and also reducing the amount of variation between the different visit levels. And so we try to do this as much as possible. We don't really have the authority or the ability without creating a very dangerous precedent to pay geographic exceptions, because who's to say what miles or what? And it doesn't happen for other providers, so we're quite concerned about doing it for a nephrologist. That said, we are also exploring other ways of alleviating this geographic issue, like for instance, potentially using telemedicine. If we can determine that it's actually valuable,

then we may look into doing that as well. So we're trying to find every which way possible. We have, since the final rule, or in between the proposed rule and the final rule, we made several changes I noted earlier and we continue to look at how we can best provide how this payment system can best provide care in all circumstances and not reducing the accessibility, so we're going to continue to look at that. But your first, you had a first portion of your question as well.

Dr. McAneny: Which was the fact that most of the dialysis providers have a series of various ratios and quality parameters that they're already looking at and the dialysis companies are already internally giving awards to units for meeting ten of ten or five of ten or however many criteria they currently meet. And I'm wondering if you're building or setting up your own.

Mr. Augustine: Well, I actually set very high standards for CMS because I actually developed many of those reports when I was in the private sector. And know that they can have outcome reports available two weeks after the end of a quarter and develop the actual payment mechanism to incentivize nurses to achieve better quality outcomes. So there's a high standard that's been set in the industry. And I believe the General Accounting Office actually wrote a report on this as well, saying CMS could learn a lot by what's going on in dialysis facilities. They have wonderful technology in these dialysis organizations in order to do this. Now the problem with it is is that everybody measures it a little bit differently. And what you say is 94% in one corporation, may be 90% in another corporation, even though adequacy of 1.2 or 1.3, some of them have different even adequacy measures. Even if they were the same, the inclusion, exclusion criteria may be different, or we exclude pediatric patients or we don't or we exclude patients that withdraw from dialysis or we don't, so just like we found out when the HEDIS measures came out in the mid '90s, there so many way to game the system and myself being a statistician, not to say I've ever gamed the system, but you know how complex it is and how easy if you forget one little thing that the numbers are not comparable. So we are trying to recreate for the ESRD program like what HEDIS did for managed care by coming up with standard means, standard measures so that when a company reports 95% of their patients are satisfied, or 95% of patients have adequate dialysis, that we know exactly what that means. Today, we can't really say that. And we have to have that in place. The system has to mature for us to move forward. That has to be in place before we move toward real strong QI, before we move toward any types of payment incentives. There has to

be transparency and belief in the system and in order to have that, you have to have well accepted, well documented community based performance measures.

Dr. Johnson: I'd like to request Council receive a copy of the journal article

Dr. Rapp: All right, that request is noted. Anything else? If not, thank you very much, Mr. Augustine.

Mr. Augustine: Thank you, sir.

Dr. Rapp: All right, now

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we have four organizations interested in public testimony. One from this morning, American College of Surgeons, Dr. Trout, I believe.

Dr. Trout: My name is Hugh Trout and I'm here today representing the American Council of Surgeons. The college represents 66,000 surgeons of all specialties. I'm a vascular surgeon in private practice in Bethesda. I spent the morning seeing patients, so I'm particularly appreciative of your flexibility in scheduling, getting around my scheduling difficulties. I'm aware the PPAC has recommended to CMS that drugs be taken out of the SGR calculation, but I would like the indulgence of the committee to express some specific concerns of the American College of Surgeons.

Drug spending is growing rapidly, increasing from 8.7% of the SRG in 2002 to 12.3% in 2004 for a total increase of 41% in just two years. There were twenty drugs in the hundred fastest growing services. At the same time, spending for major procedures has remained constant. We believe that this increase in drug spending will continue for many years as new and generally very expensive drugs are introduced. Moreover, the use of drugs varies significantly by specialty. The six specialties of gynecology/oncology, rheumatology, urology, hematology, hematology oncology, and medical oncology receive more than 40% of their Medicare income from drugs. On the other hand, 16 specialties, including the large specialties of internal medicine, family practice, general practice, OB/GYN, and general surgery had 5% of less of their Medicare income from drugs. Thus, the administration of drugs by a few specialties of small size has the unintended consequence of reducing payment for all specialties. As is laid out in some detail, in the college's written testimony, CMS clearly has the authority to remove drugs from the SGR calculation. The definition of "physicians services" in the statute that required the use of drugs in computing the SGR was dropped in 1997.

Our second concern with the SGR involves the recent legislation that gave physicians positive updates of 1.5% in 2004, 2005. Ironically the law said that this modification is not to be reflected in the SGR calculation as a change in law. This sabotages the point of the SGR by preventing it from rising to reflect legitimate increases in spending originating in the law. By not adjusting the SGR to account for this increase in spending, expenditures will far exceed the SGR and the result will be years of negative updates. On the other hand, if fundamental changes in the update can be agreed to, the cost of making changes will be artificially inflated by not including the updates in 2004 and 2005 in the SGR. It is entirely possible that this "cliff" will be so great that it will cause the defeat of a proposal that is otherwise acceptable.

We applaud PPAC's recommendation that CMS take drugs out of the SGR calculation. We hope that CMS joins us in seeking to get the 1.5% increases in 2004 and 2005 as reflected as a change in law.

With regard to medical liability, a year ago, when I appeared before this committee, one topic I addressed was liability crisis that had hit 19 states. I said at that time "in a growing number of states, surgeons are having difficulty obtaining medical liability insurance. And for those who are able to find coverage, the cost is often prohibitively high." That is still true, indeed, in some instances, it is more so, with many surgeons have to make difficult decisions about limiting their practice or even retiring early. Since the Medicare fee schedule is used as the basis for determining payment for many insurers, it is critical for the entire health care system that these costs be accounted for appropriately. For 2004, CMS did adjust the malpractice geographic practice cost adjuster, or GPCI, using 2002 actual or estimated premiums. And we want to thank them. The college believes it is important that CMS and the specialty societies put a great deal of work into the five-year review of malpractice RVUs. We urge PPAC to recommend to CMS that the proposed rule for 2005 include other alternatives that are being considered for the malpractice RVUs, including the option offered in 1999 by the Neurosurgeons. We also urge PPAC to recommend that specialties be invited to submit alternative methodologies in the proposed rule.

Thank you for the opportunity to provide testimony and I'd be happy to answer any questions.

Dr. Rapp: Any questions of Dr. Trout? What was the Neurosurgeons Proposal in 1999?

Dr. Trout: It was a methodology proposal of how to address the RVUs.

Dr. Rapp: Anything? OK. Doctor thank you very much. I'm glad you spent the morning seeing patients. The next organization on the agenda. The American Academy of Family Physicians.

Dr. Weida: Good afternoon Dr. Rapp, and members of the PPAC. I'd like to thank you for this opportunity to speak with you. I'm Tom Weida, I'm a practicing family physician in Hershey, Pennsylvania, and Vice Speaker of the American Academy of Family Physicians, which represents more than 94,000 members throughout the United States.

The hour's late, I'm going to try to give you an abridged version of my testimony, and I'm sure hopefully you'll appreciate that, and then just pass the recommendation that we ask for. Basically we'd like to share with you specific goals the academy's adopted with respect to management of Medicare patients with chronic disease. And basically those are to improve the quality of care provided to Medicare beneficiaries with chronic disease, to increase payment to physicians providing, managing and documenting high quality cost effective care to Medicare patients with chronic diseases and to seek PPAC support for pilot testing a care management fee through CMS demonstration projects for Medicare patients with chronic diseases.

As Dr. Wood indicated, Medicare patients have multiple chronic diseases and unique care needs. About two-thirds of Medicare dollars go to participants with five or more long standing conditions and seniors with six chronic conditions saw an average of 9.2 physicians in 1999. These figures argue for a single primary care physician who can provide cost-effective and coordinated care for those in Medicare. According to the Graham Center for Policy Studies in Family Practice and Primary Care, 82% of Americans have a usual source of medical care, and 60% of people over 65 identify a family physician as that source of care. This data leads us to our view that care for patients with chronic disease must be coordinated through the primary care physician. The patient's usual source of care, rather than disease management companies. Again, as eluded to by Dr. McAneny. Americans Family Physicians in the AFP are trying to do their part to narrow the performance gap between what is known to be possible and what is actually delivered in health care today. These include some major academy initiatives; to improve chronic illness care within family physician offices by utilizing evidence-based medicine concepts, to reinvent and redesign family physician practices following the crossing the quality chasm report, Six Aims and Ten Simple Rules and also through our future of family medicine initiative; to accelerate family physicians' adoption and utilization of electronic health records and other information technologies as part of our partners for patients initiative; and to promote standards and improve the quality of care and patient safety, such as the continuity of care record. As Dr. Heyman indicated, the current financing mechanism that fuels office space ambulatory care is

broken. The current visit-based, bullet riddled reimbursement system has undermined and compromised primary care's ability to deliver what they are trained and prepared to deliver to American seniors, particularly those with multiple chronic diseases. The current system has put primary care physicians on the office visit treadmill. As we all know, effective chronic care management takes time. And it involves developing a partnership with each patients; developing a care plan, it requires ongoing communication and coordination of various systems to integrate their care, and it involves patient education resources and delivery systems. And much more. This consumes time and resources and requires different models of delivering care, such as group visits, not currently captured in reimbursement levels for office visits. The Medicare Modernization Act of 2003, specifically Section 721 and 649, are designed to develop and test innovative and transformative models for chronic disease management. The AFP urges PPAC to envision, identify and discuss those innovative and transformative models for primary care physicians and to manage patients with multiple chronic diseases in the context of these demonstrations. Such models should embrace the adoption of a care management fee, for reimbursing primary care practices that agree to participate in chronic care demonstration projects and use information technology and other tools to deliver evidence-based care to produce outcomes data for improvement and accountability purposes. You've already been discussing this all morning and most of the afternoon. Similar models have been used in the Medicaid program and could be used as a model as well. Currently, small, medium sized primary care practices need financial assistance in purchasing and implementing information technology, because a key component of effective care management is electronic medical record. A care and management fee would help to amortize these investments that are necessary to provide the kind of care that everybody wants and deserves. There are many issues that would need to be addressed in designing the care, including qualifying targeted Medicare beneficiaries and voluntarily enrolling them with participating practices, determining how and if to provide incentives to participating beneficiaries, defining a basket of integrated administrative and clinical services, qualifying and enrolling in practicing physician practices, agreeing on the evidence-based performance measures, quantifying the management fee for the agreed upon basket of services, and evaluating the clinical and economic outcomes. As a result, the AFP would appreciate PPAC's support and your input in working with CMS to design and pilot test a care management fee concept for physician practices treating Medicare patients with multiple chronic diseases. These pilots can be conducted under the current authorization. As such, we hope you adopt the following recommendation. That CMS working with the primary care

community, identify a model by which primary care physicians manage Medicare patients with multiple chronic diseases. Such a model should embrace the adoption of a care management fee for reimbursing primary care physicians who agree to participate in chronic care demonstration projects, using information technology and other tools to deliver evidence-based care and that produce outcomes data for improvement and accountability purposes. Again, I thank you for the opportunity to speak with you, and happy to answer any questions.

Dr. Rapp: Dr. Powers?

Dr. Powers: I don't think you can limit this to primary care. I there are certain specialties that have their diseases that, for instance, epilepsy. I see my epileptic patients far more often then they see their primary care physician. So the care management certainly would fit with that multiple sclerosis and a few other things. So I don't think you can limit it to primary care.

Dr. Rapp: Dr. Johnson?

Dr. Johnson: Do we have any in the testimony here, it talked about seniors with six chronic conditions saw an average of 9.2 physicians in '99. Do we have more current data on that as far as 12, 13 different doctors more recently?

Dr. Weida: Don't have any, but I can find out. Of course.

Dr. Johnson: I didn't know if it had come before the Council or something, but seem like even the more recent data have supported that it was 13.2 doctors in 2003 and I don't know if it came through CMS or something. But the need is there.

Dr. Simon: 13.2 doctors per Medicare beneficiary?

Dr. Johnson: With chronic disease.

Dr. Urata: Yeah, the higher the number of diseases, the higher the number of physicians they saw. Therefore requiring coordination of the team.

Dr. Wood: This is a subject that really is going to be critical to reconfiguring how we deliver care in the next several years. But the problem here is that the current statutory basis of paying physicians that Medicare operates under limit the ability of the agency to do anything. Even in pilot projects, the usual approach, having responded to a couple of previous offerings, the usual approach of CMS is to say we will do this, but it has to be done with no net increase in spending, so that it would come out of the pockets of the people who are participating

in the trial. Here's my concern. We know that currently we are delivering only about half of what is considered to be effective care. That is care that should be delivered based on available science and guidelines. And that is the case for acute care and for chronic care and for preventive care. Perhaps the best article that describes that is Beth Lavine's article that was published in the *New England Journal* earlier this year. So the real risk here is that if we do this, it should actually result in an increase in utilization of services, because there are going to be a substantial number of people who are not currently getting the visits they should be getting. They are not getting the prescription drugs they should be getting. The rest of today's discussion I think should tell us where the problem immediately lies. So this I think is going to require a lot more than one simple recommendation, but should, I think highlight the importance of beginning discussions between physicians and CMS about how we can do a better job of caring for a larger and growing numbers of patients who have these chronic conditions. And I wish I could offer a simple recommendation, but I think this one's going to be really complicated.

Dr. Rapp: Other comments or questions? We've considered a variety of demonstration projects in the past and I must say I'm very sympathetic or interested in your proposal because most of them ended up with some organization or institution, this is the first suggestion I've seen for this kind of thing for perhaps an individual solo practitioner as a physician to be able to do that. We were just talking about end stage renal disease and there was, at our last meeting, I'd looked at a GAO report on some problems in caring for patients with end stage renal disease, but the solution was to go out and check out the centers and look at this and send more surveyors out, as opposed to putting the onus or responsibility on a physician that would pay attention to these parameters. So I'm personally very sympathetic to this. I guess I'm a little bit in agreement with Dr. Wood in that the recommendation says, OK, now CMS, take care of this. Come up with a care management fee. Come up with a model, come up with this and come up with that. Work with the primary care doctors. But CMS doesn't have a whole lot of resources, it doesn't seem to me, to do this. So it would almost seem like it was something that for primary care doctors or neurologists or whatever dealing with chronic care needs to go probably a little bit further and the payment piece is one thing, but all the structure and so forth is, I don't know. It just seems like, I think it's a great idea. I think personally that it should be that CMS is interested in promoting this type of practice, primary care doctors, single maybe solo practitioners and so forth just as much as a big institution. We just heard about the end stage renal disease. They go to the facility, not to the doctor to look at making sure that these parameters are met. So I encourage you on it.

Dr. Weida: What I would hope is that PPAC could certainly encourage CMS to try to pursue a pilot type project, or even to be receptive to organizations proposing projects to either get seed money to do that or to at least overcome some of the administrative hurdles that are out there. And that's what I would hope that PPAC would push for that so that it just doesn't wallow out there and not be looked at at all and we continue with business as usual.

Dr. Bergeron: Doctor, I agree with you 100%. I've often said we need a captain of the ship. And I'm a dermatologist. And 95% of my patients have multiple chronic skin diseases [inaudible], carcinomas, actinic keratoses, lupus, etc., etc. I know where you're coming from. I know Mike Flemming real well, he's from Shreveport, Louisiana, so am I. Give Mike my regards next time you see him before I do. But I'm in full agreement, I can see where you're coming from. I've often said, Captain of the ship. I'll see a patient come into the office, nine, ten doctors, medications, and I'll say who is the captain of his ship? I have my office manager, a nurse to get on the telephone, nine faxes later, thirteen telephone calls later, we find out what medications this patient has been on, but the multiple chronic disease, I'm a little concerned like my neurology colleague across the table from me, I wish I could help you in that respect, but I got to think about multiple chronic diseases. Especially being a dermatologist.

Dr. Weida: I don't think this excludes that in that we need to start somewhere, and if you look at patients with diabetes, hypertension, coronary artery disease, hyper lipodemia, these are very common and very expensive disorders and that we should start somewhere on some of these major chronic illnesses. That doesn't mean that this model could not then be brought down to specialists who are managing several chronic diseases as well. I don't see that it's exclusionary. I think we need to start somewhere. We might as well start with areas that may have a big impact, to address the concerns of how do we make this budget neutral? We may find that if we're doing a better job at managing chronic disease, it may be lower cost, even though we have more people getting care, they may be getting more effective care.

Dr. Simon: There are a couple of demonstration projects currently under way, regarding chronic disease care management. One of whom, particularly, that I'm thinking about involves increased risk, where the docs who participate in that model, manage the patient both inpatient and out patient and there are certain performance indicators that if they meet, after the 3-year period, the duration of time that the pilot project is in place, there would be an 80-20 savings where 80% of the money that's realized will go back to the docs, and 20% remains in a trust

fund. There are a couple other disease management projects that are placed, looking at congestive heart failure, hypertension, and diabetes. And so I know that there's at least two or three that have been operational for at least the past year. It may be worthwhile, and those are available, the information is available on the web site, so it may be worthwhile to review those to see if it intersects with the ideas that you have. Because I know that those programs that are in place are specifically looking at ways to increase the efficiency of care as well as the better utilization of drug selection for those patients that have chronic disease process, by doing just that, defining the physician who will be the principle caregiver for those patients, and having that person be the one to engage in a dialog with a specialists that also provide care for those patients. So there are some projects that are already underway that are doing just that. And hopefully over the next couple years, we'll be able to have some information, or we'll be able to determine whether in fact there are cost savings realized and more dollars realized to physicians who have participated in those studies.

Dr. McAneny: Two comments. One is that it would be easy enough to have presumably as a friendly amendment, that the patient could pick which person they see as their primary physician, the person who really manages their care. So for ESRD patients, it could be the nephrologist, for seizure patients, it could be the neurologist, etc. The second thing is since CMS did say earlier today that they were going to be doing pilot projects for disease management as Ken just alluded to, it made me wonder whether or not the projects for disease management, are they going to be funded on a risk basis from these companies? Or is there going to be extra money being put into the disease management pilot projects that were discussed under the MMA, or whether or not this whole process could a pilot project for disease management that could include primary care physicians or whoever someone designated as their primary physician. Could be set up as one of those pilot projects that were discussed earlier?

Dr. Simon: The pilot projects that are operational right now, one of them is a risk-based venture between the physicians and the agency if you will. The other two simply just are designed to identify those performance indicators that represent the standard of care, and if people meet those standards, it's projected what savings will be realized and then there would be an opportunity for cost savings between the physicians and the agency.

Dr. McAneny: So that would be a potential model to do something along those lines.

Dr. Simon: That's right.

Dr. Rapp: But aren't those always some organized groups of, as opposed to, I think the big difference is, can you have a model where individual or small groups of doctors, maybe single specialty or whatever, whether it's a family doctor or a dermatologist or neurologist, but just a office-based type thing could manage a chronic illnesses in some way and have a different payment mechanism other than the only time you get paid is when you come to the office, and they can use the money for managers within their office to handle these things, but not have the big institution or Mayo Clinic or whatever.

Dr. Simon: None of them were single physician pilot studies. But they ran the gamut from large institutional studies, large institution being 200 full time physician groups or larger, and smaller groups that had in the range of 25 full time docs working in a group. But none of them to my knowledge were single physician studies.

Dr. Rapp: So maybe the way to avoid specialty versus primary care versus whatever, just look for demonstration projects for chronic disease management that focus on small groups of doctors, one to whatever, ten or something. Dr. Heyman?

Dr. Heyman: Well I was just wondering, maybe it would be good for PPAC someway along the way to learn what the usual process is for starting these demonstration projects. I mean, it's sort of just here that a demonstration is going on that does X, Y or Z, but we don't know where that demonstration project came from. I mean, was it CMS-started? Was it organization coming to CMS and asking to start a demonstration project? Are there different ways? Is there a formal process or does it just happenstance? Or what is it?

Dr. Simon: I'd be happy to bring that topic forward to the Council to enlighten the Council. But to answer your question, the Office of Research and Development typically, one of their principle responsibilities is to deal with pilot projects. And those projects are usually posted in the *Federal Register*, so that the public is aware and then there is a filing period, where people will actually apply for those that are interested. They're competitive in nature, so that groups that are interested will apply to the agency for participation and then there's a panel within the agency that will select those groups to participate in those studies. But there have been a series of pilot projects that have been operational over the past 18 months and so most of those go through the usual rulemaking process that we have here in the agency. I would be happy to talk with those folks, to come in and give us further information about it.

Dr. Rapp: OK, anything else? If not, I thank you. The next item will be representative from the American Medical Directors Association. No? The American Academy of Home Care Physicians? Do we have somebody there? Evidently not, so we've got written statements from the American Medical Directors Association and American Academy of Home Care Physicians. Just on that last point, do you ever, does CMS ever I guess invite ideas for demonstration projects, as opposed to here it is, we've got it all set up, in other words, be somewhat less prescriptive in something that might lead American Academy of Family Practitioners, or Family Physicians to suggest something like this?

Dr. Simon: I'm sure that ORDI is open. I know that with the number of the pilot projects that are under way, some of them were initiated at the request of the Secretary, who had an interest in dealing with chronic disease management, such as diabetes, hypertension, and congestive heart failure and cardiovascular disease. But I'm not aware, again those are usually competitive in nature and there's a set pool of funds available for pilot projects, and so I'm not sure what process is used to determine which topics will gain consideration and bubble up to the top to have funding tied to it, but we can certainly explore that and find that out and bring it back to the Council.

Dr. Rapp: OK, so we're done I believe with the agenda for today. In terms of everything here, so we have a few more minutes if there's some, Dr. Heyman?

Dr. Heyman: I would like to try to do my recommendation again.

Dr. Rapp: I would suggest that you show the recorder your writing, but no, I'm not going to suggest that.

Dr. Heyman: Don't suggest it. The reporter—I'll read it to you but it's long, but it's very specific. That PPAC recommend that CMS include in the MEI all factors that more accurately account for the cost of practicing medicine, including, but not limited to, one, staffing changes, two, compliance with government-imposed regulatory requirements relating to such matters as fraud and abuse, billing errors, quality monitoring and improvement, patient safety and interpretive services for patients with limited English proficiency, and three, any other costs currently incurred by physician practices that were not included in the MEI when it was developed in 1973.

Dr. Rapp: Is there a second to that? Is there a discussion? Could we read it back?

Dana: PPAC recommends that CMS include in the MEI all factors that more accurately account for the cost of practicing medicine, including but not limited to, one, staffing changes, two, compliance with government-imposed regulatory requirements related to such matters as fraud and abuse, billing errors, quality monitoring and

improvement, patient safety, and interpretive services for patients with limited English proficiency, and three, any other costs currently incurred by physician practices that were not included in the MEI when it was developed in 1973.

Dr. Heyman: Is that woman amazing or what?

Dr. Rapp: She did a beautiful job. But how would this relate to practice expense portion of RVUs?

Dr. Heyman: This is the MEI. So this is the Medical Economic Index, which is used in figuring out how much money is going to be used for paying for physicians, depending upon where the inflation situation is, and as far as I know, there's a whole bunch of factors that don't seem to be included in that economic index which seem to have a lot to do with practicing medicine.

Dr. Rapp: All right, so it wouldn't be just a change from year to year, it would be…

Dr. Heyman: No, it would be…

Dr. Rapp: A rebasing of the MEI?

Dr. Heyman: Yeah, exactly. It would be including all the factors that currently are not included that have come into effect since 1973, when the MEI was first developed.

Dr. Rapp: OK, and that's outside the SGR formula.

Dr. Heyman: That's correct.

Dr. Rapp: OK, any discussion? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? The motion carries. OK? Dr. Castellanos?

Dr. Castellanos: On the average sales price, PPAC recommend that CMS ensure that the physician community is allotted an early notification of ASP for all affected drugs as well as the opportunity to comment on the appropriateness of ASP.

Dr. Heyman: I'll second that.

Dana: PPAC recommends that CMS ensure that the physician community is provided with early notification of average sales price for all impacted drugs, as well as opportunity to comment on the appropriateness of the average sales price.

Dr. Rapp: That got it? We had a second I presume? Is there a discussion? All in favor?

[Ayes]

Dr. Rapp: Anybody opposed to that? That motion carries. Anything else?

Dr. McAneny: Can we do the second bullet, or are they the average sales price in the AMA or do we have to read all that over again, out loud? That whole laundry list one is very good. On page three of a…

Dana: You have a shortened version of that.

Dr. McAneny: We do?

Dr. Heyman: Yes.

Dana: You're talking about the one for purposes of calculating the SGR target?

Dr. McAneny: No.

Dana: No, I'm sorry.

Dr. McAneny: The help avert possible access problems by one,

Dr. Hamilton: It's on page 3, the AMA testimony.

Dr. McAneny: It's this entire long thing, like—

Dr. Rapp: I'm just the vehicle for people to make motions here, but if you want to do that, but apparently we seems like the sense of the committee is that we've got that in there, but, Dr. Powers?

Dr. Powers: No, not [inaudible]

Dr. McAneny: Actually when I was originally going to do was to try one for the disease management projects. I was going to say PPAC recommends that when CMS is considering pilot projects for disease management, that a project be considered which involves primary care physicians with management fees, innovative fees for non traditional management arrangements, and payment for the necessary ancillary services. Which I think gets to what the testimony was. It doesn't get to the primary care issue.

Dr. Rapp: Is there a second that?

Dr. Wood: Second.

Dr. Rapp: OK, discussion?

Dr. Hamilton: I think that pilot projects like that have to be very carefully thought out as to what their end point is that they want to evaluate, instead of just doing it, because you have to evaluate, for example, you can evaluate is this going to be cost effective? Is it going to have a better outcome in terms of patient satisfaction? Is it

going to have a better outcome in terms of specific parameters of disease, such as hemoglobin A1C, whatever, so there are lots of different ways to evaluate outcomes of these studies, and I think that that needs to be considered when you get into that.

Dr. Rapp: Dr. Simon?

Dr. Simon: The only point that I would make is that it may be worthwhile if the presenter could review the pilot projects that are posted on the web site and have a knowledge of them so that we could get better information in terms of if AFP desires a pilot project, what their goals would be aimed at. Because their goals may already be captured in some of the existing pilot projects in [inaudible].

Dr. Rapp: OK, did we have that motion seconded, yes, we did.

Dana: I didn't get that motion.

Dr. McAneny: I have a question first though, are those, have you looked at the pilot projects that are on the web site? Are those sufficient for what you're trying to do in terms of have a model of community based disease management?

Dr. Weida: Again, they don't get the issue of the small practices. I think that's a [inaudible] and certainly [inaudible].

Dr. Rapp: OK, so I don't think our reporter has the motion. Are you still with that one, or…

Dr. McAneny: Sure. That PPAC recommends that when CMS is considering pilot projects for disease management that a project be considered which involves primary care physicians, with management fees, innovative fees for non traditional management arrangements, and payment for necessary ancillary services.

Dr. Rapp: Do you want to address the size of the practice?

Dr. McAneny: Well, I think CMS is already looking at various disease management project and it already is addressing the big practices and the multi-specialty practices and nobody's looking at what can be done in a smaller community where there's just a community of physicians there.

Dr. Rapp: Right, but your motion doesn't address that.

Dr. McAneny: I doesn't address that, but I

Dr. Hamilton: And include the feasibility of small practice environments.

Dr. McAneny: OK. I would take that as a friendly amendment.

Dr. Rapp: OK, friendly amendment, we have to read it back though. But while you're massaging that, Dr. Heyman. Dr. Woods first, and then Dr. Heyman.

Dr. Wood: I guess my question is as we're trying to craft again, these fairly specific motions, should we back up and first ask for a review of existing pilot projects for the Council and the process by which pilot projects might be recommended? Because I think if we look at it more generally that way, we might actually have some better ideas about how we would structure that. Because the issue for disease management really comes down to a patient-based approach over a period of time as opposed to a visit based production approach, which is how we are currently paying for this. And it would not be specialty specific in general, again, because it patient vague, so my only concern about this particular motion is that it gets us far ahead and we haven't really thought about what we want to do as a vision and then figure out what pieces we want to put in place to get us to that vision.

Dr. Rapp: So are you suggesting that that might be a topic for the agenda and then—

Dr. Wood: I think it would be a very important topic for, in fact, devoting a couple of hours to the next meeting to that kind of a discussion and then see where the new leadership wants to go and how we then could help define potential projects. I mean, it could be really one of a number of different ways you could do that. But it would also be nice, I think for the panel members to at least see some of the other projects that are out there. Some of them get in there, by the way, because a researcher has the idea and they go find a Senator or a Congress person, who can put it in the final bill, so it's kind of a version of regulatory cork. [laughter] And it might satisfy the agenda of the researcher, but it may not satisfy the needs of CMS particularly.

Dr. Heyman: Well I was just going to point out that one of the things that we heard in the testimony is that they were interested in a management fee for managing multiple chronic conditions, which is not really be addressed either in that resolution. So I think that probably the first step—pardon me?

Dr. McAneny: It was primary physicians with management fees, and it sounds like it's going to get tabled anyway.

Dr. Heyman: The management fee wasn't just for being the primary care physician, it was for managing multiple chronic illnesses, wasn't it?

Dr. Bergeron: I move that we table this motion indefinitely, to see what other…

Dr. Rapp: Is there a second to that? OK, all in favor of—any discussion on that? All in favor of tabling this motion indefinitely in other words, goodbye, say Aye.

[Ayes]

Dr. Rapp: Anybody opposed to that? The motion's gone.

Dr. Heyman: I'm opposed.

Dr. Rapp: You're opposed to it? It still carries.

Dr. Simon: Would it still be the pleasure of the Council however, to have someone for RD come in—

[assorted affirmative chatter]

Dr. Bergeron: Like Dr. Heyman said, maybe get us a protocol, how,

Dr. Hamilton: List of what pilot projects are currently in progress, or are currently planned.

??: Do we need a motion on this as well?

Dr. Heyman: No.

Dr. McAneny: I think it would be reasonable to hear back from AAFP at the next meeting about whether or not they felt any of the pilot projects that were out there address any of their concerns.

Dr. Rapp: Well, if we, what we'll do at the next meeting, assuming this goes forward, is we'll discuss the pilot project, and how pilot projects get started and so forth more generally, and he'll have an opportunity to be here and give more testimony. So we'll just note for the record that that request was made and Dr. Simon seems to be sympathetic to it. Anything else? If not, six minutes early. Thank you very much and I'll see you tomorrow morning at—

Dr. Hamilton: None of these other folks are going to testify?

Dr. Rapp: They're not here.

[chatter]

[END OF DAY ONE]

[START OF DAY TWO]

Dr. Rapp: Take your seats please. I'd like to again call the meeting to order. Thank you for coming today. And our first presenter is Dr. William Rogers who is a medical advisor and the head of the PRIT, Office of the Administrator. Bill? He's going to talk to us about his cartoons, today.

Mr. Rogers: Thanks Mike. I feel like I'm at home when I'm with the PPAC. I think this is my 137th presentation with the PPAC. I going to talk about some of the issues that are on the PRIT right now, some of the issues that we're working on, and then I'm going to talk a little bit about the enrollment problems that we've had, because I want you all to know what the agency is doing to address that very serious problem. Just got a little side of Tom Scully. You all remember him well. These were in happier days. He's working even harder than he was working before, but he seems to be tolerating it fine, and I think he's getting paid a little better. Dennis is doing a great job. This picture we actually took while we were doing the first All CMD call which had an administrator on line and he was speaking to all the Care and Medical Directors with us as we were working on improving dialog with the CMDs to bring some more consistency across the program and across the carriers, which I'm sure will be something that all of the physicians appreciate. Our web site, Robert Bennett's been working hard on making this really current and we're updating this sometimes twice a week, which is good because as things change, people want to know that they've changed. It also saves us a lot of phone calls. People don't have to call me up to find out if we've done anything because they can see it happen on the web site. We also now have our own email address, which is down there at the bottom of the web site, so the people can communicate and bring issues to us because that's the whole point, is to make ourselves available and accessible.

I'm going to go through some of the issues quickly because I want to save some time at the end to talk about the provider enrollment. Some of the issues that we've got going right now changing patient status after admission. Sometimes when patients are admitted as an inpatient and then the utilization review person says, well, you know this person isn't going to qualify for an inpatient, why don't you switch them to observation status, there is a lack of clarity about how far into the admission a physician can change that status. Clearly they shouldn't be changing the status a month after the patient's discharged, and clearly they should be able to correct an error 15 minutes after they've written it, but whether an hour afterwards, or at the time of discharge, at what time that decision to go to obs rather than inpatient, at what point that becomes irrevocable is unclear, and physicians and other providers have asked us to clarify that, so we're working on that. Another one is the home visit code. We know that that can be used for home visits. It pays a little better, because it's obviously much more expensive for a physician to provide services in the home than it is for instance at a nursing home. Some of the physicians who do a lot of house calls feel also that the higher rate should be paid for instance at assisted living facilities, since they say

there's no real assistance for them there. Nursing homes on the other hand, you have nurses and nurses aids who can help you with the patients so it's less difficult to provide the service there. Keeping my tradition of having some cartoons here, this is a little dated now. But and I supposed a little bit cynical as well.

A couple of other issues. It used to be the policy that until the initial comprehensive visit was made that nurse practitioners couldn't be paid for providing a service. So if a patient came into a nursing home and had an emergency before the physician had actually done the initial comprehensive visit, and the nurse practitioner responded to the emergency, perhaps transferred the patient to the hospital, that would be an unpaid service. It is now clear that that can be paid for and that that's not a barrier to the nurse practitioner being paid for the services.

Manual differences. This is sort of a archaic issue but some labs have been apparently concerned that when they have to do a manual differential because the automated differential is abnormal enough that they can't trust the results from the machine, that they can't get paid for that manual differential. And so we spent a lot of time and wasted, I shouldn't say wasted, but used a lot of time by our program experts in Baltimore working this issue through and we decided the best way to finally resolve it is for some laboratory that's concerned about this to ask for a national coverage decision and then we can't find any laboratories that are interested enough to do that. It was actually a couple of magazines or trade journals that brought this issue up and it turns out they were more concerned about it, I guess, than the labs were. So we're just waiting to see if this is an issue, really, to the providers. Because that's who we care about.

Minimal medical psycho therapy, another sort of arcane issue for some people, as you might know, for psycho therapy patients pay a 50% co-pay and it's called a Mental Health Treatment Limitation. And there is a code which sometimes has the Mental Health Treatment Limitation applied to it and sometimes doesn't, and there's a lack of consistency across carriers about when this is applied. If a patient has Alzheimer's disease, then that 50% co-pay should not apply and if a patient is psychotic, clearly it should, but there are a lot of other diseases which are more Alzheimer's type than psychological, so we're going try and clarify exactly which ICD9s should prevent the application of the Mental Health Treatment Limitation.

Oncology infusions. ASCO and oncologists had asked us about who's UPIN number should appear on the summary notice and this was an issue that was very important to them so that they could track which physicians were ordering the infusions. Now that we've gone to most of us, to filing digital claims, it's probably less of an

issue, because it'll be easier for the practices to track both physicians, the supervising physician and also the ordering physician. We're still working on it, but it appears pretty clear in the law that it has to be the supervising physician whose UPIN number appears. So we're actually in dialog now with ASCO about that. Another issue, ambulatory surgery centers—we had some language in one of our manuals that seemed to imply that a patient shouldn't/couldn't stay in an ASC after midnight. And I think it's pretty clear that there's nothing magical about midnight, if it's an ASC that has late hours which is a good thing, because obviously people need to work during the day and so having your mole removed at 8:00 at night maybe is a good thing in terms of providing service, and why should we mind as long as the patient's being properly monitored, why should we mind if the patient is there till 12:15 before they go home. So we're bringing some clarity to that and hopefully we'll have something official for people to look at soon.

No wonder it wasn't making sense to anybody else. I was on the wrong page. OK, Post Anesthesia Reports, this was the old policy which said that the post anesthesia visit had to be made by the anesthesiologist who had provided the anesthetic and that will be fixed in the new conditions of participation. I'm going to skip seclusion and restraint because you've been looking at that for everyone of my PPAC presentations. It's a very difficult and contentious issue and hard to resolve. Verbal orders. This was the problem that, it was sometimes difficult for the physician who made the verbal order to sign the verbal order and as you know, we've got a temporary clarification on the web site, a letter, but that's going to be also fixed in the new conditions of participation.

Anesthesia Supervision. The nurse anesthetist actually had a better deal on supervising students than the anesthesiologist did. And we're now at parity. The anesthesiologist would really like to have the rules clearly reflect the rules that their surgical colleagues have in terms of supervising residents. Which is sort of having to do with being present at the key portion of the procedure and so we're going to work on seeing if we can't make that happen. The incidentally, the picture there is a vile of PCP that I took out of the purse of one of the patients at the nice hospital that I work at now. They call it the dipper. And it seems to be a very popular drug of abuse. You dip your cigarette in the PCP and then smoke it. Makes you pretty crazy.

Chemo therapy codes issue. As you probably know there's a high paying set of infusion codes, and a low paying set of infusion codes, and the high paying set of infusion codes have been used by oncologists for a long time. They administer often very toxic medications. Now some of their rheumatology colleagues and other

specialties are also having to infuse some toxic medications. And so we're looking at whether there's, in the interest of fairness, whether the payments should be the same across specialties, based more on the drug that's infused than on the specialty of the physician infusing.

Denial of payment for local anesthetics. We had gotten complaints from office managers more than physicians that sometimes when they would submit a bill for a trigger point injection or a joint aspiration, they would get paid separately for the local anesthetic and sometimes when they did those procedures, they wouldn't get paid. And Part B News, actually, also helped us to birddog this issue. We were initially confused about what the reason was for the denials and on further investigation it turned out that the studies of practice expenses that the PEAC does when we value each of the procedures that we pay for were sort of not available to Care and Medical Directors for making decisions. So the Care and Medical Directors were sort of having to guess which procedures probably had a bundled local anesthetic and which did not. And so we had a very nice, unfortunate merging leader intern who worked with us for a month. And so we handed her the entire PEAC data base and she went through all 5,000 CPT codes and abstracted out which ones had bundled local anesthetics and which did not, created a spread sheet out of that, which we then shared with all of the Care and Medical Directors. So when a procedure like a laceration repair, which obviously would have the anesthetic bundled, is billed, if you bill a local anesthetic separately, it'll get denied, as it should because you've already been paid for the local anesthetic. But if you bill for another procedure, where the PEAC didn't consider the local anesthetic as being all as part of the procedure, then you can get paid separately for it.

Now I'll talk a little bit about the enrollment problem. We'd only known about this for about four weeks. And I've got to tell you Dennis, and Tim Hill, and Bob Loyal hit the roof when they heard particularly about how bad problems were in New York. It's sort of across the country, but it seems to be far worse in New York than any place else. PECOS is a new program which until recently each of the carriers had their own data base of providers, and that really doesn't make a lot of sense for a lot of reasons and so it seemed like a very good idea, it is a very good idea, to have a centralized data base of providers. And so PECOS was the software which is going to make it possible for us to develop that centralized data base, and it seemed that these problems got worse at about the same time that PECOS was implemented, and so there are a lot of rumors and theories going around about why provider enrollment has slowed down so much. And after talking to a lot of people, both at the care level and also internally,

it seems that there are really two major issues. One is the data entry issue. Because not all these data bases that the carriers had were completely clean, it made sense to require that providers be entered into PECOS sort of fresh rather than to crosswalk the carrier data bases into PECOS and so when large groups, like North Shore, have a few doctors who are entered into PECOS, all the doctors have to be entered into PECOS, and that's an enormous job, but it's also very important, because it makes sure that PECOS is a good clean data base and has good correct information in it. So it's obviously a huge initial hurdle, but once that's done, which is going to be in the next few months that won't be a problem that'll have to be dealt with again. The second issue was the issue of the system, the computer actually on which PECOS runs. That's the problem. It's not PECOS that's unstable so much as that there are so many people use the computer from the various carriers that there's been some problems with system instability and so the contractor that owns and maintains the computer has set up what they call a Tiger Team, which is working on getting that fixed, and they're very very focused on getting it fixed, because obviously CMS has been pretty direct with them about the happiness that CMS has with this instability problem.

With New York in particular, we sent a team out to the contractor. The PECOS contractors on the team had experts from Baltimore on the team, they sat down with the contractors, watched how they did the enrollment process, and came up with a list of recommendations about how to make the process more efficient, and also gave the contractors the funding they felt they needed for the extra staff. And this all occurred two weeks ago. Like I said, Lockheed Martin has a Tiger Team, which is working on the system instability and the goal is absolutely to get this thing fixed just as quickly as possible and we don't want to put a date on it because it's just not entirely clear how long it's going to take some of these contractors to get through the backlog, but our goal is to get back to a 60-day turnaround as quick as possible. There are a couple other sort of exciting innovations going on. There's an initiative to set up a program so that groups can enter a lot of the data from the office, which'll reduce the amount of administration work that the carriers have to do and speed things up even more. This problem doesn't have anything to do as far as I can tell with HIPPA or with the national PIN or anything like that. It really has to do with as I said, the enormous amount of initial data entry to get clean data base in PECOS and also the problems with system instability. But we would very much like to be kept in the loop. I've been talking to the medical societies in New York and to a couple of large groups. And Bob Loyal was on the physician open door yesterday, talking about this and gave everybody his email address, which seemed like a terrible mistake, but it just shows how committed he is

to seeing this thing get fixed. As I say, it would pretty difficult if you opened a store, and the store was beautiful but they told you they weren't installing the cash registers for nine months. It would be a little hard to stay in business.

So those are the issues that we're working on right now. I'm right on time. I've really enjoyed these two years sort of as an advocate for the providers and I'm pleased that the agency, I think, is still just as committed to staying open to provider issues and just as committed to making life with the Medicare Program as uncomplicated as possible and the job continues to be gratifying and I'm honored to be able to help with this. Thank.

Dr. Rapp: Does anyone have any questions of Bill? Joe?

Dr. Heyman: First of all you sort of glossed over the fact that now you're going to have the physicians offices having to fill in this information, which sounds like an incredible administrative burden for them in order to avoid have the folks at PECOS fill it in. So I think that's going to be a concern.

Dr. Rogers: Actually, it wouldn't be anything that they hadn't done in the past with the paper forms, but instead of filling stuff in on a paper, you know the enrollment package that you send into Medicare, you would actually be able to enter the data in at a keyboard, so that it didn't have to be abstracted from the paper and entered at the carrier, so it would be the same amount of work. And I think it'll be optional, but actually Johns Hopkins has been very interested in seeing if we could do something like this, because they'd like to do anything they can to accelerate the process.

Dr. Heyman: Are you converting everything into PECOS at one time? Is that the idea? In other words is my stuff, which doesn't have any changes on it at all being put in?

Dr. Rogers: No, my understanding is that if a group takes on a new member, then the entire group is transitioned over to PECOS. So it's not all January 1st, but for a group like North Shore, when they bring on 20 doctors to join their 400-doctor group, that means all 420 doctors have to be entered into PECOS. That's my understanding of it.

Dr. Heyman: And when you mentioned the couple of weeks that was, you were talking only about North Shore, I assume.

Dr. Rogers: What's that, a couple of weeks?

Dr. Heyman: Well, you said that something was going to be done in a couple of weeks.

Dr. Rogers: No, it was a couple weeks ago that we sent the team up to New York. And they've developed a list of recommendations. The recommendations may be too soft a word for the contractor and there's timeline for when those recommendations should be implemented.

Dr. Heyman: And when all of us have to reapply, what's going to happen?

Dr. Rogers: Well, by then, I think most of this initial data entry will be done. Things are going to get a lot better over the next two—

Dr. Heyman: No, but you said that everything has to be entered fresh. So when all of us—when we're all doing it at one time, what's going to happen?

Dr. Rogers: Oh, you mean when you reenroll?

Dr Heyman: Yeah.

Dr. Rogers: I think by then, 95% of the doctors will already be in PECOS.

Dr. Heyman: Why? How, because I thought they were only going if they were having a change?

Dr. Rogers: A lot of groups get a new doctor, and when they get a new doctor, the entire group gets entered into PECOS. The first three months are going to be probably absolutely the worst, in terms of the number of people that had to be entered into PECOS, but as groups get new members and get entered into PECOS, there'll be fewer and fewer that aren't in the data base.

Dr. Heyman: If there is a backlog, on the reentry, just in case it isn't as easy as you think it's going to be, will there be some sort of situation where everybody will still be protected so that they can still get their earnings and not have to worry about the fact that their numbers aren't in PECOS and all that stuff?

Dr. Rogers: We absolutely have to have that thought through. And make sure that that goes much smoother than this has

Dr. Heyman: Well you can imagine it's pretty scary to—

Dr. Rogers: We'll put the issue on our web site.

Dr. Heyman: All right. Well, I think that really it definitely has to become an issue for the PRIT.

Dr. Rogers: Yeah. I think it's a very good point. Re-enrollment could be a problem.

Dr. Rapp: Barb, Dr. McAneny, Dr. Johnson, Dr. Powers and Dr. Castellanos?

Dr. McAneny: I think that it's actually excellent to have people able to enter their own data. I also would encourage the PRIT to say when you can change your data and have it entered. Because no one really has as much interest in making sure the address is correct as the person receiving the check and my concerns about the government ending and I still have the same PPAC address. So I would like to be able to enter my own. But I would encourage there to be an update and share the concerns about the lag time, because in a small practice where cash flow is crucial, because you know your nurses won't wait for the bills, and the electric company won't accept that you've got a six month lag time in getting your earnings back from Medicare, that's really going to be a hardship for folks. We'll have folks who are taking out loans and paying interest at banks to keep their practices open waiting for this. So I would really encourage the utmost speed to get those things in the data bank, but I would also encourage that people have the option of updating their own and checking their own periodically. We're going to electronic records with the HIPPA stuff, so most people should be able to enter this stuff from their office anyway. So I think that the transitions going to be very painful. We need to make sure that we don't damage practices and risk their viability in the process, but I think getting it all on the electronic data bank is crucial.

Dr. Rapp: Dr. Johnson?

Dr. Johnson: Barbara addressed several of the issues that I wanted to bring up. But I think being able to enter the data is important for ourselves. How long before we will be able to do that from our offices as far as enter our own data or check it out?

Dr. Rogers: There are two initiatives under way that I'm aware of. One is by one of the carriers, and one is by central office. And actually the carrier is going to have a meeting with the enrollment staff in a week or so. I'm supposed to demonstrate what they've got. Then I wasn't aware that it was also being worked on by us. So I can find out for you and let you know how soon that's going to happen. But Johns Hopkins has been pushing this carrier to do it and they're very interested in seeing it happen very soon so I've got a feeling since everybody wants to have it happen, it'll probably be sooner than later, particularly because now we're in the center of this crisis.

Dr. Rapp: Dr. Powers?

Dr. Powers: Unfortunately, Doug Wood is not with us today, but he was chair of the Secretary's Advisory Committee about recommendations for regulatory reform. And I understand there were hundreds of

recommendations that came out of that. Several of which pertained to physicians. Do you know where we stand on answering those—

Dr. Rogers: Yeah, this was the Secretary's Regulatory Reform Committee. And it's actually a Secretarial level initiative, so what the PRIT did, we went through the list of initiatives. A lot of the physician ones had to do with EMTALA, and picked out the issues that we thought clearly were at the CMS level. But there's actually a team in the Office of the Secretary that's working on the more global issues and I can certainly report on that at the next meeting, because I just picked out the issues that they thought were clearly CMS issues and most of those got fixed with EMTALA. A couple of them ended up on the web site, but there are a number of issues that I don't have current information for you and that's a good point.

Dr. Powers: Thank you.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: The local anesthesia issue. You said there was a list of these procedures available to the carrier. Is that list available to the practitioner, and if so, how do we get it?

Dr. Rogers: Well, by gosh if you were visiting my web site everyday as you should be—

Dr. Castellanos: I did it last Wednesday! [laughter]

Dr. Rogers: I think there's a link. If it's not up already it'll be up next week and you can pull the spread sheet down off of that.

Dr. Castellanos: I can't wait.

Dr. Rogers: I'm sure it's great reading!

Dr. Castellanos: Thank you.

Dr. Rogers: Sure.

Dr. Rapp: Anything else for Dr. Rogers?

Dr. Bergeron: Yes. Bill, does that updating pertain to like physicians' assistants, nurse practitioners, when they enter the practice will all the data, MD as well as nurse practitioners, physicians who have Medicare ID numbers? In other words, when you said when a new provider enters a practice, does the new provider include nurse practitioners, physicians assistants? Because they have their own ID.

Dr. Rogers: Sure, well, I would think so. I don't know any reason why it wouldn't. I'll check on that for you but I would assume that anybody who enters the, that joins the group, will trigger the enrollment of the entire group.

Dr. Bergeron: Now, my next question. Will the physicians assistant, like the MD, have a national ID number that you're updating also.

Dr. Rogers: Right, right. My understanding is everybody's getting a national ID number.

Dr. Bergeron: Thank you.

Dr. Rogers: I keep looking over at Dr. Gustafson, but he keeps looking down at his desk.

Dr. Rapp: He's trying to leave. Anything else for Dr. Rogers? Bill, thank you very much. The next item on the agenda is Medical Liability Reform. Terry Kay, Deputy Director of the Hospital and Ambulatory Policy Group and Rick Ensor, Health Insurance Specialist with the Division of Practitioner Services.

Dr. McAneny: I have a procedural question.

Dr. Rapp: Yes.

Dr. McAneny: I was wondering previously we've gotten a list of the recommendations that we made yesterday. Is that forthcoming.

Dr. Rapp: Yes, that'll be at the end of the day.

Dr. McAneny: So we won't have it to look at until the end of the day when everybody's ready to leave? Can we have it earlier perhaps?

Dr. Rapp: Well, we're going to, from the point of view of the reporter, what we'll do is all of the recommendations—she'll get them together and type them up. It takes her a little bit of time to do that. Right now she has to be busy doing this part. And then at the end, she'll get them together, we'll have a chance to wrap up our meeting, discuss any other recommendations that she might have, and then we'll review them to make sure they're accurate. Will that work?

Dr. McAneny: OK.

Dr. Rapp: OK.

Mr. Kay: Good morning. The topic for this discussion is Medicare's payment for professional liability. Always nice to be back just because through pressure on sort of organizationally, I'm the Deputy Director of

Hospital and Ambulatory Policy Group. Liz Richter is Director. Our group reports to Tom Gustafson in the Center for Medicare Management. The range of issues we deal with in our group is, in addition to physician payments, we do hospital payments, ambulance, clinical lab and quite a number of others. With me today is Rick Ensor. He's in a Division of Practitioner Services within our group. He's the lead analyst on this topic, Medicare's professional liability payments. He's been at the agency now, probably ten years at least. I remembered when we hired him, so the years definitely fly by. He is going to focus on the basics, kind of a refresher on how does Medicare pay for professional liability, and then the way we thought we'd structure this today is after sort of reviewing the basics. This issue is often times sort of broader than Medicare. Medicare is just sort of a piece of it. So Rick's going to tell you what we know as far as what the President's to on this area and there are some Bills in Congress that deal with these issues. And then I understand you all might have some other thoughts or some suggestions on what CMS might do, and to the extent possible, we'll give you some reactions to that. And kind of take it from there. We're flexible. So that sounds good, we'll go ahead and start with Rick and the basics.

Dr. Rapp: That sounds good, thank you.

Mr. Ensor: Hi. As Terry said, my name's Rick Ensor, I've been with CMS for ten years. And I've been directly working with the PLI issues as related to malpractice RVUs and GPCIs for I guess the better parts of two years now. Formally, I'm sure everybody at one point or another has met Bob Ulikowski, who was sort of my mentor, so to speak in the arena of PLI. As Terry said, I'm just going to try to give a real brief history on how we pay for PLI in the various components of the fee schedule. Payment for some 8,000 services under the Physician Fee Schedule are based solely on basically three factors: it's the relative value units, the conversion factor, and the geographic practice cost and the CCR GPCIs. Each one of these factors has an element of professional liability insurance incorporated into it. I want to speak to each of those components separately. PLI RVUs are the first thing to discuss. And these are established for notice and comment. Using a methodology that incorporate county level malpractice premium data and we actually weight that data at the county level by specialty and frequency. In total, PLI, professional liability insurance accounts for 3.9% of the Physician Fee Schedule. Also this is the most volatile of the three relative value categories, it encompasses such a small percent at 3.9% that large changes in specialty specific premiums result in relatively modest impacts on total payment. Some of the reasons this volatility, as I'm sure most everyone knows, but some of the reasons surrounding the volatility of the data has to do with obvious

economic changes, the what would seem like recent increases in litigation, market shares as related to whom are the insurers in particular regions, professional business practices of the insurers. The law requires that we revise the PLI RVUs no less than every five years and the key there being that it's a budget neutral revision within the malpractice pot of relative value units, i.e., if neurosurgery codes show an increase of 25%, that is going to be paid for somewhere else in the fee schedule and vice versa. The next five year review of the PLI RVUs is scheduled to be included in our 2004 regulatory cycle. I actually just picked up when I came in, there was a comment from I believe it was the thoracic surgeons. Last year, PPAC did request that we look at the PLI RVUs in this past rulemaking cycle. We did hear and understand what PPAC's recommendation was. The problem was, we did not have time to put a contract together in order to effectuate that, but we are planning on doing this in our next reg cycle, that would go, and that would be effective of January of 2005.

The second component that again has a piece of PLI associated with it is the Physician Fee Schedule dollar conversion factor. The Medicare Physician Fee Schedule conversion factor is updated based upon a statutory formula of what one component of that is the Medicare economic index for purposes of professional liability insurance, this is the integral part of the MEI. The MEI is basically an inflation index, measuring changes in physician expenses from year to year. Again, PLI is one component piece of the Medicare economic index and then obviously what happens there is this impacts the increase or decrease of the conversion factor for a given year. An adjustment to malpractice that would increase the MEI will cause both the update and the target to be higher. So often we get into conversations about the budget neutrality issues and how the relative value pots are budget neutral, the GPCIs within their own component pieces are budget neutral. Were the increases for this recent what seems like escalation in malpractice premiums, where these are accounted for are in the dollar conversion factor, and it's based upon the MEI. I don't know a lot of detail about the MEI. Mr. Steve Heffler, from our office of the Actuary, who I think has spoke to folks before, is the guru basically of the Medicare economic index and any questions you would have about it when we end our presentation, I'd be happy to take back to Steve.

The third and final piece that I think actually Mr. Ukowski might have spoke to at the last PPAC has to do with the geographic cost indices. The law requires that we have separate geographic adjustment for the professional liability insurance, relative values, as well for the work and practice expense. There are 89 separate payment localities that we pay under the Physician Fee Schedule and 34 of those 89 are statewide localities. Making

revisions to the PLI GPCIs for the 89 separate localities requires an extreme amount of detailed information all the way down truly to the county level. This is actually, I'll get into this a little bit more later, but this is much more detailed information than the information than is used for the Medicare economic index. They use basically seven insurers that would encompass the top 15 insurers in the nation. It's a voluntary basis and it's most definitely not at the detailed level of the county. It's truly national data. We often get the question of why does the MEI incorporate 2003 data and the GPCIs for the malpractice GPCI portion, why does that incorporate data that's two years old. Because it's virtually impossible to capture real time data down at the county level. To make revisions to the PLI GPCIs, we collect county level premium data from both the State Departments of Insurance, and when we fail to receive cooperation from the State DOIs, we actually do go out to the individual PLI carriers. The law requires that we update the GPCI no less than every three years, and that we phase in this update over a two-year period. The law further requires as I discussed earlier that this is done in a budget neutral manner. I.e., it's a redistributive effect. If a particular locality such as a good example is California, not necessarily for the PLI GPCI. California's done a pretty good job with reform of keeping their malpractice portion in check. Maybe a better example would be the State of Pennsylvania, who seems to be running amuck with their malpractice premiums right now. If indeed Pennsylvania would experience a 50% increase in their malpractice GPSI, that's going to be taken from another area. It's all based on a national average, so it's how you compare to that national average, and if we have more services, basically, if we have more services, more dollars on the right side of the equation, when the GPSIs are computed then it has to be scaled back accordingly.

Dr. Rapp: So the bottom line on that is let's say the total amount of premiums doctors are paying for malpractice insurance goes from a billion or two billion, doubles in the country. But some areas of the country have a disproportionate effect. They don't all double, some don't go up at all and some quadruple. The impact on the Medicare program is that the same amount of dollars are paid. It's just they're redistributed. Is that right with regard to malpractice insurance?

Mr. Ensor: Not necessarily. You have to look at the separate piece of the puzzle. The GPCIs and the relative values are just that—relative systems. Where an increase of say a billion dollars would be accounted for is in the Medicare economic index, which would then factor into an increased conversion factor. So there is room for

growth, it's just not in the standard systems of the relative values or the GPCIs. They are kept budget neutral, but they're relative.

Dr. Rapp: But if the, how does it relate to, for example, the total cost the doctors pay for malpractice insurance doubles in the country? How would that relate Medicare—

Mr. Ensor: I can actually get into a little bit of that in the next couple of slides.

Dr. Rapp: OK. And if that doesn't answer your question—

Dr. Heyman: Well, it's the same question just in a different way which is if it goes up two billion, then how much Medicare's payments go up?

Mr. Ensor: Right, and I actually have some details on that coming, if you'd like.

Dr. Rapp: Dr. McAneny? Did you have something?

Dr. McAneny: Basically the same question, how much would it raise the target.

Mr. Ensor: Well, it'll be relatively quickly, we'll be right to that question. I want to talk a little bit about our current and future rulemaking and some things that have occurred related to professional liability insurance. The November 7th, 2003 final rule addressed two issues which were directly related to the PLI. One of them, which you guys really want to talk about, and the other one is the PLI GPCI update. And in the November 7, 2003 final rule, we should have update all three portions of the GPCI—the work GPCI, practice expense GPCI, and malpractice GPCI. Unfortunately, US Census data upon which the entire work GPCI and the majority of the practice expense GPCI are based, was not available. We were sitting in the Q with everyone else waiting for our data from US Census in order to calculate the work and practice expense GPCIs. What we did have available at that time were the malpractice premium data. Our contractor had the malpractice GPSIs and we thought because of the climate right now surrounding professional liability insurance that it was a wise move for us to go ahead forward with just the PLI GPCI portion. So we would appropriately pay throughout the nation. I think from the comments received on that, it was appreciated by the physician community. I believe even PPAC had at some point appreciated the fact that we were going ahead with the one portion of the GPCI update. There were some methodological changes associated with how we did the malpractice gypsy this year. We used real 2001 and 2002 premium data. We did not have 2003 data at that point. So after quite a bit of discussion, we decided that we were going to forecast 2003 data using a mean rate of change. So basically we looked at what was occurring with malpractice, the exponential growth, and

we forecasted 2003, our Office of the Actuary was involved in that as well, and our contractor. It will be interesting to see how well we did in forecasting that, because of the volatility associated with malpractice premiums. It's pretty incredible looking at the cyclic pattern of PLI up and down. Hopefully, we hit it on the right curve and I think we did. Another methodological change associated with the calculation of the PLI GPSI was that due to the volatility, the administration felt strongly about only implementing 50% of the change. So 50% of the total change in the PLI GPCI wouldn't be accounted for, and of course that would be phased in over a two-year period, as all the other GPCI components are.

Now what you guys are interested in, the rebasing and the revising of the Medicare economic index. I'm going to speak to this as best I can. Terry will probably take the opportunity to fill in in some areas as well. In November 7th, 2003, Final Rule, the second thing that we did as related to professional liability insurance was a rebasing and revising of the Medicare economic index. This would be effective January of 2004. Effective January 2004, the PLI portion of an average physician fee

[START SIDE TWO]

[Mr. Ensor, cont.] accounts for about 3.9%, which was up from 3.2% in 2003. The OAC, as I said before, Mr. Steve Heffler is directly responsible for the calculation of the Medicare economic index, and I think he has spoken to PPAC before. The estimate was based upon voluntary submission of data. They basically went out to some, I believe nine top insurers in the nation. Seven of those insurers cooperated with OAC and provided them data at the national level. This gets back to why we can't use the Office of the Actuary's data in order to calculate GPCIs. It is more current data, but it's on a national level. There's no adjustments for practice patterns, state, county, obviously not down at the county level. In the final rule, OAC's estimate, I think this is the number that folks are most interested in. In the final rule, OAC's estimate of the PLI portion of the MEI was a 16.9% increase. That's about it for the MEI. Like I said, probably when we've finished up, if you have some more questions, I think Terry and I together can probably field those.

Mr. Kay: Yeah, I guess the one point I had about the 16.9% is that's a national estimate so that, obviously there would be differences in geographic areas, but their estimate at the national level was 16.9. At this point, we don't have an estimate of what it might be this year, but they'll be busy collecting data for estimating the increase for next year. I would note, too, that the 16.9% was the final number. Their original proposed number they had was

6%. So they did, between the proposal and the final, collect additional information and receive many comments and I think the reaction from last year amongst you all was that the original number of 6% just didn't look right, based on your own experiences, and that in any case, they did change that to 16.9%. And just one other point, I would just throw out is in looking at this issue through the years, the number one issue tends to be getting data, and I have to say, when I first got involved with this, I sort of naively though, hey, you know, there's articles in the newspaper virtually every week about this topic. It ought to be you know relatively easy to get these data. This is not sort of like estimating physician work or something like that. This is objective information, and everybody sort of has their anecdote and is willing to share it but to get data, at the national level, and in all the detail that we need that Rick's described is just I have to say very difficult. One of the comments we got last year in our Federal Register, was that the relative value update committee had commented that they would be interested in working with us to try to look at this problem and see what we can do. We in our final rule in November 7th, in so many words, we say great, that sounds good. We're very interested in working with the physician community to try to solve this and we look forward to working with the RUC and anyone else, really, that has some suggestions. Rick's already had some initial conversations with the work staff and I don't know whether there's anything you could say at this point as far as what to expect over this year on this topic.

Mr. Ensor: I think it's funny because much like other groups we've spoken to, who have wanted to get into the PLI arena with CMS, the RUK thought, I think we walked into this process, that if the numbers were published in Newsweek Magazine, you know they must be easy to get. The RUK, in two meetings we've had with the RUK, I think the RUK understands the problem that we're having. They have actually said and stated that the best available PLI data out there right now is in the hands of CMS. We've also heard that from the Government Accounting Office, quite a few areas. But the RUK, we're definitely very happy to be working with the RUK, and I do believe that they will supply some information we can use. One problem we have, and the RUK is obviously very aware of this, is getting stuff down to the level that we need. Down at the county level, but in the same breath, if we can receive some information from the RUK, we can at least use that as bench mark type of data, as well, if they can get it at the county level, then that's just fantastic. I don't quite know at this point if they will be able to get down to that level. Not too much at this point has happened, as far as an actual collection of data with the RUK. We've been working on designing a survey instrument. They are analyzing as a group. The subcommittee is right now analyzing

the risk factor assignment associated with the various specialties. And we'll be meeting again in April to discuss it further. So we're moving along in a positive way and I do believe something is going to come from the RUK that's going to be useful for CMS.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: Yes, sir. Rick, let me present this scenario to you. Last year, the business of Dr. Bergeron cost $100,000 to operate his practice. Of the $100,000 to operate his practice, $30,000 was spent on the medical liability insurance. So therefore, in my little statistician brain, 30% of my overhead was due to my malpractice liability and the only way I can make up for it is increasing my fees. So therefore, you're going to increase my fees by .7% and if I look at .7%, most of my patients are Medicare, where do I make up the deficit of $26,000?

Mr. Ensor: I understand. This isn't the first time we've heard comments such as that. Part of the, and I don't know this to be true or not true, but we are a year behind in data. And we always will be. It's impossible to collect real time 2003 or for that matter, 2004 data. Is it a possibility that 2004 data will show that there was a 30% increase in, I'm not sure where you practice, sir—

Dr. Bergeron: Louisiana.

Mr. Ensor: Louisiana, if there's a 30%--I don't know. Maybe 2004 data will show that. We are always a year behind. That was part of the criticism of the methodology we used this year. We have real time 2001 data, 85% of the 2002 data we project at 2003. Everybody says, well you can't project 2003. That's impossible because it's not going up in uniform fashion.

Dr. Bergeron: Statistically, somebody would present you with a plus or minus 26%. Wouldn't that raise antennas?

Mr. Ensor: Well I think in an individual practice, I don't deny that 26% is the appropriate number for you. For us at this point, obviously we can base anything we do on an individual practice. It's obviously larger than that and the data that we're seeing right now—we are seeing increases. Your increase, as compared to the National Average, that is the key. So if the National Average went up by 20% and in Louisiana it went up by 26%, that's the comparison that we need to use, not that you're 30% hike in your malpractice. Does that make sense. It's all comparative to the National Average.

Dr. Bergeron: I still fight a deficit of 26%.

Dr. Ensor: Here's an interesting thought on the flip side of that. Look at a place like California. In California, they have an active tort reform. Their malpractice is low. Their malpractice GPCI is low. Still increasing, but it's not increasing at the same rate as the National Average. So they're going down. We've had discussions with representatives of SU and Far regarding this, actually all three components, but PLI was one portion of that discussion. And it's a hard thing to explain. How can my rates be going up but I'm going down in the Medicare program? Because you're not increasing at the same level as the National Average.

Dr. Bergeron: One other question—the redistribution. Louisiana's had a cap since 1977, so correct me if I'm wrong, the Louisiana physicians are being penalized for doing an excellent job legislatively, medical liability wise, are being penalized at the expense of my colleagues in Pennsylvania.

Mr. Ensor: Sure. That's a great question. It sort of makes me laugh because I had this discussion with Mr. Bob Ulokowski, who has been with the GPCIs since their inception. He was their creator. And I had the same block in my mind of why is California, Louisiana, places that have been responsible and instituted tort reform, are keeping their premiums down, why are they being penalized by our system? And Bob's answer to that is no one is being penalized. They're being paid what their costs are, so to speak. Now I understand, it would be nice if Pennsylvania was more responsible, but they're not making any more. They're paying those premiums. Now would tort reform—you know, the Administration is very interested in tort reform, obviously. Everybody's probably heard President Bush is, I think it the 26th of January was his last speech, in Little Rock, Arkansas, where it's banging fists on the table. He wants tort reform, nation wide. But your comparison of Louisiana, who has instituted tort reform and been responsible, and Pennsylvania—they're not making a penny more.

Dr. Bergeron: Let me get it down to more basics. I have one Labrador retriever over here, and one over here. This one retrieves 10 ducks, this one retrieves two. Guess what I'm going to feed tonight? [laughter]

Mr. Ensor: Yeah, I gotcha.

Dr. Bergeron: You got me? Is that as basic as you can get?

Mr. Ensor: I understand what you're saying, but I think the one point that I need to stick with is, the Pennsylvania doctors, although the state in and of itself has not instituted tort reform, their PLI is out of control. It would seem at this point. They're not making a cent more than the physician in Louisiana for that portion of the pie.

They're not making a penny more, so I would always go back to that. And if tort reform occurs, it's going to be a huge reshuffling, but still you're going to make the same as that doc in Pennsylvania would.

Dr. Rapp: I think Dr. McAneny has something about coyotes, maybe. [laughter]

Dr. McAneny: I was going to promise not to bring any animals into the process, and to appreciate your political correctness in saying PLI. One of the places where I think it does make a difference in the no-good-deed-goes-unpunished arena of people who are doing well in the states that have enacted some tort reforms and do have some control over their liability, is the shift that was done for budget neutrality in decreasing the GPCIs for physician work unit and practice expense. Because as I do the arithmetic, it looks as if you're in a state like Louisiana where you have controlled to some degree the PLI process, the decrease in your work unit and the decrease in the practice expense, may actually cause you to get a decrease in your payment in that area. Is that not correct?

Mr. Ensor: We actually, Terry and I were speaking to this this morning. Do you want to talk to this?

Mr. Kay: Yeah, we understand what you're saying. We understand the concern. Again, it just sort of goes to the basic fundamental of the payment system itself as required by law. And I think a lot of these kind of questions come up in the context of "My costs haven't gone down, so how could my practice expense RVU go down?" And I guess, all we can say is that the law itself created a fee schedule that's not cost reimbursement, so it's all, we use the word relative, because that's what it is. In this case, you have payment system where there's this fixed pool of dollars that's determined through the sustainable growth rate system. The Medicare economic index is really the only factor that increases the pool of dollars. That the changes in relative values and the GPCIs are budget neutral and so in this fixed system, if the PLI component increases a bit, then we have no discretion. We need to decrease the pools for work/practice expense. And those pools that we have, we make them equivalent to what the actuaries have estimated for purposes of the MEI, so right now, for example, the actuaries say that PLI represents 3.9% of the total MEI, so we compute our payments with, we match up the payments for the PLI component equal 3.9%; exact same number that's the MEI component.

Dr. McAneny: Would not it have been possible to decrease it through the conversion factor, which would then be somewhat mitigated by the increase that would come from the MEI? Because as it is right now, what's happening is the work unit goes down that penalizes the physician in a state who is in a low PLI specialty, and in a

well done state. So where the PLI is controlled. So if you did it with a conversion factor, would not that get rid of some of the unfairness of switching the work units, and also get rid of the idea the work units are supposed to be somewhat objective idea?

Mr. Kay: Well, I have to admit if you look at the history of the fee schedule, since 1992, depending on the situation, the circumstances, we've done it both ways. I would say, as Rick indicated, we'll be re-looking at the relative values for PLI this year. And it'll be in the proposed rule. This issue you bring in will be a live issue for this year. And depending on the comments and what our senior leadership wants to do, one could arguably say we have an option. I think the one complication that's sort of unique to this year is that the conversion factor is not established to the regular SGR system. The law says that it can't be less than 1.5%. And so it would probably take some creativity to figure out how to do that; accomplish what you're suggesting and still have 1.5%. But at this point in time, I wouldn't rule it in or out.

Dr. McAneny: Could we hear the comparisons of your two systems at the next meeting perhaps where we can look at what the effect would be on both high PLI states and low PLI states, with a change in conversion factor, versus a shift in the RVUs? Would that be possible for the next meeting?

Mr. Kay: If our proposed rule is out. Definitely we would be happy to bring to you anything that we can to help in your formulation of any recommendations on this area, but the thing to keep in mind in developing recommendations is the statutory requirement to the conversion factor be 1.5%.

Dr. Rapp: Dr. Castellanos?

Dr. Castellanos: Terry, first of all, I want to thank you for [off mike] emails. I appreciate that very much. As you know, Florida has one of the highest malpractice insurance premium's in the nation and that's due to strictly to tort reform. There was a government selected task force that showed that. And you're right. I want to make two points. One is, there is a CMS study that shows that access to care is directly tied to non economic damages. Secretary Thompson wrote our broken medical litigation system is affected by a patient's ability to find a doctor. My point is that there's a problem and we all know it's a problem. We know it tort reform and we need to do something about it, and that's what we're not beating you up about. The question I have is about the modulating factor. Now, I understand one-half is going to be taken care of this year, and another half is going to be taken care of next year. But during that year, by statute, you're going to be able to at least review the proposed change, revise

GPCIs, so it means that you're going to be able to do it next year, too. You can get these data each year, because under statute, with the modulating factor, you have to do that. Is that correct? Or…

Mr. Kay: Yeah, I mean I have to say when you get right down to it, this discussion about the modulating factor, in the end it really has to do with our level of comfort about the data we have. Obviously I couldn't speak for Secretary Thompson, but if we could come to him and say, you know, we think we have the greatest data. It's perfect. We think it accurately reflect what is going on in all the different geographic areas, then perhaps this so-called modulating factor wouldn't have been needed. So that's why part of our interest in accepting the RUCs offer to work with us on this topic is because we recognize that, we think our data is good. As Rick indicated, we think it's as good as anything anybody has, frankly. But it doesn't mean that it can't be significantly improved. And I don't think folks are going to want to move off that modulating factor until we all think that we have data that we are very comfortable with, because, as we've said, it's sort of a budget neutral system, and we don't want to unfairly penalize folks unless we think we have data that accurately reflects exactly what's going on in each of the geographic areas. This is primarily just informational, that as we all know, these issues sort of go beyond Medicare. We're not directly involved in it, but Rick did do a little bit of work on just give you a summary on what we know of that's going on in Congress right now on this topic and it would just take a minute or two, if that would be of interest?

Dr. Rapp: Yeah, fine.

Mr. Ensor: There's quite a bit going on with bills that are in Congress at one stage or another. And I'm just going to touch on two of them. One is House Bill 446. It's calling for the establishment of an emergency malpractice liability insurance commission. The commission's going to study exactly what we're talking about right now; the soaring medical malpractice premiums and they will develop strategies to try to combat these escalating costs. You might see that listed as EMLIC if you see anything like that in the news. This could be a very interesting commission to watch operate if the bill would pass. Another bill, Senate 2061, as I was saying previously, the administration's obviously very interested, I mean President Bush has made it quite clear how interested he is in tort reform. But there seems to be some roadblocks with tort reform, so what they've done, is Senators Gregg and Ensign have actually introduced a bill that would limit non economic damages for obstetricians, specifically. At the point that that occurred, so it's a specialty specific bill. So it's sort of interesting. I was surprised when I read it,

because I thought we were just talking about caps, physician caps. But no, it is very specific. Senator Frist came out, after that bill hit, Senator Frist said yeah, you know, I'm going on a different angle here. I'm very interested in tort reform national wide, but the title of a particular article is "Narrower Medical Liability Bill May be First Health Measure that Hits the Senate Floor." So he's taken an angle at this point where, all right, let me see what I can do. OB/GYN, we've heard horror stories about, and he's going to try to take it in pieces. He said this will probably not be the last specialty bill that you see out there; something that would be specific to a troubled specialty. I'm not so sure that there aren't any specialties that aren't troubled with the current crisis. But it's just kind of interesting, the angle that the Congress is taking on it. As I said, on the heels of that was Senator Frist.

Mr. Kay: So like you said, we're not directly involved in these efforts, but we just wanted you to be aware. Maybe you'd want to monitor what happens with these bills. They could be some partial solutions.

Dr. Rapp: Dr. Hamilton?

Dr. Hamilton: I'd like to comment on Dr. Bergeron's comment a minute ago. If the situation in Florida were to improve, and the situation in Pennsylvania, or in West Virginia or in other very troubled states, whether it was the result of state legislation or federal legislation, would that in fact improve the size of the pie that Dr. Bergeron would get access to in Louisiana?

Mr. Ensor: If the national average came down, I would say the answer to that is yes.

Dr. Hamilton: Oh it would.

Mr. Ensor: Yes.

Dr. Hamilton: So we all share in this pie, and as long as the improvements in one piece of the pie are going to affect the whole pie.

Mr. Ensor: And I don't mean to keep going back to my discussion before. Yes, would it help Louisiana if—I can't say this with any degree of accuracy really, but say tort reform was the best thing since sliced bread and it's going to wipe out all of our problems with PLI. That would benefit Louisiana, still, Louisiana is not going to make one cent more than Pennsylvania. So I just wanted to make sure—

Dr. Hamilton: Yeah. When you say "make more" I mean that is relative.

Mr. Ensor: Per service, come in for a level three office established office visit, you know, in real life--

Dr. Bergeron: We'll save more of that little piece of pie because I don't have—

Dr. Hamilton: He's going to get his piece of a little bit bigger piece of pie that maybe could even feed his other dog.

Dr. Rapp: Crawfish pie.

Dr. Bergeron: Crawfish pie.

Dr. Castellanos: The experience nationally is when you have tort reform, it does not decrease premiums. It levels the field. It does not decrease premiums. That's the experience to date nationally.

Dr. Hamilton: That has certainly been the experience in Texas. It has not significantly affected the premiums yet.

Mr. Ensor: The last thing, real quickly, is kind of the administration, President Bush, has been quite vocal about the medical liability reform. A lot of interesting information if you would type firstgov.gov or Whitehouse.gov, you could find some speeches that President Bush, Little Rock, Arkansas, Scranton, Pennsylvania, and numerous others and he's conveying the same message; that he sees a huge crisis here, that he is pushing Congress hard for liability reform at this point. That's about it for what I had to say.

Dr. Rapp: Anything else on that? Any thought been given to whether there's some administrative things that might be adopted that would provide for liability, improve the climate? For example, something like encouraging arbitration? Some kind of administrative solution, like people who participate in Medicare could, doctors that participate, could for example have patients sign arbitration clauses and that sort of thing? Any thought internally being given to some way of avoiding the Congressional deep pit for any liability reform?

Mr. Kay: Like I said, at this point, all we can really do is sort of give you a reaction and maybe a signal of how that might play out, but right now in the process of starting to develop the proposed rule. That kind of thing will be on our list for discussion with the same leadership as we develop the proposed rule. So at this point, I can't say anything is ruled in or out, but what we did do is have some preliminary discussions with our Office of General Counsel just to get sort of a preliminary reading on it and basically, they frankly weren't optimistic about our authority to do those kind of regulations that basically if you look at Medicare law in section, Title 18, Social Security Act, gives CMS and the department the authority to administer Medicare, and the Medicare Insurance Program, but they, and again they're not giving an exhaustive opinion at this point, but I just wanted to give you a

signal that we really didn't have the administrative authority to do these kind of things; that that was sort of why there's these other efforts to change the law itself, so.

Dr. Rapp: Dr. Hamilton

Dr. Hamilton [off mike] to address that issue, and it's a very important issue from one who has worked on tort reform for a good many years in various places, you learn what the opposition is going to be saying. And one of the things that will always come up whenever you try to any sort of tort reform is that it interferes with due process of law and a person's access to the court system. Now there are different levels of interference that can be implied, but administrative interference with one's access to due process of law would fall off the table very quickly. Legislative interference with this may have a better chance, but even that is very uncertain. And in Texas where we had legislative passage of tort reform; a cap on non economic damages, in order to make sure that that would stick, we then had to have a constitutional amendment passed, which we did. It was close but we did get it passed. But without that constitutional amendment, that legislation could be overturned by the Supreme Court, so administrative tampering with the system, will go away quickly. Legislative tampering with the system as it were, has a better chance, but even it is not secure, because the Constitutional proscription for due process is still going to be there. So even this sort of legislation has to be very carefully considered by people that do nothing something about Constitutional law, which I'm not one of.

Dr. Rapp: Dr. Urata, did you have something? Anything else on this? Thank you very much, Mr. Kay and Mr. Ensor. Appreciate it. It is 10:00. Time for a brief break if you like. So we'll resume at 10:15 for the OASIS and Home Care Benefits discussion.

[BREAK 9:56]

[RESUME 10:15]

Dr. Rapp: The next item was a request of Dr. Urata for this item on the agenda, OASIS and Home care benefits. We have Lisa Hines, the Acting Deputy Director from the Quality Measurement and Health Assessment Group, Oversight Home Health Quality Initiatives. Welcome. And Mary Weakland, Nurse Consultant, Survey and Certification Group for Center for Medicaid and State Operations Program lead for the OASIS since 1997. Who's going to first.

Ms. Weakland: Thank you for the opportunity to come and talk to you about OASIS. I've been talking about it for a long time. I was active in helping to write the regulations for that that were published five years ago in 1999 and at that time, OASIS was required for all patients who had skilled needs, Medicare and Medicaid patients, and private paid patients. Over the past couple of years, OASIS has been the hot issue with privacy folks, so we were never able to have the private paid information sent to CMS. And so this past December, Secretary Scully and Tommy Thompson made sure it got into the MMA bill that President Bush signed in December, to suspend the collection of OASIS data on non Medicare, non Medicaid private paid patients, temporarily. So that went into effect and we have a survey and certain memo were passed out to allow agencies and states to know that they don't have to collect OASIS information on private paid patients, however, they do have to continue to do a comprehensive assessment on the patient so that they can develop a plan of care to send to physicians and know what they're doing at their home care episode. During this time, over the next 18 months or so, we're also going to be conducting a study, on how OASIS information can be used by large and small agencies on private paid patients. We're just in the formative stages of doing that right now. Most of the information that we have right now for the Medicare and Medicaid patients goes into the creation of several outcome reports that we developed in 2001 and 2002. That are now in the hands of the home health agencies, and some of the measures have been adapted to home health care that Lisa will speak of. And that's been advertised nationally since last year. The outcome reports are of great interest because it tells the agencies where they're at, where they're patients are at at the beginning of care, and how they progress to the end of their care. It was a very short and sweet. We only stopped the OASIS suspension for private paid patients. Agencies still need to do a comprehensive assessment for their patients, though. However, agencies may continue to collect OASIS on their private paid patients. We have an OASIS technical experts panel that advises us on where to go and what to do on OASIS, and about half of them, most of them are clinicians, and about half of the agencies are continuing to collect OASIS information on the private pay individuals, because they find great value in using the standardized data for planning purposes. That is about the end of the information we can share about the private pay information. Although this was one of the items that was in the Secretary's reg reform on committee report that we acted on. We acted on that with the OASIS reduced burden last Christmas, and we reduced OASIS by 28%. This is another part of that, as another reduction. And we have new conditions of participation that

are expected to be published this year, either as an NPRM or as a final, and that will also have some additional reductions for OASIS.

Dr. Rapp: Thank you. Are there any questions for the presenter?

Dr. Urata: I was the one who requested some information on OASIS, and just to give you a little bit of background, I work with our local hospice and home care program in Juneau. And when Oasis first came out, it was very difficult document to fill out, and I think it took—usually initial assessments would take about an hour or so, and this took way over that amount, somewhere around two and a half hours or so. And I think that that created a major problems assessing patients, and a lot of the questions did not seem to have any use. And so I'm very pleased to hear that it's been cut back by 28%. But the other issue that I have is that through various cut backs in reimbursement for home care, I think a lot of home cares across the United States have had to close their doors. But I understand that's true. Can you expand on that?

Ms. Weakland: During the period when we had IPS, many agencies did close their doors. But now, under the PPS system, it seems to be going the other direction. More agencies are opening. We're hearing a lot of more opened initial surveys; a lot more in California. So the numbered has bottomed out and is going back up.

Dr. Urata: Are you seeing small home care programs opening up, like in smaller communities, rural areas?

Ms. Weakland: I don't have that information, I'm sorry.

Dr. Urata: Do you have a sense?

Ms. Weakland: No, I don't. I know, I think there's a lot of big agencies merging together to make a bigger agency. I'd like to address the first piece you said though about the length of time to do OASIS. Yes, it was a problem in the beginning, because everything was brand new to them. As people have learned the items, it has gotten down to about an hour, hour and a half process, which is what it should be. To address this concern, we believed that many agencies, clinicians, didn't know how to do a comprehensive assessment using these questions. So we've created a web site, it's called TheOasisTraining.org web site that allows clinician to learn and assess every item we have. That just came out this October, and we sent a copy of the CD to every home health agency, if they don't have internet access.

Dr. Rapp: Dr. Bergeron.

Dr. Bergeron: Yes, ma'am. Do you have, or where can I get access to exactly what parameters, what duties, what professional attributes a home health individual visiting a home? Example, I had a patient the other day, said this home health agency is the best thing beside butter and bread, and little other things to go along with it. I had my house vacuumed, hadn't had my bathtub cleansed in I don't know how long, and the individual did this cleansing and stuff. Exactly where can I get a specific guideline to find out what is being done and basically what are we paying these home health agency individuals to visit the patient's home?

Ms. Weakland: Well, the guidelines are in the Conditions of Participation and that's at 484. I have, it's 482 CFR, 484, where all the conditions of participation are.

Dr. Bergeron: Where can I get this?

Ms. Weakland: I can get a copy to you.

Dr. Bergeron: Today, before I leave?

Ms. Weakland [to someone else]: Do we have a CFR here? You could find one. OK. 42 CRF, Code to Federal Regulations, 44. And it's about 20 items in there that outline what happens in home health, and then right after that, it talks about the prospective payment system.

Dr. Bergeron: Can you get it to me in the future? Thank you.

Dr. Rapp: Any other questions for Ms. Weakland?

Ms. Hines: Just to build on what Mary was saying. I think there's a lot of confusion. People use the term "home health agency" kind of globally. There's, when we're talking, it's certified Medicare Medicaid home health agencies, versus people that are out doing services like you said. I'd love to have that person come to my house. But I think that's confusion and I think the CFR should help with that.

Ms. Weakland: Yeah, although if the person does usually the nurse of the physical therapist assesses the patient in the home to see what they need, and then they communicate that with the physician who approves or disapproves. And usually, if you have somebody who's pretty home bound and they can't do these activities in their house, they'll have an aid come in periodically until they're able to do that.

Dr. Bergeron: When I said something about the form he did for two hours an assessment. And a lot of times, I don't want to be their primary care physician, but they have, let's say, chronic Bullis disease, and blistering and really they have no other specific disease and we act as their prime—and I just get things and then all of a

sudden, it's like what's going on? I made no assessment, you didn't ask me specifically the infirmity of this patient had and their requirements and all the sudden I'm just getting things I'm looking at so, where do I sign?

Ms. Weakland: OK. You know, physicians are entitled to have a copy of the assessment, if you want more than that, you're welcome to ask the agencies to give them to you.

Dr. Bergeron: I mean we're just getting into it. I don't want to get into home health care. [laughter] Out of necessity.

Dr. Rapp: And a few other things.

Dr. Urata: The basic requirement referred to home care is to be home bound. Initially, that definition was quite restrictive, but now it's not as restrictive, but still restrictive. Do you see anything in the future to change that to be less restrictive?

Ms. Weakland: Right now it's restrictive. You do need the required to home. It's a difficult and taxing effort to get out for short periods to see a doctor or to go to the grocery store or whatever. There is a home bound study being conducted as part of this MOI Act, and it's supposed to be a year and a half study, so there may be something new out of that, too.

Dr. Urata: So that might loosen up a bit?

Ms. Weakland: I don't know that. You're talking payment then—I'm not on payment policy side.

Dr. Urata: Do you have any other changes to the prospective payment system?

Ms. Weakland: I'm not aware of any right now. I believe they're going to have a new NPRM in a couple of years. I think it was supposed to be in 2005, but I think it's been pushed back. The prospective payment system did go up, again this year, so that the base rate is around just under $2900 for the lowest level of care, and goes up much higher than that for wound care.

Dr. Rapp: The Medicare Conditions of Participation, how are they developed?

Ms. Weakland: There's a center in CMS that does develop regulatory changes based upon the industry and from individuals—

Mr. Gustafson: There's two responsibilities of the Office of Clinical Standards and Quality. There's a group over there that Rachel Weinstein heads that for the various organizations that we established EOPs for.

Dr. Rapp: Office of Standards and Quality, is that what you said?

Mr. Gustafson: Clinical Standards and quality.

Dr. Rapp: And they do it for hospitals as well?

Mr. Gustafson: Yes. All the COP activity is handled in that group?

Dr. Rapp: OK. Anything else—did you have something, Ms. Hines?

Ms. Hines: Just wanted to give you and update on the Home Health Quality Initiative. A lot of times we collect a lot of data, it seems, at CMS and we wonder what we ever do with it. So certainly the OASIS data is used for not only payment and survey and certification enforcement, but also for quality. In May of 2003, we did a pilot study as many of you know, in eight states, using 11 quality measures from the outcomes based quality indicators, the OBQIs that are developed from the OASIS data. We've rolled out nationally, in November of 03, home health compare went wide. Similar to the nursing home effort, all of this part of the Secretary's quality initiatives that started with the nursing home roll out,

[START SIDE THREE 10:33:45 am]

[Ms. Hines cont.] but home health was a little different because the home health agencies had seen their own data for years and getting the outcome reports that Mary talked about, but no one had seen each others. So it was a little bit different going live with Home Health Compare. With the traditional, we traditionally did our ads. There were ads in the pilot and newspaper and newspaper ads in the national roll out in November. My phone was deluged with people who wanted to know why they weren't in the ads. I had no one complain that they were in the ad. So certainly much more of a marketing focus in home health with the data. Home Health Compare has all of the Medicare Medicaid certified home health agencies. It's part of our www.Medicare.gov web site. We update our demographics monthly, on all of the home health agencies, and the quality measures are updated quarterly and reflect a year's worth of rolling data. It's a little different with home health. Because with nursing homes, we had a building that sat at the corner of 1st and Main. Certainly with home health, we're dealing with service areas. So there was no easy answer in how to identify to allow consumers to identify home health agencies that they were choosing from. We ended up going with Zip codes that had been served by a provider in the past, originally two years, then we backed it down to a year. So that if you lived in the District of Columbia, you may very well see home health agencies from Northern Virginia and from Maryland, because if there were agreements that they could

have circular agreements for practicing, you would have a broader choice. You wouldn't just be limited to the agencies in the District. It's a little confusing at first, because it wasn't anything we'd ever done, and probably 90% of our questions came across because their certificate of needs in some states and it wasn't reflected in the zip code search and there were situations where it was either a data entry error, or somebody transposed numbers in a zip code, and that's why an out of state showed up in a zip code base, or in some cases, people were really not abiding by the certificate of needs and participating and providing services wherever they were called to. And we'd never had a mechanism to have that identified in the past. With home health we also were able to try something a little bit different. We've always heard with our compared pages that I serve a special population, I have a high Medicaid chronic patient population. The state of New York had a unique situation where they actually identified provide, the chronic care Medicare waiver programs and also the special needs population providers with a separate provider, so we could actually tease those out of the data and on the web site identify them as either serving a long term chronic population or a special needs population. And then, we provided links back to a page to give a little bit more information on what that actually meant. There was the fear that because they did have a special needs population, which may have been AIDS patients, or hospice patients, that they would not be compared favorably with other providers that did not have the same type of patients. So we were able to try that as a pilot, and we're working on ways to be able to implement that across the spectrum of not only home health but of nursing home and our settings as well. A big piece of all of our quality initiatives, is the training and technical support that our quality improvement organizations provide. And there are 7,000 active home health agencies to date. 75% of those, 5,275, have been trained in the OBQI and also 62% of those, 4,400, have submitted plans of action to improve their quality. So it's been out there for a short time, but we're already seeing results.

Dr. Rapp: Dr. Bergeron?

Dr. Bergeron: With a home health agency associated with your medical center, with its supposedly quality control, be a parameter to use if you were choosing a home health agency compared to a free standing one down the street? Do you have privy to those quality controls?

Ms. Hines: At this point, we can haphazardly identify them as being associated within a system.

Dr. Bergeron: Would you be safe in assuming that your medical center may or may not be a [inaudible] quality control? You may not have answers. I mean I know.

Ms. Weakland: The agencies I've been associated with who do have associations with the hospital is required by the hospital to have a QA program. A free standing agency may not, but now these are the same reports that every agency can use to find out where they're at and see where they can improve.

Dr. Bergeron: In other words, a score card.

Ms. Weakland: That's right. And patients have access to this too, so they can look on the internet to find this. Tell them your web site. [laughter]

Dr. Bergeron: What is that web site?

Ms. Hines: www.Medicare.gov and I'll take you into the home page because there you can get to nursing home compare, and health compare.

Dr. Bergeron: www.Medcare?

Ms. Hines: Medicare.gov. That's our consumer side. Later this year, you'll have hospital compare up as well. Let me give the professional side because we post all of our documents, our technical specifications everything is there. www.cms.hhs.gov\quality. Now that's going to take you to the quality home page and you'll be able to choose hospital nursing home, home health, physician office.

Dr. Bergeron: Oh, there's a list?

Ms. Hines: Yes. You can get to the MDS instrument, you can get the OASIS instrument. It's kind of one-stop shopping for any of that information.

Dr. Bergeron: Thank you.

Ms. Hines: You're welcome.

Dr. Rapp: OK. Anything else? If not, thank you both for coming today. The next item on the agenda is the Wheelchair Billing Brochure. PPAC was intrigued by this issue previously and asked that they have an opportunity to review the brochure. And so you have it. Dr. Heyman?

Dr. Heyman: Well, on reviewing the brochure, there were two things that struck me. One was that if it's directed at physicians, it's seven pages long, when it only needs to be one page long. And it just needs to say what the criteria are for you to use to authorize the wheelchair. I think it's too long. Most physicians would not read seven pages of this. And my second criticism of it is, there's an explanation at the end of it that describes the

difference between renting and purchasing wheelchairs, and I can't figure it out for the life of me and I don't know how a patient does. But it may just be my lack of understanding.

Mr. Gustafson: Clearly the product is not helping you with that lack of understanding, which means it is failing.

Dr. Heyman: I mean I'm not sure that it's important for me to know that, as a physician. But if it is important for me to know it, I can't understand it.

Mr. Gustafson: Is it rent versus own, is that what you're . . .

Dr. Heyman: Yeah. I mean it talks about the different number of payments, but I don't understand how, I don't know the advantage of one versus the other. I don't understand why three more payments will get you an ownership and eleven payments or something will get you a rental.

Dr. Urata: Perhaps that information is for the social worker. And not for the physician.

Dr. Heyman: Well, that could be too. In that case, they probably, since they're a lot more intelligent, would be able to understand it. But I can't understand it.

Dr. Rapp: Yes, Dr. Urata?

Dr. Urata: Was there a reason why a specialist needs to fill out a prescription for this? Is this what is normally done for wheelchairs and stuff?

Dr. Rapp: What are you referring to?

Dr. Urata: The POB is ordered by one of the following specialists:

Dr. Rapp: What page are you on?

Dr. Urata: Page two.

Dr. Rapp: Where are you on that?

Dr. Urata: Top, under the fifth bullet or dot. POB is ordered by one of the following specialists. Exceptions is when a specialist is not reasonably accessible.

Dr. Rapp: So your question is . . .

Mr. Gustafson: Why is it restricted to that set of specialists?

Dr. Urata: Yeah. So I have like three or four patients in wheelchairs. Two of them already have told me that our local DME has told them to come for prescription for scooter. And so what I really need to do is refer them to the rehab specialists that I have in town. Is that correct?

Dr. Rapp: Right.

Dr. Simon: I mean typically they like to have a rehab doctor evaluate the individual. I think what they've found over the past couple of years is for example, cardiologists have been ordering wheelchairs for patients that have obesity and so they want to have a better understanding that the clinicians who actually prescribe wheelchairs have been able to physically assess those patients in the appropriate manner so that it would be medically reasonable and necessary for that patient to have a power wheelchair.

Dr. Urata: Does that same hold true for a manual wheelchair?

Dr. Simon: I think that there are a couple of criteria that's used to determine eligibility for wheelchairs that existed prior to revision of this document. I think that the criteria have been changed, as I understand it. I don't know all of the criteria in the past. The two criteria was whether the patient had the upper body strength to be able to use a manual wheelchair, and/or were there other physical limitations which would prevent them from using a manual wheelchair. Since the revision of this document, the criteria have been expanded to better identify those individuals that really would require a power wheelchair.

Dr. Rapp: So I guess the question you may be raising, a physical medical specialist is a physician, but a lot of times these assessments would be done, or could be done by physical therapists, I suppose. Isn't that the type of occupational health? Who does those sorts of assessments?

Dr. Powers: A lot of times the physical therapist gives you what's called a seating evaluation and they're recommending the type of wheelchair, not necessarily the eligibility for a wheelchair, although their general physical evaluation can tell you if they meet the requirements. For instance, for an electric wheelchair, which is a lot more expensive, then just a power operated vehicle, a scooter, you really should be totally non-ambulatory from what I can tell. Not independently ambulatory. Power operated vehicle for my MS patients. Yeah they can walk a little distance, but they couldn't get all the way through their house without a significant amount of fatigue, and so maybe some of that can have that. And the therapist can help you with that assessment. Obviously, there's an exclusion so that if you don't have one of these specialists, you can use a physical therapist to do the assessment and

then you can sign the form. But then, I was just going to say, I appreciate this. I guess I knew all this before, because I neuro rehab for so long, but one of the hardest things for me for power chairs, power operated vehicles and wheel chairs, is that patients simply don't understand. They question you and I open my little book from Medicare that says: This is your eligibility. If the patient had something in lay terms that would help them understand that no, if you're minimal assistance with gate, and that means someone has to be touching you to walk, that you don't get a wheelchair, or unless you have a certain pulmonary condition, you can't have a wheelchair, because you send these people home, and they don't understand why grandma can't get a wheelchair so you can take her to church. Even though she can walk through the house independently with a walker.

Mr. Gustafson: The concern there focuses on wheelchairs, not power wheelchairs.

Dr. Powers: The whole thing. The whole thing. So that you can hand them this sheet of paper that says: This is why I'm not giving you a wheelchair. This is why you don't qualify when they're calling me up and saying, "Well, I called that person on TV and they say I qualify." And then you've got something from Medicare that says they don't. When I'm trying to tell them that if I sign on the dotted line, it's a felony for me.

Dr. Rapp: Maybe the brochure—I don't know if that's a good idea to include that or not. Dr. Urata?

Dr. Urata: Are you folks going to have a form out that's like a prescription that you have for DME? You know, those DME prescriptions that you have for oxygen and hospital beds, and then it has the little checkmarks, like four or five criteria that and you need to have one or two of those criteria? Those are really easy because they're in most cases they're easy, because they state objective evidence that you have to meet in order to qualify for whatever equipment that you're ordering. Do you understand?

Dr. Powers: [off mike]

Dr. Urata: There are for wheelchairs, but do you have one for power wheelchairs? That might be helpful to produce one of those things. To make it more objective and just show the patient, well, you didn't meet this criteria. You need to meet this criteria, this criteria and you don't meet them so I can't sign on the bottom line. Or if I do, I'll get thrown in jail. That's a typical comment. They seem to understand. But it's there in black and white.

Dr. Simon: OK, well, I can bring that forward because I have spoken to representatives from family practice, internal medicine and neurology to work with the program integrity section to help develop this document

a few months back. So they didn't address that particular need, but we can make them aware of it and see what the recommendations would be.

Dr. Castellanos: We were asked to read this. Obviously, I don't deal in this, but at the top of page four, I just see a tremendous inconsistency where if you rent the equipment, Medicare is going to pay a service every six months, whether or not the equipment is actually serviced. And then if you buy it, it's going to do it every time it's needed. I don't see why Medicare is going to pay something that whether the service is done or not. I just see that as an inconsistency. Again, I'm not involved in this very much, so maybe you want to clarify that point.

Mr. Gustafson: There's a short answer to that. That's the law. So I mean—

Dr. Castellanos: There's a lot of things I don't understand that's the law.

Mr. Gustafson: The going back to 1988, Congress set up a structure for how we pay for durable medical equipment and it has to fall within certain categories. One of which is rental. And there are rules attached to that about frequent servicing and we pay, even though a service is not delivered in all instances.

Dr. Powers: It would be helpful if we had a patient-oriented sheet. And I'm talking just a small sheet of paper, plain language, that they could understand, for that also to say that the original prescription comes from your physician, so that they understand that they should go to their physician first, and not to the equipment company first.

Dr. Urata: Well, this says they ought to go to the specialist first. And this takes the primary care physician out of the loop.

Dr. Powers: A problem with that.

Dr. Urata: Yeah.

Dr. Bergeron: This brochure is very flawed because I'd have to determine what weight, normal weight, skinny, etc. etc., what horsepower. I don't see the horsepower in here. I think we need to add the amount of horsepowers needed to propel the patient where they want to go. So may I say we include horsepowers in here to? And therefore add a mechanic or automotive expert to that and put it in your specialist? I don't know how we could incorporate that. [laughter]

Dr. Rapp: Any other words of wisdom on this? OK, hopefully that feedback is of some help.

Mr. Gustafson: I could summarize what I heard is the desire for at least two different communication vehicles other than the one that's here, which might profit some first time revision. One was essentially a one-pager for the busy doc, a provider education notice, or something of that sort. We do these with you know, red light, green lights, what do you need to know? What do you need to stop doing, and so forth. So we could consider that. And the other is for some patient-oriented brochure or something to help the physician in their interaction with the patient, help the patient and their interaction with the physician and the equipment company and so forth. And we will take that back to our beneficiary education folks and consider that with them.

Dr. Simon: That's right, and a document indicating the physical impairments that the patient would have, that would better identify their needs for what type of vehicle. Is that what was stated? That's what I thought I heard.

Dr. Heyman: Yeah, one prescription pad that had all the different prescription [inaudible] on it.

Dr. Iglar: What about the situations where somebody asked if [inaudible] heart disease or [inaudible]? Is that up to the primary care, then, or do they have to go with [inaudible]?

Dr. Simon: I would defer that question back to the specialist. Again, I brought—I'll touch bases again with the representatives from neurology, orthopedics, family medicine, internal medicine that we had talk with program integrity. Because when we became aware of this issue five or six months ago, we had all of those specialties involved working with program integrity to help them better design a document that would be physician friendly and better address the needs for doctors, so I'll be happy to communicate with those individuals to get back with program integrity. We can revisit this.

Dr. Rapp: Dr. Urata?

Dr. Urata: Is anything going to be done about the advertising by these companies that I think is somewhat misleading?

Mr. Gustafson: We have a multi-pronged project in place called I think something cute like Operation Wheeler Dealer [laughter] which I believe—

Dr. Bergeron: That's what I wanted to hear all morning!

Mr. Gustafson: That Tom Scully himself came up with this name. [laughter] And I confess not to have in my mind right at the moment all of the aspects of that, but we are attempting to address concern about explosive growth and utilization, particularly concentrated in certain areas of the country where there may have been

equipment supplies pushing the envelope, shall we say, in terms of what they're up to. We have a limited ability to control folks advertising in a free country, free speech, that sort of thing. Concerns could arise in so far as they were identifying themselves as somehow associated with Medicare, because we can control the use of basically that trademark. So I don't know exactly what we can do about that, but we certainly share the concern that consumers are maybe mislead by this and need to try to do what we can about this situation.

Dr. Rapp: OK, anything else on that? Did our reporter get the feedback? We, I guess Mr. Gustafson summarized our feedback. We had three points.

Dana: You're saying you want the notes to reflect the three points that he made?

Dr. Rapp: Yeah, so that it's sort of a form of a recommendation. But there are three specific points and one that Dr. Simon mentioned. OK. Anything else on that? If not, we're done with the agenda. Basically except the wrap and recommendations and so, let's see. I would open the floor for any additional recommendations. Then after we complete that, then I'm going to take a brief break and allow the reporter to get them down on paper for us. We seem to be ahead of the game so that's good. And then she'll come back and we'll finalize those and add to them or subtract, whatever. Dr. Powers?

Dr. Powers: If I may be allowed to present two recommendations. The first: PPAC recommends that in the event there is a delay in processing the enrollment of physicians, due to problems in the PECOS system, CMS institute a contingency plan to ensure payment of claims to providers whose enrollment has been delayed.

Dr. Heyman: I'll second that.

Dr. Rapp: All right. Want to explain that, Dr. Powers?

Dr. Powers: We understand that hopes are that there won't be a delay. But for those that are re-enrolling, we don't think they should be out of the ability to charge Medicare during the time that it's the system's problem. And have to borrow money and pay interest on that money in order to keep their practice up.

Dr. Rapp: All right. Any discussion on that? Just for my curiosity. I'm a new doctor in practice and I applied for a number and I begin in practice and see patients. What happens with regard to Medicare patients that I might see before such time as I get a number. [off mike]

Dr. Rogers: My understanding is that the bill's held until you have a UPIN because you can't file a claim. Then once the claim is processed, then you bill the patient for the co-pay.

Dr. Rapp: And is there some outer limit of that?

Dr. Simon: Six months, I believe.

Dr. Urata: You have to submit a claim within six months.

Dr. Rogers: Yeah, I'm not sure if we delay the processing of the UPIN number—I think the claim has to be submitted within six months for a person who has a UPIN number. I don't think that—

Dr. McAneny: If you provide the service today and then you don't have a UPIN number because the system hasn't given you one yet, and you hold that for six months from today, if it's longer than that, you're out of luck.

Dr. Rogers: The claim's thrown away?

Dr. McAneny: I think the claim is—I thought it was the date on the claim

Dr. Rogers: Twelve months, and after twelve months ten percent is deducted from the payment automatically, if it's more than twelve months old. But the problem is that as you all know as practicing physicians is that your chances of collecting the co-pay drop dramatically, and also, you've got this nice store and you're paying rent but you don't have a cash register, so it's hard to pay your bills.

Dr. Rapp: So in terms of the contingency plan that you're thinking of, did you have something in mind there?

Dr. Powers: [off mike] in the instance that you get a new doc and everyone has to reenroll at the same time. It's the opportunity to electronically reenroll at the same time, the whole practice could be up for not getting their medical bills paid during that time, but also enrollment, and I'm saying if it's the system's fault and not if it's routine. You know the routine amount of time it would take to get your number as a new doc, or—

Dr. Rapp: But in terms of the idea of a contingency plan, the possibilities would be one, that you would be exempted, I suppose from some time limit or given interest, or something, I don't know—

Dr. Powers: If you're reapplying, theoretically it should be seamless. And in this case, if there's something wrong with the system, it's not seamless.

Dr. Heyman: Well, I was just going to say it's hard for us to design whatever the plan should be because we're not familiar with all of the intricacies of how this billing and all the new things in the PECOS system, but I think what we're asking for is let's be prepared because judging from what's happened so far, there is a chance that

when we get to the time for re-enrollment and everything has to be entered by hand that there could be a scary moment there. So we would like CMS to come up with something that will reassure us that there won't be an interruption in payments for those of us who do it the right way and then there's a problem.

Dr. Rapp: Further discussion? All in favor—wait a minute—do you have the…

Dana: PPAC recommends that in the invent there is a delay in processing the enrollment of physicians, do to problems in the PECOS system, CMS institute a contingency plan to ensure payment of claims to providers whose enrollment has been delayed.

Dr. Rapp: All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? Motion carries. All right, any other proposed recommendations? Bill, did you want to say something?

Dr. Rogers: If you're talking about reenroll, not new physicians. Yeah, because I think they're two entirely different issues. I mean re-enrollment really, there shouldn't be any reason why we can't make that seamless, just like your VDA number, you apply for it three months ahead of time, and so that really should, always works smoothly and that's a lot easier problem. The other issue is the initial enrollment, and that really is sort of a new and revolutionary request that may be we need to do something magical so that you can start submitting those claims right away. Now if we get back to our 60-day expectation, it should be a huge problem. So I just ask you to clarify whether you want us to address re-enrollment or new enrollment. And if so, in what way.

Dr. Rapp: Dr. Powers?

Dr. Powers: [off mike]

Dr. Heyman: But on the other hand—

Dr. Rapp: That was a bad question to ask! [laughter]

Dr. Heyman: On the other hand, there should be any reason for there to be a problem with new enrollment. I mean that's been a problem for at least five years that I know about, so I think you know in that period of time, it would be good to come up with a solution for that problem. Because that's a continuing chronic problem.

Dr. Rapp: All right, so the motion pertains to re-enrollment, but Dr. Heyman has made some communications to Dr. Roger, who is head of the PRIT.

Dana: Would you like to change the wording of the motion to say re-enrollment of physicians?

Dr. Rapp: That's what you were referring to.

Dana: OK. It doesn't say that.

Dr. Rapp: You have another?

Dr. Powers: PPAC recommends that CMS ensure early involvement of the physician community, including PPAC the [inaudible] and the CPT panel, in the process of developing codes related to relative values for Medicare preventative services mandated by the MMA. And in cases where a CPT code already exists and is used for Medicaid or private payer purposes, CMS should use that code, or at least use it as a crosswalk for the new Medicare covered preventative care services.

Dr. Rapp: Do you have that written down for the reporter?

Dr. Simon: Can you repeat that please?

Dr. Power: This is basically page three of the AMA recommendations.

Dr. Simon: OK, they're unchanged?

Dr. Powers: Without a change.

Dr. Rapp: Page three?

Dr. Powers: Middle of the page.

Dr. Rapp: All right is there a second to that?

[Seconds]

Dr. Rapp: OK. Do you want to explain that at all?

Dr. Powers: I'm just asking for them not to reinvent the wheel and to use codes that we're already familiar with, that we already have.

Dr. Rapp: All right. Is there discussion on that? Dana do you have that?

Dana: Mm Hmm.

Dr. Rapp: All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? That motion carries. Anything else? If not, we'll take a break. Dr. McAneny?

Dr. McAneny: I'm aware that the Secretary's advisory committee on regulatory reform has a whole series of recommendations that affect physicians, and I would like to request, and we'll make it as a motion if we have to, that in future agenda items that we have an update and preferably an ongoing update of the progress that CMS is making implementing those recommendations. There's many of them that apply to physicians.

Dr. Rapp: I think Dr. Rogers communicated that he would look into that and update us at the next meeting through the PRIT.

Dr. Rogers: Yeah, and I just want to make one thing clear. That's actually not a CMS process. That's actually a Secretarial level process. And that's why we have not been making regular reports, because that was the Secretary's committee, not the administrator's committee. So we did bring some of the issues into the PRIT, but we'll have to ask the Secretary's office if they'd be willing to make a report, because that really belongs to them.

Dr. McAneny: Then I would amend what I just said to request the Secretary's office to make a report on those recommendations which would affect physician practice.

Dr. Rapp: Are you satisfied with Dr. Rogers at the next PPAC meeting, through his PRIT hat?

Dr. McAneny: Well, I guess what the question would be is if these are going to affect physicians, and it's the Secretarial level thing, then perhaps either Dr. Rogers could agree to do it, or that we could ask somebody from the Planning and Evaluation Department, the Assistant Secretary or somebody at that level, to come and tell us what regulatory changes they're planning on making that would affect physicians.

Dr. Rapp: Well, I guess the only thing is that Secretary's advisory panel came up with a whole raft of recommendations. Would it be, I think it might be helpful to narrow it down, the items that you're interested in, or that we're interested in.

Dr. McAneny: Yes, I'm aware that there's many of them, but perhaps what we could do is have the list of the, or a link, to that recommendation email to everybody on the panel so that if there are things that caught people's eye we could request for the next agenda item that those particular issues be brought up and then get an update on those.

Dr. Rapp: OK, why don't I, I'll send you the link to the Secretary's advisory committee and you can look through there, and as I say, they've got—I've actually looked at it myself, when it was ongoing. It's quite extensive. The testimony's quite extensive and so forth, and rather than put the burden on Dr. Rogers to try to figure out the

things we're interested in, why don't we figure out what we're interested in and then we'll ask what's going on with that. All right?

Dr. McAneny: That's acceptable.

Dr. Rapp: OK. Anything else? If not, we'll take a brief break. How long do you think you'll need for this, Dana?

Dana: Fifteen minutes, tops.

Dr. Rapp: We'll take a fifteen minute break. We'll make that sixteen.

[BREAK 11:10:40 am]

[RESUME 11:26:10 am]

Dr. Rapp: I'd like to call the meeting back to order. You have the recommendations to read.

Dana: The data at the top should read…

Dr. Rapp: This D6 was not adopted.

[off mike chat]

Dr. Rapp: Processing re-enrollment of physicians. See that? OK. Are there any corrections to any of the recommendations here? D6 was not adopted. Any changes, we see that the Medicaid is capitalized in Item F. Item H should read: in processing re-enrollment of physicians. Any other typographical or administrative changes to those items. OK.

Dr. Hamilton: I'm sorry, where is re-enrollment?

Dr. Rapp: Item H recommends that in there's a delay in processing, re-enrollment of physicians due to problems in the PECOS system.

Dr. McAneny: Laura, did we make that change?

Dr. Rapp: Yes, that was the, that's what she was talking about. All right. So those are the recommendations. Any other business?

Dr. McAneny: I'd like to try to restructure D6, if I might. To read: PPAC recommends CMS study the assumption that point of service for infusion and chemo therapy will not shift from physicians' offices to hospital outpatient facilities to ensure that beneficiaries will continue to have access to infusion and chemo therapy services, and report back in one year.

Dr. Rapp: Is there a second to that?

Dr. Hamilton: Second.

Dr. Rapp: Is there discussion on that?

Dr. McAneny: I think leaving the last sentence in there would be acceptable, too.

Dr. Rapp: Pardon me?

Dr. McAneny: And I'd want to leave in the last sentence of that that—

Dr. Rapp: There's no last sentence—

Dr. McAneny: This says the plan should include a comparison of, or the study should include a comparison of costs, safety, and patient satisfaction, etc.

Dr. Rapp: Is there discussion on that? Dana, could you read that back?

Dana: PPAC recommends CMS study the assumption that point of service for infusion and chemo therapy will not shift from physicians' offices to hospital out patient facilities, to ensure that beneficiaries will continue to have access to infusion and chemo therapy services, and report back in one year. The plan should include a comparison of costs, safety, and patient satisfaction between hospital out patient facilities and physician offices.

Dr. Rapp: OK, any discussion?

Dr. Heyman: I think that it could be a lot shorter and a lot less—it sounds hostile somehow and I'm thinking to myself that it could be that PPAC recommends that CMS study the affect of the new rules having to do with infusion services and whether or not they affect the access to care for patients and patient satisfaction. Something like that, so it's not quite so. . .

Dr. Simon: I would be in support of that, because I think the way it reads, is that it would require us going back for the last two or three years to trend to see what patients have already shifted from the office setting to the hospital as a baseline to be able to know if there's been any impact from the changes [inaudible], and I think the question is, what we want to know is what's the impact of the legislation.

Dr. Heyman: Right. In particular on this particular aspect of care, which is infusion therapy.

Dr. Rapp: OK, are you withdrawing your motion then?

Dr. McAneny: I will accept as a friendly amendment.

Dr. Rapp: Well, it seems totally different.

Dr. Heyman: Oh, I don't think it's totally different. I think it's essentially what she wants, it's just

Dr. Rapp: It's another motion, though.

Dr. Heyman: I could move that we amend it by substitution if that's what you—

Dr. Rapp: All right.

Dr. McAneny: That's fine.

Dr. Rapp: So, let's read the substituted motion then.

Dana: PPAC recommends CMS study the affect of new regulations on infusion and chemo therapy services, specifically whether the new regulations affect access to care and patient satisfaction.

Dr. McAneny: Can we leave cost and safety in there?

Dr. Heyman: Whatever you want.

Dr. Rapp: We have to have a statement, we have to have a motion. Are you changing the motion?

Dr. Heyman: Sure, we can include cost and safety, if that won't make it—

Dr. Rapp: OK, let's read the motion then.

Dana: PPAC recommends CMS study the affect of new regulations on infusion and chemo therapy services, specifically whether the new regulations affect access to care, cost,

[START SIDE FOUR]

[Dana cont.] safety, and patient satisfaction.

Dr. Rapp: OK, is there discussion that?

Dr. Heyman: Cost, safety, access to care, and patient satisfaction, is that what you said?

Dana: Yes.

Dr. Heyman: OK.

Dr. Simon: I have one question. When we use the word "safety" what's the context and what does that refer to?

Dr. McAneny: Medication errors in particular, patient safety.

Dr. Rapp: CMS, what this is supposed to do, they're supposed to decide whether the work from the physicians' offices are safer than in the hospital? Or not more safe?

Dr. Heyman: They're supposed to just look and see whether there has been a change in [inaudible] the law that affects patient safety, regardless of what—we don't even know that there's going to be a shift. There may be no shift.

Dr. Rapp: So they'll have to decide if there was cost safe, they'd have to compare the previous situation?

Dr. Simon: I guess one concern I have is that errors that occur in physicians' offices are self-reported. That's a different mechanism than hospitals use. So you're comparing apples to oranges, and I'm not sure that that's a fair. . .

Dr. McAneny: That's true. So patient safety is more than CMS can come up with. OK.

Dr. Heyman: So take safety out of there.

Dr. Hamilton: If you wanted to get to that, you might quantitate immediate need for hospitalization after the treatments or something like that, but that might not really relate.

Dr. Heyman: I think we're asking a lot.

Dr. McAneny: Yeah, we're asking a lot.

Dr. Simon: If patients sustain tissue injuries as a result of extravasation of contrast, or chemo therapy, that may occur over several days. So one may not have, be able to develop the relationship between administration and hospitalization.

Dr. Hamilton: I'd just take that out.

Dr. McAneny: OK, so the data's not collectible, basically.

Dr. Heyman: If they find out that any significant change, you can always go back and look and see if the problem is. . .

Dr. Rapp: Let's read the—

Dr. Heyman: Latest version.

Dr. Rapp: Resolution.

Dana: PPAC recommends CMS study the affect of the new regulations on infusion and chemo therapy services, specifically whether the new regulations affect access to care, cost, and patient satisfaction.

Dr. Heyman: Perfect.

Dr. Rapp: All right, any further discussion on that? All in favor, raise your hand? All opposed? All right, that motion carries. Anything else? Yes, Dr. Urata?

Dr. Urata: In regards to the powered wheel chair and after thinking about it, I would like to see if PPAC would recommend that primary care physician of the patient would be allowed to fill out these prescriptions. I think that the information is so specific, the criteria is so specific, that any practicing physician, particularly the patient's physician, ought to be able to fill out those prescriptions and prescribe a powered wheelchair or any wheelchair for that matter.

Dr. Heyman: I'd second that.

Dr. Urata: I don't think it needs to be in the realm of specialist.

Dr. Rapp: OK, let's formulate it in the form of a recommendation.

Dr. Urata: Well, I recommend that the patient's primary care physician be allowed to fill out a prescription for the powered wheel chair, which they now are being excluded from.

Dr. Rapp: OK, PPAC recommends that. Yes, Bill?

Dr. Rogers: I think they can for the powered wheelchairs, just not the POBs, isn't it? Just not the scooters.

Dr. Urata: What's the difference between a powered wheelchair and a scooter?

Dr. Rogers: There's different standards. I think that restriction of neurologist, [inaudible], is only the scooters, not the powered wheelchairs.

Dr. Urata: OK, I don't see why a scooter is any different in terms of prescriptions, filling out a prescription because there are specific criteria by which you can have a scooter, just like there is a for a powered wheel chair, just like there is for wheelchairs.

Dr. Rogers: I'm not saying [inaudible]

Dr. Urata: Oh OK. I'll stop attacking you. [laughter]

Dr. Rapp: Where is the—let's look at the brochure. That tells us what it is. OK, page 2, it says the POV, and that means, is that a scooter? POV is a—

Dr. Bergeron: Power operated vehicle.

Dr. Heyman: You mean after reading those seven pages, you still don't know that POV is a scooter?

Dr. Rapp: Well, what's the difference between a power wheelchair and a scooter? I thought that we were just—

Dr. Powers: You have to be able to walk to get into the scooter. [off mike] It's a huge difference in expense.

Dr. Rapp: I don't see anything about a scooter in this form, though.

Dr. Powers: At the very top of page two?

Dr. Heyman: He's just making my point from the very beginning. [laughter]

Dr. Rapp: Oh, that's scooter. What…

Dr. Urata: Scooter's the one that everybody's coming for.

Dr. Rapp: Oh, the scooter's POV?

Dr. Urata: Yeah, scooter's the one that's being—

Dr. Rapp: So there's scooter and non-scooter.

Dr. Urata: Yeah, that we're being inundated with, that requests are being asked of us.

Dr. Rapp: All right, so motion is PPAC recommends that a patient's primary care physician be authorized to order the scooter POV. Is that the motion?

Dr. Urata: Yes.

Dana: To order or to prescribe?

Dr. Rapp: Well, to order. Well, it says order here. Is there a difference between prescribe and order? I thought you prescribe medicine and order DME. Order or prescribe.

Dr. Urata: Now, my understanding is the reason for this is because of the cardiologists have been prescribing scooters for their obese patients. Is that correct?

Dr. Rapp: I guess that [inaudible]

Dr. Simon: There's been shown that there were cardiologists that were ordering wheelchairs for obese patients. Correct.

Dr. Urata: With these five points of patient criteria, the patient needs to meet, that ought to be easy for anybody to figure out. It seems to me, so it seems to be unnecessary to exclude various specialties from this ability to prescribe or order.

Dr. Rapp: All right. So you're giving the basis for your motion.

Dr. Urata: Yes.

Dr. Rapp: Could you read the motion back and make sure that Dr. Urata is satisfied with the formulation?

Dana: PPAC recommends CMS authorize a patient's primary care physician to order a power operated vehicle for the patient.

Dr. Rapp: Does that do what you want?

Dr. Urata: Yes. I think that is.

Dr. Rapp: As opposed to the current limitations?

Dr. Urata: I want to eliminate that limitation.

Dr. Rapp: And eliminate the current limitations to specialists and physical medicine, orthopedic surgery, neurology, or rheumatology. Is that clear? And eliminate the current limitations, which are to specialists in physical medicine, orthopedic surgery, neurology, or rheumatology.

Dr. Urata: Yes.

Dr. Rapp: Does everybody agree with this?

Dr. Castellanos: No, the reason we're doing this is to try to prevent the abuse that we've seen. Not saying that primary care physician who's responsible for that person's care is not capable of—because you're opening Pandora's box to any primary care physician. I think you're keeping the box open to abuse. I don't know how to tighten that down. I think the physician who's taking care of the patient, if you can strictly say that's the primary care doctor, then he has that responsibility and can do it. But if you're putting any doctor, signing that piece of paper, I think you're keeping it open for abuse.

Dr. Rapp: So Dr. Castellanos, I believe, speaking against that motion. Other discussion. Dr. Bergeron?

Dr. Bergeron: But would the criteria of filling out the form and evaluation still hold true whether you're physical medicine, family practitioner or rheumatologist? Those criteria have to be satisfied, right?

Dr. Powers: I have a friendly amendment.

Dr. Rapp: Dr. Urata's next, then Dr. Powers, then Dr. Heyman.

Dr. Urata: I was just going to reiterate what Dr. Bergeron was saying. If you base this on criteria, and not on specialty then that's fine. But if you're going to put down criteria and eliminate a full blown licensed physician, who's been taking care of the patient for ten or fifteen years, that doesn't make sense to me.

Dr. Bergeron: I agree with Dr. Urata.

Dr. Rapp: Dr. Powers?

Dr. Powers: I think I have a friendly motion—and I want to preface that by saying I am sensitive to the issue of the [inaudible] specifying specialties for a lot of different things; something that traditionally we try to avoid. But the friendly amendment that would help reduce the risk of abuse would be that instead of saying the patient's physician, or any physician, would be the physician treating the patient for that condition, so that could be any type of physician, but it would limit it to the physician. So for instance, it could be another physician that was not even treating you that signed—

??: It wouldn't be like buying it over the internet.

Dr. Urata: No, I mean the patient's physician. That's what I meant when I said—

Dr. Powers: Well, that's why I wanted to specify that, because as a friendly amendment, because then that—

Dr. Urata: Yeah, that's a great friendly amendment.

Dr. Rapp: The only trouble with that is, CMS would have to decide when that's the patient's treating physician. Is it for like five minutes over the internet, or is it like, a year? Or fifteen years? That's the only problem with that. Dr. Heyman's next.

Dr. Heyman: I'm opposed to the friendly amendment, and I'm also in favor of the original motion. There have been abuses with specialists doing it. And the reason there are probably most of those abuses is because the specialists don't under stand what the restrictions are. And I think if all of the other recommendations that we've made today were incorporated, it wouldn't matter which physician was doing it, because they would be perfectly clear about what the restrictions are. There's no reason to think that any particular physician is going to be more ethical than any other particular physician. It doesn't take any more skill to read those, that list of restrictions and in addition to that, there could be great confusion about who is actually treating the patient for that condition. You can have more than one physician—you can have a primary care physician who's responsible for multiple chronic

conditions and having specialists who are taking care of one particular condition that might have something to do with the reason a person needs a scooter. So for all those reasons, I think we should just go with Dr. Urata's original language with the modification by Dr. Rapp.

Dr. Rapp: You're in favor of Dr. Urata's motion. I'm trying to avoid confusion. If Dr. Urata accepted that language and there was no objection, but there is an objection, so we're not going to take it. The motion is Dr. Urata's that we previously read. So any further discussion on that? OK. You want to read the motion back, please?

Dana: PPAC recommends CMS authorize the patient's primary care physician to order a power operated vehicle for the patient and eliminate the current limitation of ordering specialists in rheumatology, neurology, [inaudible] surgery.

Dr. Rapp: What's that? We want to make the current limitation—to

Dr. Heyman: You don't even really need and the, and eliminate. I mean, the original motion makes it plain that what we're asking is that—

Dr. Rapp: Yeah, it probably does, but I wasn't sure Dr. Urata thought it was plain enough. I mean without that.

Dr. Urata: No, that was just part of the discussion.

Dr. Rapp: OK, stop with comma, and, not just read it back in its plain vanilla form.

Dana: PPAC recommends CMS authorize the patient's primary care physician to order power operated vehicle for the patient.

Dr. Rapp: Is that OK? All right. All in favor?

[Ayes]

Dr. Rapp: Anybody opposed? That motion carries. All right, is there anything else?

Dr. McAneny: I would like to move that PPAC request CMS continue to work with the renal physician association and other pertinent groups to monitor any access problems for rural clinics and home dialysis programs created by the new dialysis codes.

Dr. Rapp: Is there a second to that?

[Second]

Dr. Rapp: Did you write that down? Did you get it, Dana? You want to just hand it to her? I assumed your handwriting would be legible—Dr. Heyman, I made him read it. [laughter]

Dana: PPAC recommends CMS continue to work with the renal physicians associations and other pertinent groups to monitor access problems for rural clinics and home dialysis programs created by the new dialysis codes.

Dr. McAneny: That's really rural dialysis clinics.

Dana: OK.

Dr. Rapp: What was created by the rural dialysis codes?

Dr. McAneny: Access problems. The concern is the thing that was brought up yesterday about the ability of rural dialysis clinics to continue to exist, given the current codes and whether or not there's going to be an access problem for dialysis patients where they have to move out of Juneau if they can't get access to dialysis.

Dr. Urata: That's not a problem in Juneau right now.

Dr. McAneny: It is in other places—I shouldn't use Juneau.

Dr. Hamilton: It will be.

Dr. Rapp: Dr. Heyman?

Dr. Heyman: I guess I have the same problem with this one that I had with the other one, which is that it already is presuming that there's going to be a problem when we don't know that that's the case.

Dr. McAneny: No, it just asks to monitor for access problems.

Dr. Heyman: No, it doesn't just—if you read it again, you will hear that it presumes that there is going to be a problem. It says that you're going to monitor, just read the first sentence.

Dr. Rapp: That's called begging the question isn't it? Read it please?

Dr. Heyman: I've forgotten the exact wording, if you would just read the first part, it sounds awfully—

Dr. Rapp: Just read the motion back, and we'll—

Dana: PPAC recommends CMS continue to work with renal physicians associations and other pertinent to monitor access problems for rural dialysis clinics and home dialysis programs created by the new dialysis codes.

Dr. Heyman: It's saying that we are going to have access problems created by these rules and we have no evidence that that's the case. So I think that if we want to look at whether there's a problem, then I think that's perfectly reasonable, but I don't think we should presume that there's going to be a problem.

Dr. McAneny: What my little scrawl in there, where I crossed things out and put it in, it says to monitor for any access problems, which is I think what you're asking for. And I scrawled that out because—

Dr. Rapp: Well, I agree with Dr. Heyman, that I think we've got to be a little bit cautious in loading one or seeking to load one more study on things that may be assumed to be the case. I believe that CMS access problems just in general. We've heard numerous reports on that. And to focus on one item or another—I mean we could go through a whole raft of things like that. So I'm supporting what Dr. Heyman said. Dr. Johnson?

Dr. Johnson: Could we just strike "problem" and monitor access?

Dr. Heyman: I'm not opposed to asking that somebody monitor it, I'm just opposed to presuming what the outcome is going to be, and so I think it would be added language that Dr. McAneny stuck in there is sounds a little bit less judgmental about the result.

Dr. Bergeron: How about if we just say: urge CMS to continue to monitor access? Strike it out after that.

Dr. Johnson: Just continue to monitor access, with [inaudible]

Dr. McAneny: That works.

Dr. Heyman: I think that's fine.

Dr. Bergeron: Friendly amendment.

Dr. Rapp: OK. Does our reporter have that?

Dana: PPAC recommends CMS continue to work with renal physicians associations and other pertinent groups to monitor access to rural dialysis clinics and home dialysis programs in light of the new dialysis codes.

Dr. Heyman: Just put continue to monitor.

Dr. Rapp: And eliminate the "in light of…"

Dana: Oh.

Dr. Rapp: Is that right?

Dr. Heyman: No, where it says "monitor", just put in the words "continue to"—

Dr. Bergeron: Because then we assume that they will and are monitoring and will continue to, and if they're not monitoring, that will be put them on later.

Dr. Rapp: OK. Can you read that back now in its final form?

Dana: PPAC recommends CMS continue working with renal physicians associations and other pertinent groups, to continue to monitor access to rural dialysis clinics and home dialysis programs in light of the new dialysis codes.

Dr. Bergeron: And can we put in there, thanks? [laughter]

Dr. Rapp: What is that now?

Dr. Bergeron: Thanks, thank you. Thank y'all.

Dr. Rapp: Is there discussion on that? All in favor?

[Ayes]

Dr. Rapp: All opposed? Motion carries. Any other items? If not, thank you all for coming. I appreciate your participation. I would acknowledge since Dr. Heyman wasn't here when we previously acknowledged his four years of service on the Council that I know we're all grateful for your active involvement and I know CMS appreciates that and I think you deserve a [applause]. We I presume would expect you to come back and testify and give us your guidance in the future.

Dr. Heyman: Thank you.

Dr. Rapp: Is there anything else anyone wants to bring up? Yes, Oh, and I do want to once more acknowledge the work of the staff that's been involved in this. Cheryl Slay, thank you for all your behind-the-scenes work in organizing the meeting and doing all these details that make it so that it comes together. Thanks to our reporter. Thank you Mr. Clark, thank you Dr. Simon, and thank you, Mr. Gustafson, but I made a mistake at a prior meeting, because as you see in the minutes, it says that Mr. Gustafson is supposed to be part of the wrap-up here—

Mr. Gustafson: I've been listening very carefully.

Dr. Rapp: I know. You're supposed to now say something.

Mr. Gustafson: It's been great having you all here. [laughter]

Dr. Rapp: When Mr. Grissom was here one I didn't do that one time, I felt bad about it. Dr. Simon is supposed to have an opportunity as well.

Dr. Simon: I think the only comment I have to the Council is that you can anticipate receiving electronic email in the very near future on a fraud and abuse document that was just given to us by the provider education

group for your review, and hopefully at the upcoming meeting in May, we'll be able to get your insight and comments on that document, so that it can be incorporated into the final document.

Dr. Rapp: And then, I'll get to you in one second, Dr. Johnson. I invite members of the Council to suggest items for the agenda that you could email to me or anyone else that has suggestions for items for the agenda, please do that. Dr. Johnson?

Dr. Johnson: Do we updated information of who the next four appointees will be, been selected, or?

Dr. Rapp: Dr. Simon?

Mr. Gustafson: It's still under review by the administration. We hope to have news shortly, but I can't share anything with you right now.

Dr. Rapp: All right. Anything else? If not, thank you all very much. We stand adjourned.

[ADJOURNED 12:00 p.m.]